# Logical Observation Identifiers Names and Codes (LOINC®)

# **Users' Guide**

**Edited by:** 

Clem McDonald, MD, Stan Huff, MD, Jamalynne Deckard, Kathy Mercer, Jacqueline Phillips, Daniel J. Vreeman, PT, DPT

Send questions and comments to:

loinc@regenstrief.org

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record and other clinical database systems, and the messaging of patient information collected through the use of these instruments.

# Preface

LOINC provides a set of universal names and ID codes for identifying laboratory and clinical test results.<sup>i,ii</sup> LOINC facilitates the exchange and pooling of results, such as blood hemoglobin, serum potassium, or vital signs, for clinical care, outcomes management, and research. Currently, many laboratories use ASTM 1238<sup>iii</sup> or its sister standard, HL7<sup>iv</sup>, to send laboratory results electronically from production laboratories to clinical care systems in hospitals. Most laboratories identify tests in HL7 messages by means of their internal (and idiosyncratic) code values. Receiving medical informatics systems cannot fully "understand" the results they receive unless they either adopt the producer's laboratory codes (which is impossible if informatics system receives results from multiple source laboratories, e.g., the hospital lab, the local commercial lab, and a nursing home lab), or invest in the work to map each laboratory's coding system to their internal code system.<sup>v</sup>

If medical information producers who wish to communicate with each other adopt LOINC codes to identify their results in data transmissions, this problem would disappear. The receiving system with LOINC codes in its master vocabulary file would be able to understand and properly file HL7 results messages that identified clinical observations via LOINC codes. Similarly, if test and observation codes were reported test with the LOINC codes, government agencies would be able to pool results for tests from many sites for research management and public health purpose. The LOINC codes (and names) for test observations should be of interest to hospitals, clinical laboratories, doctors' offices, state health departments, governmental health care providers, third-party payers, and organizations responsible for quality assurance and utilization review.

The LOINC codes are not intended to transmit all possible information about a test or observation. They are only intended to identify the test result or clinical observation. Other fields in the message can transmit the identity of the source laboratory and special details about the sample. (For instance, the result code may identify a blood culture, but the message source code can be more specific and identify the sample as pump blood.) The level of detail in the LOINC definitions was intended to distinguish tests that are usually distinguished as separate test results within the master file of existing laboratory systems. Indeed, at the outset, we used the master files from seven U.S. laboratories to shape this effort, and requests from commercial labs and hospitals continue to shape the content of the LOINC effort.

Each LOINC record corresponds to a single test result or panel. The record includes fields for specifying:

- 1. Component (analyte) e.g., potassium, hemoglobin, hepatitis C antigen.
- 2. Property measured e.g., a mass concentration, enzyme activity (catalytic rate).
- 3. Timing i.e., whether the measurement is an observation at a moment of time, or an observation integrated over an extended duration of time e.g., 24-hour urine.
- 4. The type of sample e.g., urine, blood.
- 5. The type of scale e.g., whether the measurement is quantitative (a true measurement) ordinal (a ranked set of options), nominal (e.g., E. coli; Staphylococcus aureus), or narrative (e.g., dictation results from x-rays).
- 6. Where relevant, the method used to produce the result or other observation.

It also contains information about the amount, route, and timing of physiologic or pharmacologic challenges. For example, a glucose tolerance test could be expressed in LOINC as Glucose^1H post 100 g glucose PO. LOINC does not usually include the method in the name for chemistry tests, where tests are more often standardized to normalized methods; they do include methods for most serological tests and coagulation studies. This same principle is usually reflected in the master files of existing laboratories. Of course, the method can always be reported as a separate item of information in a result message, regardless of whether it is part of the test name.

We used many sources for constructing the database, including the Silver Book from the International Union of Pure and Applied Chemistry (IUPAC) and the International Federation of Clinical Chemistry (IFCC), <sup>vi</sup> textbooks of clinical pathology (e.g., Henry<sup>vii</sup> and Tietz<sup>viii</sup>), the expertise and work of the LOINC members, and EUCLIDES. We have also reviewed the master test files of seven sources (Indiana University/Regenstrief, University of Utah, Association of Regional and University Pathologists (ARUP), Mayo Medical Laboratories, LDS Hospital in Salt Lake City, the Department of Veterans Affairs, Quest Diagnostics, and University of Washington). This has been an empirical effort. Our goal is to provide codes that correspond to the concepts in real world laboratories' and clinical departments' master files.

LOINC includes fields for each of the six parts of the name. In addition, it also contains short names (as of the August 2002 version for laboratory tests), related words, synonyms, and comments for all observations. Related words (synonyms) are included to facilitate searches for individual laboratory test and clinical observation results.

We have defined fields in LOINC for a number of data elements, e.g., typical units, sample normal ranges, but most of those fields are only partially populated. In a few cases, we have suggested standard answer lists for tests whose results are usually reported as codes. LOINC is an ongoing project. We have established guidelines for users who wish to request additions and changes, which are detailed in Appendix D.

For some kind of tests and observations, the database provides several ways to report values. For example, blood cell antigens might be presented as a "panel" with separate "tests" which report each possible antigen as present or absent if the test is to establish paternity; for cross matching, the result would be reported as a list of antigens found. We try to provide for both methods of reporting in LOINC by including codes for both types of test identifiers.

Laboratories and managers of medical records systems should record the LOINC codes as attributes of their existing test/observation master files. They should also use the LOINC codes and names in the OBSERVATION ID field (OBX-3) of the ASTM and HL7 OBX segment and the corresponding CEN TC251 and DICOM messages to identify laboratory results.

The overall organization of LOINC is divided first into four categories, "lab", "clinical", "attachments" and "surveys". (This split is recorded in CLASSTYPE field of the LOINC Table.) The laboratory portion is further divided into the usual categories of chemistry, hematology, serology, microbiology (which includes parasitology and virology), and toxicology. We have separated antibiotic susceptibilities into their own category. The clinical portion of LOINC contains entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, pulmonary ventilator management, and other clinical observations. Appendix B lists these classes in more detail. There is nothing sacred about these categories, and you are free to sort the database by whatever class is convenient for your application.

The Regenstrief Institute maintains LOINC and makes it available in a number of file formats. LOINC and the related files (such as this document) are copyrighted to assure that multiple variants of the standard do not emerge. Having many variants would defeat the purpose of a universal identifier for test results. LOINC is made available at no cost worldwide under the license at <a href="http://loinc.org/terms-of-use">http://loinc.org/terms-of-use</a>. The LOINC Table, supporting documentation and supplemental files, and the RELMA<sup>®</sup> mapping program are all made available by the Regenstrief Institute on the LOINC website (<a href="http://loinc.org/terms-of-use">http://loinc.org/terms-of-use</a>.

The primary files in the LOINC distribution are listed below.

#### LOINC Table – Microsoft Access Format

All the fields of the LOINC Table available in a Microsoft Access<sup>™</sup> database format.

### LOINC Table – Text Format (Tab Delimited)

All the fields of the LOINC Table with each record on a separate line (terminated by CR/LF), and each field delimited by a tab character. Non-null text fields are enclosed in double quotes (").

### LOINC Table – Text Format (Comma Delimited)

All the fields of the LOINC Table with each record on a separate line (terminated by CR/LF), and each field delimited by a comma character. The data files in this package are provided in the Comma Separated Value (CSV) format according to RFC 4180 and encoded with UTF-8. This package also contains basic scripts for loading the data into some popular databases (Oracle and MySQL for now). This comma-delimited format will become the only text format of the LOINC Table distributed in the December 2013 release.

### LOINC Users' Guide (this document)

The LOINC Users' Guide is the definitive document about LOINC and is available as a PDF file. It explains the structure of the table, its rationale, and the rules we used for naming test results.

### RELMA

The Regenstrief Institute also produces a Windows-based mapping utility called the Regenstrief LOINC Mapping Assistant (RELMA<sup>®</sup>) to facilitate searches through LOINC and to assist efforts to map local codes to LOINC codes. This program is also available for free use.

### **RELMA Users' Manual**

The definitive guide to using the RELMA program.

All of the above files are available from the LOINC website at http://loinc.org.

Additionally, Regenstrief provides a web-based search application available at <u>http://search.loinc.org</u> that can be used to search the latest version of LOINC right from your Internet browser.

We welcome corrections or extensions to the database. We are not interested in adding terms that might be needed in some future situation but we are interested in adding test observations that are actively being reported today. Appendix D provides instructions for submitting new terms.

Clem McDonald Chairman, LOINC Committee Chairman, Laboratory LOINC Committee Stan Huff Co-Chairman, LOINC Committee Chairman, Clinical LOINC Committee

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# **1** Introduction

The goal of the LOINC project is to create universal identifiers (names and codes) used in the context of existing ASTM E1238, HL7, CEN TC251, and DICOM observation report messages employed in the various sub-domains of healthcare informatics such as Clinical Laboratory Information Management Systems and Computer-Based Patient Record Systems.<sup>ix, x</sup> Specifically, the identifiers can be used as the coded value of the "Observation Identifier" field (# 3) of the OBX segment of an ORU HL7 (HL7 vs. 2.x and vs. 3.9 or ASTM 1238-9410) messages, or in a corresponding field in future versions of these HL7 and DICOM standards. LOINC codes identified in HL7 as code system "LN" provide "universal" identifiers. When used in the context of the messaging standards, LOINC codes allow the exchange of clinical laboratory data between heterogeneous computing environments.

To facilitate this process, each identifier requires a fully specified name created in a standard way so that users can create long names for their tests that can be linked to the universal test identifier using semi-automated methods.

We focused our initial effort on creating names for results of reportable tests or clinical measurements rather than request-able batteries, because the issues involved in naming results of tests are less complex than those involved in naming the batteries. However, we have also defined codes for some order panels. It is important to note that LOINC codes for single tests, reports, and observations are equally suitable for the ordered item in an order record or message, or as the result identifier in a result message.

The LOINC database is a "universal" master file of standard "test" names and codes that will cover most of the entries in these files of operational laboratory systems, so that the terms in these operational master files could be mapped directly to universal codes and names. The names we create correspond most closely to the "long test descriptions" seen in test master files. The LOINC names are "fully specified" names. That is, if a person wanted to map her local test dictionary to the LOINC codes, all the information needed to map a local test name to one of the fully specified names should be present in the LOINC name.

We aim to achieve a level of detail in the definition of a test that will map one-to-one to the separately reported observations on a clinical laboratory report. If a test has its own column on a clinical report, or has a reference range that is significantly different from other tests, or has a different clinical meaning than other related tests, it will usually be assigned a separate LOINC code and name. We deliver these fully specified names, their codes, and their related names as a database in which each line corresponds to a unique test measurement.

### 1.1 Successes

The LOINC codes have been greeted enthusiastically since they were released to the Internet in April of 1996. Today, LOINC has been adopted widely. It is used in settings of all kinds, from clinical institutions to health systems, IT vendors, research projects, government agencies, and international e-Health projects spanning many countries. There are now more than 19,700 users in 149 different countries. LOINC adoption worldwide has steadily accelerated. We are now adding 17 new users per day or more than 520 per month. Many countries have adopted LOINC as a national standard, including Australia, Brazil, Canada, Cyprus, Estonia, France, Germany, Mexico, Mongolia, the Netherlands, Rwanda, Thailand, Turkey, and the United States. There are large-scale health information exchanges using LOINC in Hong Kong, Italy, the Philippines, Spain, Singapore, and Korea as well. The LOINC content and associated documentation have been translated into many languages. We have developed a mechanism to make the process more efficient for our translators by using the atomic parts that a term is composed of. Both

RELMA and the online LOINC search application (<u>http://search.loinc.org</u>) now have multilingual searching capabilities. We have described how our approach to translations supports international adoption,<sup>xi,</sup> and we highlight the work of our international colleagues in a special section on the LOINC website at <u>http://loinc.org/international</u>. We provide a voluntary directory of organizations that have adopted LOINC on our website (<u>http://loinc.org/adopters</u>) and give news updates on domestic and international adoption at our meetings.

### 1.2 What is not part of the name

Certain parameters and descriptions pertaining to test performance are specifically excluded from the fully specified test name. These parameters will typically be reported in separate fields (attributes) of a test/observation report message, not as part of the observation name. Attributes that we explicitly exclude from the fully specified name are:

- the instrument used in testing
- fine details about the sample or the site of collection such as "right antecubital fossa"
- the priority of the testing, e.g., whether stat or routine
- who verified the result
- the size of the sample collected
- the place of testing (e.g., home, bedside, clinical lab)

In the case of laboratory tests, the name does include information that identifies the type of sample (or specimen). However, the "sample" part of the name is not meant to carry all possible information about the sample, but only enough to indicate significant differences in the result and to reflect current usage in test names. For example, laboratories usually define urine sodium, sweat sodium, and serum sodium as different tests because each of these has a different normal range. But laboratories do not define different tests to distinguish the concentration of arterial serum sodium from venous serum sodium, though the lab may report that the sample was venous or arterial in another part of the report. We are guided by the pragmatics of conventional usage. If laboratories define separate tests for the same measurements done on different specimens (this usually implies a well-defined normal range difference), we will define different "result-able" tests in our dictionary. If they do not, we will not.

The extent to which we include methods as part of the name is also guided by pragmatics. We distinguish tests/observations by the type of method used to produce the results only if a given type of method has an important effect on the interpretation of the result. This is a complex subject and it is difficult to fully describe our rationale in this report. Where laboratories do not tend to include the method in the name (e.g., most of chemistry) we do not include the method in the name. Where they tend to (e.g., in immunochemistry) we do. For some tests, this can be justified by the standardization of methods to produce "equivalent" results, and sometimes by the many variables (method, reagent) that one could never hope to represent fully in a single name. However, even when we do distinguish these cases, we distinguish by type of method, not the most detailed possible method distinction. (See section 2.7, Type of Method, for more details.)

The College of American Pathologists produces statistical summaries of the results for measurements of standard samples broken down by laboratory and by instrument or procedure. (These are called CAP surveys.) We considered using this CAP survey data to decide empirically when test names should be distinguished by method, but decided this was not feasible because many of the apparent differences in method obtained with the standard samples were artifacts of the sample matrix and did not apply to serum specimens. In addition, the variation among laboratories was often of the same magnitude as the variation among methods within laboratories for the same method.

We do not mean to underrate the importance of method differences. The result message will still include information about the normal range for that particular test, the source laboratory and, if the laboratory wishes, specific information about the method (e.g., OBX 17 can carry very specific method information). However, such information is reported in separate fields in the HL7 message. It is not embedded in the names of the test.

### 1.3 Scope of LOINC

The current scope of the existing laboratory portion of the LOINC database includes all observations reported by clinical laboratories, including the specialty areas: chemistry, including therapeutic drug monitoring and toxicology; hematology; serology; blood bank; microbiology; cytology; surgical pathology; and fertility. A large number of terms used in veterinary medicine have also been included. In addition, the scope includes those non-test measurements that are commonly required to interpret test results and are usually included as part of the report with the laboratory observations. Examples include:

- for cervical pap smears, the phase of menstrual cycle or use of estrogens
- for arterial blood gases, inspired oxygen
- for drug concentrations used in pharmacokinetics, the dose
- for a blood bank, the number of units dispensed

The June 2000 release contained our first foray into order sets/batteries. Existing LOINC codes could always be used to order the specific tests observation, but prior to 2000 there was no mechanism to use LOINC codes to order a set of observations. We have currently only addressed a group of observations that are either naturally produced as a panel (e.g., urinalysis) or are defined by some national body. For example, the Basic metabolic 2000 panel that was defined by HCFA (which is now CMS).

The clinical portion of the LOINC database covers the areas of blood pressure, heart and respiratory rates, critical care measures, cardiac output, body dimensions, body temperature, intake and output, electrocardiography, cardiac echo, obstetric ultrasound, urologic ultrasound, gastrointestinal endoscopy, ventilator management, dental, Data Elements for Emergency Department Systems (DEEDS) reporting, radiology study reporting, claims attachment and the major headings of history and physical, discharge summary, and operative note reports and tumor registry variables. Further work on clinical obstetrics and nursing observations is ongoing. There are separate sections for Claims Attachments and Survey Instruments.

## 1.4 The LOINC Code Identifier

To each name, we have assigned a unique permanent code that we call the LOINC code. This is the code that systems should use to identify test results in electronic reports. The LOINC code has no intrinsic structure except that the last character in the code is a mod 10-check digit. The algorithm to calculate this check digit is given in Appendix C. All of the structure associated with a single LOINC entity is stored in other fields in the LOINC database.

# 2 Major "Parts" of a Test/Observation Name

The fully specified name of a test result or clinical observation has five or six main parts including: the name of the component or analyte measured (e.g., glucose, propranolol), the property observed (e.g., substance concentration, mass, volume), the timing of the measurement (e.g., is it over time or momentary), the type of sample (e.g., urine, serum), the scale of measurement (e.g., qualitative vs.

quantitative), and where relevant, the method of the measurement (e.g., radioimmunoassay, immune blot). These can be described formally with the following syntax.

# <Analyte/component>:<kind of property of observation or measurement>:<time aspect>:<system (sample)>:<scale>:<method>

The colon character, ":", is part of the name and is used to separate the main parts of the name.

The first part of the name can be further divided up into three subparts, separated by carats (^). The first subpart can contain multiple levels of increasing taxonomic specification, separated by dots (.). The third and fourth parts of the name (time aspect and system/sample) can also be modified by a second subpart, separated from the first by a carat. In the case of time aspect, the modifier can indicate that the observation is one selected on the basis of the named criterion (maximum, minimum, mean, etc.); in the case of system, the modifier identifies the origin of the specimen if not the patient (e.g., blood donor, fetus, and blood product unit). The hierarchical structure is outlined in Table 1, with references to the section numbers where each item is explained in detail.

Table 1: Hierarchical Structure of Fully Specified Analyte Names				
Subpart Name	Section			
Component/analyte	2.2			
Name and modifier	2.2.1			
Component/analyte name	2.2.1.1			
Component/analyte subname	2.2.1.2			
Component/analyte sub-sub-name	2.2.1.3			
Information about the challenge (e.g., 1H post 100 gm PO challenge)	2.2.2			
Adjustments/corrections	2.2.3			
Kind of Property (mass concentration, mass)	2.3			
Time Aspect (point or moment in time vs. time interval)	2.4			
System/Sample type (urine, serum)	2.5.1			
"Super System" (patient, donor, blood product unit)	2.5			
Type of Scale (nominal, ordinal, quantitative)	2.6			
Method Type	2.7			

We used Tietz<sup>xii</sup>, Henry<sup>xiii</sup>, IUPAC<sup>xiv</sup>, EUCLIDES<sup>xv</sup>, diagnostic microbiology textbooks, such as Mahon and Manuselis<sup>xvi</sup>, the American Association of Blood Banking<sup>xvii</sup>, and other sources as well as the expertise of the individuals or the committee to choose preferred names.

Examples of fully specified LOINC names:

Sodium:SCnc:Pt:Ser/Plas:Qn Sodium:SCnc:Pt:Urine:Qn Sodium:SRat:24H:Urine:Qn Creatinine renal clearance:VRat:24H:Ur+Ser/Plas:Qn Glucose^2H post 100 g glucose PO:MCnc:Pt:Ser/Plas:Qn Gentamicin^trough:MCnc:Pt:Ser/Plas:Qn ABO group:Type:Pt:Bld^donor:Nom Body temperature:Temp:8H^max:XXX:Qn Chief complaint:Find:Pt:^Patient:Nar:Reported

Physical findings:Find:Pt:Abdomen:Nar:Observed

Binocular distance:Len:Pt:Head^fetus:Qn:US.measured

### 2.1 General naming conventions

#### 2.1.1 Abbreviations in names of component/analyte

Except for enumerated exceptions (Table 2), abbreviations should not be used in the component (analyte) of the name. We require the use of "total", not "tot", "fraction", not "frac", "Alpha", not "A-," "Beta" not "B-" (and so on for any Greek letter), "oxygen", "not  $O_2$ ", and so on.

Table 2: Example Component Abbreviations				
Abbreviation Full Name				
Ab	Antibody			
Ag	Antigen			
DNA	deoxyribonucleic acid			
HIV human immunodeficiency virus				
HLA	human histocompatibility complex derived antigens			
HTLV 1	human t-cell lymphotropic virus-1			
Ig "X"	immunoglobulins (e.g., IgG for immunoglobulin G, IgM for immunoglobulin M)			
NOS	not otherwise specified			
RNA	ribonucleic acid			
rRNA	ribosomal ribonucleic acid			

- 2.1.2 General naming rules for the component (analyte) part of the fully specified name.
- 2.1.2.1 Place the identifier of the substance being measured first. This means "Hepatitis A antibodies (Ab)"not "Antibodies, Hepatitis A."
- 2.1.2.2 Use the generic name of a drug, not the brand name, when referring to drug concentrations and antimicrobial susceptibilities, e.g., Propranolol, not Inderal. We will usually include the brand or trade names in the related names (synonyms) field.
- 2.1.2.3 Use full taxonomic name of an organism or virus name (not the disease) when describing a test that diagnoses that disease. Say "Rickettsia rickettsii Ab" not "Rocky Mountain spotted fever Ab". Say "herpes simplex virus Ab" not "HSV Ab." The disease name should be included as a synonym in the related name field.
- 2.1.2.4 **Species and groups of species:** SP identifies a single species whose identity is not known. SPP identifies the set of species beneath a genus. We have a third case, however. In some tests, antibodies apply to different strains of species. In rickettsial diseases, the antibodies are then against groups of species, e.g., the spotted fever group or the typhus group. In this case we use Rickettsia spotted fever group and Rickettsia typhus group.
- 2.1.2.5 When tests include the name of a bacterium (e.g., Neisseria gonorrhoeae DNA probe) for the formal LOINC name we use the full bacterial name from the International Journal of Systematic

and Evolutionary Microbiology<sup>xviii</sup>. When it includes the name of a virus (e.g., West Nile Virus IgM antibodies), we use the viral name as given by Index Virum<sup>xix</sup>.

- 2.1.2.6 When the test measures an antigen to a specific species of organism but cross-reactivity is such that other organisms are identified, the name should be the principal organism that is targeted by the test.
- 2.1.2.7 Avoid "direct" and "indirect" except as parts of synonym names. Avoid "conjugated" and "unconjugated" when a more precise term, such as "glucuronidated" or "albumin-bound" is available.
- 2.1.2.8 Use "platelets", not "thrombocytes."
- 2.1.2.9 **Name vitamins by the chemical name.** For example, use thiamine not Vitamin B1, The name containing "Vitamin" will be included as a synonym. This is the only reasonable approach because all vitamins have a chemical name but not all vitamins have a "numbered" vitamin name.
- 2.1.2.10 Always specify whether serology tests measure the antigen or antibody, using the abbreviation "Ab" for antibody and "Ag" for antigen. Remove the "anti" from "ANTI X Ab." It is redundant and obscures the most significant word in the name. Thus, "anti-smooth muscle Ab" becomes "Smooth muscle Ab." Common abbreviations or shortened names, e.g., ANA for anti-nuclear antibody, will be found in the related names field.
- 2.1.2.11 VDRL will be named Reagin Ab because that is what it is. We will have to depend upon synonyms and aliases to equate our "standardized" names with the old names.
- 2.1.2.12 Use the noun form of the target of the antibody, e.g., Myocardium Ab, not Myocardial Ab.
- 2.1.2.13 **Anion vs. acid:** Always use the anionic name for chemicals, not the acid name, e.g., lactate, citrate, and urate, not lactic acid, citric acid, and uric acid. The acid form of the name will be included in the related names field of the database.
- 2.1.2.14 **Alcohols:** Always use the single-word names for alcohols: methanol, not methyl alcohol; ethanol, not ethyl alcohol, and so on.
- 2.1.2.15 Always spell out OH as Hydroxy, or as ol, with no space or hyphen between Hydroxy and the next word.
- 2.1.2.16 Greek letters, alpha, beta, gamma, etc., are always spelled out (e.g., alpha tocopherol, not A-tocopherol), with a space between the spelled out Greek letter and the rest of the chemical name
- 2.1.2.17 Use pH, not log (H+).
- 2.1.2.18 Whenever possible, the component will contain the scientific names of allergens. NOTE: This is a new convention implemented in January 2002.
- 2.1.2.19 Avoid use of the word "total" in laboratory test names, except when denoting the denominator of a fraction. Thus it is Alkaline phosphatase, not Alkaline phosphatase.total, but Alkaline phosphatase.bone/Alkaline phosphatase.total.
- 2.1.2.20 For drug metabolites, we will use the "nor" form rather than "desmethyl", e.g., for instance nordoxepin not desmethyldoxepin.

#### 2.1.3 Punctuation in analyte names

A number of analyte names include punctuation characters such as commas, for example, to identify the position of multiple alkyl groups in a carbon chain. We will avoid special characters, e.g., commas, dashes, and parentheses, except where they are included in the name specified by IUPAC, the Chemical Abstract Service (CAS) convention, or another international convention. So commas will appear in multiple substitutions of alkyl chains per the CAS standard, dashes will appear in HLA antigen names, and parentheses (i.e., round brackets) will appear in the names of red blood cell antigens.

#### 2.1.4 Case insensitivity

All names are case insensitive. Prior to December 2006, we used upper case in the database and our examples, but change to mixed case for easier readability. In electronic messages senders and receivers can use upper, lower or mixed case. However, the meanings should not be sensitive to case conversions to avoid any possibility of confusion when the information is sent over networks that may apply case conversion. To identify parts of the few names that by international convention are case sensitive, such as red blood cell antigens, we use the word "little" in front of the letter that is lower case. We use a similar convention to indicate superscripts with the word SUPER. See examples in Table 3.

Table 3: Example Case Specifying Conventions			
Our conventions	Standard mixed case		
L little u super little a	Lu <sup>a</sup>		
little i-1 subtype	i-1 Subtype		

#### 2.1.5 Roman numerals vs. Arabic numerals

Whenever possible, numerals shall be represented in their Arabic form. However, when the conventional name uses Roman numerals as is the case for clotting factors such as factor VIII, the LOINC primary name will use Roman numerals and we define a synonym containing Arabic numerals.

### 2.2 Component/analyte (1st part)

The first main part consists of three subparts: (1) the principal name (e.g., the name of the analyte or the measurement); (2) the challenge or provocation, if relevant, including the time delay, substance of challenge, amount administered, and route of administration; and (3) any standardization or adjustment.

The three subparts of the first part follow this syntax:

```
<[analyte].[subclass].[sub-subclass]> ^
<[time delay] post [amount] [substance] [route])> ^
<adjustment>
```

In the above syntax, the carat (^) is a required delimiter and the "dot" (.) separates the analyte name from its subspecies.

This convention also implies that dots (.) and carats (^) cannot be a formal part of any of the words that are connected by these delimiters.

These subparts are described in greater detail below, Sections 2.2.1 through 2.2.3.

### 2.2.1 Analyte Name (1st subpart)

The first subpart names the analyte, including any relevant sub-classifications, separated from the main analyte name by dots.

### 2.2.1.1 Analyte/Subclass

The principal name (the first subpart) can be divided further by subclass (e.g., Calcium by itself is one component, Calcium.ionized names another test that measures a subclass of calcium.) Subclasses are separated by dots. Examples of common subclasses include: bound, free, and bioavailable; ionized and non-ionized; glycated; glucuronidated and non-glucuronidated; IgA, IgD, IgE, IgG, and IgM as modifiers indicating the subspecies of antibodies. Note that bio-available is distinguished from free by including both free and partially bound moieties.

If the antibody is from a particular subclass of antibodies specify the type of immunoglobulin (IgM, IgG, IgA, or IgD) e.g., Hepatitis A virus Ab.IgG, Hepatitis A virus Ab.IgM. If more than one subclass of immunoglobulin is included in the measurement, all are listed in the subclass, e.g., "Mumps virus Ab.IgG+IgM" with a plus sign (+) to separate the subspecies. There should be no spaces between the plus sign and the words it connects.

If two constituents are measured as one quantity, both should be named and the component separated by a plus sign, e.g., Cyclosporine+metabolites.

If analytes are measured separately, such as in a panel, the analytes are separated by an ampersand (&) surrounded by spaces, e.g., ABO & Rh panels. In panels, each analyte is measured individually. Impressions provide another use of the ampersand, for example, Hepatitis A virus Ab.IgM & total impression. In the case of the Hepatitis antibody impression, both the IgM antibody and the total impression are described separately.

### 2.2.2 Challenge test (2nd subpart)

The second subpart contains information necessary to interpret "challenge" (or loading or tolerance) tests. Variables that report the result of a measurement taken a certain amount of time post challenge (e.g., glucose after an oral glucose tolerance test) must be distinguished according to the challenge and the time post challenge. Thus, the second subpart has a substructure that identifies the time interval or time difference and the challenge, using the following syntax, where the word "post" (or base line) is required.

```
<time delay> "post" <challenge>
```

where the challenge can be further characterized as

<amount given> <substance/treatment given> <route given>

An example of a challenge that used all parts would be: Aldosterone^1H post 25 mg captopril PO The time difference follows the syntax: n < S|M|H|D|W> where n is a number (possibly a decimal); S denotes seconds; M denotes minutes; H denotes hours; D denotes days; and W denotes weeks. The time delay can be preceded by a 'greater than' (>) sign, e.g., >4H. Table 4 lists some possible values for time difference, but any time specification that follows the above syntax would be legal. In addition to specifying a time elapsed since challenge, the time delay slot can be used to name a clock time when the measurement was taken, e.g., Glucose^10 AM specimen, or to specify the ordering of specimens, e.g., ^1st specimen, ^2nd specimen. Use this syntax to indicate pre- and post-immunization specimens, acute and convalescent specimens, or a series of specimens for which no more detailed information is available.

Table 4: Example Time Delay Post Challenge						
BS Baseline (time just before the challenge)						
PEAK	The time post drug dose at which	the highest drug level is reached (differs by drug)				
TROUGH	The time post drug dose at which	h the lowest dru	g level is reached (varies with drug)			
RANDOM	Time from the challenge, or do	se not specified (	(random)			
n minutes/ho	n minutes/hours/days/weeks/months/etc. after challenge begun:					
1M	1 minute post challenge	6H	6 hours post challenge			
2M	2 minutes post challenge	7H	7 hours post challenge			
3M	3 minutes post challenge	8H	8 hours post challenge			
4M	4 minutes post challenge	8H SHIFT	8 hours aligned on nursing shifts			
5M	5 minutes post challenge	12H	12 hours post challenge			
6M	6 minutes post challenge	24H	24 hours post challenge			
7M	7 minutes post challenge	2D	2 days			
8M	8 minutes post challenge	3D	3 days			
9M	9 minutes post challenge	4D	4 days			
10M	10 minutes post challenge	5D	5 days			
15M	15 minutes post challenge	6D	6 days			
20M	20 minutes post challenge	7D	7 days			
25M	25 minutes post challenge	1W	1 week			
30M	30 minutes post challenge	10D	10 days			
1H	1 hour post challenge	2W	2 weeks			
1.5H	1 <sup>1</sup> / <sub>2</sub> hour (90 min) post challenge	3W	3 weeks			
2H	2 hours post challenge	4W	4 weeks			
2.5H	2 <sup>1</sup> / <sub>2</sub> hours post challenge	1MO	1 month (30 days) post challenge			
3Н	3 hours post challenge	2MO	2 months (60 days) post challenge			
4H	4 hours post challenge	3MO	3 months (90 days) post challenge			
5H	5 hours post challenge					

The second subpart is also used to describe measurements taken at a specified point after the beginning of an ongoing treatment, such as peritoneal dialysis, e.g., Creatinine^12H post peritoneal dialysis. More generally, this syntax can be used to indicate that observations were recorded, e.g., ^post partum, ^post surgery, or ^post EDTA therapy.

The syntax of the second subpart can be specified in various ways to indicate challenges of greater or lesser specificity, corresponding to the amount of detail that the laboratory knows about the challenge specimen.

Examples of the range of possibilities include:

Table 5: Example Challenge Subparts						
Analyte	"^"	Time	"Post"	Amount	Sub/Treat	Route
11-Deoxycortisol	^	8H	post	30 mg/kg	Metyrapone	PO
Corticotropin	^	45M	post	dose u/kg	Insulin	IV
Ascorbate	^		post	dose		PO
11-Deoxycortisol	^	2 <sup>ND</sup> specimen	post		XXX challenge	
17-Hydroxyprogesterone	^	6H	post		XXX challenge	
11-Deoxycortisol	^		post		XXX challenge	
Calcium	^	12H	post		CFst	
C peptide	^		post		CFst	

2.2.2.1 Reporting the baseline measure as part of a challenge test

We define one baseline term for different challenge batteries when the challenge is given by the same dose and route. So we define one baseline test for the 100 gm oral glucose tolerance test regardless of the number of separate measurements defined in the battery. For example, the baseline serum glucose for 100 gm oral glucose by mouth would be:

Glucose^pre 100 g glucose PO

A laboratory could use this same test identifier to identify the baseline result of a two hour glucose tolerance and a three hour glucose tolerance, for example.

We would define different baseline measurements for challenges with different substances. The baseline serum glucose before a challenge with 50 U insulin challenges would be defined as a different test from the baseline glucose for an oral glucose tolerance test. These different baseline tests are defined to accommodate laboratories that conventionally do the same. However, baseline glucose for any challenge is not affected by the challenge and could in principle be reported as glucose without specifying the relation to a coming challenge.

We denote the route of the challenge by HL7 Version 2.3 "abbreviations for medication routes" (Table 6). An oral route of administration would be denoted by "PO," <sup>1</sup>an intravenous route by "IV."

	Table 6: Example Route Abbreviations for Challenge Part(from HL7 v.2.3, Chapter 4)					
Abbr.	Challenge Description	Abbr.	Challenge Description			
AP	Apply Externally	MM	Mucus Membrane			
В	Buccal	NS	Nasal			
DT	Dental	NG	Nasogastric			
EP	Epidural	NP	Nasal Prongs			
ET	Endotrachial Tube	NT	Nasotrachial Tube			
GTT	Gastronomy Tube	OP	Ophthalmic			
GU	GU Irrigant	ОТ	Otic			
IMR	Immerse (Soak) Body Part	OTH	Other/Miscellaneous			
IA	Intra-arterial	PF	Perfusion			
IB	Intrabursal	PO	Oral			

<sup>1</sup> In the United States, PO (an abbreviation for per ora) is used to identify medications taken by mouth.

IC	Intracardiac	PR	Rectal
ICN	Intracervical (uterus)	RM	Rebreather Mask
ID	Intradermal	SD	Soaked Dressing
IH	Inhalation	SC	Subcutaneous
IHA	Intrahepatic Artery	SL	Sublingual
IM	Intramuscular	TRH	Thyrotropin-releasing hormone
IN	Intranasal	TP	Topical
IO	Intraocular	TRA	Tracheostomy
IP	Intraperitoneal	TD	Transdermal
IS	Intrasynovial	TL	Translingual
IT	Intrathecal	UR	Urethral
IU	Intrauterine	VG	Vaginal
IV	Intravenous	VM	Ventimask
MTH	Mouth/Throat	WND	Wound

#### Examples:

Glucose^pre 100 g glucose PO:MCnc:Pt:Ser/Plas:Qn

Glucose^30M post 100 g glucose PO:MCnc:Pt:Ser/Plas:Qn

Gentamicin^trough:MCnc:Pt:Ser/Plas:Qn

For drug peak (obtained at a time presumed to reflect the highest concentration) and trough (obtained at a time presumed to reflect the lowest concentration) measures the nature of the substance loaded is the same as the analyte name, and need not be included.

#### 2.2.2.2 Physiologic challenges

Some challenges are defined in terms of a physiologic stress, not a dose of a chemical substance. The LOINC names currently cover calorie fasts (no calorie intake), exercise, and fluid restrictions. These challenges are denoted by codes given in Table 7.

In the case of such challenges, the syntax also includes the duration of the challenge.

For example:

post <duration><physiologic challenge> Triglyceride^post 12H CFst

Table 7: Example Nature of Challenge			
Туре	Description		
CFst	Calorie fast. No caloric intake (food) for the period specified in the time part of the term, e.g., POST 12H CFst		
Exercise	Exercise undertaken as challenge (can be quantified)		
FFst	Fluid "fast." No fluid intake for the period specified		

The naming structure is an exact analogous structure to that of chemical challenges. A test for glucose after 12 hours of an energy fast would be represented as:

Glucose^post 12H CFst:MCnc:Pt:Ser/Plas:Qn

A test for osmolality after a 12-hour fluid restriction would be:

Osmolality^post 12H FFst:Osmol:Pt:Urine:Qn

A test for triglyceride after 12-hour energy fast would be:

Triglyceride^post 12H CFst:MCnc:Pt:Ser/Plas:Qn

Two durations can appear in one specification, for example:

Cortisol^1.5H post 0.05-0.15 U insulin/kg IV post 12H CFst:MCnc:Pt:Ser/Plas:Qn

Our rules for naming challenge tests work well only when there is a single intervention followed by a test for one or more components over time. Complex challenge tests involving more than one intervention or complicated sampling techniques need a unique name, but the name may not provide a complete description of all of the test parameters.

2.2.2.3 Reporting characteristics of challenge as separate observations

Because we cannot anticipate every type of challenge and route of administration, and because some challenge tests have no usual dose, some challenge tests will not contain a dose. Challenge observations that do not include a specific dose in the name have the word "dose" where a numeric dose would otherwise appear. The general form is:

<analyte>^<time> post dose <route>

Examples:

Glucose^1H post dose insulin IV:MCnc:Pt:Ser/Plas:Qn

The actual dose might then be sent as a comment or as a separate "test" that carries the dose as its value. To accommodate laboratories that wish to transmit the relevant challenge dose as a separate observation, we also define separate test names (and codes) for reporting such doses. This dose could then be sent by the reporting service as a separate result in a separate OBX segment. The name of the observation that identifies the value of the dose would have the form:

<drug or challenge substance>: <time> post dose <challenge substance>

Examples:

Glucose.PO:Mass:Pt:Dose:Qn

Gentamicin:Mass:Pt:Dose:Qn

Thus we distinguish a drug concentration from the drug dose by means of the system (sample), 4th part, of the test name (see Section 2.5). You can find the observations that carry the dose of drugs or challenges grouped in the class DRUGDOSE in the LOINC database. This approach has the advantages of parsimony and practicality. It also provides an observation ID for the piece of information that must be transmitted along with the request for the observation.

Another example would be:

Oxygen:PPres:Pt:BldA:Qn

Oxygen inhaled:VRat:Pt:Inhl gas:Qn (liters/minute or milliliters/second)

Oxygen inhaled mechanism:Type:Pt:Dose:Nom (to report kind of delivery mechanism, e.g., nasal cannula)

An analogous approach is used for reporting many kinds of associated variables when the variables are not conventionally embedded in the name, in part because there are too many levels of the variables and it is not feasible.

### 2.2.2.4 Generic challenge specifications

We allow for a range of specificity regarding challenges from fully specified to very generic.

Some challenges will be specified fully as described above, e.g., ^30M post 100 g glucose PO . We will also include: challenges without the amount specified, e.g., ^30M post dose glucose ; those that specify a time elapsed but not a particular challenge, e.g., ^1H post XXX challenge ; those that do not specify the exact time but provide ordering information, e.g., ^2nd specimen post XXX challenge ; or even more generic, ^ post XXX challenge . These latter variants are needed to accommodate challenges that do not fit any common protocol, or referrals to reference laboratories where the study protocol is not reported.

2.2.2.5 Acute and convalescent, pre and post immunization

To assess the efficacy of immunizations, we measure antibody levels before and after the immunization; similarly, we obtain evidence for acute infection by assessing acute and convalescent screens. Both of these cases are reported with the 1st specimen, 2nd specimen syntax, for example:

Acute specimen, 1st specimen, pre-immunization specimen: Streptococcus pneumoniae Ab.IgG^1st specimen:ACnc:Pt:Ser:Qn Convalescent specimen, 2nd specimen, post-immunization specimen: Streptococcus pneumoniae Ab.IgG^2nd specimen:ACnc:Pt:Ser:Qn

2.2.3 Adjustments/corrections (3rd subpart)

The third subpart of the data element contains calculations that adjust or correct some measured value. We use this subpart to distinguish corrected or adjusted values from the uncorrected measurement, e.g., corrected cell counts from the raw cell counts. Since these attributes are unique to each measurement, they will be short phrases of text rather than a controlled vocabulary to define the content of the third subpart. However when defined, such a test will have a unique LOINC code and the meaning will be fixed by the text in the third part.

Examples:

Calcium.ionized^^adjusted to pH 7.4:SCnc:Pt:Ser/Plas:Qn

Leukocytes^^corrected for nucleated erythrocytes:NCnc:Pt:Bld:Qn

2.2.4 Distinguishing multiple values for any test via the test name (4th subpart)

HL7 messaging allows for multiple results for one observation. Some systems, however cannot distinguish separate answers per observation, so they made the test names like organism 1, organism 2 or substance 1, substance 2 to report multiple organisms or substances identified in samples. We do not encourage this type of reporting because that distinction can more clearly be accomplished by using one test name (e.g., organism identified) and the HL7 sub ID to distinguish the multiple

organisms/substances. However, we have created a few terms to accommodate systems that bind the distinction into their test names. The fourth subpart of the component name will allow reporting of repeat observations taken at the same time and/or on the same specimen.

Example:

Bacteria identified^^^2:Prid:Pt:Stool:Nom:Culture

## 2.3 Kind of Property (also called kind of quantity) (2nd part)

The second part of the fully specified name distinguishes between different kinds of quantities relating to the same substance, e.g., the mass concentration versus the substance (molar) concentration of sodium in a urine sample, or the absolute eosinophil count versus the percent of the total white count that is made up of eosinophils. The type of property (kind of quantity) is an IUPAC concept described in the Silver Book<sup>xx</sup>. We include most of the relevant IUPAC types of property in the LOINC properties table. (See Appendix F for more detailed examples.)

Main property categories

**Mass:** Observations reported with mass (milligrams, grams, etc.) in the numerator of their units of measure have properties that begin with the word mass: mass content, mass concentration, etc.

**Substance:** Observations reported with moles or mill equivalents in the numerator of their units of measure have properties that begin with the word substance.

**Catalytic activity:** Observations that report enzymatic activity have properties that begin with catalytic, e.g., catalytic concentration, catalytic content.

**Arbitrary:** Results that report arbitrary units in the numerator of their units of measure have a property that begins with arbitrary.

**Number:** Counts are associated with properties that begin with **number**, e.g., a white blood cell count reported as number of WBCs divided by volume of blood, would have a property of Number Concentration.

The pharmaceutical industry has the need for laboratory terms that are not specific as to whether the test measures a substance (substance concentration or substance rate) or mass (mass concentration or mass rate). We have created terms with the properties of MSCnc or MSRat to represent these more general test observations. By default, both RELMA and the online search application (<u>http://search.loinc.org</u>) hide these terms from the search results, but they can be displayed by adjusting the search limit settings in these programs.

**Category subtypes:** Each of the above major property categories has number of derivatives: **concentration, content, ratio, fraction**, and **rate** (See LOINC properties table).

Concentrations: An amount divided by a volume. These have units such as mg/dL, or gm/L.

**Contents:** An amount divided by a mass. These have units such as mg/gm sample or mg/total protein.

**Ratios:** When a result is reported as one measure divided by another taken from the same system, the property is a ratio. The ratio of the mass concentration of substance A divided by the mass

concentration of creatinine in a urine sample, for instance, is a mass ratio (MRto). The numerator and denominator of a ratio must come from the same system. If the measures come from different specimens, e.g., PT patient/PT control or creatinine serum vs. creatinine urine, it is a relative ratio (RelRto). The ratio of times coming from an actual and normal control (as in some coagulation tests) will be relative time (RelTime), a ratio of mass concentrations coming from two different specimens will be relative mass concentrate (RelMCnc), and a ratio of catalytic concentrations from different specimens will have the property of relative catalytic concentrate (RelCCnc).

**Fractions:** Fractions are ratios of a part over a whole: Creatine kinase.MB/Creatine kinase.total, if measured in grams, is a mass fraction (MFr). Fractions are usually reported as percent. In Canada and other countries, fractions are measured as pure decimal fraction. For instance, a 95% O<sub>2</sub> saturation would be resulted as 0.95. For some analytes, both styles of reporting are used in Canada, so we were asked to distinguish decimal fractions from pure fractions. Beginning with the June 2012 release, we now include terms that have ".DF" appended to the existing fraction properties. For example, some terms now have properties of "MFr.DF", "SFr.DF", "VFr.DF", etc. Because of the confusion that occurs in countries that report results as both decimal fraction and percent, these properties were created to represent decimal fractions that are reported without units.

**Rates:** A rate is a measure per a time period, e.g., mg/day would be a mass rate (MRat). Clearances have the property of volume rate, but "Clearance" will be included in analyte name to clarify meaning, e.g., Sodium renal clearance:VRat:24H:Urine:Qn

Some measures do not fit the above schema. For instance, IUPAC describes an entitic quantity. This refers to measure per entity (e.g., cells, receptors, and molecules). Entitic quantities usually have units that include the name of some entity, e.g., red blood cells ("per  $10^6$  RBCs").

One must be careful when mapping measures of constituents of red blood cells to LOINC code because they can be expressed many ways, e.g., as an amount "per mass of hemoglobin", "per liter of blood" or "per red blood cell". The first is a mass content, the second a mass concentration, and the last is an entitic mass (mass per entity) — all different properties.

Some tests report the name of an organism (or initially report the presence of any organism, and later identify the particular strain), toxic substance, antibody or antigen, as a test result. Use "Prid" (presence or identity) as the type of property field for results of this sort.

For example:

Bacteria identified:Prid:Pt:Isolate:Nom:Bacterial subtyping

Barbiturates positive:Prid:Pt:Urine:Nom:Confirm

ACnc means the number of arbitrary units in a volume (arbitrary concentration). We have long used ACnc as a "temporary" place-holder for observations with ordinal answers. We now have a plan for a more appropriate property for many ordinal measures. We will us "Threshold" as the property for observations reported as "positive" or "negative" based on an internal threshold or cut off. This property will apply to most toxicology and chemistry tests and antigen and antibody tests that are reported as positive/negative or detected/not detected. For organism specific cultures that report simply that and organism is present or not, we will use "Pr" for presence. Property of "Prid" will continue to be used when the result is selected from a list of organisms, as described above. This transition is underway (starting with the June 2012 release), but being implemented gradually.

NOTE: For order sets/panels, the property field may be populated by a dash (-).

Correct assignment of properties tends to be the most difficult task for new users of LOINC. Appendix E provides more explanation and many detailed examples.

Table 8: Example LOINC properties				
Eı	nzymatic Activity			
CAct	*Catalytic Activity			
CCnc	Catalytic Concentration			
CRto	Catalytic Ratio			
CCnt	*Catalytic Content			
CFr	*Catalytic Fraction			
CFr.DF	Decimal catalytic fraction			
CRat	Catalytic Rate			
RelCCnc	Relative Catalytic Concentration			
CSub	Catalytic Substance			
	Entitic			
EntCat	*Entitic Catalytic Activity			
EntLen	Entitic Length			
EntMass	Entitic Mass			
EntNum	*Entitic Number			
EntVol	*Entitic Volume			
EntSub	Entitic Substance			
	Mass			
Mass	Mass			
MAric	Mass Aeric			
MCnc	*Mass Concentration			
MRto	Mass Ratio			
MCnt	Mass Content			
MFr	*Mass Fraction			
MFr.DF	Mass Decimal Fraction			
MRat	Mass Rate			
MRto	Mass Ratio			
RelMCnc	*Relative Mass Concentration			
RelMRat	Relative Mass Rate			
ThrMCnc	*Threshold Mass Concentration			
MCncDiff	Difference in Mass Concentration			
MCPctDiff	Percent Difference in Mass Concentration			
Substance	(Moles/Milliequivalents)			
RelSCnc	*Relative Substance Concentration			
Sub	*Substance Amount			
SCnc	*Substance Concentration			
SRto	*Substance Ratio			
SCnt	*Substance Content			
SFr	*Substance Fraction			
SFr.DF	Decimal Substance Fraction			
SRat	*Substance Rate			

Table 8: Example LOINC properties				
RelSRat	Relative Substance Rate			
ThrSCnc	Threshold Substance Concentration			
SCncDiff	Difference in Substance			
~	Concentration			
LsCnc	Log substance concentration			
	Counts			
Num	*Number			
Naric	Number Aeric (number per area)			
NCnc	*Number Concentration (count/vol)			
NCnt	Number Content = Count/Mass			
NFr	*Number Fraction			
NRat	Number=Count/Time			
NRto	Number Ratio			
LnRto	Log Number Ratio			
LnCnc	Log Number Concentration			
	Volumes			
Vol	*Volume			
VCnt	*Volume Content			
VFr	*Volume Fraction			
VFr.DF	Volume Decimal Fraction			
VRat	*Volume Rate			
VRatCnt	Volume Rate Content			
VRatRto	Volume Rate Ratio			
VRto	*Volume Ratio			
RelVol	Relative Volume			
RelVRat	Relative Volume Rate			
ArEnrg	Energy/Area			
ArResis	Resistance/Area			
ArVol	Volume/Area			
ArVRat	Volume Rate/Area			
VFrDiff	Difference in Volume Fraction			
VPctDiff	Percent Volume Difference			
VRtoPctDiff	Percent Volume Ratio Difference			
	Time			
Time	Time			
TmStp	Time Stamp—Date and Time			
TRto	Time Ratio			
TQ2	Timing Quantity 2			
RelTime	*Relative Time			
DateRange	Date Range			
ClockTime	Clock Time			
TmStp	Time Stamp—Date and Time			
TimeDif	Time Difference			
	Arbitrary			
ACnc	Arbitrary Concentration			
ACnt	Arbitrary Content			
	shawy content			

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FldConduct Fluid Conductance	
Force Mechanical Force	
Imp Impression/interpretation of	of study
ID Identifier	
Instruct Instructions	
InvLen Inverse Length	

Table 8:	Example LOINC properties
Inverse VI	Inverse Inspired Volume
Hx	History
Len	Length
LenFr	Length Fraction
LenRto	Length Ratio
Loc	Location
MoM	Multiple of the median
Morph	Morphology
OD	Optical density
Osmol	*Osmolality
Pn	Person name
Pr	Presence
Prctl	Percentile
Prid	Presence or Identity
PPres	*Pressure (partial)
PPresDiff	Difference in Partial Pressure
Pres	Pressure
PresRat	Pressure Rate
PressDiff	Difference
PresRto	Pressure Ratio
Quintile	Quintile
Ratio	Ratio
RatDiff	Rate Difference
RelRto	Relative Ratio
Resis	Resistance
SatFr	*Saturation Fraction
Seq	Nucleotide sequence
Shape	Shape
Susc	Susceptibility
Temp	*Temperature
Tele	Telephone number
Txt	Text
Threshold	*Threshold
Titr	Dilution Factor (Titer)
Туре	Туре
Vel	*Velocity
VelRat	Velocity Rate
VelRto	*Velocity Ratio
Visc	Viscosity

### 2.4 Time Aspect (Point or moment in time vs. time interval) (3rd part)

One can either measure a property at a moment (point) in time or measure it over a time interval and integrate, in the mathematical sense, over time. In the latter case, we aggregate a "series" of physiologic states into a single scalar value that reflects some "average" property measured over the specified time interval. Intervals also have relevance for rate measurements such as excretion (substance rate or mass

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rate) or clearances (volume rates). The amount over an interval is often expressed as a mass rate (MRat, e.g., g/24h) or a substance rate (SRat, e.g., mol/24h). Interval measurements often apply to urine and stool (e.g., collection over 24 hours and calculation of a concentration, total amount, or clearance). They also apply to clinical measurements such as urine outputs where we have shift totals and 24-hour totals. Event counts on physiologic monitors, such as the number of premature ventricular contractions (PVCs) over 24 hours on a Holter monitor, are also of this type.

The allowed values for non-point time aspect are defined as a syntax exactly like the syntax for the times in challenge tests, e.g., <numeric value><S|M|H|W> The most common one is 24H. Table 9 gives some other examples.

For urine collection, 24H is the "standard" integrated measure and these are almost always reported as mass rates (MRat), substance rates (SRat), or catalytic (CRat) rates. These would contrast with spot or random urine tests that are represented as point (PT) measures in our nomenclature and usually reported as concentrations -- MCnc, CCnc, or SCnc for mass, catalytic, and substance concentrations respectively. However, we can also report the average concentration on a 24-hour specimen – in this case the time aspect value would be 24H but the property would be MCnc/SCnc/CCnc instead of MRat/SRat/CRat.

The designation of 24H collection is maintained for tests that traditionally have reference ranges based on amount of substance of a component cleared or excreted in 24 hours. However, a given specimen could have a 23-hour collection time and would still be called a 24H study. Depending upon the policies and procedures of the lab, they might extrapolate the reported value to what it would have been if the collection continued for the full 24 hours and report it as moles per day.

We also allow indirect specifications of a time window. Stdy identifies the duration of the study (without specifying an exact time); Enctr identifies the Encounter (ER visit, hospital stay, etc.).

Sample volumes reported for timed measurements are carried in other fields or as separate "test" results in other OBX segments.

	Table 9: Example Duration Categories				
Abbr.	Duration Descriptions				
Pt	To identify measures at a point in time. This is a synonym for "spot" or "random" as applied to urine measurements.				
Stdy	Duration of the study	1			
Enctr	Duration of an encou	inter (hospital stay, vis	sit).		
Episode	Episode				
Gt 1H	Greater than 1 hour				
Ge 1 Hr	Greater than or equa	l to 1 hour			
Lt 1H	Less than 1 hour				
Procedure dur	Duration of the proc	edure (surgery, etc.)			
XXX	Not specified; time v	vill be reported in anot	her part of the electroni	c message	
* (star)	Life of the "unit". U	Life of the "unit". Used for blood products.			
Abbr.	Description	Abbr.	Description	Abbr.	Description
1M	1 minute	7H	7 hours	2W	2 weeks
5M	5 minutes	8H	8 hours	3W	3 weeks
10M	10 minutes	9H	9 hours	4W	4 weeks
15M	15 minutes	10H	10 hours	1MO	1 month (30 days)
20M	20 minutes	12H	12hours	2MO	2 months
30M	30 minutes	18H	18 hours	3MO	3 months
45M	45 minutes	24H	24 hours		
90M	90 minutes	48H	48 hours		
1H	1 hour	1D	1 day		
2H	2 hours	2D	2 day		
2.5H	2.5 hours	3D	3 day		
3Н	3 hours	4D	4 day		
4H	4 hours	5D	5 day		
5H	5 hours	6D	6 day		
6H	6 hours	1W	1 week		

## 2.4.1 Time Aspect Modifier

The second and optional subpart of the time component allows an indication of some sub-selection or integration of the measures taken over the defined period of time: 8H<sup>^</sup>max heart rate would be the highest heart rate observed over 8H (Shift). Min, max, first, last, mean are the other possible values for this subpart. When nothing is stored in this subpart, we assume a mean value over the time period in questions. Valid values for this subpart are listed in table below.

Table 10: Time Aspect Modifier Codes		
Time	Description	
min	Minimum value over interval	
max	Maximum value over interval	
frst	First value observed during an interval	
last	Last value observed during an interval	
mean	Mean of all of the values observed on the interval (This is the default selection.)	

## 2.5 System (Sample) Type (4th part)

System (sample) type is the fourth part of the fully specified test name. It consists of two subparts; the first part names the system, the optional second part, delimited with a "^", indicates the super system source of the sample if it is not the patient, e.g., fetus, blood product unit, donor, etc.

We define different tests for the combination of component (analyte) and type of system (sample) that are commonly reported. In practice, laboratories include a relatively small range of sample types in their test names. Chemical tests commonly distinguish between serum, urine, blood, and cerebrospinal fluid. Microbiology cultures tend to distinguish between greater numbers of sources.

The first part of the system field should be coded using the abbreviations listed in Table 11. Since this list was defined for reporting sample type in a field of the HL7/ASTM message that is quite independent of the test/measure name, we do not imply that all such types will find their way into distinct LOINC names. However, when a distinction by type of system is required in the name, it should be represented by one of these codes.

For many chemistry tests we have included in the LOINC database a test name for identifying miscellaneous types of body fluid (Body fld), to provide a way to distinguish tests that are performed on fluid types that are not explicitly represented in the database. We use the code XXX to identify a material that is not specified — it could be solid or fluid, for example.

When should we lump a variety of specimen types under the nonspecific code "Body fld" and when we should give a body material its own unique name for a given component? The decision depends upon the degree to which laboratories have reported the system-component pair as a separate "result" and the degree to which the normal ranges for a given component-system have been standardized. By this rule, we will always define different tests for serum and for urine, when a component can be measured in both. We define sweat sodium as a distinct test because it is a standardized test used to diagnose cystic fibrosis. We did not define duodenal fluid sodium as a separate LOINC code because this measure has not been standardized. This does not mean that the specifics about the system would be ignored. It just means that this information would be recorded in another field of the message (the specimen field of the HL7 OBR segment), not in the name. Generally, we will specify the type of system to distinguish at least among blood, urine, cerebrospinal fluid, pleural fluid, synovial fluid, and peritoneal fluid.

For many types of tests, the distinction between plasma and serum is irrelevant. When testing on serum or plasma is clinically equivalent, the system should be recorded as Ser/Plas. Sometimes the test can only be run on either plasma or serum; the component will then be associated with either Ser or Plas in one observation. If the test can be run on either but the results are different and standardized (a very rare circumstance), two separate tests will be defined in our file, one with a system Plas and one with a system Ser. The current LOINC database includes some Ser tests and some Plas tests that should really be Ser/Plas. As we determine that a Ser or Plas test really should have been designated Ser/Plas, we will change the designation.

If the test is run on a combination of types of system (such as a ratio of substance found in CSF and plasma) the codes are joined with a "+": Plas+CSF, Ser+CSF, Isolate+Ser, etc.

Details about the exact source and collection method (e.g., blood drawn from the right arm and maintained on ice) are not a proper part of the test name and are reported in other parts of the message, e.g., OBX and OBR of the HL7 message.

## Special issues related to XXX as system

Increasingly we get requests, often from the public health context, for tests with XXX as the specimen. XXX is a valid LOINC specimen, and often needed in many cases. However, LOINC typically needs a term with a more specific specimen instead of, or in addition to the XXX. Recall that XXX can be used to represent any specimen of any kind (insects, road kill, and ingested food). LOINC already has some general specimen terms that are broad but more constrained than XXX. For example, we have Bld/tiss and Body fld, which represents fluid from all of the serosal cavities, (though this also deserves discussion). We can create more such general specimen terms if needed.

Use of XXX for the specimen can create problems. Firstly, the reference ranges for measures on a continuous scale change with specimen differences, and most systems depend upon the test code to get to the reference ranges. So using the same code for very different specimens can break the range checking in many systems. Of course the XXX specimen type is most commonly requested for microbiology tests used to identify micro-organisms by culture, DNA/RNA or specific antigens. In this case the nature of the specimen might not change the clinical implication for some organisms; we suspect that anthrax found anywhere in the body has the same implication. But it does make a big difference for some organisms that are natural inhabitants of the skin or digestive system, but not of the blood.

Thirdly, if there is no hint of the specimen in the test name, clinicians will have a more difficult time ordering common microbiology tests. They won't be able to order urine culture and blood culture each with a single click, and laboratories will have a more difficult time managing these orders. This is especially true given the current state of many HL7 messages that only rarely use codes in the specimen field. (Granted, there is hope for the future). Fourthly, and most importantly, there is the issue of approved use. Package inserts are very specific and limiting about the specimens for which the test kit is approved. We have had a recent request for a test with specimen of XXX whose package insert allowed its use only on Saliva. What do we do? Referral laboratories tend to define tests for class of specimens approved for use on the instruments/test kits they employ. We have received requests for terms with XXX but the test is really only used for specimens from body parts that can "catch" STD.

So, the bottom line is that we won't accept requests for tests with XXX specimens without a narrative description of the most common specimen and some sense of the range of specimens for which it is used. We will likely argue for either adding a distinct code for the dominantly common specimen (e.g. Stool for ameba histolytica) or the specimen prescribed by the package insert, or for entertaining a new specimen code broader than those now available but narrower than XXX to accommodate a particular need, e.g. sterile body fluid, or Genital/anal/throat (for STD specimens). This will, of course, take time and discussion.

Table 11: Example Laboratory System/Sample Types					
Abbr.	Name	Abbr.	Name	Abbr.	Name
Abscess	Abscess	Fistula	Fistula	Ser	Serum
Amnio fld	Amniotic fluid	Body fld	Body fluid, unsp	Skin	Skin
Anal	Anus	Food	Food sample	Sputum	Sputum
Asp	Aspirate	Gas	Gas	Sptt	Sputum - tracheal aspirate
Bil fld	Bile fluid	Gast fld	Gastric fluid/contents	Stool	Stool = Fecal
BldA	Blood arterial	Genital	Genital	Sweat	Sweat
BldL	Blood bag	Genital fld	Genital fluid	Synv fld	Synovial fluid (Joint fluid)
BldC	Blood capillary	Genital loc	Genital lochia	Tear	Tears
BldCo	Blood – cord	Genital muc	Genital mucus	Thrt	Throat
BldMV	Blood- Mixed Venous	Hair	Hair	Platelets	Thrombocyte (platelet)
BldP	Blood – peripheral	Inhl gas	Inhaled gas	Tiss	Tissue, unspecified
BldV	Blood venous	Isolate	Isolate	Tlgi	Tissue large intestine
Bld.dot	Blood filter paper	WBC	Leukocytes	Tsmi	Tissue small intestine
Bone	Bone	Line	Line	Trachea	Trachea
Brain	Brain	Liver	Liver	Tube	Tube, unspecified
Bronchial	Bronchial	Lung tiss	Lung tissue	Ulc	Ulcer
Burn	Burn	Bone mar	Marrow (bone)	Urethra	Urethra
Calculus	Calculus (=Stone)	Meconium	Meconium	Urine	Urine
Cnl	Cannula	Milk	Milk	Urine sed	Urine sediment
СТр	Catheter tip	Nail	Nail	Unk sub	Unknown substance
CSF	Cerebral spinal fluid	Nose	Nose (nasal passage)	Vag	Vagina
Cvm	Cervical mucus	Nph	Naspopharynx	Vitr fld	Vitreous Fluid
Cvx	Cervix	Penile vessels	Penile vessels	Vomitus	Vomitus
Col	Colostrum	Penis	Penis	Bld	Whole blood
Cnjt	Conjunctiva	Pericard fld	Pericardial fluid	Water	Water
Crn	Cornea	Periton fld	Peritoneal fluid /ascites	Wound	Wound
Dentin	Dentin	Dial fld prt	Peritoneal dialysis fluid	XXX	To be specified in another part of the message
Dial fld	Dialysis fluid	Placent	Placenta		
Dose	Dose med or substance	Plas	Plasma		
Drain	Drain	Plr fld	Pleural fluid (thoracentesis fld)		
Duod fld	Duodenal fluid	PPP	Platelet poor plasma		
Ear	Ear	PRP	Platelet rich plasma		
Endomet	Endometrium	Pus	Pus		
RBC	Erythrocytes	RBCCo	Red Blood Cells Cord		
Eye	Eye	Saliva	Saliva		
Exhl gas	Exhaled gas (=breath)	Semen	Seminal fluid		
Fibroblasts	Fibroblasts	1			

These abbreviations are used in the laboratory LOINC codes. Systems in clinical LOINC terms are spelled out in full and should be easily understood.

## 2.5.1 Super system (2nd subpart)

The second subpart of the system identifies a "super-system" when it is not the patient, e.g., a blood

product unit (BPU), a bone marrow donor, or a fetus. When the super system is not included in a name, "patient" is the assumed default value. This subpart can take on the values in Table 11. Note: we use the term "fetus" broadly to include embryo, placenta and products of conception.

For instance, an example of representing a coagulation study that uses measures on both patient and a control might be:

Coagulation reptilase induced:Time:Pt:PPP:Qn:Coag

Coagulation reptilase induced:Time:Pt:PPP^control:Qn:Coag

Blood banks often report red blood cell antigens for the patient and for each blood product pack assigned to that patient. So we have:

A Ag:ACnc:Pt:RBC:Ord

A Ag:ACnc:Pt:RBC^BPU:Ord

**Note:** The inclusion of the super system as part of the system represents a change from versions of LOINC prior to Release 1.0K, May 1998. Earlier versions included this information in the (no longer valued) fourth subpart of the component.

## 2.6 Type of Scale (5th part)

The fifth data part of the test name specifies the scale of the measure, and is a required part. The abbreviation of the type of scale (previously called precision), given in Table 12, should be used in the fully specified name. Note that with the release of Version 1.0K, May 1998, we changed the codes for these from SQ to ORD and from QL to NOM to more accurately identify the meaning.

Table 12: Type of Scale			
Scale Type	Abbr.	Description	
Quantitative	Qn	The result of the test is a numeric value that relates to a continuous numeric scale. Reported either as an integer, a ratio, a real number, or a range. The test result value may optionally contain a relational operator from the set {<=, <, >, >=}. Valid values for a quantitative test are of the form "7", "-7", "7.4", "-7.4", "7.8912", "0.125", "<10", "<10.15", ">12000", 1-10, 1:256	
Ordinal	Ord	Ordered categorical responses, e.g., 1+, 2+, 3+; positive, negative; reactive, indeterminate, nonreactive. (Previously named SQ)	
Quantitative or Ordinal	OrdQn	Test can be reported as either Ord or Qn, e.g., an antimicrobial susceptibility that can be reported as resistant, intermediate, susceptible or as the mm diameter of the inhibition zone. (Previously named SQN) We discourage the use of OrdQn in other circumstances.	
Nominal	Nom	Nominal or categorical responses that do not have a natural ordering. (e.g., names of bacteria, reported as answers, categories of appearance that do not have a natural ordering, such as, yellow, clear, bloody. (Previously named QL)	
Narrative	Nar	Text narrative, such as the description of a microscopic part of a surgical papule test.	
"Multi"	Multi	Many separate results structured as one text "glob", and reported as one observation, with or without imbedded display formatting.	
Document	Doc	A document which could be in many formats (XML, narrative, etc.)	
Set	Set	Used for clinical attachments	

Quantitative (Qn) identifies scales that can be tied to some physical quantity through a linear equation. This means that if we have two reports for the same quantity one with a value of 5 and the other a value of 10 we know that the two are related in amount through the linear equation Y = aX + b. When the intercept, b, is non-zero, we have a difference scale. (Fahrenheit temperature is a difference scale.) When it is zero we have a ratio scale (Kelvin temperature is a ratio scale).<sup>xxi,xxii</sup>A Qn value may be reported as a value for a "continuous" scale, as is the case for serum sodium, or it may be reported from a series of

discrete values, as is the case for titers, e.g., 1:16, 1:32.

Ordinal (Ord): Some observations have values that are well ordered, e.g., "present, absent", "1+, 2+, 3+", or "negative, intermediate, positive", but the values have no linear relationship to one another. We do not know that positive is two or three times as much as intermediate, we just know that positive is more than intermediate. These kinds of observations have an ordinal scale (Ord). Tests with "yes/no" answers are always ordinal (Ord). Tests reported as negative when less than the detection level but as quantified values otherwise should be regarded as quantitative (Qn).

Quantitative/Ordinal (OrdQn): Rarely, a result can be reported in either an ordinal or quantitative scale. The principal example of this scale is a MIC, which can be reported as either resistant/intermediate/susceptible or by the MIC numeric value. The need for terms with OrdQn as scale was further obviated by clarification from HL7 that results such as "POS" and "NEG" should go in the OBX-8 field for normalcy status. Thus, LOINC codes with scale of Qn can be appropriately used in these cases even if the "values" coming back are coded interpretations of the true numeric result value.

Nominal (Nom): Some observations take on values that have no relative order. Think of the numbers on football jerseys. These simply identify the players; they do not provide quantitative information or rank ordering of the players. We refer to these as nominal (Nom) in scale. Blood culture results provide a good example. Possible values could be Escherichia coli (or a code for E. coli) or Staphylococcus aureus. Other examples are admission diagnoses and discharge diagnoses. Any test or measure that looks broadly at patient or specimen and reports the name of what it finds is a Nom scale. The values of nominal scaled observations are assumed to be taken from a predefined list of codes or from a restricted vocabulary (e.g. a menu of choices). These observations would typically be sent in an HL7 message OBX segment with a Coded Element (CE) data type (in earlier HL7 versions) or its superseding Coded with No Exceptions (CNE) and Coded With Exceptions (CWE) variants (later HL7 versions). It is important to note that the CE and CWE data types allow values to be set as codes with their print text or just as their print text alone. These data types and the Nom scale would not be used for running narrative.

Narrative (Nar): Some observations are reported as free text narrative. The content is not drawn from a formal vocabulary or code system. A dictated present illness would be an example of a scale of narrative (Nar). Many clinical LOINC codes will come in two versions: one for the nominal (coded) version and one for a narrative (free text) version.

We strongly encourage all reporting to be at the most granular level of detail. That is, if three numbers are reported they would each be reported under a unique LOINC code and transmitted in a separate HL7 OBX segment. Occasionally reporting systems are not able to comply with this dictum. For example some chromatography instruments can identify chemicals from the entire spectrum of known chemicals (CAS identifies more than 10 million distinct chemicals) and we may not have specific LOINC codes for reporting out these details. We have designated the scale of Multi to identify results that include many separately structured results as one text "glob" with or without imbedded (display formatting). Some laboratories report all of the details of many multiple measure tests under such globs with test names that correspond to their order name. We strongly discourage such reporting. It defeats the very purpose of individual codes to tag content.

**Note:** Because the individual components of an Order set/Panel often have different scales, the scale for the order set term may be populated by a dash (-).

## 2.7 Type of Method (6th part)

The method by which the test was performed is the sixth part of the test name. Methods need only be

expressed as part of the name when they provide a distinction between tests that measure the same component (analyte) but which have different clinical significance or have a different clinical reference ranges. For instance, whole blood glucose tested with a test strip might be distinguished in the method field.

The list of methods given in Table 13 is not exhaustive; we have included only those methods that are abbreviated in the database or which otherwise require explanation or clarification. Most methods are fully spelled out in the database and should be self-explanatory.

Laboratories do not include the method as part of the name for most common chemical and hematological tests. They often need the freedom to choose the instrument according to time of day, urgency of the request for service, availability of the instruments and so on, even though the instruments may employ different methods. The laboratories then adjust each of the "interchangeable" instruments to produce equivalent results even though the instruments may use different methods. Therefore, we do not want to distinguish too finely on the basis of methods. Though method is rarely significant for many chemical and hematological tests, it is often important to immunochemical/serology testing, because the sensitivity and specificity of some tests varies greatly with the method. For this reason, you will commonly see methods included in microbiology tests and coagulation tests within the LOINC database.

This does not mean that information about the method is irrelevant, but that it is not always a meaningful part of the test name. It is an essential element of the internal quality assurance of laboratories. Remember that both reference range and method can be sent in other fields of ASTM, HL7, and CEN TC251 result messages.

Table 13: Examples of Method Abbreviations				
Method	Abbr.	Comment		
Agglutination	Aggl			
Coagulation Assay	Coag	To distinguish coagulation assays based on clotting methods		
Complement Fixation	Comp fix			
Computerized Tomography	СТ			
Cytology Stain	Cyto stain	The staining method used for pap smears, fine needle aspirates and other cell stains.		
DNA Nucleic Acid Probe	Probe	See section 2.7.1 for more information about probes.		
Chromogenic/Enzymatic Assay	Chromo	To distinguish coagulation assays based on chromogenic (enzymatic) activity.		
Immunoassay	EIA	Encompasses all immunoassays		
Flocculation Assay	Floc			
Hemagglutination Inhibition	HAI			
Hemagglutination	HA	Encompasses direct and indirect		
Immune Blot	IB			
Immune Fluorescence	IF	Encompasses DFA, IFA, FA		
Latex Agglutination	LA			
Leukocyte Histamine Release	LHR			
Minimum Inhibitory Concentration	MIC	Antibiotic susceptibilities		
Minimum Lethal Concentration	MLC	Also called MBC (minimum bactericidal concentration)		
Molecular Genetics	Molgen	General class of methods used to detect genetic attributes on a molecular basis including RFL, PCR and other methods.		
Neutralization	Neut			
Radioimmunoassay	RIA			
Serum Bacterial Titer	SBT	Determines the serum dilution that is capable of killing microorganisms.		
Rapid Plasma Reagin	RPR	Microscopic flocculation test, using cardiolipin-lecithin-cholesterol antigen with carbon particles.		
Ultrasound	US			

Vertical Auto Profile	VAP	Developed by Atherotech, Inc.
Visual Count	VC	
Venereal Disease Research Laboratory	VDRL	Microscopic flocculation test

2.7.1 DNA/RNA probes/measures

We distinguish three kinds of DNA probe methods:

- 1. Probe without amplification (Probe)
- 2. Probe with target amplification (Probe.amp.tar)
  - a. See Table 14a for a list of methods that would be identified as Probe.amp.tar in the method part of the LOINC term.
- 3. Probe with signal amplification (Probe.amp.sig)
  - a. See Table 14b for a list of methods that would be identified as Probe.amp.sig in the method part of the LOINC term.

Table 14a: Examples of specific methods that would be classed as target amplified DNA/RNA         Probe.amp.tar (includes nucleic acid target amplification and probe)			
PCR*	Polymerase Chain Reaction	Applies to DNA, RNA Roche Molecular Systems (thermal cycler) Requires repeated cycles of heating and cooling-each cycle doubles the target	
TMA*	Transcription Mediated Amplification	Applies to DNA, RNA Gen-Probe, Inc. (isothermal)	
NASBA*	Nucleic Acid Sequence Based Analysis	Applies to RNA, DNA Organon-Tenika Corp (isothermal)	
SDA*	Strand Displacement Amplification	Applies to DNA Becton Dickinson (isothermal)	
LAT*	Ligation-Activated Transcription		
3SR SR*	3 Self-Sustaining Sequence Replication	Applies to RNA, DNA Bartel's Diagnostic (isothermal)	
LCR*	Ligase Chain Reaction	Also probe amplification category method Abbott Laboratories (thermal cycler)	
QBR*	Q-Beta Replicase or probe amplification category method	Applies to DNA RNA Gene Track Systems. (isothermal)	
Table 14b: Examples of specific methods that would be defined in LOINC as signal amplification methods         Probe.amp.sig (includes nucleic acid signal amplification and probe)			
HPA*	Hybridization Protection Assay	Applies to RNA Gen-Probe Accuprobe	
bDNA*	Branched Chain DNA	Applies to DNA, RNA Chiron Corp (isothermal)	
	Hybrid Capture		

\*The items in the first column of the above table are not meant to be used as methods in LOINC terms.

### 2.7.2 Immunofluorescence (IF)

We do not distinguish among many variants of immunofluorescent tests. DFA, ACIF, are all classed as immunofluorescence (IF).

### 2.7.3 Immune Stain

We classify peroxidase and all other immune stains of tissue under the method category immune stain.

## 2.7.4 Enzyme Immunoassay (EIA)

We classify many variants of enzymes under EIA, including ELISA, CEIA, etc.

### 2.7.5 Coagulation

We distinguish among three kinds of coagulation method: coagulation (Coag), which measures the coagulation activity, immune (Imm), which measures the amount of the coagulant protein, not its activity, and chromogenic (Chromo), which measures the coagulation factor via enzyme rate (also called enzymatic).

## 2.7.6 Stains

We provide very detailed distinctions among various tissue stains, naming them in full. Stain methods that are modifications of a basic method are named using a <basic>. <modification> syntax, e.g., Methenamine silver stain.Jones

## 2.7.7 Clinical measures

We distinguish reported from estimated and measured values; so reported body weight would be the stated weight from a patient or surrogate. Estimated would be the body weight estimated by an observer, and measured body weight.

### 2.7.8 Imaging studies

We distinguish among the major imaging modalities for most measures derived from such imaging studies (e.g., cardiac outputs from a MUGA scan, angiography, 2D Echo, Doppler, etc.).

## 2.8 Short Convenient Names

As of the August 2002 release of LOINC we have included a new field in the LOINC database called "SHORTNAME". This field will carry a short, mixed case name for the LOINC concept. We have populated these fields for all laboratory and radiology tests. Our goal was to produce names no longer than 30 characters in order to fit within the space allocated by most laboratory reporting systems. In contrast to the formal LOINC name case is significant in the LOINC short name. When possible, we have used common acronyms and common names rather than the more formal name rules of the full LOINC name. For example, we used the English names of allergens in the short names rather than the formal Latin species names (in part because they were shorter). The LOINC short names are subject to change and should not be used as identifying keys in any database.

These names have been created via a table driven algorithmic process. We have used all upper case to represent acronyms, and mixed case in organism names as specified in naming conventions (e.g., genus is capitalized, species is not). For virus names we used the acronym assigned by Index Virum where available.

## 2.9 Long Common Names

LOINC has received periodic requests from users to produce "pretty" display names that could be used in user interfaces, etc. While systematically created names (like the standard LOINC short names) can be guaranteed to be unique, they are sometimes not the most user-friendly. We have always expected that users would link their own local preferred names to LOINC terms for use in reports and displays. In contrast to systematically-created names, user-friendly names are often ambiguous.

After collecting and reviewing display names from several sources, we decided to create a new algorithmically-generated Long Common Name based on patterns we observed. As of the January 2009 release, we have included a new field in the LOINC Table called "LONG\_COMMON\_NAME". These names have been created by an algorithmic process and are checked for uniqueness. Most abbreviations and acronyms that are used in the LOINC database have been fully spelled out in English. For allergens, the common English names are used instead of the more formal Latin species names. For coagulation, the more commonly used phrases such as "Prothrombin time" have been used.

We started creating long common names first for laboratory terms, but are now producing them for all terms. The text strings for the long common names are subject to change over time as we continue to refine the algorithmic process and collect feedback from users. In particular, many of the long common names for clinical terms have not had as intense focus as the laboratory terms have, so we expect these to be refined over time.

## 2.10 LOINC term names in HL7 messages

Messaging standards like HL7 typically use a triplet <identifier code>^<descriptive text>^<coding system> for fields that contain coded entries, such as the OBX-3 Observation Identifier field. Given that LOINC now produces at least 3 names for each term (i.e., the six-part Fully-Specified Name, Short Name, and Long Common Name), users have wondered which LOINC name they should use in the <descriptive text> part of that field (or the equivalent displayName attribute in HL7 V3). In general, we recommend the use of the Long Common Name because they are probably the most understandable to human readers. However, the Long Common Names can be quite long and some systems may not be able to accommodate them. In these cases, we would recommend the use of the Short Name because they would fit within the space allocated by most reporting systems, could potentially work as a column name on a flow sheet, and mostly use common acronyms. Using the Fully-Specified Name (e.g. a colon-separated aggregate of the six part name) is generally not recommended because they are not as human friendly and contain more instances of 'reserved characters' like "^" and "&", which would need to be properly escaped in the message.

Furthermore, we recommend the simultaneous communication of the sender's local code and local name (in addition to the LOINC code and name) as allowed in the messaging structure to facilitate debugging and detection of mis-mappings.

## 2.11 Classes

We assign each LOINC term to a general category called a Class. These categories are relatively broad and are intended to make it easier to sort and browse the database. They are not intended to be binding definitional characteristics of the term, and we may refine them over time. A more detailed listing of the Classes is presented in Appendix B. Throughout this document many of the naming conventions and approaches are described in reference to a Class of terms. Here we provide a bit of explanation about some of the laboratory term classes.

The class of Microbiology includes all tests used to identify microorganisms and evidence for infection

by specific organisms as well as cultures direct microscopic exams that identify organisms or prove evidence for present or past infection with specific organisms. Microbiology includes tests for antibodies, antigens, DNA and RNA. The Serology class does not include measures antibodies or antigens related to microorganisms. Molecular pathology class does not include RNA or DNA based tests for infectious organisms. (They are all included in Microbiology.)

The class Blood bank includes all blood bank testing including ABO-Rh testing. Allergy class includes testing for antibodies to allergens (cat dander, trees, etc.). Serology includes rheumatological, and autoantibodies, and antigen measures not covered by these two classes. Hematology/cell counts exclude coagulation studies that are found in a separate class. Measures of complement activity are included within Hematology, not Chemistry. Chemistry does not include challenge tests such as Glucose tolerance, ACTH stimulation, etc.; these are in a separate category called Challenge tests.

# **3** Special Cases

## 3.1 Findings viewed as variables or as values

For some complex tests there are two ways to organize the results into a report.

## 3.1.1 Value

Assume a set "X" is made up of five "results" that can have a scale of (absent present) or (0 1). These results could be reported as:

Finding 1 =	Present	- or -	1
Finding 2 =	Absent	- or -	0
Finding 3 =	Present	- or -	1
Finding 4 =	Absent	- or -	0
Finding $5 =$	Absent	- or -	0

Each finding is then considered a binary variable. This is sometimes called a "panel" approach.

## 3.1.2 Variable (Multiple Choice) Approach

The alternative would be to report this information as a single variable (or multiple-choice question) with many possible values:

Variable X - Finding 1, Finding 3

In this case the findings are the values of a variable called Variable X; only the positive findings are reported as values. Many laboratory tests, e.g., those that test for HLA antigens, red blood cell antigens, or screens for toxic substances, could in theory be presented either way. The microscopic part of the differential count and urinalysis could also be described either way. History and physical findings and (given a real stretch) even culture results could be structured in the panel or multiple choice/multiple answer format.

A single lab may report red blood cell antigens in either way, as a binary panel or a multiple-choice result, depending upon the purpose of the test. The routine cross and type are reported out in the multiple choice pattern format (only positives from a modest fixed set of tested antigens are reported). But if the tests are being used to prove fatherhood, the results are usually reported as a binary panel.

Blood cultures could in theory be regarded as panels:

Test Name	Value
Escherichia coli	absent
Staphylococcus aureus	present
Diphtheroids	absent
Streptococcus pneumoniae	absent
Pseudomonas aeruginosa	present

Although in practice such tests are almost always reported in the multiple choice/multiple answer format, as follows:

Test Name	Values
Blood culture	P. aeruginosa, S. aureus

We bring up these issues to explain why we use a somewhat different data format for some types of tests, and why we sometimes provide for both reporting methods (e.g., HLA blood cell antigen tests) in the LOINC database. When a binary scale is used, the kind of property will usually be arbitrary concentration (ACnc) and the scale ordinal (Ord). As mentioned in section 2.3 we are transitioning to property of presence (Pr). When the multiple-choice multiple-answer approach is used, the scale will be nominal (Nom) and the type of property will be presence or identification (Prid).

## 3.2 Blood bank

Red cell antigens will be named in accordance with the American Association of Blood Banking (AABB) naming standards.<sup>xxiii</sup> In addition to the antigen or antibody, a modifier would be included in the supersystem (the second subfield of the System field); to indicate whether testing was performed on the patient, donor, or blood pack. Unless explicitly stated, testing is assumed to have been on a material collected from a patient. Additional information about the person identified in the fourth subpart, such as the donor's name or relationship to patient, should be placed in other OBX segments, or comment segments of the message, and would not be part of the test name.

Blood bank reporting illustrates the need for a method of reporting by panel and by multiple-answer mechanism. The LOINC database provides observation names for both kinds of reporting.

## 3.2.1 Panel reporting:

Each reportable antigen must have its own test, so that each element in a full set of binary tests could be reported as (negative, positive) or (0, 1).

The fully specified names of A, AB, B, and O blood types (as observations) would be as follows:

Measure of serum antibody against type A blood of donor:

A Ab:ACnc:Pt:Ser/Plas^donor:Ord

Presence of A antigen on donor's red blood cells:

A Ag:ACnc:Pt:RBC^donor:Ord

Presence of A antigen on the blood cells in a pack of blood given to the patient:

A Ag:ACnc:Pt:RBC^BPU:Ord

3.2.2 Multiple answer reporting:

All blood antibodies found (or not found) can also be reported in one result term:

Antigens absent:Prid:Pt:BBL^BPU:Nom Antibodies identified:Prid:Pt:Ser/Plas:Nom

The LOINC database provides other "observations" for reporting: the status of each blood pack (e.g., held, given, discarded), and for reporting that information when HIS and medical records systems want it; how much of each type of blood product was given at a moment in time; the type of each pack; any adverse reaction to that pack; and the pack number to accommodate laboratories that send this information as discrete observations.

Blood product disposition:Type:Pt:^BPU:Nom Blood product type:Type:Pt:^BPU:Nom

## 3.3 Immunocompetence studies (flow cytometry)

The CD (Cluster of Differentiation) markers in the LOINC database include all of the single markers and the most commonly reported combinations, e.g., CD11C+CD20C+. Most of these are really measuring the number or percent of cells that bear the specific T-cell marker pattern, in which case they should be specified as a subtype of a lymphocyte, e.g., Cells.CDx. There are other possibilities, and these cell types can also be named; for instance Blasts.CD2 or Abnormal blood cells.CD5.

Two kinds of measures are of interest.

3.3.1 The "absolute" number of such cells per cubic millimeter is represented as number concentrations, for example:

Cells.CD16C+CD56+:NCnc:Pt:Bld:Qn

3.3.2 Percent of cells containing the named marker per 100 cells of that type is represented as number fraction, for example:

Cells.CD16C+CD56+/100 cells:NFr:Pt:Bld:Qn

The database also includes fully specified names for all of the commonly reported HLA antigens. These are grouped in the class HLA. Experimental methods can define many subtypes of many antigens, so this list is not exhaustive, and is also likely to expand over time.

Example:

HLA-A1:ACnc:Pt:Bld:Ord

## 3.4 General approach to microbiology results

The inherently complex structure of the results of microbiological cultures presents unique challenges for the goal of standardized observation names.

**Result Status** (Preliminary, Final) should not be reported as a separate observation or as part of the name. It should be reported in the Result Status field (OBR-25) of the HL7 OBR segment.

**Specimen Type** (Serum, Blood, Urine, etc.) will be indicated in the HL7 OBR segment with the Specimen Source field (OBR-15), but may also be represented in the name.

**Details of specimen collection** will usually be noted as OBX segments or comment segments that accompany the culture result message. The observation identifier for the OBX segment will have the fully specified name of "Specimen collection description:Find:Pt:\*:Nom" and the Observation Sub-ID field will be used to order or group sets of observations. That is, if the material was collected by swabbing a wound of the right upper arm, multiple OBX segments would be created, each with the name "Specimen collection description:Find:Pt:\*:Nom" and the Observation Results fields of the OBX segments would contain respectively "Swab," "Right," "Arm," and "Wound." (The granularity of the actual terms used in the specimen description is at the discretion of the user. Thus, "Right Arm Wound" as the value of a single OBX segment could be used in place of the three codes described in the previous sentence.)

**Descriptions of measurement and culture growth** will be noted as separate OBX segments that accompany the culture result message. The name of the observation identifier will provide the context of the observation. For instance, the name for a quantitative test of bacteria in a specimen would be:

Colony count:Num:Pt:XXX:Qn:VC

**Descriptions of Gram stain findings** will be noted as OBX segments that accompany the culture result message. The name of the observation identifier will be:

Microscopic observation:Prid:Pt:XXX:Nom:Gram stain

The result values that could be reported with this test (which is a multiple-choice, multiple answer type or observation) might include one or more of the following:

Epithelial cells Gram-positive cocci in chains Many Gram-negative diplococci

**The organisms identified in a culture** will be sent as result values in OBX segments. A separate table of allowable organism names and/or codes is necessary if these are to be sent as understated results. Euzéby's list of bacterial names approximately 20 other authoritative sources (SNOMED CT is an appropriate source for these organism concepts) may be used as the standard. While "Throat Culture" is the source of the culture inoculum, it is also a label that indicates what kind of media was inoculated and the other techniques used in the laboratory. So, it is a short hand for a kind of method and such will be recorded as the method part of the name. Thus, "Throat Culture", "Blood Culture", and "Clostridium difficile Culture" all represent labels for how a culture was performed. Examples of names of culture results are:

Bacteria identified:Prid:Pt:Bld:Nom:Culture Bacteria identified:Prid:Pt:Brn:Nom:Culture Bacteria identified:Prid:Pt:Stool:Nom:Culture

Names of methods of staining directly on a sample/material (where many descriptive observations are possible):

Microscopic observation:Prid:Pt:XXX:Nom:Gram stain

Microscopic observation:Prid:Pt:XXX:Nom:Dry mount

Microscopic observation:Prid:Pt:XXX:Nom:India ink preparation

Microscopic observation:Prid:Pt:XXX:Nom:Trichrome stain

Microscopic observation:Prid:Pt:XXX:Nom:Giemsa stain

Names for results of staining procedures performed on organisms that are growing in culture will use Isolate as the system/sample type. For example:

Fungus identified:Prid:Pt:Isolate:Nom:Fungal subtyping

Names for organism-specific cultures:

Brucella sp identified:Prid:Pt:Bld:Nom:Organism specific culture

Bordetella pertussis identified:ACnc:Pt:Thrt:Ord:Organism specific culture

Chlamydia sp identified:Prid:Pt:Gen:Nom:Organism specific culture

Legionella sp identified:Prid:Pt:Sputum:Nom:Organism specific culture

Note if a test applies to a specific species of organism, the component should include the genus AND species (at least). If the measure applies to a series of species in the same family the string "sp" must be included. If it applies to as subgroup of the genus, then that subgroup should be named.

Names for method for general class of organism:

Fungus identified:Prid:Pt:Wound:Nom:Culture

Bacteria identified:Prid:Pt:CSF:Nom:Culture

Again, the Result Value of these tests would be either organism names or other statements of culture outcome. The table below contains valid values of the culture result from the HL7 OBX segment:

Table 15: Example Culture Results
No growth
Gram-positive cocci
Small Gram negative rod
Escherichia coli
Normal flora
Candida albicans

Presence or Identity (Prid) as a property should be used when the value of a test can identify one set of alternative infectious agents. If the culture is for herpes virus and the culture can have results of herpes virus 1, herpes virus 2, etc., then Prid is the right property. If the culture is for herpes virus and the answer is positive/negative or yes/no, then the property should be arbitrary concentration (ACnc) and the scale ordinal (Ord). As described in section 2.3 we are transitioning to property of presence (Pr) to represent ordinal terms.

## 3.5 Antimicrobial susceptibilities

The drug susceptibility tests are grouped together in the LOINC database under the class ABXBACT.

Antimicrobial susceptibility tests are named according to the generic name of the drug tested and the methodology used in testing, with property of susceptibility (Susc), and with scale of quantitative (Qn), ordinal (Ord), or OrdQn. Thus, appropriate names would be:

Ampicillin:Susc:Pt:Isolate:OrdQn:MIC Ampicillin:Susc:Pt:Isolate:OrdQn:Agar diffusion Ticarcillin+clavulanate:Susc:Pt:Isolate:Qn:MLC

Table 16 lists methods in drug-susceptibility tests.

Table 16: Drug Susceptibility Methods		
Method	Description	
Agar diffusion	Bacterial sensitivity via agar diffusion (Kirby-Bauer)	
MIC	Minimum inhibitory concentration	
MLC	Minimum lethal concentration	
SBT	Serum bactericidal titer	
Gradient strip	Susceptible by E-Test or gradient strip method	

Methodless codes also exist for each antimicrobial agent.

## 3.6 Cell counts

Quantitative counts of various entities and cells in blood, urine, CSF, and other body fluids may be performed and reported in one of three ways. Cell counts in blood are often reported as absolute counts per unit volume (property number concentration, NCnc), or percent of a general cell type, e.g., percent eosinophils, (property number fraction, NFr). Blood cells are usually reported in such a manner, via either a manual or automated count method. Counts on urine and other body fluids can also be done as direct counts and reported as NCnc or NFr. However, they are more often reported as the number of entities or cells per microscopic high power or low power field, e.g., 5-10 cells per high power field. These are really numbers per area (property Naric). For example, the number of erythrocytes casts per low power field would be reported as:

```
Erythrocyte casts:Naric:Pt:Urine sed:Qn:Microscopy.light.LPF
```

Note that even though the values are reported as a range, the scale is still quantitative (Qn), because the values can be related through a ratio. We use HPF or LPF to identify high power and low power fields respectively. Large entities (such as casts) are usually reported per low power fields, smaller entities per high power fields.

One other way such entities are reported is as a pure ordinal, e.g., none, few, moderate, loaded. These would be specified as arbitrary concentration (ACnc) properties with ordinal scale, for example:

Erythrocytes:ACnc:Pt:Semen:Ord:Microscopy.light

## 3.7 Skin tests

These follow the pattern of a challenge test. For a TB skin test it would be:

Tuberculosis reaction wheal^3D post 25 TU ID:Diam:Pt:Skin:Qn

Where TU means tuberculin units, ID means intradermal, Diam indicates a measure of the diameter of the wheal and so on.

## 3.8 Toxicology – Drug of Abuse Screening and Confirmation

Many kinds of test methods are used in toxicology: Screening tests include HPLC, EIA, TLC, RIA, GC, and GCMS (rarely). Confirmation tests are GCMS, LCMS, GC, and HPLC.

Table 17: Drug of Abuse Methods		
Abbr.	Description	
HPLC	high pressure liquid chromatography	
TLC	thin layer chromatography	
GC	gas chromatography	
EIA	enzyme immunoassay	
RIA	radioimmunoassay	
GCMS	gas chromatography/mass spectrometry	
LCMS	liquid chromatography/mass spectrometry	

Many laboratories use GCMS to signal that the test is a confirmation of a previous screening test, but other methods are also used to confirm, and a given method can be used to screen or to confirm a test. However, it is important that two different methods be used for screen and for confirm and that they both be applied with techniques appropriate to the mode (screen or confirm). So the LOINC committee has determined it is better to distinguish the screening from the confirming procedure by the use of the words "screen" or "confirm," in the method part of the name, rather than by naming a specific method. Hence LOINC will distinguish toxicology method by Screen and Confirm but not by particular methods.

Toxicology tests can also be performed on a group of drugs/substances or on individual drugs/ metabolites/ substances. We will develop LOINC names and codes for both categories: groups of analytes, e.g., "barbiturates" and individual analytes, e.g., "phenobarbital."

Group test results are usually reported as ordinal (present /absent) but can also be reported as mass concentrations when the numerator is the total mass of the detectable substances in the group. Group tests at the screening level may also be followed by a confirmation at the group level or by confirms of the individual drug/substance tests at the confirmatory level. Individual drug/substances may be reported as present/absent (Ord) or as mass (or substance) concentrations (Qn).

When individual drugs/substances are reported ordinally, the reporting threshold (the threshold at which a test level is considered positive) may also be reported as a separate "result." Thus we have separate LOINC codes to report the cutoff used for defining a positive or negative value.

## 3.8.1 Toxicology drug groups

General principles: for each "group" of drugs (amphetamines, benzodiazepines, opiates, etc.) we will define the following kinds of LOINC observations:

3.8.1.1 Screen for a group of drugs/ toxic substances

"X": Threshold:Pt:Ord:SYS:Screen for the group as a whole (Answer = present/absent)

For example, Amphetamines:Threshold:Pt:Urine:Ord:Screen Example answer: "present"

Identify the set of drugs/substances screened for by the group test. The answer will be a list discrete drug/substance names or codes.

"X" tested for:Prid:Pt:SYS:Nom:Screen (Answers = individual drugs that this screening test could detect, from a fixed list)

For example, Amphetamines tested for:Prid:Pt:Urine:Nom:Screen (nominal) Example answer = "amphetamine, methamphetamine, dextroamphetamine, levoamphetamine, pseudoephedrine"

3.8.1.2 Identify the drugs substances screened for (and perhaps other information). The answer will be a "glob" of narrative text.

"X" tested for:Prid:Pt:SYS:Nar:Screen (Answers = individual drugs that this screening test could detect, as a "blob" of text or canned comment)

For example, Amphetamines tested for:Prid:Pt:Urine:Nar:Screen (narrative) Example answer = "The EMIT urine screen for amphetamines detects amphetamine, methamphetamine, dextroamphetamine, levoamphetamine as indications of methamphetamine abuse. It is also reactive with a component present in over-the-counter nasal decongestant inhalers, and a positive result must be confirmed by a quantitative method that rules out the non-abuse situation"

When a screen is reported as negative, confirmatory testing is not performed. When a screening test is reported as positive, the result must be confirmed by an independent testing method.

3.8.1.3 Confirmatory testing for the presence of one or more members of the group represented as a single observation.

"X":Threshold:Pt:SYS:Ord:Confirm (Answers = present/absent)

For example, Amphetamines:Threshold:Pt:Urine:Ord:Confirm Example answer: "present"

3.8.1.4 List of the actual drug/substances confirmed.

"X" positive:Prid:Pt:SYS:Nom:Confirm (Answers = list of analytes detected)

For example, Amphetamines positive:Prid:Pt:Urine:Nom:Confirm Example answer: "dextroamphetamine, methamphetamine"

3.8.1.5 More commonly, confirmatory testing is reported as a set of observations, one to report the presence (or quantitative amount detected) of each analyte in the group.

"X":Threshold:Pt:SYS:Ord:Confirm (Answers = present/absent) or "X":MCnc:Pt:SYS:Qn:Confirm

#### (Answers = quantitative amount)

For example:

Amphetamine:Threshold:Pt:Urine:Ord:Confirm [present] Dextroamphetamine:Threshold:Pt:Urine:Ord:Confirm [present] Methamphetamine:Threshold:Pt:Urine:Ord:Confirm [present] Levomethamphetamine:Threshold:Pt:Urine:Ord:Confirm [present]

#### 3.8.2 Cutoffs

The cutoff levels for screens and confirms of a given substance or group of substances will usually differ. There are three ways to indicate specific cutoffs in LOINC.

- 3.8.2.1 We provide separate LOINC terms for reporting the cutoff levels of a number of commonly abused substances and substance groups.
  - "X" cutoff:MCnc:Pt:Urine:Qn:Screen "X" cutoff:MCnc:Pt:Urine:Qn:Confirm

For example, Amphetamines cutoff:MCnc:Pt:Urine:Qn:Screen Example answer: "1000 ng/ml"

For example, Methamphetamine cutoff:MCnc:Pt:Urine:Qn:Confirm Example answer: "500 ng/ml"

3.8.2.2 Two general cutoff terms, one for screen and one for confirm, can be applied to any substance whether or not a pre-coordinated term exists.

XXX cutoff:MCnc:Pt:SYS:Qn:Screen XXX cutoff:MCnc:Pt:SYS:Qn:Confirm

3.8.2.3 For commonly used cutoffs, such as those mandated by regulatory agencies, we provided precoordinated terms for reporting a "present/absent" result with the cutoff specified in the method field:

```
"X":Threshold:Pt:SYS:Ord:Screen>"N"
"X":Threshold:Pt:SYS:Ord:Confirm>"N"
```

For example, Amphetamines:Threshold:Pt:Urine:Ord:Screen>1000 ng/mL Example answer: "not detected"

#### 3.8.3 Reporting the method used for screen and confirm

We provide terms for reporting the method used for screen and confirm tests:

"X" screen method:Prid:Pt:SYS:Nom:\* "X" confirm method:Prid:Pt:SYS:Nom:\*

These would normally be reported in conjunction with terms reporting levels and possibly cutoffs, as in the following example:

Amphetamines:Threshold:Pt:Urine:Ord:Confirm [Answer = positive] Amphetamines cutoff:MCnc:Pt:Urine:Qn:Screen [Answer = 1000 ng/ml] Amphetamines screen method:Prid:Pt:Urine:Nom:\* [Answer = EIA] Amphetamines positive:Prid:Pt:Urine:Nom:Confirm [Answer = amphetamine, methamphetamine] Amphetamine cutoff:MCnc:Pt:Urine:Qn:Confirm [Answer = 500 ng/ml] Methamphetamine cutoff:MCnc:Pt:Urine:Qn:Confirm [Answer = 500 ng/ml] Amphetamines confirm method:Prid:Pt:Urine:Nom:\* [Answer = GC/MS]

3.8.4 Individual drug/metabolite test results

Individual substances can be reported as screens (ordinal), confirms (ordinal) or confirms (quantitative -- usually mass or substance concentrations).

Group test screens may be confirmed by group confirms (as described above) or by individual confirms (Either ordinal or quantitative-depending upon the laboratory's preference)

3.8.4.1 Individual test screen (ordinal)

Methamphetamine:Threshold:Pt:Urine:Ord:Screen Example answer: "present"

3.8.4.2 Individual test confirm (ordinal)

Methamphetamine:Threshold:Pt:Urine:Ord:Confirm Example answer: "present"

3.8.4.3 Individual test confirm (quantitative)

Methamphetamine:MCnc:Pt:Urine:Qn:Confirm Example answer: "250 ng/ml"

Individual tests may also be reported as simple quantitative (without confirm or screen), as is the case for therapeutic drug level monitoring.

3.8.4.4 Individual substance measured quantitatively; screen/confirm is not relevant

Digoxin:MCnc:Pt:Ser/Plas:Qn Example answer: "1.2 ng/ml"

3.8.5 Naming issues

For confirms, you would always be looking for specific analytes. For example, you would never look for tetrahydrocannabinol, but would look for delta-9-tetrahydrocannabinol, 11-hydroxycannabinol, etc.

3.8.6 Summary

#### For each "group" LOINC defines the following set of terms:

"Analyte group": Threshold:Pt:Urine:Ord:Screen "Analyte group": Threshold:Pt:Urine:Ord:Confirm "Analyte group":MCnc:Pt:Urine:Qn:Confirm "Analyte group" tested for:Prid:Pt:Urine:Nom:Screen "Analyte group" tested for:Prid:Pt:Urine:Nar:Screen "Analyte group" positive:Prid:Pt:Urine:Nom:Confirm "Analyte group" screen method:Prid:Pt:Urine:Nom:\*

For each individual analyte LOINC now defines the following set of terms:

Analyte:Threshold:Pt:Urine:Ord:Screen Analyte: Threshold:Pt:Urine:Ord:Confirm Analyte:MCnc:Pt:Urine:Qn:Confirm Analyte:MCnc:Pt:Urine:Qn Analyte cutoff:MCnc:Pt:Urine:Qn:Screen Analyte cutoff:MCnc:Pt:Urine:Qn:Confirm

## 3.9 Molecular Genetics LOINC Naming

### 3.9.1 Introduction

Molecular pathology testing can be used for many purposes. In infectious disease testing to identify organisms and mutations in organisms; in genetic analysis to identify mutations including substitutions, deletions/ insertions, frame shifts and trinucleotide repeats; to identify specific chromosomal translocation and clonality in leukemia and lymphomas; to identify various tumor associated genes and gene deletions; in paternity testing to determine the probability that a person is the parent of a child; and in forensic testing to determine the probability that a criminal is associated with genetic material he/she left as evidence. <sup>xxiv</sup> As this area of testing expands, we are evolving our naming conventions. Existing terms are being reviewed for compatibility with current naming conventions.

### 3.9.2 Terminology

The main methods used are Southern Blot which applies hybridization to selected DNA "chopped" up by restriction enzymes, Northern Blot which applies hybridization to all cellular RNA (which comes naturally in smaller segments) and Restriction Fragment Length Polymorphism (RFLP). RFLP depends on the Variable Number of Tandem Repeats (VNTR) which are normal, but specific variants of each person's DNA. Southern Blot may be combined with RFLP to target mutations whose exact gene molecular chemistry is not known. For completeness sake, we mention Western Blot, which applies an analogous blot method to protein analysis.

In situ hybridization is a method that applies probes to intact tissue. The cellular patterns of the homologies can then be read microscopically. There are a variety of methods for detecting such in situ probes. One popular method is Fluorescent In-Situ Hybridization (FISH). This technique is analogous to an immune stain except that the molecular binding is based on DNA/RNA homologous instead of antigen-antibody binding.

DNA chips provide a radical new way to identify DNA and RNA sequences. In the patented AFYMETRIX<sup>®</sup> technique, the nucleoside chains are grown using lithography-like methods. Target DNA is tagged with a detector and "washed" over the chip in steps. The locations of the tags on the chip identify the DNA (RNA) in the sample.

Identity testing is used to identify relationships among people and has special complexity. In paternity testing, it can be helpful to have DNA from the child, the putative father and the mother when possible to distinguish the alleles that come from the father.

Blood is the most common specimen for molecular pathology studies. The DNA comes from the leukocytes, bone marrow, tumors, products of conception and forensic specimens are also important specimens.

Forensic testing has special requirements of stringency and often mixes blood antigen testing with RFLP testing. The results are usually reported as a probability.

Genetic changes that occur during the life of the patient such as tumor mutation are called somatic and those that are inherited are referred to as germ line. The nature of the specimen and the testing usually distinguishes these two, so it is not necessary to include this distinction in the test names.

Alleles refer to different forms of a gene. Alleles are distinguished at the phenotype level. Locus refers to a specific DNA (or RNA) codon or the corresponding amino acid in the protein produced by this codon.

The term mutation is usually applied to a genetic variant that causes a functional change in the gene and results in disease. An allele, the term is usually applied to a genetic variant that does not cause a disease.

The string of DNA that codes for a protein is usually interrupted by DNA segments called introns, which do not contribute to the protein definition. The coding sequences of DNA between the introns are called exons. Linked together, the exons provide the instructions for creating the specific protein. Exons may be numbered e.g., exon 1, exon 2, etc. Exon numbers sometimes appear in the names of DNA mutations, but for a number of reasons, identifying codon locations relative to an exon is unreliable and we will try to avoid such nomenclature when possible in LOINC names.

A codon refers to the sequence of three nucleotides that code for one amino acid. Codons are numbered from the first codon participating in the protein (in humans the codon for Methionine) starting with codon number 1.

Defects in genes are coded in LOINC by one of four different nomenclatures as described in Table 18.

Table 18: Four types of nomenclatures for identifying the location of a genetic defect		
Designation	Explanation	
р	Identify the defect by codon by counting the amino acids in the protein produced by the gene counting the first amino acid.	
с	Identify the defect by counting nucleotides from the messenger RNA used to produce the protein with intron excluded. These will produce numbers 3x as large as those in the first method.	
g	Identify the defect by counting from the first nucleotide in the DNA as it exists as a gene natively in the chromosome with introns included.	
m	Identify the defect by counting from the first nucleotide in the full mitochondrial DNA sequence	

3.9.3 General molecular genetics naming rules

LOINC's approach to naming tests for individual genetic variations remains close to how we named these in the past. Gene names are based on the Human Genome Organization (HUGO) approved gene nomenclature. We specify the mutation by use of the Human Genome Variation Society (HGVS, http://www.hgvs.org/mutnomen/) conventions. In our early approach, we used the extant protein-based naming convention to get the following name for the commonest mutation causing cystic fibrosis:

## CTFR gene.p.F508 del:Arb:Pt:Bld/Tiss:Ord:Molgen

The HGVS naming rules have evolved since then. For clarity sake, HGVS now prefers the three letter amino acid abbreviations over the single letter amino acid abbreviations we used in the above example. So under the current HGVS rules, the above name would be:

## CTFR gene.p.Phe508del:Arb:Pt:Bld/Tiss:Ord:Molgen

And in the coding DNA reference sequence based naming it would be:

## CTFR gene.c.1521\_1523del:Arb:Pt:Bld/Tiss:Ord:Molgen

HGVS has made other changes in naming style. Overall they now prefer the describing the variant at the coding DNA level as nucleotide changes rather than at the protein level as amino acid changes. For the nucleotide changes, they have adjusted the syntax for representing a change from one nucleotide string to another as # String1>String2 rather than String1 # String2, where # is an integer representing the nucleotide position of the variation.

Another common cause of cystic fibrosis is a mutation that at the amino acid level would be named p.Gly551Asp with the new protein based naming convention, c.G1652A with the old DNA naming convention and c.1652G>A with the new genetic naming convention. (Realize, of course, that more than one genetic level variation name can correspond to a single amino acid variation name).

We fully support the HGVS naming style for naming mutations at the amino acid level, but the world has not been consistently quick to adopt it. The old style, perhaps because of its brevity, persists. As we update existing codes to harmonize with current HGVS guidelines, we will make it easy for users to find our test names by including the old style as synonyms for the new style.

When reporting variants at the amino acid level, we use the nomenclature for human gene mutations proposed by Beaudet<sup>xxv</sup> in the component or in the answer when the mutation is reported as an answer. A list of single and three letter amino acid codes are given in Table 19.

Table 19: List of single letter amino acid codes			
Amino Acid	1-Letter Symbol	3-Letter Symbol	
Alanine	А	Ala	
Arginine	R	Arg	
Asparagine	Ν	Asn	
Aspartic acid	D	Asp	
Cysteine	С	Cys	
Glutamic acid	Е	Glu	
Glutamine	Q	Gln	
Pyroglutamic acid	pQ	pGlu	
Glycine	G	Gly	
Histidine	Н	His	
Hydroxyproline, 4(R)-L-	0	Нур	
Isoleucine	Ι	Ile	
Leucine	L	Leu	
Lysine	K	Lys	

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Methionine	М	Met
Phenylalanine	F	Phe
Proline	Р	Pro
Serine	S	Ser
Threonine	Т	Thr
Tryptophan	W	Trp
Tyrosine	Y	Tyr
Valine	V	Val
Unknown	Х	

If clear guidelines are not in place for a given variant when a LOINC code is created, the familiar or common variant name may be used. LOINC will resort to using the disease name only when the gene has no name and/or the genetic defect is not yet fully specified. We will always include the genetic disease name in the related name field of the database when the disease is not part of the component. This allows users to easily find the LOINC term by the disease name as well.

The system (specimen) used in the LOINC name for genetic testing will usually be Bld/Tiss since the distinction between these two specimens is rarely important to the result of a molecular pathology test. We have split this further to accommodate fetal specimens (Tiss^fetus). Other specimens include amniotic fluid, CVS, bone marrow, and fixed tissue, and CSF.

In general, we do not create separate variables for each kind of molecular genetics method, (e.g., Southern Blot Northern Blot, PCR, restriction fragment length polymorphism (RFLP)) because the different methods do not provide significantly different results. Moreover, there are a plethora of minor method variants, and we would not be able to keep up with their proliferation. Therefore, instead we use a generic method of Molgen (for molecular genetics method) to indicate that a result of the analysis is based on a molecular genetics method rather than some chemical or antigen method.

However, when results for a given molecular pathology technique are significantly different, we will distinguish the method. Examples of specific molecular pathology methods in LOINC include fluorescent in situ hybridization (FISH), sequencing, multiplex ligation probe amplification (MLPA), and microarray comparative genomic hybridization (arrCGH).

Bulk narrative reports in molecular pathology are often used to provide results for mutation analyses but have no discrete coded answers. We discourage the use of this approach because it is not useful for automated analyses.

#### 3.9.4 Infectious diseases

For most infections disease reporting, the existing LOINC nomenclature (e.g., detecting a particular species of organism by detecting DNA homology) works fine. The word DNA or RNA is included as part of the component name and we distinguish the type of method used for detecting the microorganisms (Probe, Probe.amp.tar, Probe.amp.sig). See the Microbiology section for more information.

#### 3.9.5 Genetic diseases

3.9.5.1 Diagnostic assays for the detection of specific disease mutations or variants

We currently have at least four different styles for mutation analyses in LOINC:

- 1) Looking for one mutation
  - a. Diagnostic assays for the detection of a specific mutation or variant
- 2) Targeted mutation analysis
  - a. Diagnostic assays for a fixed set of the most common or important mutations
- 3) Known mutation analysis
  - a. Diagnostic assays for one or more mutations that have been previously identified in an affected family member
- 4) Full gene mutation analysis
  - a. Diagnostic assays usually done by sequencing of the entire coding region of a gene

3.9.5.1.1 Diagnostic assays for the detection of a specific mutation or variant

When looking for one mutation, use LOINC's single mutation style of gene name followed by the specification of the nomenclature (p, g, c, or m) and the mutation name. A dot will separate the gene name and the mutation identifier:

<gene name> gene.<mutation nomenclature>.<mutation and its location>

For example, Factor V Leiden mutation would be represented as F5 gene.p.R506Q. Where "F5" identifies the gene, "gene" is a fixed part, "p" identifies the kind of mutation nomenclature (protein) and "R506Q" indicates that the amino acid arginine (R) is replaced by glutamine (Q) (see Table 19) at codon #506.

Some examples of fully specified LOINC names for tests of specific mutation are:

F5 gene.p.R506Q:Arb:Pt:Bld/Tiss:Ord:Molgen Synonyms = Factor V Leiden, Factor V resistance, APC resistance gene

HFE gene.p.C282Y:Arb:Pt:Bld/Tiss:Ord:Molgen Synonyms = HLA-H gene, hemochromatosis gene

CFTR gene.p.F508 del:Arb:Pt:Bld/Tiss:Ord:Molgen Synonyms = Cystic Fibrosis Transmembrane Regulator

As mentioned above, HGVS now recommends the three letter amino acid abbreviations over the single letter amino acid abbreviations. As existing codes are updated, we will add synonyms for the old style to make it easy for users to find our test names.

The scale used for LOINC codes of this type is ordinal (Ord). One type of testing procedure identifies a single mutation using two DNA probes: one for the normal locus and the other for the abnormal locus. When only the normal probe reacts, the laboratory reports "no mutation" or "wild type". When both the normal and mutation probes react, the laboratory reports "heterozygous". When only the mutation probe reacts it reports "homozygous". Consequently, such single mutation testing produces one of three ordinal "answers":

- a) no mutation (wild type)
- b) heterozygous mutation (the mutation found in one gene)
- c) homozygous mutation (the mutation was found in both genes in the gene pair)

Specific testing such as this is only possible when the molecular pathology of the gene is very well known and only one defect is being reported.

Results for specific mutations or variants may also be reported as two separate observations: one observation reports the kind of mutation (allele) found in the first chromosome and another for reporting the kind of mutation for the paired chromosome. In this case, the identity of the allele is reported in the answer. For example:

APOE gene allele 1:Prid:Pt:Bld/Tiss:Nom:Molgen Answers = E2, E3, or E4

APOE gene allele 2:Prid:Pt:Bld/Tiss:Nom:Molgen Answers = E2, E3, or E4

## 3.9.5.1.2 Targeted mutation analysis

LOINC's approach to represent gene mutation analysis for many genetic variations within one or more genes has had the following form:

<gene or disease name> gene mutation analysis:Prid;Pt:Bld/Tiss:Molgen

For Example:

```
CFTR gene mutation analysis:Prid:Pt:Bld/Tiss:Nom:Molgen
Synonyms = Cystic fibrosis transmembrane regulator
```

```
BRCA1 gene mutation analysis:Prid:PT:Bld/Tiss:Nom:Molgen
Synonyms = breast cancer risk gene
```

Answers for these variables could also be "Identifiable Mutation" or "Not Identifiable Mutation". For each such mutation analysis we usually created a companion LOINC observation code with the words "mutations tested for":

<Gene or disease name> gene mutations tested for:Prid:Pt:Bld/Tiss:Nom:Molgen

For example:

CFTR gene mutations tested for:Prid:Pt:Bld/Tiss:Nom:Molgen The answers could include "Delta F508", "G542X", "R553X", "W1282X", "N1303K", etc.

This additional LOINC code is needed for reporting the mutation(s) that could have been found in a given analysis so that clinicians can know what was looked for when no abnormalities were found.

The above terms could be used for ordering or reporting the results of a given mutation analysis. Results for such an analysis could be: 1) no pathologic mutations found or 2) a list of individual mutations/variations found. When reporting discrete mutations as results, we propose using the HGVS nomenclature and including (in parentheses) the historic versions of the mutation names when such names exist.

#### 3.9.5.1.3 Known mutation analysis

The first two approaches are commonly called "targeted" mutation analyses, or looking for specific mutations within a given gene. Labs may offer testing for both targeted mutation analysis and analysis for known familial mutations. Known familial mutations are those previously identified within an affected

family member. To distinguish these testing approaches, LOINC further defines testing for known familial mutations:

<Gene name> gene mutation analysis limited to known familial mutations:Prid:Pt:Bld/Tiss:Nom:Molgen

For example:

TNFRSF13B gene mutation analysis limited to known familial mutations:Prid:Pt:Bld/Tiss:Nom:Molgen

Since testing may involve more than one known mutation, especially for autosomal recessive conditions, LOINC uses the plural form of mutations in the Component. However, these terms also refer to testing for only one known familial mutation.

### 3.9.5.1.4 Full gene mutation analysis

To describe mutation analysis by sequencing of the entire coding region of the gene, we use:

#### TNFRSF13B gene full mutation analysis:Prid:Pt:Bld/Tiss:Nar:Sequencing

Here, we include the method of sequencing since this is a technique commonly used to identify mutations with the entire coding region of a gene.

## 3.9.5.2 Diagnostic assays for large deletions and/or duplications

Detection of larger (>50 bp) genomic duplications or deletions is done by various techniques, including multiplex ligation-dependent probe amplifications (MLPA) and array-based comparative genomic hybridization (arrCGH). MLPA and aarCGH techniques detect gene dosage. To describe testing for large deletions and/or duplications (insertions) within a gene, we use:

LDLR gene deletion+duplication:Prid:Pt:Bld/Tiss:Nar:MLPA

In this case, we specify the method of multiplex ligation-dependent probe amplification (MLPA). MLPA is a common technique used to detect gene dosage of genomic deletions and duplications (e.g. one or more entire exons) and determine gene copy number.

### 3.9.5.3 Trinucleotide repeats

A number of diseases, most of which manifest as neurologic disorders are caused by excessive repeats of specific trinucleotides, and the age of onset of the disease is inversely proportional to the number of excess repeats. Examples of these disorders include:

Fragile X syndrome Huntington disease Spinocerebellar ataxia (SCA1)

We name the component of these terms by the gene when the gene is well defined or the disease, and the name of the trinucleotide that repeats plus the word "repeats".

<sup>&</sup>lt;disease or gene name>.<trinucleotide> repeats

#### For example, Huntington disease would be represented as HTT gene.CAG repeats

Examples of some fully specified LOINC names are:

FRAXE gene.CGG repeats:Arb:Pt:Bld/Tiss:Ord:Molgen Synonym = Fragile x syndrome

HTT gene.CAG repeats:Arb:Pt:Bld/Tiss:Ord:Molgen Synonym = Huntington Disease, It15, HD, Huntington Chorea

Spinocerebellar ataxia genes.CAG repeats:Arb:Pt:Bld/Tiss:Ord:Molgen

DMPK gene.CTG repeats:Arb:Pt:Bld/Tiss:Ord:Molgen Synonym = Myotonic Dystrophy

These are usually reported "not expanded", "indeterminate" or "expanded", so the scale is Ord.

If the actual number of trinucleotide repeats were reported, the property would be entitic number (EntNum) and the scale would be quantitative (Qn). We are not aware of any labs that currently report the actual number. We will define these quantitative variants when they are requested.

3.9.5.4 Hematopathology gene re-arrangement.

Immunocells have an innate genetic variability due to rearrangement. The unique rearrangement can be used to identify the development of a clone of one cell type as occurs in many lymph cell tumors (e.g., lymphoma). We use the following format to identify clonal excess.

Immunoglobulin heavy chain gene rearrangements:Arb:Pt:Bld/Tiss:Ord:Molgen Immunoglobulin kappa light chain gene rearrangements:Arb:Pt:Bld/Tiss:Ord:Molgen Immunoglobulin lambda light chain gene rearrangements:Arb:Pt:Bld/Tiss:Ord:Molgen TCRB gene rearrangements:Arb:Pt:Bld/Tiss:Ord:Molgen Synonym = T cell receptor beta chain TCRD gene rearrangements:Arb:Pt:Bld/Tiss:Ord:Molgen Synonym = T cell receptor delta chain TCRG gene rearrangements:Arb:Pt:Bld/Tiss:Ord:Molgen Synonym = T cell receptor delta chain TCRG gene rearrangements:Arb:Pt:Bld/Tiss:Ord:Molgen Synonym = T cell receptor gamma chain

3.9.5.5 Chromosomal alterations: translocations, deletions, and inversions

LOINC nomenclature follows the International System for Human Cytogenetic Nomenclature (ISCN) guidelines when describing chromosomal alterations, including translocations, large deletions and inversions. Tests to detect fused genes or transcripts (RNA, cDNA) due to a chromosomal alteration are designated as follows:

t(<Chromosome of breakpoint gene 1>;<Chromosome of breakpoint gene 2>)(<Location on chromosome 1>;<Location on chromosome 2)(<gene1>,<gene2>) fusion transcript

For example:

t(9;22)(q34.1;q11)(ABL1,BCR) fusion transcript:Arb:Pt:Bld/Tiss:Ord:Molgen Synonyms = Philadelphia chromosome, BCR1, chronic myeloid leukemia, CML

t(14;18)(q32;q21.3)(IGH,BCL2) fusion transcript:Arb:Pt:Bld/Tiss:Ord:Molgen Synonyms = Follicular B cell lymphoma, oncogene B-cell leukemia 2, CLL, chronic lymphatic leukemia, follicular

lymphoma

t(15;17)(q24.1;q21.1)(PML,RARA) fusion transcript:Arb:Pt:Bld/Tiss:Ord:Molgen Synonyms = RAR, promyelocytic leukemia, myelogenous, retinoic acid receptor, acute promyelocytic leukemia, APL

For chromosomal deletions and inversion, 't' above would be replace with 'del' or 'inv', respectively:

del(1)(p32p32)(STIL,TAL1) fusion transcript:Arb:Pt:Bld/Tiss:Ord:Molgen Synonyms = SCL/TAL1 interrupting locus, T-cell acute lymphoblastic leukemia, ALL, T-ALL, TAL-1 deletions

inv(16)(p13.1;q22.1)(MYH11,CBFB) fusion transcript:Arb:Pt:Bld/Tiss:Ord:Molgen Synonyms = inversion 16, AML, Acute myeloid leukemia

In some cases, testing may involve comparing the fused transcript to a control transcript and results may be reported as a number ratio (NRto), log number ratio (LnRto), or relative ratio (RelRto):

t(9;22)(q34.1;q11)(ABL1,BCR) fusion transcript/control transcript:NRto:Pt:Bld/Tiss:Ord:Molgen

t(9;22)(q34.1;q11)(ABL1,BCR) fusion transcript/control transcript:LnRto:Pt:Bld/Tiss:Ord:Molgen

t(9;22)(q34.1;q11)(ABL1,BCR) b3a2 fusion transcript/control transcript (International Scale):RelRto:Pt:Bld/Tiss:Ord:Molgen

To specify "major" or "minor" breakpoints, we use:

t(9;22)(q34.1;q11)(ABL1,BCR) fusion transcript major break points:Arb:Pt:Bld/Tiss:Ord:Molgen

t(9;22)(q34.1;q11)(ABL1,BCR) fusion transcript minor break points:Arb:Pt:Bld/Tiss:Ord:Molgen

To specify specific breakpoints, we use:

t(9;22)(q34.1;q11)(ABL1,BCR) b2a2+b3a2 fusion transcript:Arb:Pt:Bld/Tiss:Ord:Molgen Synonyms = major breakpoints, p210, e13a2, e14a2,

t(15;17)(q24.1;q21.1)(PML,RARA) bcr1 fusion transcript:Arb:Pt:Bld/Tiss:Ord:Molgen Synonyms = breakpoint cluster region 1, long form

Translocation terms can also be expressed as a fraction of cells that have the rearrangement versus total cells of interest:

Cells.t(9;22)(q34.1;q11)(ABL1,BCR)/Cells.total:NFr:Pt:Bld/Tiss:Qn:Molgen

If specific partner genes are not known, we use the pattern:

CCND1 gene rearrangements:Arb:Pt:Bld/Tiss:Ord:Molgen Synonyms = Lymphoma 1

BCL2 gene rearrangements:Arb:Pt:Bld/Tiss:Ord:Molgen Synonyms = Lymphoma 2

#### 3.9.6 Identity testing

The identity testers usually look at 4 genetic loci (each locus is polymorphic enough that any one match has a 10% error of being incorrect). The loci are independent so if all 4 probes match (including all

exclusions and inclusions) the probability of an erroneously match is .0001 (one out of 10,000). They may use more than four depending upon the degree of confidence required by the circumstances of the testing. The forensic community chooses from a set of about 20 probes.

We propose two styles for reporting identity testing: atomic and pre-coordinated definitions.

#### 3.9.6.1 Atomic style

This style uses a series of LOINC names to report the kind of index case, the kind of comparison case, the results of the identity testing, and all of the other separate components of the testing. It includes an observation for reporting the actual probes used, and another observation for reporting the population that the probes assume. The method will be MOLGEN.IDENTITY.TESTING. For example:

DNA probes used:Prid:Pt:Index case^comparison case:Nom: Molgen.identity.testing

Population base:Prid:Pt:Probes:Nom: Molgen.identity.testing

Relationship:Type:Pt:index case:Nom: Molgen.identity.testing Answers = child, victim, suspect

- Relationship:Type:Pt:^comparison case:Nom: Molgen.identity.testing Answers = mother, alleged mother, father, alleged father, evidence (external to victim)
- Confidence of relationship:likelihood:Pt:Index case^comparison case:QN: Molgen.identity.testing (gives the statistical confidence in the conclusion)
- Conclusion:Imp:Pt:index case^comparison case:Nar: Molgen.identity.testing (gives a summary statement of the conclusion about identity of relatedness)

#### 3.9.6.2 Pre-coordinated definitions alternative

Some of the above atomic terms (e.g., DNA probes used) could also be reported with the pre-coordinated results.

Relationship:likelihood: child^alleged mother:Qn:Molgen.identity.testing Synonyms= maternity testing (gives the likelihood that the alleged mother is the mother of the index child)
Relationship:likelihood:child^alleged father:Qn:Molgen.identity.testing Synonyms = paternity testing (gives the likelihood that the alleged father is the father of the index child)
Relationship:likelihood: victim^suspect:Qn:Molgen.identity.testing (gives the likelihood that the genetic material on the victim is that of the suspect)
Relationship:likelihood: suspect^victim:Qn:Molgen.identity.testing (gives the likelihood that the genetic material on the suspect is that of the victim)
Identity:likelihood:Evidence^suspect:Qn:Molgen.identity.testing (gives the likelihood that the genetic material on the evidence is that of the suspect)
Identity:likelihood:evidence^victim:Qn:Molgen.identity.testing (gives the likelihood that the genetic material on the evidence is that of the victim)

### 3.9.7 Tumor Relation Tumor Genetics

Looking at copy number of N-Myc gene (Growth control gene)

N-Myc gene amplification: EntNum:Pt:Bld/Tiss:Qn:Ord:Molgen

N-Myc gene amplification: ArbEnt:Pt:Bld/Tiss:Ord:Molgen Answers = Non-amplified, indeterminant, amplified

(Comment: these are numbers of excess copies resulting from biologic events, not the true measuring process)

Gene loss

p gene loss:Arb:Pt:tumor:Ord:Molgen Answer: gene loss, no gene loss

Compare signal from tumor with normal tissue adjusted for total DNA.

## 3.10 Allergy Testing

The allergy testing industry provides tests for more than 450 different allergens today. Most testing detects IgE antibodies against these allergens. For some allergens testing for IgG and IgA antibodies are available, as well.

For LOINC terms that represent allergen testing, the component is the allergen name plus the type of the antibody (mostly IgE). Most allergens relate to animals, plants or derivatives of such entities. In the past (prior to LOINC vs. 2.04), we used the common name, rather than the scientific name to identify the allergen. However, this approach led to some duplicate term definitions, because two different companies would name the same allergen differently. It also led to ambiguity because two different species of animal or plant would sometimes have the same common name. As of version 2.04, we corrected these problems. To help reduce the ambiguity we now use the Latin name of the species of the biologic entity that causes the allergy.

Some background: First, most allergens can also be identified with a special 2-5 character code assigned by Pharmacia<sup>xxvi</sup> that most allergy testing companies reference in their catalogue of testing. We used these codes to identify duplicate and ambiguous LOINC allergy test terms. These Pharmacia codes are also included in the related names field of the database. Second, allergen tests are often reported in two styles: a quantitative raw measure and an ordinal (0-6) severity rank (RAST class). LOINC defines separate terms for each of these reporting styles. For example, the two LOINC codes for reporting IgE antibodies to Japanese Millet are:

Echinochloa crus-galli Ab.IgE:ACnc:Pt:Ser:Qn Echinochloa crus-galli Ab.IgE.RAST class:ACnc:Pt:Ser:Ord

The RAST class is a categorization of the raw measurement based on specific allergy criteria. The specific IgE class result values (0, 1, 2, 3, 4, 5, or 6) are an ordered categorical response rather than a continuous numeric scale, therefore "RAST class" terms have an ordinal (ORD) scale.

Laboratories also test mixtures of allergens to produce one result. These will be represented in LOINC as follows:

(Acer negundo+Quercus alba+Ulmus americana+Populus deltoides+Carya pecan) Ab.IgE:ACnc:Pt:Ser:Ord:Multidisk Related name = tx2

There may be more than one type of allergen for each plant. For instance, IgE antibodies can develop towards tree pollen and the fruit of the same tree. Similarly, antibodies exist for grain and for grain pollen.

In these cases, the LOINC component will contain the word "POLLEN" to distinguish the pollen allergen from the food allergen. For example, the LOINC term for corn (maize) IgE antibody would be:

Zea mays Ab.IgE:ACnc:Pt:Ser:Qn: Related names = f8; cultivated corn; maize

Zea mays pollen Ab.IgE:ACnc:Pt:Ser:Qn Related names: g202: cultivated corn; maize

### Naming rules for allergens

The component (analyte) for an allergen consists of the name of the biologic organism that is the source of the allergen. The formal name will use the Latin taxonomic name e.g. Arachis hypogaea. The long common name will use the common name of that entity, e.g. Peanut, if one exists.

In the case of very well specified allergens, the component will also indicate whether the allergen has a natural source or has been generated via recombinant method by adding the word, "native" or "recombinant, respectively. Different antigens from the same species are distinguished by the addition of a sequence number that roughly reflects when in time they were identified.

So you will see names that contain content like :

Arachis hypogaea recombinant 1 Arachis hypogaea recombinant 3 Arachis hypogaea native 1 Arachis hypogaea native 3

However, as is true in other classes of LOINC, we sometimes embed synonyms within the allergen analyte name to help users recognize the term by their naming rules. Using the LOINC wide convention, synonyms are enclosed in parentheses and immediately follow the word or words which they represent. We insert standard acronym names used by most allergen manufacturers as synonyms. These begin with lower case "n" or "r" to distinguish native from recombinant allergens followed by the first 3 letters of the genus (in Latin), a space and the first letter of the species (in Latin). Of course we also append Ab.IgE to the end of this entity name.

Putting this all together formal and common name for the component for the allergens listed above become:

LOINC code	Formal name of component	Long common name of component
58779-0	Arachis hypogaea recombinant (rAra h) 1 Ab.IgE	Peanut recombinant (rAra h) 1 IgE Ab
58777-4	Arachis hypogaea recombinant (rAra h) 3 Ab.IgE	Peanut recombinant (rAra h) 3 IgE Ab
65769-2	Arachis hypogaea native (nAra h) 1 Ab.IgE	Peanut native (nAra h) 1 IgE Ab
65771-8	Arachis hypogaea native (nAra h) 3 Ab.IgE	Peanut native (nAra h) 3 IgE Ab

# 4 Clinical observations and measures

## 4.1 Introduction

For most of the measures we include separate observations for summary data, e.g., shift and 24-hour urine output totals. We also provide varying degrees of pre-coordination for the observation, the body site at which it was obtained, and the method. For example, a cardiac output based on the Fick method is distinguished from a cardiac output computed from 2D cardiac echo data.

Physiologic measures are often monitored continuously over time and the instrument reports summary

"statistics" over that reporting period. For vital signs these can include minimum, maximum, and mean value over a time period. For intake and output the total is the summary statistic usually reported. When we address measures taken over time, we usually include 1 hour, 8 hour, 10 hour, 12 hour, and 24 hour intervals to cover the varying lengths of work shifts within and across institutions. The LOINC names of these correspond to the form of a 24-hour urine specimen. The times are recorded in the duration (third part) of the name.

The parts of clinical measurement names are largely the same as for laboratory measures, with some subtle differences that are detailed below.

Parts 2, 3, 5 and 6 (type of property, timing, scale, and method) correspond exactly in meaning between laboratory and clinical LOINC codes.

System: Part 4, body system, has the same general meaning for clinical and laboratory measures, but whereas in the case of laboratory tests the system usually identifies a fluid and a body compartment by implication (e.g., serum, cerebral spinal fluid), for clinical terms, the system is usually a body part (e.g., chest), organ (e.g., heart), or part of an organ (e.g., heart.ventricle). In some cases the system may be an instrument or device attached to the system (e.g., OB ultrasound imaging device).

Component: In the case of laboratory test observations, the component (part 1) usually identifies some chemical moiety that is distributed in the system (glucose, or HIV antibodies). In the case of clinical terms, the component usually identifies a particular projection of a three or four dimension space to a measure of a particular feature (e.g., QRS interval, systolic) of a time changing measure (ventricle.left.outflow tract). In addition, the component is used to distinguish the various ranges or inflections of a physiologic tracing, or to define precisely the section in three-dimensional space in which an area or range is being measured.

The component includes such things as the special kinds of length (e.g., circumference, diameter, or radius) when length is the property, and the specific level and axis on which a measurement of a body part is taken, e.g., circumference taken at the nipple line. The component should remove all ambiguity as to what projection or axis or specific sub-time frame is being measured. So if one is measuring the diameter of the kidney, the system would have to specify kidney.right (or kidney.left), and the component would identify the axis and level at which the diameter was measured (e.g., cross-sectional at level of pelvis). For a measure of chest circumference the system = chest, the component = circumference at nipple line, and the property = length. Areas, lengths, and volumes of organs all have to be specified enough in the component to distinguish a particular area or length that is being measured. When a measure changes over some cycle (e.g., inspiration, expiration, diastole, and systole), then that should also be specified in the component. (Duration is used to identify the duration of an overall study.)

For most clinical measurements, the component is an attribute of a patient or an organ system within a patient. However, attributes of non-patient systems are also often of interest. For example, we might want to know the class of instrument used to obtain the measurement: i.e., the vendor model number or institutional inventory number of an endoscopy. Such identification numbers have a property of ID. Infection control might want the latter reported in order to track nosocomial infections.

When attributes of an instrument or device are being reported, the system is the name of instrument. The same is true when we report characteristics of tubes used to move fluid in and out of body cavities. For example, we might want to report the size and type of a nasogastric tube.

 Table 20: Subjects covered to date in clinical LOINC

 Body pressure (systolic, diastolic, and mean)

Body measurements		
Body weight (and measures used to estimate ideal body weight)		
Cardiac ultrasound		
Cardiac output, resistance, stroke work, ejection, fraction, etc.		
Circumference of chest, thighs, legs		
Critical care measures		
Dental		
Electrocardiographic measures		
Emergency department case reports (CDC DEEDS)		
Gastroenterology endoscopy		
Heart rate (and character of the pulse wave)		
Intake and output		
Major headings in operative note		
Major headings in discharge summary		
Major headings of history and physical		
Obstetric ultrasound imaging		
Ophthalmology measurements		
Pathology protocols		
Pulmonary ventilator management		
Radiology reports		
Respiratory rate		
Standardization survey instruments		
Urology ultrasound imaging		

To accommodate the special dimensions of clinical observations we have introduced new options for the kind of property. The new kinds of property are what you might expect from the new kinds of dimensions being measured (e.g., resistance, voltage, work per beat). However, we have also introduced three important new properties:

- Anat Anatomic is a special case of Prid that identifies anatomic sites.
- Imp Impression is a diagnostic statement, always an interpretation or abstraction of some other observation (a series of test results, an image, or a total patient), and almost always generated by a professional. (We could also consider the EKG cart's automated diagnoses as impressions.) Impressions are used in laboratory medicine as well as clinical medicine, so you will see them appearing there as well.
- **Find** Finding is an atomic clinical observation, not a summary statement as an impression. Physical, historical, review of systems and other such observations have a property of Finding. These may have a scale of Nom for coded findings, Nar for findings reported in narrative text or Ord for ordinal findings.

In clinical measures, super systems (the second subpart of the system component) may be required. For example, we distinguish head measures of a patient versus a fetus as follows:

Circumference.occipital-frontal:Len:Pt:Head:Qn

Diameter.biparietal:Len:Pt:Head^fetus:Qn

## 4.2 Atomic versus molecular (pre-coordinated names)

With clinical terms we almost always have two ways of reporting. Using the first, we can report an observation by reporting a number of atomic variables which together fully describe the observation. For example, we have the following atomic observations for circumference measures. These variables let us deal with all of the unique kinds of circumferences for which we have not yet defined a pre-coordinated term.

Table 21: Examples of Pre-Coordinated Names		
Code	Description	
Circumference:Len:Pt:XXX:Qn	The actual measure of some circumference	
Circumference site:Anat:Pt:*:Nom	Identifies the body part measured (specifies the system)	
Circumference method:Type:Pt:XXX:Nom:*	Identifies the measuring technique used to obtain the circumference (answers = tape measure, derived, imaging)	

We also provide pre-coordinated terms that combine some of the atomic variables into one LOINC code. For example, we have:

8279-2 Circumference.at nipple line:Len:Pt:Chest:Qn

and

8293-3 Circumference^inspiration:Len:Pt:Chest:Qn

which provide more specificity and permit the key components of the measure to be expressed as one variable as is the convention in many clinical systems. We call these pre-coordinated codes "molecular" variables.

Within the LOINC database molecular variables will vary with respect to how many atomic components are aggregated. As is true in some laboratory areas, methods often are not included as part of a name, nor are they always reported. The most common molecular aggregation is between functional measure and a particular site of measurement. (e.g., the many different intravascular sites for blood pressure measurements.) But in some cases the molecular variables represent combinations of specific measures and particular methods (e.g., the cardiac output measures). Please note that most molecular variables could also be accompanied by one or more atomic measures to provide special information about the measure, e.g., special circumstances of the measure, or the vendor model number or institutional inventory number of the measuring instrument.

When we have a variable that really reports what would have been contained in the name in a fully pre-coordinated term, we will place an asterisk in the part that will be reported as a value. For example, a variable that is used to report the anatomic site as an atomic variable, would have an asterisk (\*) in the system part of the name. The variable used to report the method of a particular measure would have an asterisk (\*) in the method part of the name.

## 4.3 Radiology Reports

The creation of LOINC codes for naming radiology reports began with a special subgroup of committee members and a collection of report names from a variety of clinical sites. Radiology LOINC codes were first released in 2000. A bolus of over 2,000 new codes were added in December 2004, and the Radiology section of LOINC continues to be an active area of growth.

LOINC names for radiology reports follow the general pattern of other clinical observations and measures, with some subtle differences noted below. Parts, 2, 3, and 5 (type of property, timing, and scale) correspond exactly in meaning to other clinical and laboratory LOINC codes.

### 4.3.1 Diagnostic Radiology Reports

#### 4.3.1.1 Component

Like other clinical LOINC codes, the component identifies a particular projection of a three dimensional space. The component should remove all ambiguity about what projection is being measured.

#### a) Component/Analyte name

The first subpart of the component field delineates the projections and spatial conditions that are present during image acquisition. The first subpart is named using the syntax:

<descriptor> [<number of views>] [<projection beam orientation>] [<body position>]

The <descriptor> identifies the type of images in the report. For diagnostic x-ray and mammography studies, the <descriptor> is either View or Views. For diagnostic ultrasound, MRI, CT, and tomography studies, the <descriptor> is Multisection. The descriptor is the only required field in the component.

Where it is appropriate, additional words are added to the first subpart of the component to clarify the focus of the exam (e.g., Multisection limited, or Multisection for pyloric stenosis).

The <number of views> is an optional parameter to describe a specific integer number of views in the projection. Many radiology report names do not specify the actual projections taken, but rather only the number of views. Some report names describe the number of views in relative terms like "minimum of 3 views" or "less than 4 views". Where necessary to specify these relative qualifications, we use the following expressions:

\* Gt = greater than \* Ge = greater than or equal to

\* Lt = less than

\* Le = less than or equal to

The <projection beam orientation> is an optional parameter that specifies the orientation(s) of the beam with respect to the patient. Widely used abbreviations with unambiguous meanings are employed where appropriate (e.g., PA, AP, etc.). Multiple images with different orientations are combined using "&".

The <body position> is an optional parameter to remove ambiguity about the subject's body position with respect to gravity. Examples positions include prone, upright, supine, for example:

View PA prone:Find:Pt:Abdomen:Doc:XR

In order to accommodate special groupings of views and challenges, where necessary, we will make an exception to the principle of not using parentheses in the component for radiology studies (see section 2.1.3). For example:

Views (AP^standing) & (lateral^W hyperextension):Find:Pt:Knee:Doc:XR

b) Report names for portable studies

In general, we do not make names for reports of portable studies, except when the image produced by a portable study is different than the normal study. For example, portable chest x-ray studies are typically taken at a shorter distance than those taken in the radiology department, and thus we create separate LOINC codes for them:

Views AP portable:Find:Pt:Chest:Doc:XR

c) Eponyms and colloquial expressions

Radiology tests are often commonly referred to by eponyms or colloquial expressions. When they are widely used and understood, these names can represent a concise way to communicate the test(s) being reported. In many cases, these expressions convey meaning that spans multiple parameters or even multiple LOINC axes (e.g., COMPONENT, METHOD, and SYSTEM). LOINC names typically employ these expressions only when their meaning is unambiguous, and confine the use of these expressions within one axis. For example:

View Merchants:Find:Pt:Knee:Doc:XR

d) Challenge tests

The second subpart of the component is chemical, physical, and/or functional challenges. The naming convention for chemical challenges (e.g., administration of contrast agents) follows the previously described pattern, including abbreviations for route of administration. For example:

Multisection^W & WO contrast IV:Find:Pt:Kidney.bilateral+Collecting system:Doc:XR.tomo

When describing administration of contrast into specific spaces for which abbreviations do not exist, the space is spelled out in full, and preceded by "intra" or "via" according to these guidelines:

We use "intra: when the contrast injected goes directly into this anatomic space, and this space is what is visualized in the study. For example:

Views^W contrast intra lymphatic:Find:Pt:Lymphatics:Doc:XR.fluor

We use "via" when the contrast injected goes through this device (e.g., catheter) and into the anatomic space being visualized. For example:

Views^W contrast via T-tube:Find:Pt:Biliary ducts+Gallbladder:Doc:XR.fluor

Views^W contrast via colostomy:Find:Pt:Colon: Doc:XR.fluor

Physical challenges that are present during imaging are denoted using a similar pattern:

[<existence>] <challenge>

where existence is denoted W, WO, or W & WO. The existence of W & WO denotes separate views, with and without the challenge. For example:

Views^W & WO weight:Find:Pt:Acromioclavicular joint:Doc:XR

### 4.3.1.1.1 Ambiguity related to "decubitus" in radiology projections and positions

This section describes several issues surrounding radiology naming conventions involving the term "decubitus" in abdomen and chest x-ray terms, and to describe an LOINC's accepted naming conventions. The primary point of confusion concerns an ambiguous naming convention that mixes projection and body position.

#### 4.3.1.1.1.1 Accepted Term Definitions

Excerpts from Merrill's Atlas of Radiographic Positions and Radiologic Procedures<sup>xxvii</sup>:

#### a) Decubitus

Indicates that the patient is lying down and that the central ray is horizontal and parallel with the floor.

Three decubitus positions are named according to the body surface on which the patient is lying:

#### (i) Lateral decubitus (left or right)

In a lateral decubitus position, the patient is side-lying. The position is named left or right by the side of the patient lying on the table.

If the patient's back is closest to the IR (image receptor, e.g., unexposed x-ray film), this resulting projection is AP. If the patient's ventral surface (stomach) is closest to the IR, the resulting projection is PA.

The AP projection in the left lateral decubitus position is the most common (and perhaps implied) decubitus view.

However, it is also possible to do a lateral projection in a right or left lateral decubitus (recumbent) position. (Figure 16-17, Merrill, Vol. 3)

The lateral decubitus position is most often used to demonstrate the presence of air-fluid levels or free air in the chest or abdomen because air rises to the right side and views, are not obliterated by air that may be in the stomach.

ii) Dorsal decubitus

In a dorsal decubitus position, the patient is supine. The central ray provides a lateral projection. The position can be named left or right by the side of the patient that is closest to the IR.

This is also called a cross-table lateral view (abdomen).

This type of position is commonly used in lateral x rays of the spine when the patient cannot be moved into a standard lateral position and premature infants that cannot be positioned easily.

iii) Ventral decubitus

In a ventral decubitus position, the patient is prone; rarely performed, usually in cases of trauma when the patient cannot be moved. The central ray provides a lateral projection. The position can be named left or right by the side of the patient that is closest to the IR.

#### b) KUB

The Kidneys, Ureters, Bladder (KUB) imaging technique is an Abdomen AP projection, often with the patient in the supine position. The KUB view includes anatomical structures from the diaphragm to the symphysis publs.

#### 4.3.1.1.1.2 Radiology Naming Conventions

In Radiology, LOINC has typically allowed several levels of granularity to accommodate differences in naming conventions (e.g., specifying laterality or not, explicitly specifying contrast use or not). Different levels of granularity have been observed in this domain as well.

Example local term names:

- Abd R Lat Decub XR
- Abd R Decub Port XR
- Abdomen Decubitus
- Chest Decub XR
- Chest L Decub XR
- Xray Chest Decubitus

4.3.1.1.2.1 Decubitus is a body position, not a projection. To add clarity to the names, we will use decubitus only to refer to the lateral decubitus position.

a) When using decubitus to specify body position, we will explicitly say "L-lateral-decubitus" or "R-lateral-decubitus". Including the word "lateral" adds clarity as to which projection we are talking about, and the dashes "-" help link the words together.

(i) Where the intent is to not name a side, we will use "lateral-decubitus", rather than the more ambiguous, naked "decubitus".

4.3.1.1.1.2.2 We will not use the term "dorsal decubitus" to refer to the supine position. Supine will be used as a valid body position where needed.

a) Because it is common and clear, we use "lateral crosstable" to mean a lateral projection (right or left) in the supine position, thus encompassing both a projection and body position.

- 4.3.1.1.1.2.3 The term "ventral decubitus" will not be used to refer to the prone position. Instead, we use prone as a valid body position where needed.
- 4.3.1.1.2.4 Historically, we created some terms in which there was an implied projection (e.g., AP). Through careful review, we revised or deprecated these ambiguous terms so as to make the particular projection explicit include in the name.
- a) When a particular projection is not named, it is implied that any potential projection could be done/reported with this code (e.g., AP, PA, or lateral).

- b) An AP L-lateral-decubitus and AP R-lateral-decubitus are considered distinct "views" in our naming conventions. Thus, use plural "views" and not the singular "view" in such terms.
- c) A naked "lateral" in the component means a lateral projection (in any body position).
- d) Historically, LOINC included some terms with the abbreviation KUB as a named view. Through careful review, we have discontinued its use in favor of simply using the projection (AP) and a specified patient position (e.g., supine or upright) where necessary. This avoids the ambiguity about what KUB means with respect to the patient position.
- e) As in other areas tricky spots of Radiology names, parentheses will clarify which projections are being done in which body positions.

#### 4.3.1.2 Timing

Most radiology reports will have a time aspect of "point in time" (PT). A few reports indicate a specific time window (e.g., timed fluoroscopy imaging), and these are named in the usual manner, e.g., <numeric value><S|M|H|W>. Where qualifiers are needed to indicate a relative time frame, we use the following conventions:

- Gt = greater than
- Ge = greater than or equal to
- Lt = less than
- Le = less than or equal to

For example, Le 1H

#### 4.3.1.3 System

For all clinical LOINC terms, the system is spelled out in full and should not be ambiguous. For most radiology reports, the system describes what is being viewed, not only the anatomic area of interest. For example, a common study to identify anterior glenoid pathology is the West Point view x-ray. Because this view demonstrates the entire shoulder, not just the glenoid rim, the system is Shoulder:

View West Point:Find:Pt:Shoulder:Doc:XR

We name systems that encompass multiple organ systems by joining them with a "plus" (+). The individual parameters are arranged in cephalocaudal and/or proximodistal order:

Views:Find:Pt:Spine.cervical+Spine.thoracic+Spine.lumbar:Doc:XR

Views:Find:Pt:Spine.lumbar+Sacrum+Coccyx:Doc:XR

While the system describes what is being viewed, it is not an exhaustive list of all structures in the view. For example, in practice, a standard lateral view x-ray of the radius and ulna shows these bones in their entirety as well as the proximal row of carpal bones and the elbow joint. Yet, the system for this report would simply be Radius+Ulna.

4.3.1.3.1 Vessels

For reports of vascular studies, if the system contains multiple vessels, each vessel is named separately and connected by a plus (+), (e.g., Celiac artery+Superior mesenteric artery+Inferior mesenteric artery). If the vessel(s) being viewed is part of a common root, it is named with the common part first, then a dot (.) separator, and then the division (e.g., Vena cava.inferior). If the vessel(s) are independent branches, then they are named independently and connected by a plus (+), (e.g., Superior mesenteric artery+Inferior mesenteric artery).

For studies that view all the vessels in an area, the SYSTEM is typically named in plural form (e.g., Lower extremity vessels, Lower extremity veins). The rationale for this is that most angiography studies demonstrate some vessel branches, not just a single vessel.

### 4.3.1.3.2 Brain, head, cerebral, and skull

There is presently much variation in radiology system naming patterns pertaining to the anatomical area of the head. We have modeled our naming patterns largely after prevailing conventions. We generally use a system containing Head for reports of MRA, CTA, CT, and US studies. We use the system of Brain with reports of MRI and nuclear medicine studies, and Skull with plain film study reports. For conventional fluoroscopic angiography reports, we use a system containing Cerebral when not specifying a particular artery.

### 4.3.1.3.3 Extremities

Test names for studies of the extremities often vary in their terminology. The term "arm" technically means the part of the upper limb from shoulder to elbow, but is also commonly used to refer to the entire upper limb, and the term "leg" technically means the part of the lower limb between the knee and ankle, but is also commonly used to refer to the entire lower limb (Dorland's Illustrated Medical Dictionary<sup>xxviii</sup>). In lieu of this, we have included "arm" and "leg" as broad synonyms, but do not use them as a system. We use "Upper extremity" and "Lower extremity" to refer to the limbs in their entirety or when the visualized region of the limb is not specified. For more specific regions, we name the system based on the anatomy visualized with that particular method. For example, we name an x-ray of the upper arm as:

Views:Find:Pt:Humerus:Doc:XR

### 4.3.1.3.4 Laterality

For most bilaterally symmetric entities, we create separate LOINC codes for radiology reports differentiated by laterality. Thus, for many studies we have LOINC codes that differ only by the laterality of the system (e.g., Shoulder, Shoulder.left, Shoulder.right, Shoulder.unilateral, and Shoulder.bilateral).

### 4.3.1.3.5 Series projections with multiple systems

For radiology reports on a series of projections that include multiple systems (e.g., Ribs+Chest), the order the projections are listed in the COMPONENT corresponds with the order of the anatomical sites in the system. In addition, the secondary anatomical site is added to the COMPONENT to clarify which views were for which anatomical region. For example:

### 4.3.1.3.6 Use of dot (.) in system

Using a dot (.) in the SYSTEM signifies that the modifier is a subdivision or component of the main word. No dot (.) is used when the modifier is just an adjective used for clarification. So, we have: Chest.pleura, but Superficial tissue.

#### 4.3.1.3.7 Method

In general, the method for radiology reports corresponds to the method for other LOINC terms. The pattern for naming a radiology method is:

<modality>.[submodality]

#### 4.3.1.3.7.1 Method for angiography terms

LOINC terms use the methods of XR.fluor.angio, MRI.angio, and CT.angio to describe angiography study reports. Radiology systems often use the abbreviations MRA, MRV, CTA, and CTV in test names of angiography studies. Because MRA and CTA can refer to studies of arteries, veins, or both, they are equivalent synonyms to the LOINC methods MRI.angio and CT.angio and are included in the database as synonyms. MRV and CTV are added as synonyms only to terms where the method is MRI.angio or CT.angio and the system contains the word "Vein" or "Veins."

#### 4.3.2 Interventional Radiology Reports

#### 4.3.2.1 Component

Radiology reports for interventional studies under imaging guidance typically contain a component of the form: Guidance for <indication>, where <indication> is description of the nature of the guidance. For example:

Guidance for biopsy:Find:Pt:Breast:Doc:Mam

Guidance for drainage:Find:Pt:Kidney:Doc:US

#### 4.3.2.2 System

The system for interventional radiology reports is named for the anatomical structures being viewed, similar to the pattern for systems of diagnostic radiology reports.

#### 4.3.2.3 Method

In general, the method for interventional radiology reports corresponds to the method for diagnostic radiology and other LOINC terms. The pattern for naming the method is:

<modality>.[submodality]

## 5 Tumor registry

In collaboration with North American Association of Central Cancer Registries, Inc (NAACCR, Inc), we have developed a set of LOINC codes that can be used to communicate tumor registry variables from clinical institutions to tumor registries and among tumor registries. These LOINC terms map to the content of NAACCR data set, and include variables for such things as the hospital at which the tumor was first diagnosed, the primary anatomic site of the tumor, it size, its degree of spread at the time of diagnoses, and a host of other variables of interest to the tumor registries. The NAACCR data set and other cancer-related demographics are identified by the class TUMRRGT.

The NAACCR standards and an implementation guide for transmitting these LOINC tumor registry variables within HL7 messages are available from the NAACCR website: <u>http://naaccr.org/</u>.

## 6 Claims attachments

For more information see HIPAA Attachments display in RELMA, the HIPAA Attachment section in RELMA Users' Manual, the respective documents published by HL7 Attachments Working Group, and the Attachments section of the LOINC website (<u>http://loinc.org/attachments</u>).

## 7 HL7 LOINC Document Type Vocabulary Domain

This section describes our approach to creating a set of document type codes. This work has been collaboration between the LOINC committee and the HL7 document ontology task force, with initial contributions from Stan Huff, Pavla Frazier, Bob Dolin, Clem McDonald, and continued refinements from many others.

## 7.1 Use of document type codes in HL7 messages

In creating and maintaining document type codes it is important to distinguish between the purpose of local document names and the names represented by the document type code. Document type codes are created to provide consistent semantics for the names of documents when they are shared or exchanged between independent facilities or enterprises. The names and codes that are used locally within an enterprise are entirely under the control of the local enterprise, and these names are valuable to the work flow and access of information within the enterprise. It is assumed that the exact local name for the document will be retained in the system that created the document and that the local name can be sent along with the document type code when the document is sent to an external organization. The document type code should only express the meaning in a document name that can be shared between independent organizations.

For example, it is appropriate to have local document names like "Dr. Smith's Tuesday Pain Clinic Note" or "Albuquerque VA General Medicine Consult Note" for use within an enterprise. However, some parts of these very specific local names are not meaningful outside of the originating enterprise Thus, proper document type codes would have names like "Outpatient Pain Clinic Note," or "General Internal Medicine Consult Note."

Table 22: Example Clinical Notes					
Possible local terms	Document type codes				
Dr. Smith's Tuesday Pain Clinic Note	Outpatient Pain Clinic Note				
Albuquerque VA General Medicine Consult Note	General Internal Medicine Consult Note				

## 7.2 Relationship with terminologies

### LOINC

HL7 will use LOINC codes for clinical document codes, and will not develop an independent document code system for clinical documents. At its option, HL7 may choose to limit its domain to a subset of LOINC codes. HL7 can incorporate any LOINC document code into the HL7 domain.

The naming rules in this document only apply to "clinical notes." For purpose of this Users' Guide, a clinical note is a clinical document (as defined by the HL7 CDA Standard), where clinical professionals and trainees produced the document either spontaneously (e.g., I write my admitting note) or in response to a request for consultation. "Clinical Notes" provides a better description of the process.

"Clinical Notes" are to be distinguished from patient reports such as radiology reports, pathology reports, laboratory reports, cardiac catheterization reports, etc., that are generated in response to an order for a specific procedure. Names for most of these later concepts are accommodated well by the clinical LOINC naming structure, and many such codes already exist within the LOINC database.

#### **Relationship with HL7 V2.x values**

The HL7 document type code domain will overlap with similar concepts found in HL7 V2.x (user defined table 0270 Document Types; user defined table 0496 Consent Types). Our approach to manage this overlap is:

- Create a mapping from LOINC codes to HL7 V2.x document codes.
- Continue to develop LOINC codes to meet the needs of the HL7 V3 domain that are not present in the V2.x tables.

#### Relationship to a reference terminology

As soon as possible, the component terms used in the creation of the names of document type codes will be mapped to either the UMLS Metathesaurus or SNOMED CT. This mapping will help to establish the meaning of the terms and will allow aggregation and classification of document type codes based on definitions, computable relationships, and subsumption hierarchies that exist in the reference terminology.

## 7.3 Elements of Document Type codes

In the following, synonymy or equivalent terms are designated by parenthesis. Document codes are defined by their component parts. The first list of axis values was published in 2003, and served as the basis for an initial set of LOINC codes.

Through both empiric analysis and expert review, we have continued evaluating and refining this list. The following listing contains the current set of axis values for the elements of document type codes that have been vetted by the LOINC Committee. *We are in the process of carefully harmonizing our existing Document terms with these new values*.

#### **Kind of Document**

**Description:** Characterizes the general structure of the document at a macro level. Document types are differentiated based on the need to define distinct document headers.

#### Allowed Values:

1. Note

Description: Clinical Note – (also known as "Clinical Document"). Documents generated by clinicians as part of patient care, which includes notes written at the initiative of "individual clinic and consulting clinicians." It does not include clinical reports such as, radiology, pathology, and cardiac catheter reports that are usually stimulated by a particular order. Clinical documents meet five criteria, as defined in CDA 1.0: wholeness, stewardship, authentication, persistence, and human readability.

2. Working draft of additional values for Kind of Document:

Work is presently underway to more fully define the other potential values for Kind of Document. The following list shows the working draft of these values:

#### 1. Administrative note

- a. Against medical advice note
- b. Agreement
- c. Certificate

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- 1. Birth Certificate
- 2. Death Certificate
  - Evaluation of mental and physical incapacity certificate
- d. Consent
  - 1. Abortion Consent
  - 2. Anesthesia Consent
  - 3. Hysterectomy Consent
  - 4. Organ Donation Consent
  - Procedure Consent
     Release of Information Co
  - 6. Release of Information Consent
  - 7. Sterilization Consent
  - 8. Surgical Operation Consent
- e. Contract
- f. Health Insurance Card
- g. Health Insurance-related Form
- h. Health Record Cover Sheet
- i. Legal Document
  - 1. Power of Attorney
- 2. Advance directive
  - a. Do not resuscitate
    - Rescinded do not resuscitate
  - b. Living will
  - c. Rescinded advance directive
  - Diagram
- 4. Flowsheet
- 5. Legal

3.

- 6. Letter
- 7. Note
  - a. Adverse event note
  - b. Alert
- 8. Report

#### **Type of Service**

**Description:** Characterizes the kind of service or activity provided to/for the patient (or other subject of the service) as described in the note. Common subclasses of service would be examinations, evaluations, and management. The notion of time sequence, e.g., at the beginning (admission) at the end (discharge) is subsumed in this axis.

- Communication 1.
- Conference 2

3.

9

- Case Conference a.
- Consultation
  - a. Confirmatory Consultation
- Individual Counseling 4.
- 5. Group Counseling
- 6 Daily or End of Shift Signout
- 7. Diagnostic Study
  - Inhalation challenge test a.
- 8. Education
  - Discharge Instructions a.
    - 1. Hospital Discharge Instructions
  - b. **Discharge Teaching**
  - Preoperative Teaching c.
  - Evaluation and Management
    - Annual Evaluation a. b.
    - Assessment
      - Functional Status Assessment 1. 2.
      - Readiness for Military Duty Assessment 3.
        - Risk Assessment and Screening
      - Fall Risk Assessment a.
    - Crisis Intervention (Psychosocial Crisis Intervention) c.
    - d. **Disease Staging**

2.

- **Disability Examination** e.
  - Social Security Administration Compensation Examination 1.
    - Compensation and Pension Examination
      - 1. VA Compensation and Pension Acromegaly
      - VA Compensation and Pension Aid and Attendance or Housebound Exam 2.
      - 3. VA Compensation and Pension Arrhythmias
      - VA Compensation and Pension Arteries Veins and Miscellaneous (Misc) 4
      - VA Compensation and Pension Audio 5.
      - VA Compensation and Pension Bones 6.
      - 7. VA Compensation and Pension Brain and Spinal Cord
      - 8 VA Compensation and Pension Chronic Fatigue Syndrome
      - 9. VA Compensation and Pension Cold Injury Protocol
      - 10. VA Compensation and Pension Cranial Nerves
      - VA Compensation and Pension Cushing's Syndrome 11.
      - 12. VA Compensation and Pension Dental and Oral
      - VA Compensation and Pension Diabetes Mellitus 13.
      - VA Compensation and Pension Digestive Conditions 14.
      - 15. VA Compensation and Pension Ear Disease
      - VA Compensation and Pension Eating Disorders 16.
      - 17. VA Compensation and Pension Endocrine Diseases
      - VA Compensation and Pension Epilepsy and Narcolepsy 18.
      - VA Compensation and Pension Esophagus and Hiatal Hernia 19.
      - 20. VA Compensation and Pension Eye
      - VA Compensation and Pension Feet 21.
      - 22. VA Compensation and Pension Fibromyalgia
      - 23 VA Compensation and Pension General Medical
      - VA Compensation and Pension Genitourinary 24.
      - 25. VA Compensation and Pension Gulf War Protocol
      - VA Compensation and Pension Gynecological Conditions and Disorders of the Breast 26.
      - 27 VA Compensation and Pension Hand Thumb and Fingers
        - VA Compensation and Pension Heart 28.
      - VA Compensation and Pension Hemic Disorders 29
      - VA Compensation and Pension Human Immunodeficiency Virus (HIV)-Related Illness 30
      - VA Compensation and Pension Hypertension 31
      - 32. VA Compensation and Pension Infectious Immune and Nutritional Disabilities
      - 33. VA Compensation and Pension Intestines
      - 34. VA Compensation and Pension Joints (Shoulder Elbow Wrist Hip Knee Ankle)
      - VA Compensation and Pension Liver Gall Bladder and Pancreas 35
      - 36. VA Compensation and Pension Lymphatic Disorders
      - VA Compensation and Pension Mental Disorders 37
      - 38. VA Compensation and Pension Mouth Lips and Tongue
      - VA Compensation and Pension Multiple Exam 39
      - 40. VA Compensation and Pension Muscles
      - 41 VA Compensation and Pension Neurological Disorders
      - 42. VA Compensation and Pension Nose Sinus Larynx and Pharynx
      - 43. VA Compensation and Pension Peripheral Nerves
      - VA Compensation and Pension Post Traumatic Stress Disorder (PTSD) Initial Evaluation 44.
      - 45. VA Compensation and Pension Post Traumatic Stress Disorder (PTSD) Review

- 46. VA Compensation and Pension Prisoner of War Protocol
- 47. VA Compensation and Pension Pulmonary Tuberculosis and Mycobacterial Diseases
- 48. VA Compensation and Pension Rectum and Anus
- 49. VA Compensation and Pension Residuals of Amputations
- 50. VA Compensation and Pension Respiratory Diseases
- 51. VA Compensation and Pension Respiratory - Obstructive Restrictive and Interstitial
- 52. VA Compensation and Pension Scars
- 53. VA Compensation and Pension Sense of Smell and Taste
- 54. VA Compensation and Pension Skin Diseases
- 55. VA Compensation and Pension Spine
- 56. VA Compensation and Pension Stomach Duodenum and Peritoneal Adhesions
- 57. VA Compensation and Pension Thyroid and Parathyroid Diseases
- Evaluation and Management of a Specific Problem b.
  - 1. Evaluation and Management of Anticoagulation
  - Evaluation and Management of Hyperlipidemia 2.
  - Evaluation and Management of Hypertension 3.
  - Evaluation and Management of Overweight and Obesity 4
  - Evaluation and Management of Smoking Cessation 5.
- c. History and Physical
  - Annual History and Physical 1
  - 2. Admission History and Physical
  - 3. Comprehensive History and Physical
  - Labor and Delivery History and Physical 4
  - Targeted History and Physical 5.
- Initial Evaluation d.
  - 1. Admission Evaluation
  - Admission History and Physical 2.
- e. Plan

g.

h.

- Asthma Action Plan 1.
- 2. Care Plan
- 3. Treatment Plan
- f. Restraint
  - Subsequent Evaluation
  - Progress Note 1.
  - Surgical Operation
    - Postoperative Evaluation and Management 1.
    - 2. Preoperative Evaluation and Management
- i. Summarization
  - Antepartum Summary 1.
  - 2. Discharge Note
  - 3. Discharge Plan
  - 4. **Discharge Summary**
  - Maternal Discharge Summary 5.
  - 6. Labor and Delivery Summary
  - Summarization of Episode 7.
  - 8. Summary of Death
  - Transfer Summarization 9
  - Transplant Candidate Evaluation
- j. k. Transplant Donor Evaluation
- 1. Well Child Visit
- Exercise Testing 2. 3.
  - Medication Management
  - Medication Reconciliation a.
- 4 Outreach
- 5. Procedure
  - Interventional Procedure a.
    - Pathology Procedure
  - 1. Autopsy
  - Referral Transfer of Care Referral 1.
- 7. Respite
- Supervisory Direction 8.

b.

9. Triage

#### Setting

6.

**Description:** Setting is a modest extension of CMS's (also known as HCFA) coarse definition of settings, which have well defined meanings. Setting is not equivalent to location, which typically has more locally defined meanings and is reported in other parts of the message. Setting would be limited to one of the

following categories (with some future extensions possible).

Most clinical report names would include a setting (at least at the top level) to avoid confusion between important classes of reports. For example, The Admission H&P is usually taken to be the Hospital Admission H&P, but it could be confused with the nursing home H&P if not distinguished by the setting. Setting is not a required component of the name.

- 1. Ambulance
- 2. Birthing Center
- 3. Emergency Department
- 4. Inpatient Hospital
- 5. Intensive Care Unit 6.
  - Long Term Care Facility
    - a. Custodial Care Facility b.
      - Nursing Facility 1.
        - Skilled Nursing Facility 2. Unskilled Nursing Facility
- 7 Outpatient
  - Ambulatory Surgical Center a.
  - Office b.
  - **Outpatient Hospital** c.
  - d. Urgent Care Center
- 8. Patient's Home
- 9. Rehabilitation Hospital
- 10. Telehealth
- 11. Telephone Encounter

## Subject Matter Domain (SMD)

Description: Characterizes the subject matter domain of a note.

- 1. Acupuncture
- 2. Aerospace Medicine
- 3. Allergy and Immunology
  - a. Clinical and Laboratory Immunology
  - Anesthesiology
  - Pain Medicine a.
- Audiology 5.

4.

- Chiropractic Medicine 6.
- Critical Care Medicine 7.
- Dentistry 8.
- Dermatology 9.
  - Clinical and Laboratory Dermatological Immunology a.
  - Dermatopathology b.
  - Pediatric Dermatology c.
- 10. Emergency Medicine
  - Medical Toxicology a.
  - Pediatric Emergency Medicine b.
  - Sports Medicine c.
  - d. Undersea and Hyperbaric Medicine
- 11. Ethics
- 12. Family Medicine
  - a. Adolescent Medicine
  - b. Geriatric Medicine
  - Sports Medicine c.
- 13. General Medicine
- 14. Internal Medicine

c.

d.

- Adolescent Medicine a.
- b. Cardiovascular Disease
  - Advanced Heart Failure and Transplant Cardiology 1.
  - Clinical Cardiac Electrophysiology 2.
  - 3. Interventional Cardiology
  - Endocrinology
    - 1. Diabetology
  - Thyroidology 2
  - Gastroenterology

- 1. Hepatology
- Geriatric Medicine
- f. Hematology and Oncology
- Infectious Disease g.
- h. Nephrology
- i. Pulmonary Disease
- Rheumatology j. Sports Medicine
- k.

e

- 15. Medical Genetics
  - **Clinical Biochemical Genetics** a.
  - Clinical Cytogenetics b. Clinical Genetics c.
  - d.
  - Clinical Molecular Genetics Molecular Genetic Pathology
- e. 16. Mental Health
- Psychiatry a.
  - 1 Addiction Psychiatry
  - 2. Child and Adolescent Psychiatry
  - 3. Forensic Psychiatry
  - 4. Geriatric Psychiatry
  - Psychosomatic Medicine 5.
  - Psychology b.
- 16. Multi-specialty Program
- 17. Neurological Surgery
- 18. Neurology
  - a. Clinical Neurophysiology
  - Neurology Neurodevelopmental Disabilities b.
  - Neurology with Special Qualifications In Child Neurology c.
  - d. Pain Medicine
  - e. Vascular Neurology
- 19. Nuclear Medicine
- 20. Nutrition Dietetics
- 21. Obstetrics and Gynecology
  - Maternal and Fetal Medicine a.
  - b. Reproductive Endocrinology
- 22. Occupational Therapy
- 23. Ophthalmology
- 24. Optometry
- 25. Oral Surgery
- 26. Orthopedic Surgery
  - Orthopedic Sports Medicine a.
  - Surgery of the Hand b.
- 27. Orthotics Prosthetics
- 28. Otolaryngology
  - Neurotology a.
  - Pediatric Otolaryngology b.
  - Plastic Surgery within the Head and Neck c.
- 29. Palliative Care
- 30. Pastoral Care
- 31. Pathology
  - Anatomic and Clinical Pathology a.
    - Blood Banking Transfusion 1.
    - 2. Dermatopathology
- 32. Pediatrics
  - Adolescent Medicine a.
  - Child and Adolescent Psychiatry b.
  - **Developmental-Behavioral Pediatrics** c.
  - Hepatology d.
  - Medical Toxicology e.
  - Neonatal Perinatal Medicine f.
  - Pediatric Cardiology g.
  - Pediatric Critical Care Medicine h.
  - i. Pediatric Dermatology
  - Pediatric Endocrinology į.
  - k. Pediatric Emergency Medicine
  - Pediatric Gastroenterology 1.
  - Pediatric Hematology-Oncology m.
  - Pediatric Infectious Diseases n.
  - Pediatric Nephrology о.
  - Pediatric Otolaryngology p.
  - Pediatric Pulmonology q.
  - Pediatric Radiology r.

- Pediatric Rehabilitation Medicine s.
- Pediatric Rheumatology t.
- u. Pediatric Surgery
- Sports Medicine v.
- 33. Pharmacy
- 34. Physical Medicine and Rehabilitation
  - Kinesiotherapy a.
  - b. Pain Medicine
  - Pediatric Rehabilitation Medicine c.
  - Spinal Cord Injury Medicine d.
  - e. Vocational Rehabilitation
- 35. Physical Therapy 36. Plastic Surgery
  - Plastic Surgery within the Head and Neck a.
  - Surgery of the Hand b.
- 37. Podiatry
- 38. Preventive Medicine
  - Medical Toxicology a.
  - b. Occupational Medicine
  - c. Undersea and Hyperbaric Medicine
- 39. Primary Care
- 40. Public Health
- 41. Radiology
  - **Diagnostic Radiology** a.
  - Nuclear Radiology b.
  - c. Pediatric Radiology
  - Radiation Oncology d.
  - e. Radiological Physics
  - f. Vascular and Interventional Radiology
- 42. Recreational Therapy
- 43. Research
- Respiratory Therapy 44.
- 45. Social Work
- 46. Speech Pathology
- 47. Surgery
  - Colon and Rectal Surgery a.
  - b. Pediatric Surgery
  - Surgery of the Hand c.
  - Surgical Critical Care d.
  - Thoracic Surgery e.
  - f. Transplant Surgery
  - g. Vascular Surgery
- Tumor Board 48.
- 49. Urology
  - Pediatric Urology a.

Role Description: Characterizes the training or professional level of the author of the document, but does not break down to specialty or subspecialty.

- 1. Assistant
- 2. Case Manager
- 3. Clerical
- 4. Counselor
- Fiduciary 5.
- 6. Hygienist
- 7. Interdisciplinary
- a. Team
- Medical Assistant 8.
- 9. Nursing
  - CRNA a.
    - b. Certified Nursing Assistant
    - Clinical Nurse Specialist c.
    - d. Nurse Midwife
    - Nurse Practitioner e.
    - Licensed Practical Nurse f.
  - Registered Nurse g.
- 10. Patient
- 11. Physician
  - Attending a. b.
    - Fellow

- c. Intern d. Resident
- 12. Physician Assistant
- 13. Student a. Sub Intern
- 14. Technician
- 15. Therapist

\* Physician subsumes medical physicians and osteopathic physicians.

## 7.4 Rules for Creating Clinical Notes from Multiple Components

Names for required clinical notes would be constructed by picking entries **from the Kind of Document axis and at least one of the other four axes.** The LOINC committee will create LOINC codes for all required combinations (not all possible combinations).

The original document ontology terms were created only for the document type of "note" and with the general naming pattern:

<Subject Matter Domain> : <Training / Professional Level>: <Setting>: <Type> : Note

As we have revised and refined the elemental axes in the document ontology, simple names would be constructed and ordered as follows:

Table 23. Document Ontology LOINC Naming Rules						
Component         Property         Time         System         Scale         Method         Class						
<type of="" service=""> <kind document="" of="">     Find     Pt     <setting>     Doc     <smd>.<role>     DOC.CLINRPT</role></smd></setting></kind></type>						

In general, combinations from within an axis are allowed in a term name where they make sense (SMD, Service), but are disallowed where they do not (Role, Setting). Combinations will be represented with a plus (+), so as to distinguish from elements containing "and" or "&". Where a particular element is not defined for a given term and leaves a LOINC axis blank, the LOINC name will include the {} naming convention. For example, if a Setting is not designated, the System will be "{Setting}".

LOINC codes for clinical notes designed according to this model and are assigned a class of DOC.CLINRPT.

Example LOINC codes in the Document Ontology include:

Table 24. Example Document Ontology LOINC Codes								
Component Property Time System Scale Method Class								
Group counseling note	Find	Pt	Hospital	Doc	{Provider}	DOC.CLINRPT		
Note	Find	Pt	Outpatient	Doc	{Provider}	DOC.CLINRPT		
Note	Find	Pt	{Setting}	Doc	{Provider}	DOC.CLINRPT		
History and physical note	Find	Pt	{Setting}	Doc	{Provider}	DOC.CLINRPT		

## 7.5 Future Work

We continue active development and refinement of the Kind of Document axis. As we continue this work, we intend to develop equally specific definitive documents for other kinds of health case associated documents.

## 8 Order Panels (Batteries)

Beginning with version 1.00, the LOINC database was expanded to include order sets/panels. These have been identified with the word "panel" in the component name. Since the property type will vary depending on the panel elements, the second part of the LOINC name may be populated by a dash (-). The scale (5th part of the LOINC name) will be populated by a dash (-) if the panel elements could have different scales.

If a government authority recognizes the order set, it will include the year that an order set took effect. For example:

Comprehensive metabolic 2000 panel.

Using RELMA, you can view the list of the individual test components included in each panel (order set). The elements will be accompanied by a flag that will denote the expected appearance of the panel element in the panel when resulted. A flag is always one of three states:

- R Required. The panel element is always expected to be reported when the panel is resulted.
- O Optional. The panel element may not be reported with a panel result depending upon institutional policy or capabilities of the reporting lab.
- C Conditional. The panel element is a key finding in the panel report and should be assumed to be negative, absent or not present if the panel result does not include data for this element.

Some example order sets:

	Table 25: Example Order Sets							
24358-4	Hemogram WO platelets panel	-	Pt	Bld	Qn	R		
26464-8	Leukocytes	NCnc	Pt	Bld	Qn	R		
26453-1	Erythrocytes	NCnc	Pt	Bld	Qn	R		
718-7	Hemoglobin	MCnc	Pt	Bld	Qn	R		
20570-8	Hematocrit	VFr	Pt	Bld	Qn	R		
30428-7	Mean corpuscular volume	EntVol	Pt	RBC	Qn	R		
28539-5	Erythrocyte mean corpuscular hemoglobin	EntMass	Pt	RBC	Qn	R		
28540-3	Erythrocyte mean hemoglobin concentration	MCnc	Pt	RBC	Qn	R		
30384-2	Erythrocyte distribution width	EntVol	Pt	RBC	Qn	0		
30385-9	Erythrocyte distribution width	Ratio	Pt	RBC	Qn	0		
24326-1	Electrolytes 1998 panel	-	Pt	Ser/Plas	Qn	R		
2951-2	Sodium	SCnc	Pt	Ser/Plas	Qn	R		
2823-3	Potassium	SCnc	Pt	Ser/Plas	Qn	R		
2075-0	Chloride	SCnc	Pt	Ser/Plas	Qn	R		
2028-9	Carbon dioxide	SCnc	Pt	Ser/Plas	Qn	R		
330373	Anion gap	SCnc	Pt	Ser/Plas	Qn	0		

LOINC has created a series of spreadsheets that contains sets of related panels. These spreadsheets may include information on multiple panels or just a single panel. Each spreadsheet contains three worksheets: list of LOINC terms within the union of the panels in the package, a table that defines the nesting of the panels within a given panel, and a table that defines all of the answer lists in the panel. This content can be easily used to load a database, but every panel in LOINC is not yet represented this way.

You can also get to the panels content by going to the panel screen in RELMA. You can look at the content of every panel on this screen in report format. You can also pick any panel in the grid of a search, right click, and then export.

## 8.1 Goals

We have gotten many requests for a standard set of test order codes from Medical Information System vendors. They want standard codes for the common orders so they can install their system with a set of usable starter set of order codes. They also want them to ease the cross communications among merging hospitals.

LOINC codes have been defined for most individual laboratory observations and for many clinical observations, and claims attachments. Obviously, these same LOINC codes can be used to order individual laboratory and clinical observations, as well as to report the LOINC code for Blood Hemoglobin (LOINC # 718-7) could as easily be used to order a Blood Hemoglobin, as well as to report the result of that test. Pre-existing LOINC codes could also be used to order more complex observations. The Urinary Creatinine Clearance (LOINC # 2164-2) could also be used order code Creatinine Clearance. Since the calculation of creatinine clearance requires two distinct measures (serum creatinine and 24-hour urine creatinine), an order for creatinine clearance implies an order for these two other measures. However, the existing single value LOINC codes could not be used to order many laboratory and clinical procedures that are ordered as a single-named test (battery), such as CBC, urine dipsticks, blood differential count, LDH isoenzymes. Similarly physicians order Blood pressure measures and expect to get (at least) the diastolic blood pressure and the systolic blood pressure. Though these are separate observations, for practical purposes one is never measured without the other. Initially, we created LOINC codes for the common "fixed" observation packages. By fixed, we mean that certain kinds of measures will always be part of the battery, and the production of that particular set of measurements is tightly bound to the procedure or instruments that produce the values and or by a government mandate (e.g., LOINC # 24325-3: Hepatic function HCFA 2000 panel). Other types of order codes have evolved.

#### Background on kinds of results found in order sets

To understand the rules about creating order sets, we distinguish several kinds of results in orderable test batteries (or sets).

### 8.2 Reflex tests

Testing can be done in steps. A certain number of analyses are done at the first step, then depending upon the values of those analytes different analyses (observations) are performed. For example, a TSH test might be done first and depending upon its value, other confirmatory tests would be done. We have not yet addressed the naming of Panels with reflex components in LOINC. This is work for the future.

## 8.3 Calculated or derived results

The results in an order set often include results that simple calculations based on the primary measurements. For example, it might include the absolute concentration and the percent concentration of a given element, such as basophils. In the information theoretic sense these do not provide additional information. So we will usually use one order panel name regardless of how many values were calculated from the primary measurement.

## 8.4 Associated observations

Some sets consist of a set of measures produced by the laboratory and a set of observations obtained by the placer and sent along with the request. For example, placers will usually report the percent inspired O2 when they request an arterial blood gas and the laboratory reports that value along with the values it measures directly. We call these "associated observations" and count the volumes and times of collection in this category for the purpose of this discussion. We will not define distinct order panels that vary with the number of clinical variables (not measured by the lab) that are included in the report.

## 8.5 LOINC Rules for representing order panel names

We will use most of the same general LOINC naming rules for Batteries of Observations (Panels) as for individual observations.

Component Name: For orders sets consisting of three or more constituent tests, the component name will be a concatenation of:

- (1) A name (e.g., Hemogram, Differential count, Vital Signs) to convey the content of the panel
- (2) The word "Panel" included to unambiguously identify that this LOINC term refers to a panel or battery

In the case that a well-defined panel exists but has no conventional name, we will include each of the distinct measured entities separated by ampersand (&) in the component name. So for example, when a creatinine is measured along with sodium in a 24-hour urine, we will use this convention to build up panels from other panels. We may also use a more efficiently syntax, which implies repeat of the first part of the name, e.g., Chlamydia Ab IgM & IgG Panel.

Any of these batteries may variously include in the report a variety of other values derived from the reported measures, information sent along with the request (e.g., inspired O2 for blood gases). In most cases we will not make up different names for the same set of tests done by different methods. Because of the possible mixtures of methods within a panel, representing these distinctions would cause an explosion of the distinct Panel, which would (usually) be a burden on the ordering provider. Further, in a given setting the ordering provider can only order the methods that are provided by his usual producer. Implied in the order is "Give me the battery produced by your usual methods". In special circumstances, we might provide method specific observation panels, e.g., when blood pressure is usually done by automated methods, the provider might want the option of obtaining a blood pressure by manual methods as a double check.

Property, Timing, Scale and Method: We will not usually value the property type (the second part of a LOINC name) of an order panel because the property varies within the measures included in a battery. But since this field cannot be null in a LOINC name, we will include a dash (-) in this field, but we will usually value the timing and the system and the scale field.

At this first phase we have defined batteries for:

- Hemograms and differential counts (both automated and manual)
- Arterial blood gases
- Urinalyses
- Isoenzymes
- Antibodies for IgG and IgM when they are done in pairs
- Common toxicology batteries
- Susceptibility testing
- Chemical batteries defined by HCFA

• A few clinical orders

Description of some LOINC Panels (Order Set Names):

	Table 26: Examples of LOINC Panel Names (Order Set Names)					
LOINC_NUM	LOINC Fully Specified Name	Description				
24358-4	Hemogram WO platelets panel:-:Pt:Bld:Qn	HCT & HGB & WBC & RBC & Indices				
24359-2	Hemogram WO platelets & W manual differential panel :-:Pt:Bld:Qn	Hemogram & Differential Count				
24317-0	Hemogram & platelets WO differential panel:- :Pt:Bld:Qn	HCT & HGB & WBC & RBC & Indices & Platelets				
24338-6	Gas panel:-:Pt:Bld:Qn	pH & PO2 & PCO2 on blood without specifying whether arterial, venous, or other source. The report would usually include an observation about the inspired O2 sent along with the report. It may include a variety of other patient characteristics sent by the requester and a variety of computed variables.				
24336-0	Gas panel:-:Pt:BldA: Qn	pH & PO2 & PCO2 on arterial blood. The report would usually include an observation about the inspired O2 sent along with the report. It may include a variety of other patient characteristics sent by the requester and a variety of computed variables.				
24339-4	Gas panel:-:Pt:BldV:Qn	pH & PO2 & PCO2 on venous blood. The report would usually include an observation about the inspired O2 sent along with the report. It may include a variety of other patient characteristics sent by the requester and a variety of computed variables.				
29274-8	Vital signs measurement:Find:Pt:^Patient^Multi	Diastolic Blood Pressure & Systolic Blood Pressure & Pulse Rate & Respiratory Rate				
24357-6	Urinalysis macro (dipstick) panel:-:Pt:Urine:-	Urinalysis dipstick results. Usually includes Glucose, Bilirubin, estimate of leukocytes, estimate of RBCs, estimate of bacteria, Ph, Specific gravity. But we do not make distinctions about the exact set of measures on the dipstick. The ordering clinician will not necessarily know what particular dipstick is being used and is not able or interested in making those distinctions.				
29576-6	Bacterial susceptibility panel:-:Pt:Isolate:OrdQn	Would include susceptibility results for the antibiotics relevant to the isolates and the kind of culture.				

## 9 Evolving principles for naming collections

## 9.1 Goals and general approach

We are in the process of evolving our model for naming collections in LOINC. Our goals in refining this model are to:

- Create names that are consistent across different subject domains within LOINC
- Make it easy to create a list of all codes that could be used as document type in CDA
- Make it easy to create a list of all codes that could be used as section headings in CDA
- Avoid proliferating names

To this end, we are developing rules for naming of collections will apply to both laboratory collections (CBC, CHEM7) coded and structured clinical collections (Vital Signs), documents (Admit History and Physical Exam), Apgar scores, Braden Scale, Pain scales, etc. There will be two categories of names for collections:

- Names for panels with enumerated discreet contents, and
- Names for general collections of information.

Using the existing panel mechanisms, the LOINC database will record the association between LOINC

collections and individual observations where these associations are known. For example, LOINC already records the expected contents for CBC, Liver Enzymes, etc. It will also include definitions for Vital Signs, Cardiac Catheterization, Braden Scale, surveys, etc. We will create a single LOINC code for any general collection of information where the information content of the collection is the same, regardless of whether the content is a text document, a scanned image of text, or a sound file of the same information.

Since collections are named by their real or anticipated contents, the same LOINC code could be used as either a document type or as a section type.

## 9.2 Collections as orders and observations

The same LOINC code will be used for ordering a procedure, naming the document produced as the description of the procedure, or naming the structured and coded set of observations from the procedure.

For panels, the same code for CBC would be used as the ordered item in an order record or message, and as the panel identifier in the OBR segment of a result record or message. The same pattern would be followed for laboratory procedures and clinical procedures.

For general collections, the same code would be used as the ordered item in an order record or message, and as the result identifier in a result message. For example, the general collection name could be used in a result message as the identifier of a document type, as a section label, as the universal identifier in an OBR segment, or as the identifier in and OBX segment depending on the circumstances. The same pattern would be followed for radiology procedures and clinical procedures.

We are not taking away the flexibility of having the ordered code be different from the result code. For example, it is often desirable for the order code to be less specific and more abstract than the result code. LOINC would contain codes for something like "Exercise EKG" with the expectation that the result could come back as "AHA Protocol Stress EKG Result". The point is that when appropriate we would use the same LOINC code in the contexts of orders and results. We would NOT make LOINC codes that meant "CBC Order" and "CBC Result", we would use the same LOINC code for CBC in both orders and results.

Current practice would also continue where a "pure" procedure is ordered and discreet results would be returned. For example, Urine Microscopic Exam could be ordered and discreet values for cell types, casts, amorphous material, etc. would be returned.

## 9.3 LOINC SCALE for collections

The SCALE for panels will be "Panel." The Scale for general information collections will be "Doc", short for document, which is used in the most general sense of a text document, image, scanned text image, etc. "Doc" would replace the current use of Nar (narrative) or Nom (nominal) for general information collections in the current LOINC database.

The LOINC committee will review current contents of the LOINC database and modify names appropriately to conform to the new conventions. We will not implement the name changes until after the current Attachments NPRM is final.

	Table 27: Example of Proposed Changes						
LOINC#	Component	Property	Time	System	Scale	Method	Class/Type
24358-4	Hemogram panel	-	Pt	Bld	Panel		PANEL.HEM/BC
24320-4	Basic Metabolic HCFA 98 panel	-	Pt	Ser/Plas	Panel		PANEL.CHEM
24362-6	Renal Function HCFA 2000 Panel	-	Pt	Ser/Plas	Panel		PANEL.CHEM
34566-0	Vital signs panel	-	Pt	^Patient	Panel		PANEL.VITALS
11488-4	Consultation note	Find	Pt	{Setting}	Doc	{Provider}	ATTACH.CLINRPT
34066-1	Boxed warning section	-	-	^FDA package insert	Doc		DOC.REF.
35511-5	Background information section	-	-	^Clinical trial protocol	Doc		DOC.REP.CTP
35660-0	Path report.final diagnosis section – text	Imp	Pt	Specimen	Doc		TUMRRGT
24534-0	Multisection	Find	Pt	Abdominal vessels	Doc	US.doppler	RAD

### 9.4 Examples of proposed changes according to new policy

## **10 Standardized Assessment Measures**

### 10.1 Introduction

The LOINC committee approved inclusion of standardized assessment measures (e.g., survey instruments) with version 1.0p. Representing the observations in these assessments within LOINC required a modest extension of the System axis to include aggregate units of analysis, such as "family", and storage of additional attributes within the LOINC database. Bakken<sup>xxix</sup> provides a detailed description of the methodology for inclusion and evaluation into LOINC and the extensions to the LOINC axes.

The initial corpus of material represented in LOINC came from standardized nursing assessment instruments, including: Home Health Care Classification (HHC), Quality Audit Marker (QAM), Signs and Symptoms Checklist for Persons with HIV (HIV-SSC), Living with HIV, and the Omaha System. We have since expanded the content to cover standardized assessment instruments in many other domains. As we have added content, we have iteratively refined our modeling. Vreeman et al have published a summary of our approach and its evolution.<sup>xxx</sup>

## 10.2 Consolidated Health Informatics endorsement

As national interest in using standards for communicating the results of patient assessment instruments has increased, we have collaborated with members of the Consolidated Health Informatics (CHI) Disability Workgroup and many others to more fully develop the content and infrastructure to support patient assessment instruments. LOINC now contains full representations of CMS's Minimum Data Set version 2 (MDS) used in nursing homes, CMS's Outcome and Assessment Information Set (OASIS) used in home health care, and the Social Security Administration's Residual Functional Capacity (RFC) instrument.

Our work with CHI Disability Workgroup has led to the endorsement of Clinical LOINC as a CHI standard for federally-required assessment (i) questions and answers, and (ii) assessment form that include functioning and disability content. The recommendations of the CHI Disability Workgroup were endorsed by the NCVHS and subsequently the HHS Secretary.

## 10.3 LOINC Representation

The overall organization of the survey instruments and other collections are represented in LOINC using a nested panel structure consistent with the existing model for laboratory panels. LOINC codes are created for the individual questions/items within an instrument, as well as for the panels/groups of terms representing the hierarchical nature of the instrument. We recognize that standardized assessments have psychometric properties that are essential to their interpretation, and so the data model includes elements such as the actual question text and allow answer options as attributes of the LOINC observation code.

10.3.1 Naming rules and conventions for names of collection terms (e.g. a panel, survey instrument, form, etc.) in LOINC

LOINC creates codes for the collection as described in the section on Order Panels (batteries). Typically, the Property and Scale attributes are a hyphen "-", because the child elements (questions) vary in these axes. We create different panel terms for different versions of the same instrument where there are meaningful changes (e.g. different questions asked, different answer choices, etc). Some assessment instruments of the same version have different "forms" for various purposes that contain unique collections of items. For example, the OASIS-C has five unique forms that represent different subsets of questions that are used at various times: Start of Care, Resumption of Care, Follow-up, Transfer to a Facility, and Discharge from Agency. LOINC creates different panel terms for each of these forms.

10.3.2 Attributes of the LOINC terms for individual questions or variables

The LOINC table contains fields that store additional attributes relevant to many terms for individual questions or variables. Examples include the fields that store the exact question text, external copyright notice, example units, and the HL7 field where the content should be delivered (if Null, presume OBX).

In order to accommodate inclusion of instruments that are copyrighted by a third party, we have added an External Copyright field to the LOINC table. This field stores the specified terms of use, and additionally, these terms are visually highlighted in the RELMA program when they appear in search results. We have only included content in this manner that is consistent with LOINC's overall aim, so the content allows free use and distribution for clinical, administrative, and research purposes either with permission or under applicable terms of use.

LOINC does not usually create terms for information that has a designated field in an HL7 message. But, in order to create complete sets of items for some instruments we have created LOINC terms for items such as patient first name. To identify this content, we added an HL7 Field Sub ID to the LOINC table and indicate the corresponding HL7 place (e.g. PID-5.2).

#### 10.3.3 Structured answer lists

The questions/items in standardized assessment instruments often have highly specialized, fixed answer lists. In many contexts, it is the answer list that most completely defines the meaning of concept represented by the question. Additionally, because many of the answer choices are highly specialized, few are represented by existing codes in reference terminologies. For these reasons, we have created a structured representation of the answer lists for the questions in assessment instruments represented in LOINC.

We identify answer lists as "normative" or "example". Normative lists are those specifically defined by a validated instrument or other authoritative source. Example lists are meant to be illustrative, or thought of as a starter set to which a user may add or subtract depending on their use case. Not all answer lists are fully enumerated within LOINC. For example, some questions may have their answers drawn from a large terminology such as ICD-9-CM or CPT. These lists are identified with a flag that indicates the external code system, its OID, and optionally a URL pointing to an external system.

Individual answers are assigned a non-semantic identifier with a "LA" prefix and a mod-10 check digit (see Appendix C). The answer codes LOINC assigns are unique by lexical string (ignoring capitalization), and by intention do not distinguish between strings that may have different meanings depending on their contextual use.

10.3.4 Attributes of items that vary depending on the parent collection

Some important attributes of a LOINC term for a question or variable may vary when that concept is used in different assessments or on different forms of the same assessment. For example, "measured body weight" is a variable of many different assessments. In the context of each instrument, that same concept could have different local codes, help text, validation rules, or associated branching logic. We therefore store these attributes at the level of the instance of the item in a particular panel.

10.3.5 Choosing the "display text" for a question or variable

As discussed in the previous sections, we have three fields that can capture the exact display of the question/item on the form in question. (For some instruments, it can be difficult to determine what exactly *is* the question text). The Component of a LOINC term represents the thing or attribute being measured, and is the default for capturing the item text. However, there are several reasons why the component may not be the exact item text. The most important ones include: our LOINC naming conventions do not permit certain characters (e.g. "/" or "?") because of our internal "Part" parsing rules, that some aspects of the question are modeled in other parts of the formal LOINC name, or that there is some important aspect to the "thing being measured" (e.g. a look back period of the last 7 days) that is not represented explicitly on the form for that particular item. In general, for purposes of displaying the item text as it appears on the instrument, one can follow this rule:

- SURVEY\_QUEST\_TEXT in the LOINC table [if populated]. This field is populated when the variable/item is asked as a question. In some cases, the variable has both a question and a label. In these cases, the SURVEY\_QUEST\_TEXT field is populated with both, in the pattern of [Label].[Question text]. For example, for item J0300 on the MDS version 3 we have "Pain Presence. Ask resident: "Have you had pain or hurting at any time in the last 7 days?"
- 2. **DISPLAY\_NAME\_FOR\_FORM** in the FORM\_DATA table (RELMA) or FORMS table (CSV file export) [if populated]. This field provides an override display that is linked to the instance of the LOINC question code in a particular form. It allows for the same clinical concept to have slight presentation variances on different forms where those variances have no change in the concept meaning and accommodates instances where the LOINC naming conventions require some difference between the item and the LOINC Component. For example, an item might have the form label of "Body Mass Index (BMI)" but the LOINC Component would simply be "Body mass index".
- 3. **COMPONENT** in the LOINC table. This is the default display.

In addition to these fields, some LOINC codes used in survey instruments may have other LOINC name fields such as a Short Name, Long Common Name, or our newly created Consumer Name. These additional names may be useful in some contexts for these items, be we will still use the above rule to capture the item's representation in the instrument. Some of the original survey instruments modeled in LOINC may not follow this rule exactly, in part due to the fact that we did not have full survey representation model as we do presently. Ongoing work includes reviewing where modifications may be needed.

10.3.6 Type of Method (6th part) for a question or variable

For variables linked to a defined answer list that come from an external source, it has become our policy to enter the initial source as the Method. For example, variables first entered for the Minimum Data Set (MDS) will have a method of MDS. This does not mean that the term cannot be used in any other

contexts, such as other panels or surveys. Many variables from MDS, for example, were later used in the CARE instrument. These variables in the CARE panel still have a method of MDS. As long as the defining context of use is understood, the variable can be used in other contexts where the term is exactly the same, including the answer lists, as the original term.

## 10.4 Assessment Content in the LOINC Distribution

All of the assessment content is included within RELMA. Beginning with LOINC version 2.26 (January 2009), an export of panels and forms content has been available as a separate download in the LOINC release available from <u>http://loinc.org</u>. This spreadsheet contains separate worksheets for the three files defining the full assessment content:

- 1. The hierarchical structure (parent/child relationships) and panel-specific attributes
- 2. An extract of the main LOINC Table for all of the terms in the set
- 3. The structured answer list for each LOINC variable term in the set

The full set of all of the panels and forms content, as well as several domain-specific subsets, are available for download from the LOINC website.

## **11 Editorial Policies and Procedures**

## 11.1 Concept orientation and LOINC name changes

LOINC is a concept-based terminology, which means that it provides a way of naming classes of things that exist in the real world. Each concept (term) is given an identifier and a fully-specified name. Other attributes, including other names such as a Short Name and Long Common Name, are also provided in the LOINC database. The concept is anchored by the LOINC code, not by the particular strings in the formal name we happen to use to explain the code. It is certainly not possible to convey all of the subtleties that exist in the world with formal machinery alone, which is why we are also working very hard to include narrative text descriptions with each term that further elaborate and explain the concept.

In a complex, organic terminology like LOINC, name changes and modifications are unavoidable for many reasons. Since its inception, LOINC has maintained a set of editorial policies that guide our adherence to this concept-oriented ideal even as the terminology evolves over time. An over-arching policy is that we can change the name (i.e. the human-readable representation of the concept) in any way that does not change the meaning of the concept. In other words, a modification is allowable and valid if it is still an unambiguous reference to a class of things in the real world.

For example, two different numbering systems have been used to identify the serotypes of *Streptococcus pneumoniae*, which are important in gauging the coverage of polyvalent pneumonia vaccines. The U.S. system uses only numbers while the Danish system includes numbers and letters. For a period of time, LOINC term names were split and used a mixture of the Danish and U.S. identifiers, which was inconsistent and confusing. To clarify, we converted the few Danish serotype identifiers to their corresponding U.S. serotype identifiers (and included the Danish identifiers as synonyms). This was not a fundamental change to the underlying concept, but rather just the particular labels used to express it.

Not all situations are crystal clear, so our general policy is to seek as much input as is feasible, and typically such cases are brought for discussion to the LOINC Committee.

## 11.2 Classification of LOINC term status

LOINC development follows best practices for terminology system development by never reusing or deleting codes. If a LOINC term is identified as erroneous or a duplicate of a previous term it is flagged as "deprecated" in the database, but the record is not removed. Changes in concept status are made very judiciously.

Prior to the LOINC version 2.31 release (June 2010), we identified such deprecated terms by populating the STATUS field of the database with "DEL" and wherever possible identified superseding concepts in the MAP\_TO field of the LOINC Table. Active (non-deprecated) records had no value (null) in the STATUS field. Based on new use cases and input from the LOINC community, LOINC 2.31 implemented an expansion to that classification. The presently supported values for term status, with the definition and implications for use, are:

ACTIVE TRIAL	Concept is active. Use at will. Concept is experimental in nature. Use with caution as the concept and
	associated attributes may change.
DISCOURAGED	Concept is not recommended for current use. New mappings to this concept are discouraged; although existing may mappings may continue to be valid in context. Wherever possible, the superseding concept is indicated in the MAP_TO field of the MAP_TO Table (see Appendix A, Table 28b) and should be used instead.
DEPRECATED	Concept is deprecated. Concept should not be used, but it is retained in LOINC for historical purposes. Wherever possible, the superseding concept is indicated in the MAP_TO field of the MAP_TO Table (see Appendix A, Table 28b) and should be used both for new mappings and updating existing implementations.

Furthermore, LOINC 2.31 added two new fields:

STATUS_REASON	Classification of the reason for concept status. This field will be Null for
	ACTIVE concepts, and optionally populated for terms in other statues
	where the reason is clear. DEPRECATED or DISCOURAGED terms
	may take values of: AMBIGUOUS, DUPLICATE, or ERRONEOUS.
STATUS_TEXT	Explanation of concept status in narrative text. This field will be Null for
	ACTIVE concepts, and optionally populated for terms in other statues.

Our initial implementation of these new concept status values populated the STATUS field with "ACTIVE" or "DEPRECATED" based on their existing status and have identified a limited set of terms that have been designated "DISCOURAGED" or "TRIAL".

The principal reason identifying terms as DISCOURAGED is where we have strong inclinations that a particular term is no longer valid given current practice. For example, we have flagged as DISCOURAGED several lutropin terms with Properties consistent with mass or molar units because all lutropin sources that we could reach report concentrations in international units (IU) per volume and the drug lutropin is prescribed in terms of international units per volume. To avoid help confusion on the part of mappers, the DISCOURAGED status steers them away from these terms to the more likely candidates.

The principal reason for identifying terms as TRIAL is a very constrained circumstance, such as when the source of the term is still equivocating. This has been illustrated in our work to create a LOINC representation of federally-required patient assessment instruments. Here, the item meaning is defined in the context of use within that instrument. We have been fortunate to work with assessment developers in

the early stages of instrument development. This is advantageous because it enables the codes to be included in data specifications and documents as they are developed, but we are in the position of creating codes and names for data elements whose attributes are still in flux. As the instrument evolves, the specific representation of the item (question) or answer options on the form may change. Ultimately, the representation will be settled by an authoritative body (such as CMS) and they are intended for use in one context – the official release of the instrument. Identifying these terms as TRIAL allows us to include them in the public distribution while clearly flagging their "pending" status. Once the final concept representation has been determined, terms initially labeled TRIAL would be reclassified as ACTIVE (or perhaps in rare circumstances DEPRECATED or even rarer DISCOURAGED).

In LOINC 2.42, the MAP\_TO field of the LOINC Table was removed and replaced with a separate MAP\_TO table. The original MAP\_TO field was created to store a single replacement LOINC term number for when a LOINC was deprecated. We later learned that there were times when there was more than one possible replacement term, depending on certain conditions. To address this problem we created a new MAP\_TO table that was first released with version 2.34. The original MAP\_TO field was retained for a few releases, but was removed from the LOINC Table in version 2.42. See Appendix A, Table 28b for information about the MAP\_TO table.

## 11.3 Concept persistence and term deprecation

LOINC codes are never reused or deleted, and the concept meaning is persistent over time despite the fact that there may be modifications to the name (as described above). If we discover that a LOINC term's meaning is a duplicate of another existing term or it is somehow erroneous, it will be given a status of DEPRECATED but not removed from the database.

In the past, when we encountered duplicate terms (i.e. terms that had different names but meant the same thing), our general policy was to deprecate the newest term. Many times, this convention worked well because the older term was more likely to have been incorporated into user's systems through mappings, etc. However, this was not always the case. Sometimes, the new term had the clearer, more recognizable label and thus it was most likely the most mapped-to term.

Therefore, our current policy is to make the change to require (in our estimation) the least amount of remapping for existing users.

Table 28a: LOINC Table Structure						
Field Name	Туре	Width	Description			
1. LOINC_NUM	Text	10	The unique LOINC Code is a string in the format of nnnnnnn-n.			
2. COMPONENT	Text	255	First major axis-component or analyte			
3. PROPERTY	Text	30	Second major axis-property observed (e.g., mass vs. substance)			
4. TIME_ASPCT	Text	15	Third major axis-timing of the measurement (e.g., point in time vs 24 hours)			
5. SYSTEM	Text	100	Fourth major axis-type of specimen or system (e.g., serum vs urine)			
6. SCALE_TYP	Text	30	Fifth major axis-scale of measurement (e.g., qualitative vs. quantitative)			
7. METHOD_TYP	Text	50	Sixth major axis-method of measurement			
8. CLASS	Text	20	An arbitrary classification of the terms for grouping related observations together. The current classifications are listed in Table 29. We present the database sorted by the class field within class type (see field 23). Users of the database should feel free to re-sort the database in any way they find useful, and/or to add their own classifying fields to the database. The content of the laboratory test subclasses should be obvious from the subclass name.			
9. SOURCE	Text	8	This is for our internal use and should be ignored by database users.			
10. DATE_LAST_CHANGED	Date/Time	-	Date last changed.			
11. CHNG_TYPE	Text	3	Change Type Code DEL = delete (deprecate) ADD = add NAM = change to Analyte/Component (field #2); MAJ = change to name field other than #2 (#3 - #7); MIN = change to field other than name UND = undelete			
12. COMMENTS	Memo	-	Free-text comments relating to the test result.			
13. STATUS	Text	11	ACTIVE = Concept is active. Use at will. TRIAL = Concept is experimental in nature. Use with caution as the concept and associated attributes may change. DISCOURAGED = Concept is not recommended for current use. New mappings to this concept are discouraged; although existing may mappings may continue to be valid in context. Wherever possible, the superseding concept is indicated in the MAP_TO field in the MAP_TO table (see Table 28b) and should be used instead. DEPRECATED = Concept is deprecated. Concept should not be used, but it is retained in LOINC for historical purposes. Wherever possible, the superseding concept is indicated in the MAP_TO field (see Table 28b) and should be used both for new mappings and updating existing implementations.			
14. CONSUMER_NAME	Text	255	An experimental (beta) consumer friendly name for this item. The intent is to provide a test name that health care consumers will recognize; it will be similar to the names that might appear on a lab report and is not guaranteed to be unique because some elements of the LOINC name are likely to be omitted. We will continue to modify these names in future release, so do not expect it to be stable (or perfect). Feedback is welcome.			
15. MOLAR_MASS	Text	13	of chemical moieties when they are provided to us. This release contains values kindly contributed by IUPAC.			
16. CLASSTYPE	Number	-	1=Laboratory class; 2=Clinical class; 3=Claims attachments; 4=Surveys			
17. FORMULA	Text	255	Regression equation details for many OB.US calculated terms.			

# Appendix A - LOINC Database Structure

18. SPECIES	Text	20	Codes detailing which non-human species the term applies to.
19. EXMPL ANSWERS	Memo	_	If blank, "human" is assumed. For some tests and measurements, we have supplied examples
_		_	of valid answers, such as "1:64", "negative @ 1:16", or "55". Chemical name synonyms, alternative name synonyms, and
20. ACSSYM	Memo	-	chemical formulae supplied by the Chemical Abstract Society.
21. BASE_NAME	Text	50	Chemical base name from CAS Maps to North American Association of Central Cancer
22. NAACCR_ID	Text	20	Registries Identification Number
23. CODE_TABLE	Text	10	Examples on CR0050 Cancer Registry
24. SURVEY_QUEST_TXT	Memo	-	Verbatim question from the survey instrument
25. SURVEY_QUEST_SRC	Text	50	Exact name of the survey instrument and the item/question number
26. UNITSREQUIRED	Text	1	Y/N field that indicates that units are required when this LOINC is included as an OBX segment in a HIPAA attachment
27. SUBMITTED_UNITS	Text	30	Units as received from person who requested this LOINC term.
28. RELATEDNAMES2	Memo	-	This is a new field introduced in version 2.05. It contains synonyms for each of the parts of the fully specified LOINC name (component, property, time, system, scale, method). It replaces #8, Relat_NMS.
29. SHORTNAME	Text	40	Introduced in version 2.07, this field is a concatenation of the fully specified LOINC name. The field width may change in a future release.
30. ORDER_OBS	Text	15	Defines term as order only, observation only, or both. A fourth category, Subset, is used for terms that are subsets of a panel but do not represent a package that is known to be orderable we have defined them only to make it easier to maintain panels or other sets within the LOINC construct.
31. CDISC_COMMON_TESTS	Text	1	"Y" in this field means that the term is a part of subset of terms used by CDISC in clinical trials.
32. HL7_FIELD_SUBFIELD_ID	Text	50	A value in this field means that the content should be delivered in the named field/subfield of the HL7 message. When NULL, the data for this data element should be sent in an OBX segment with this LOINC code stored in OBX-3 and with the value in the OBX-5.
33. EXTERNAL_COPYRIGHT_NOTICE	Memo	-	External copyright holders copyright notice for this LOINC code.
34. EXAMPLE_UNITS	Text	255	This field is populated with a combination of submitters units and units that people have sent us. Its purpose is to show users representative, but not necessarily recommended, units in which data could be sent for this term.
35. LONG_COMMON_NAME	Text	255	This field contains the LOINC term in a more readable format than the fully specified name. The long common names have been created via a table driven algorithmic process. Most abbreviations and acronyms that are used in the LOINC database have been fully spelled out in English.
36. HL7_V2_DATATYPE	Text	255	HL7 version 2.x data type that would be sent in OBX-2 when this data is delivered in an HL7 message.
37. HL7_V3_DATATYPE	Text	255	HL7 version 3.0 data type that is compatible with this LOINC code.
38. CURATED_RANGE_AND_UNITS	Memo	-	A curated list of normal ranges and associated units (expressed as near UCUM codes) for physical quantities and survey scores. Intended as tailorable starter sets for applications that use LOINC forms as a way to capture data. Units are separated from normal ranges by XXX and sets of normal range/units pairs are separated by YYY.
39. DOCUMENT_SECTION	Text	255	Classification of whether this LOINC code can be used a full document, a section of a document, or both. This field was created in the context of HL7 CDA messaging, and populated in collaboration with the HL7 Structured Documents Technical Committee.
40. EXAMPLE_UCUM_UNITS	Text	255	The Unified Code for Units of Measure (UCUM) is a code system intended to include <i>all</i> units of measures being contemporarily used in international science, engineering, and business. ( <u>www.unitsofmeasure.org</u> ) This field contains example units of measures for this term expressed as UCUM units.

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41. EXAMPLE_SI_UCUM_UNITS	Text	255	The Unified Code for Units of Measure (UCUM) is a code system intended to include <i>all</i> units of measures being contemporarily used in international science, engineering, and business. ( <u>www.unitsofmeasure.org</u> ) This field contains example units of measures for this term expressed as SI UCUM units.
42. STATUS_REASON	Text	9	Classification of the reason for concept status. This field will be Null for ACTIVE concepts, and optionally populated for terms in other status where the reason is clear. DEPRECATED or DISCOURAGED terms may take values of: AMBIGUOUS, DUPLICATE, or ERRONEOUS.
43. STATUS_TEXT	Memo	-	Explanation of concept status in narrative text. This field will be Null for ACTIVE concepts, and optionally populated for terms in other status.
44. CHANGE_REASON_PUBLIC	Memo	-	Detailed explanation about special changes to the term over time.
45. COMMON_TEST_RANK	Number	-	Ranking of approximately 2000 common tests performed by laboratories in USA.
46. COMMON_SI_TEST_RANK	Number	-	Corresponding SI terms for 2000 common tests performed by laboratories in USA
47. COMMON_ORDER_RANK	Number	-	Ranking of approximately 300 common orders performed by laboratories in USA.
48. HL7_ATTACHMENT_STRUCTURE	Text	15	This field will be populated in collaboration with HL7. Text will either be STRUCTURED or UNSTRUCTURED for relevant terms. The STRUCTURED terms are the allowed document type codes in the Consolidated CDA Implementation guide. USTRUCTURED terms are based on the PIUC guide.

Table 28b: MAP_TO Table Structure						
Field Name	Туре	Width	Description			
1. LOINC	Text	10	The deprecated term to which the replacement term(s) apply.			
2. MAP_TO	Text	10	A replacement term that is to be used in place of the deprecated or discouraged term.			
3. COMMENT	Memo	-	Narrative text that explains the rational for using the recommended replacement term.			

Table 28c: Source Organization Table Structure			
Field Name	Туре	Width	Description
1. COPYRIGHT_ID	Text	255	Used in the LOINC table as a foreign key.
2. TERMS_OF_USE	Memo	-	Terms of use text for an external source.
3. NAME	Text	255	Name of the organization or institution.
4. COPYRIGHT	Memo	-	Copyright notice to be displayed for the organization or institution.
5. URL	Text	255	URL link to the reference.

# Appendix B - Classes

Table 29a: Clinical Term Classes			
Abbreviation	Clinical Term Class		
ART	Antiretroviral therapy		
BDYCRC.ATOM	Body circumference atomic		
BDYCRC.MOLEC	Body circumference molecular		
BDYHGT.ATOM	Body height atomic		
BDYHGT.MOLEC	Body height molecular		
BDYSURF.ATOM	Body surface atomic		
BDYTMP.ATOM	Body temperature atomic		
BDYTMP.MOLEC	Body temperature molecular		
BDYTMP.TIMED.MOLEC	Body temperature timed molecular		
BDYWGT.ATOM	Body weight atomic		
BDYWGT.MOLEC	Body weight molecular		
BP.ATOM	Blood pressure atomic		
BP.CENT.MOLEC	Blood pressure central molecular		
BP.MOLEC	Blood pressure molecular		
BP.PSTN.MOLEC	Blood pressure positional molecular		
BP.TIMED.MOLEC	Blood pressure timed molecular		
BP.VENOUS.MOLEC	Blood pressure venous molecular		
CARD.RISK	Cardiac Risk Scales Framingham		
CARD.US	Cardiac ultrasound (was US.ECHO)		
CLIN	Clinical NEC (not elsewhere classified)		
DENTAL	Dental		
DEVICES	Medical devices		
DOC.ADMIN	Administrative documents		
DOC.ADMIN.LEGAL	Legal Administrative documents		
DOC.CLINRPT	Clinical report documentation		
DOC.EPSOS	Smart Open Services for European Patients (epSOS) documents		
DOC.MISC	Miscellaneous documentation		
DOC.PUBLICHEALTH	Public health documentation		
DOC.QUALITY	Quality documents		
DOC.REF	Referral documentation		
DOC.REF.CTP	Clinical trial protocol document		
DOCUMENT.REGULATORY	Regulatory documentation		
ED	Emergency (DEEDS)		
EKG.ATOM	Electrocardiogram atomic		
EKG.IMP	Electrocardiogram impression		
EKG.MEAS	Electrocardiogram measures		
ENDO.GI	Gastrointestinal endoscopy		
EYE	Eye		
EYE.CONTACT_LENS	Ophthalmology contact lens		
EYE.GLASSES	Ophthalmology glasses: Lens manufacturer (LM) & Prescription		
EYE.HETEROPHORIA	Ophthalmology heterophoria		
EYE.OCT	Ophthalmology Optical Coherence Tomography (OTC)		
EYE.PX	Ophthalmology physical findings		
EYE.REFRACTION	Ophthalmology refraction		
EYE.RETINAL_RX	Ophthalmology treatments		
EYE.TONOMETRY	Ophthalmology tonometry		

EYE.US	Ophthalmology ultrasound
EYE.VISUAL_FIELD	Ophthalmology visual field
FUNCTION	Functional status (e.g., Glasgow)
GEN.US	General ultrasound
H&P.HX	History
H&P.PX	Physical
H&P.SURG PROC	Surgical procedure
HEMODYN.ATOM	Hemodynamics anatomic
HEMODYN.MOLEC	Hemodynamics molecular
HRTRATE.ATOM	Heart rate atomic
HRTRATE.MOLEC	Heart rate molecular
HRTRATE.PSTN.MOLEC	Heart rate positional molecular
HRTRATE.TIMED.MOL	Heart rate timed molecular
IO.TUBE	Input/Output of tube
IO_IN.ATOM	Input/Output atomic
IO_IN.MOLEC	Input/Output molecular
IO_IN.SUMMARY	Input/Output summary
IO_IN.TIMED.MOLEC	Input/Output similary
IO_IN_SALTS+CALS	Input/Output electrolytes and calories
IO_OUT.ATOM	Input/Output electrolytes and calories
IO_OUT.MOLEC	Input/Output atomic Input/Output molecular
IO_OUT.TIMED.MOLE	
	Input/Output timed molecular
NEMSIS	National EMS Information System data
NEONAT	Neonatal measures
OB.US	Obstetric ultrasound
OBGYN	Obstetric/Gynecology
PANEL.ART	Antiretroviral therapy order set
PANEL.BDYTMP	Body temperature order set
PANEL.BP	Blood pressure order set Cardiac studies order set
PANEL.CARDIAC	
PANEL.CV	Cardiovascular order set
PANEL.DEVICES	Medical devices order set
PANEL.DOC	Documents panels
PANEL.DOC.CLINRPT	Clinical report documentation set
PANEL.ED	Emergency (DEEDS) order set
PANELEYE	Ophthalmology panels
PANEL.FUNCTION	Function order set
PANEL.H&P	History & Physical order set
PANEL.IO	Input/Output order set
PANEL.NEMSIS	National EMS Information System data set
PANEL.NEONAT	Neonatal measures order set
PANEL.OB.US	Obstetrical order set
PANEL.PATIENT SAFETY	Patient safety order set
PANEL.PHENX	PhenX Panel
PANEL.PHR	Public health record order set
PANEL.PULM	Pulmonary order set
PANEL.RAD	Radiology order set
PANEL.TUMRRGT	Tumor registry order set
PANEL.US.URO	Urology ultrasound order set
PANEL.VACCIN	Vaccination order set
PANEL.VITALS	Vital signs order set

PATIENT SAFETY	Patient safety
PHENX	PhenX
PUBLICHEALTH	Public Health
PULM	Pulmonary ventilator management
RAD	Radiology
RESP.ATOM	Respiratory atomic
RESP.MOLEC	Respiratory molecular
RESP.TIMED.MOLEC	Respiratory timed molecular
SKNFLD.MOLEC	Skinfold measurements molecular
TRNSPLNT.ORGAN	Organ transplant
TUMRRGT	Tumor registry (NAACCR)
US.URO	Urological ultrasound
VACCIN	Vaccinations
VOLUME.MOLEC	Volume (specimen) molecular

Table 29b: Laboratory Term Classes		
Abbreviation	Laboratory Term Class	
ABXBACT	Antibiotic susceptibilities	
ALLERGY	Response to antigens	
BLDBK	Blood bank	
CELLMARK	Cell surface models	
CHAL	Challenge tests	
CHALSKIN	Skin challenge tests	
CHEM	Chemistry	
COAG	Coagulation study	
СУТО	Cytology	
DRUG/TOX	Drug levels & Toxicology	
DRUGDOSE	Drug dose (for transmitting doses for pharmacokinetics)	
FERT	Fertility	
HEM/BC	Hematology (coagulation) differential count	
HL7.CYTOGEN	Clinical cytogenetic report	
HL7.GENETICS	Clinical genetic report	
HLA	HLA tissue typing antigens and antibodies	
HPA	HPA typing	
LABORDERS	Laboratory order codes	
MICRO	Microbiology	
MISC	Miscellaneous	
MOLPATH	Molecular pathology	
MOLPATH.DEL	Gene deletion	
MOLPATH.INV	Gene inversion	
MOLPATH.MISC	Gene miscellaneous	
MOLPATH.MUT	Gene mutation	
MOLPATH.REARRANGE	Gene rearrangement	
MOLPATH.TRINUC	Gene trinucleotide repeats	
MOLPATH.TRISOMY	Gene chromosome trisomy	
MOLPATH.TRNLOC	Gene translocation	
NR STATS	Normal range statistics	

PANEL.ABXBACT	Susceptibility order sets
PANEL.ALLERGY	Allergy order set
PANEL.BLDBK	Blood bank order set
PANEL.CELLMARK	Cell marker order sets
PANEL.CHAL	Challenge order set
PANEL.CHEM	Chemistry order set
PANEL.COAG	Coagulation order set
PANEL.DRUG/TOX	Drug level & Toxicology order set
PANEL.FERT	Fertility testing order set
PANEL.HEDIS	Healthcare Effectiveness Data and Information Set order set
PANEL.HEM/BC	Hematology & blood count order set
PANEL.HL7.CYTOGEN	HL7 cytogenetics panel
PANEL.HL7.GENETICS	HL7 genetics panel
PANEL.HLA	HLA order set
PANEL.HPA	HPA order set
PANEL.MICRO	Microbiology order set
PANEL.MISC	Miscellaneous order set
PANEL.MOLPATH	Molecular pathology order set
PANEL.OBS	Obstetrics order set
PANEL.PATH	Pathology order set
PANEL.SERO	Serology order set
PANEL.SPEC	Specimen set
PANEL.UA	Urinalysis order set
PATH	Pathology
PATH.PROTOCOLS.BRST	Pathology protocols - breast
PATH.PROTOCOLS.GENER	Pathology protocols - general
PATH.PROTOCOLS.PROST	Pathology protocols - prostate
PATH.PROTOCOLS.SKIN	Pathology protocols - skin
SERO	Serology (antibodies and most antigens except blood bank and infectious agents)
SPEC	Specimen characteristics
UA	Urinalysis

Table 29c: Attachment Term Classes		
Abbreviation	Attachment Term Class	
ATTACH	Attachment	
ATTACH.AMB	Ambulance attachment	
ATTACH.CARD	Cardiac attachment	
ATTACH.CLINRPT	Clinical report attachment	
ATTACH.CPHS	Children's Preventative Health System attachment	
ATTACH.ED	Emergency department attachment	
ATTACH.GENERAL	General attachment	
ATTACH.GI	Gastrointestinal attachment	
ATTACH.LAB	Laboratory attachment	
ATTACH.MEDS	Medication attachment	
ATTACH.MODIFIER	Modifier attachment	

ATTACH.OBS	Obstetrics attachment
ATTACH.REHAB	Rehabilitation attachment
ATTACH.REHAB.ABUSE	Alcohol/Substance abuse rehabilitation attachment
ATTACH.REHAB.CARDIAC	Cardiac rehabilitation attachment
ATTACH.REHAB.NURS	Specialized nursing attachment
ATTACH.REHAB.OT	Occupational therapy attachment
ATTACH.REHAB.PSYCH	Psychiatric rehabilitation attachment
ATTACH.REHAB.PT	Physical rehabilitation attachment
ATTACH.REHAB.PULM	Pulmonary rehabilitation attachment
ATTACH.REHAB.RT	Respiratory rehabilitation attachment
ATTACH.REHAB.SOCIAL	Medical social work attachment
ATTACH.REHAB.SPEECH	Speech therapy rehabilitation attachment
ATTACH.RESP	Respiratory attachment

Table 29d: Survey Term Classes		
Abbreviation	Survey Term Class	
PANEL.SURVEY.AAOS	American Academy of Orthopaedic Surgeons	
PANEL.SURVEY.BIMS	Brief Interview for Mental Health Status (BIMS) set	
PANEL.SURVEY.CAM	Confusion Assessment Method (CAM) set	
PANEL.SURVEY.CARE	Continuity Assessment Record and Evaluation (CARE) set	
PANEL.SURVEY.CDC	Centers for Disease Control (CDC) set	
PANEL.SURVEY.CMS	Centers for Medicare & Medicaid Services set	
PANEL.SURVEY.EPDS	Edinburgh Postnatal Depression Scale set	
PANEL.SURVEY.ESRD	End Stage Renal Disease (ESRD) facility survey set	
PANEL.SURVEY.GDS	Geriatric Depression Scale (GDS) set	
PANEL.SURVEY.GNHLTH	General Healthy survey set	
PANEL.SURVEY.HHCC	Home Health Care Classification set	
PANEL.SURVEY.HHS	Department of Health and Humsn Services set	
PANEL.SURVEY.HIV-SSC	Signs and Symptoms checklist for persons living with HIV set	
PANEL.SURVEY.howRU	howRU outcomes instrument set	
PANEL.SURVEY.LIV-HIV	Living with HIV set	
PANEL.SURVEY.MDS	Minimum Data Set for Nursing Home Resident Assessment and Care Screening set	
PANEL.SURVEY.MFS	Morse Fall Scale set	
PANEL.SURVEY.MTLHLTH	Mental Health survey set	
PANEL.SURVEY.NEUR	Neurological survey set	
PANEL.SURVEY.NEUROQ	Quality of Life Outcomes in Neurological Disorders (NeuroQol) set	
PANEL.SURVEY.NMMDS	Nursing Management Minimum Data set	
PANEL.SURVEY.OASIS	Outcome and Assessment Information Survey set	
PANEL.SURVEY.OMAHA	OMAHA survey set	
PANEL.SURVEY.OPTIMAL	Outpatient Physical Therapy Improvement in Movement a Assessment Log set	
PANEL.SURVEY.PHQ	Patient Health Questionnaire set	
PANEL.SURVEY.PROMIS	Patient Reported Outcomes Measurement System set	
PANEL.SURVEY.QAM	Quality Audit Marker set	
PANEL.SURVEY.QRDA	Quality Health Reporting Document Architecture set	
PANEL.SURVEY.RFC	Residual Functional Capacity set	
PANEL.SURVEY.SAMSHA	Substance Abuse and Mental Health Services Administration (SAMHSA) set	
PANEL.SURVEY.USSGFHT	United States Surgeon General Family Health Tool (USSGFHT) set	

PANEL.TIMP	Test of Infant Motor Performance (TIMP) set
SURVEY.AAOS	American Academy of Orthopaedic Surgeons (AAOS) survey
SURVEY.CARE	Continuity Assessment Record and Evaluation (CARE) survey
SURVEY.CDC	Centers for Disease Control (CDC) survey
SURVEY.CERNER	Cerner survey
SURVEY.CMS	Centers for Medicare & Medicaid Services (CMS) survey
SURVEY.EPDS	Edinburgh Postnatal Depression Scale (EPDS)
SURVEY.ESRD	End Stage Renal Disease (ESRD) facility survey
SURVEY.GDS	Geriatric Depression Scale (GDS) survey
SURVEY.GNHLTH	General Health survey
SURVEY.HHS	Department of Health and Human Services (HHS) survey
SURVEY.howRU	howRU outcomes instrument survey
SURVEY.MDS	Minimum Data Set (MDS) for Nursing Home Resident Assessment and Care Screening survey
SURVEY.MFS	Morse Fall Scale (MFS) survey
SURVEY.MTLHLTH	Mental Health survey
SURVEY.NEURO	Neurological survey
SURVEY.NEUROQ	Quality of Life Outcomes in Neurological Disorders (NeuroQol) survey
SURVEY.NMMDS	Nursing Management Minimum Data Survey (NMMDS)
SURVEY.NURSE.HHCC	Home Health Care Classification (HHCC) survey
SURVEY.NURSE.HIV-SSC	Signs and Symptoms Checklist (SSC) for persons living with HIV survey
SURVEY.NURSE.LIV-HIV	Living with HIV survey
SURVEY.NURSE.OMAHA	OMAHA survey
SURVEY.NURSE.QAM	Quality Audit Marker (QAM) survey
SURVEY.OASIS	Outcome and Assessment Information Survey (OASIS)           Outpatient Physical Therapy Improvement in Movement and
SURVEY.OPTIMAL	Assessment Log (OPTIMAL)
SURVEY.PHQ	Patient Health Questionnaire (PHQ)
SURVEY.PROMIS	Patient Reported Outcomes Measurement System (PROMIS) survey
SURVEY.QRDA	Quality Health Reporting Document Architecture (QRDA) survey
SURVEY.RFC	Residual Functional Capacity (RFC) survey           Substance Abuse and Mental Health Services Administration (SAMHSA)
SURVEY.SAMSHA	survey
SURVEY.USSGFHT	United States Surgeon General Family Health Tool (USSGFHT) survey
TIMP	Test of Infant Motor Performance (TIMP) survey

## **Appendix C - Calculating Mod 10 Check Digits**

The LOINC code is a numeric code with a Mod 10 check digit. The algorithm for calculating a Mod 10 check digit is as follows:

#### Instructions

	Example
1. Using the number 12345, assign positions to the digits, from right to left.	1st = 5 2nd = 4 3rd = 3 4th = 2 5th = 1
2. Take the odd digit positions counting from the right (1st, 3rd, 5th, etc.)	531
3. Multiply by 2.	1062
4. Take the even digit positions starting from the right (2nd, 4th, etc.).	42
5. Append (4) to the front of the results of (3).	421062
6. Add the digits of (5) together.	4+2+1+0+6+2 = 15
7. Find the next highest multiple of 10.	20
8. Subtract (6) from (7).	
Thus, 5 is the Mod 10 check digit for 12345.	20 - 15 = 5.

#### Calculating the check digit for LOINC Parts, Answers, and other identifiers with characters

We use a variant of the basic Mod 10 algorithm to calculate LOINC parts and answer identifiers because those identifiers contain the alpha prefixes "LP" and "LA" (which stand for LOINC Part and LOINC Answer). A detailed description of the method is available here:

https://wiki.openmrs.org/display/docs/Check+Digit+Algorithm

This same method could be used for calculating check digits for user-assigned "X codes" (that contain a leading "X" character) as well.

# Appendix D - Procedure for Submitting Additions/Changes to LOINC

#### Introduction

Since its inception, LOINC has been developed as an open standard. We welcome requests for new terms! Submissions from LOINC users have helped us grow and adapt quickly. Likewise, we welcome suggestions for changes to existing terms or other enhancements like additional synonyms or term descriptions.

Regenstrief balances the desire to respond quickly to new term submissions with the review processes necessary for a high quality standard. We can only be quick if the requesters provide **clear** and **comprehensive** information about the terms they are submitting.

The full list of information required for a submission is shown in Table 30.

New requests are often for variations on observations we already have in the database. For example, there may be an existing term for a particular test result with serum as the specimen (system) and a user requests an identical term for a specimen of gastric contents. With the supporting information, these kinds of requests are usually straightforward.

Even when requesters provide complete information with their submission, some requests require discussion and decision by the LOINC Committee before Regenstrief completes them. These kinds of requests are for things like:

- (1) an entirely novel kind of measurement
- (2) use of LOINC codes in ways not previously agreed upon by the LOINC Committee

#### Before you Submit

Please note that we tend to avoid the use of methods for chemistry tests. We will not routinely accept requests for method-specific chemistry tests. Only in very special circumstances will we distinguish among analytic methods in chemistry. We do distinguish microbiology, serology, and coagulation tests by method type. Even here, however, we do not distinguish every variation in method. Look in the body of this User's guide for information about the kinds of distinctions that we make.

Note that our policy is to allow both method-vague (no method) as well as method-specific measures in serology (measures of Ab and Ag), and in antibiotic susceptibility testing.

Please pay special attention to submissions that include the system of serum or plasma alone. For most chemical analyses there is no important clinical difference between the values obtained from serum and those obtained from plasma, and we would like to represent them in the database as Ser/Plas to indicate our indifference to the distinction. Unfortunately, many requestors of new terms define their request in terms of the one that they happen to use (e.g., serum or plasma) without telling us that the measure can really be done on either serum or plasma. Most such requests should be for Ser/Plas as the system (sample). If the measurement MUST be done on either serum or plasma, please scientifically justify your request and send documentation; otherwise you will greatly delay our response to your submission.

Survey instrument content has some additional complexity. If the instrument is copyrighted by a third

party, Regenstrief will need to obtain permission prior to being able to model it in LOINC. In general, new LOINC terms are required for questions or variables that have different enumerated answer lists.

#### How to Submit

#### First things first

The information you provide about your local test/measurement and how it is used is more important than the proposed LOINC name you come up with. Having complete information on what your local test is makes the review process much smoother and helps us create clear term definitions as well as verifying and enhancing other accessory content, which benefits everyone. The kinds of information we need does vary a bit depending on the type of content (lab, radiology, document titles, survey questionnaires, etc), so not all items are applicable all of the time.

#### Format for submissions

We recommend that you send requests using the RELMA generated file, or one of the templates available on the LOINC web site:

#### http://loinc.org/submissions/new-terms

The preferred format (and the one that RELMA will produce on your behalf) is a Microsoft Access database (mdb), but we also accept properly formatted Microsoft Excel spreadsheets (xls).

#### Other essential information

In addition to an Access or Excel file with your term requests, please provide:

- a package insert,
- user manual,
- implementation guide (for terms designed for use in the context of a specific messaging implementation guide),
- original survey form (for questionnaires or survey content),
- or any other documentation that may assist us in creating the requested codes.

These files can be attached to the email you send us with the submission file.

#### Required information

Table 30 lists the information we need to process your request. Take note of the Required or Optional column which tells the circumstances under which certain fields are required (e.g. we always need answer lists with Ordinal or Nominal terms).

Table 30: Submission File Fields				
Field name	Access Access Description		Required	
	Data	Field		or
	Туре	Size		Optional
REFERENCE_ID	Text	255	Regenstrief Institute identifier	Ignore
NAME	Text	150	Name of person submitting term	Required
ORGANIZATION	Text	100	Name of organization submitting term	Required
PHONE	Text	15	Submitter's phone #	Optional
FAX	Text	15	Submitter's FAX #	Optional
EMAIL	Text	255	Submitter's email	Required
ORG_SOURCE_CARE_ORG	Text	255	Name of healthcare organization that stimulated	Optional
			the request for this term (if you are submitting on	
			behalf of someone else)	

Table 30: Submission File Fields				
Field name	Access Data Type	Access Field Size	Description	Required or Optional
PROJECT_DESCRIPTION	Text	255	Description of the project or activity that stimulated the request for this term (e.g. IHE Antepartum Record Profile, Indiana Network for Patient Care health information exchange project, etc.)	
LOCAL_BATTERY_CODE	Text	50	Order code	Optional
LOCAL_BATTERY_DESCRIPTION	Text	255	Order description	Optional
LOCAL_TEST_CODE	Text	50	Local coded used to identify the test/observation in the submitter's master file	Required (if no master file, then use 1, 2, 3, etc.
LOCAL_TEST_DESCRIPTION	Text	255	Name of test or observation as it appears in the submitter's file or report	Required
REFERRAL_LAB_CODE	Text	50	Test code that performs the test	
REFERRAL_LAB	Text	255	Name of laboratory that performs test.	Required if applicable
TEST_DESCRIPTION	Memo		Description of what is measured, how it is used, what it is used for, and clinical relevance	
LOCAL_TEST_UNITS	Text	50	Units of measure for the observation	Required for quantitative terms
TEST_INSTRUMENT	Text	255	Name of vendor of instrument or test kit	
TEST_INSTRUMENT_MODEL	Text	255	Name of instrument	
TEST_REAGENT_KIT	Text	255	Name of test kit.	
SIMILAR_LOINC	Text	10	LOINC code for similar term that was used as model.	Optional
UNITS	Text	25		Ignore
EXAMPLE_ANSWERS	Memo		List of possible answers	Required if Scale is Ord or Nom
ANSWER_COMMENTS	Text	255	Additional comments about the answers	Optional
EXAMPLE_REPORT	Memo		Use for small reports. For larger reports, please send pdf along with submission and put name of pdf here.	Optional
GENERAL_COMMENTS	Memo		Additional comments to assist LOINC developer in understanding need for a new LOINC code.	
REFERENCE_INFO	Memo		URLs to supporting information, package inserts, protocols, etc.	
NORMAL_RANGE	Text	255		If appropriate
ANALYTE	Text	150	Component or analyte (User Guide 2.2.1)	Required
DIVISOR	Text	50	(User Guide 2.2.)	Can be
SUFFIX	Text	50	(User Guide 2.2)	included in ANALYTE
CHALLENGE ADJUSTMENT	Text	75 50	(User Guide 2.2.2)	field
	Text		(User Guide 2.2.3) (User Guide 2.2.4)	
COUNT PROPERTY	Text Text	2 30	Kind of property (User Guide 2.3)	Required (your best shot)
TIME_ASPCT	Text	15	Time aspect (usually "Pt") (User Guide 2.4)	Required
TIME_MOD	Text	15	(User Guide 2.4.1)	Can be included TIME_ASPCT field
SYSTEM	Text	100	System or sample type (User Guide 2.5)	1
SUPER_SYS	Text	20	(User Guide 2.5.1)	Can be included in SYSTEM field
SCALE_TYP	Text	30	Type of scale (User Guide 2.6)	

Table 30: Submission File Fields				
Field name         Access         Access         Description         Required				Required
Data Fie		Field		or
	Туре	Size		Optional
METHOD_TYP	Text	50	Type of method (User Guide 2.7)	

#### **RELMA** submission

The RELMA program can aid you in creating submissions by allowing you to create, manage and store submission terms in a way that is similar to how the program creates, manages and stores local working sets. With RELMA, you can create terms for submission over time and submit groups of terms in batches. The program will track when the term was created and the date when you submitted the term. The program will help you organize the terms that you create and it will automate the process of creating the submission files.

For detailed instructions on how to use the RELMA propose a term feature, please see Appendix A of the RELMA manual. You can be downloaded the RELMA Manual here: <a href="http://loinc.org/downloads/files/RELMAManual.pdf">http://loinc.org/downloads/files/RELMAManual.pdf</a>.

#### Access file submission

You can use the template provided on our website.

#### **Excel file submission**

You can use one of the templates provided on our website. Please take into account the Access field size shown in table 30 to ensure that text isn't truncated in the import procedure.

#### Sending Submission Files to Regenstrief Institute

Regardless of the file type, please email your submission and related documents to submissions@loinc.org.

Within a day or two of receipt of your file, you will receive a confirmation email and the submission process will be underway. You may receive additional communication from Regenstrief with requests for further information if required. Once the submission process has completed, you will receive files containing your requested codes.

# **Appendix E - Examples for LOINC Property Matching**

- **1. Content (Cnt).** Like concentration except that volume in the denominator is replaced by mass. By extension:
  - CCnt Catalytic Content, catalytic activity of a component per unit mass of a sample (system). 24048-1|Alpha galactosidase:CCnt:Pt:Fib:Qn
  - MCnt Mass Content, mass of component per unit mass of a sample (system). 9435-9|Isopropanol:MCnt:Pt:Tiss:Qn Note: All of the heavy metal measurements in hair, nails, and tissue should all be mass
    - contents.

8157-0|Arsenic:MCnt:Pt:Nail:Qn

- NCnt Number Content, number of component entities per unit mass of a sample (system). 20771-2|Coliform bacteria:NCnt:Pt:Egg:Qn:Viability count
- 2. Fraction (FR). Fraction of component A in a group of entities B, C, Y, N in system 1. By extension:

CFr	Catalytic Fraction 2536-1 Lactatedehydrogenase1/Lactatedehydrogenase.total:CFr:Pt:Ser/Plas:Qn:Electrophoresis 9642-0 Creatine Kinase.BB/Creatine kinase.total:CFr:Pt:Ser/Plas:Qn
NFr	Number Fraction 10602-1 Spermatozoa.abnormal head/100 spermatozoa:NFr:Pt:Semen:Qn 764-1 Neutrophils.band form/100 leukocytes:NFr:Pt:Bld:Qn:Manual count
MFr	Mass Fraction 2614-6 Methemoglobin/Hemoglobin.total:MFr:Pt:Bld:Qn
SFr	Substance Fraction 4546-8 Hemoglobin A/Hemoglobin.total:MFr:Pt:Bld:Qn
VFr	Volume fraction.

- r Volume fraction. 4545-0|Hematocrit:VFr:Pt:Bld:Qn:Spun
- **3. Ratio** (**RTO**). Ratio of component A to component B in system 1. By extension:

CRto	Catalytic Ratio (previously Catalytic Concentration Ratio, CCRto) 2325-9 Gamma glutamyl transferase/Aspartate aminotransferase:CRto:Pt:Ser/Plas:Qn
SRto	Substance Ratio (previously Substance Concentration Ratio, SCRto) 2958-7 Sodium/Potassium:SRto:Pt:Sweat:Qn
MRto	Mass Ratio (previously Mass Concentration Ratio, MCRto) 2768-0 Phenylalanine/Tyrosine:MRto:Pt:Ser/Plas:Qn
NRto	Number Ratio 11138-5 Myeloid cells/Erythroid cells:NRto:Pt:Bone mar:Qn
VelRto	Velocity Ratio 12022-0 Resistivity index:VelRto:Pt:Uterine artery.right:Qn:Doppler.calculated
VRatRto	Volume Rate Ratio 29462-9 Pulmonic flow/Systemic flow:VRatRto:Pt:Circulatory system.XXX:Qn:US.doppler
Ratio	1811-9 Amylase/Creatinine renal clearance:Ratio:24H:Urine:Qn

#### Note:

CSF/Serum Protein calculation is not a ratio, because the measured components are not in the same system. Its property type is relative mass concentration, RelMCnc (see below).

#### Note:

If the units of the denominator and numerator are both mass (e.g., mg/g), use MRto 13719-0|Carnitine/Creatinine:MRto:Pt:Urine:Qn

If the units of the denominator and numerator are both substance (e.g., mmol/mol) use SRto 22695-1|Carnitine/Creatinine:SRto:Pt:Urine:Qn

If the units of the denominator and numerator are different (mmol/g), use Ratio 17866-5|Carnitine/Creatinine:Ratio:Pt:Urine:Qn

4. Relative (REL). Relative amount of component A in system 1 compared to system 0. By extension:

REL should be used anywhere an actual measurement is divided by a measurement on a normal or control. It should also be used when a quotient is created by dividing a measured substance in Serum by the same substance measured in CSF, Urine, etc.

RelMCnc	Relative Mass Concentration (as noted previously) 2858-9 Protein.CSF/Protein.serum:RelMCnc:Pt:Ser+CSF:Qn 3235-9 Coagulation factor XII Ag actual/Normal:RelMCnc:Pt:PPP:Qn:Imm
RelTime	Relative time 3232-6 Coagulation factor XII activity actual/Normal:RelTime:Pt:PPP:Qn:Coag
RelCCnc	Relative Catalytic Concentration 28660-9 Plasminogen actual/Normal:RelCCnc:Pt:PPP:Qn:Chromo
RelRto	Relative Ratio 1756-6 Albumin.CSF/Albumin.SerPl:RelRto:Pt:Ser/Plas+CSF:Qn
RelVol	Relative Volume 19853-1 Capacity.inspiratory.bs/Capacity.inspiratory.preop:RelVol:Pt:Respiratorysystem:Qn:Spirometry
RelVrat	Relative Volume Rate 20161-6 Voluntaryventilation.max^postbronchodilator/MVV:predicted:RelVRat:Pt:Respiratory system:Qn

- **5. Cmplx.** Other divisions of one measurement by another that are not covered by the above rules should be classed as having Complex (Cmplx) properties, and the exact formula for deriving the quantity should be explicitly stated.
- **6. Arbitrary.** Arbitrary concentration of items. If we are not measuring the activity of an enzyme then the units of measure and properties are:

Possible Values	Property	Scale
Units/mL, IU/mL, etc.	ACnc	Qn
Units/gm, IU/gm, etc.	ACnt	Qn
Unit/min, IU/24hr, etc.	ARat	Qn
Unitless (Patient/Control)	AFr	Qn

When measuring presence/absence or ordering measures of a component, ACnc is also the correct property with scale of Ord

NOTE: If we are measuring the activity of an enzyme then the units of measure and properties are:

Possible Values	Property	Scale
IU/mL, Units/mL, etc.	CCnc	Qn
IU/gm, Units/gm, etc.	CCnt	Qn
IU/24hr, Unit/min, etc.	CRat	Qn
Unitless (Patient/Control)	CFr	Qn

7. If the property is Titr then the scale is always Qn.

For any X Ab or Ag:

Possible Values	Property	Scale
<1:2, 1:4, 1:8	Titr	Qn

#### 8. For Any X Ab or Ag:

Urine Turbidity

Possible Values	Property	Scale	
Neg, Indeterminate, Pos	Threshold	Ord	
1+, 2+, 3+	ACnc	Ord	
<1:2, 1:4, 1:8	Titr	Qn	
Neg, 1:4, 1:8	Titr	Qn	
Neg, 0.90	ACnc	Qn	(EIA units)

9. For any intensive evaluation whose value comes from a finite set of unranked (independent) coded items the property will be Prid (or Type) and scale Nom. Prid is used in cases where the value set includes the option of reporting "none", "not present", etc. Type is used in cases where the result always specifies a value from the finite set. For extensive measures whose value comes from a finite set of unranked coded items, the property will be the extensive property, and the scale will be Nom.

<b>Intensive Properties</b>	Possible Values (coded)	Property	Scale
Organism Identified	E. coli, S. aureus, etc.	Prid	Nom
ABO Group	A, B, AB, O	Prid	Nom
Surgery (Dis. Summary)	Cholecystectomy, Appendectomy	Prid	Nom
<b>Extensive Properties</b>	Possible Values (coded)	Property	Scale
Urine Color	Amber, straw, etc.	Color	Nom

Hazy, cloudy, opaque

**10**. For any intensive evaluation whose value comes from a finite set of unranked (independent) free text items (or a paragraph) the property will be Prid, or Find and scale Nar to indicate that the result is free text narrative. For extensive measures whose value comes from a finite set of unranked text items (or a paragraph), the property will be the extensive property, and the scale will be Nar.

Turbidity

Nom

<b>Intensive Properties</b>	Possible Values (text)	Property	Scale
Organism Identified	E. coli, S. aureus, etc.	Prid	Nar
ABO Group	A, B, AB, O	Prid	Nar
Surgery (Dis. Summary)	Cholecystectomy	Prid	Nar
<b>Extensive Properties</b> Urine Color Urine Turbidity	<b>Possible Values (text)</b> Amber, straw, etc. Hazy, cloudy, opaque	<b>Property</b> Color Turbidity	<b>Scale</b> Nar Nar

**11.** Imp is used to represent the property when the evaluation is a mental abstraction based on one a collection of measurements and or data. For example, if several measurements are made relative to

immunoglobin levels in Serum and CSF in a myasthenia gravis panel, and if by examining all of the evidence a pathologist decided that this pattern of findings represented active disease (which could be represented as a coded value), the result of the pathologist thought process would be represented as:

	Possible Values (text)	Property	Scale
Myasthenia Evaluation	No disease, chronic disease	Imp	Nom

If the pathologist evaluation is reported free text or a paragraph of information, the representation would be:

Myasthenia Evaluation No disease, chronic disease Imp Nar

- **12.** Methods are only used to distinguish things that are identical in the other five LOINC fields but may differ because the sensitivity or specificity is different for the given methods.
- 13. Need to be careful in distinguishing end point detection method from property. For example, if sodium is measured using an ion specific electrode, the property is not a voltage difference. The voltage difference is just a method for indirectly measuring the sodium concentration. Concentration is the real property. Likewise, many antigens and antibodies are now measured using optical density as the detection method. However, the property we are really measuring is an arbitrary concentration (ACnc), not the optical density. If it is a ratio of optical densities (as with Gliadin Ab, Parvovirus B19 Ab, etc.) that are compared (patient value divided by a standard control), then the property should be RelACnc (relative arbitrary concentration).
- **14.** ml/min/1.73sqM (Milliliters per min per 1.73 square meters BSA): Similar to the immediately preceding item. This result has the same property as if it had units of ml/min/sqM. The property of this measurement should be called "areic volume rate" (ArVRat).

Table 31: Example Acronyms used in LOINCAcronymMeaningACAbdominal CircumferenceADLActivities of Daily LivingAEAnion Exchange proteinAPAnterio-PosteriorAPADAnteroPosterior Diameter of the AbdomenAUTAutomated Ultrasound TestingB2GP1Beta 2 Glycoprotein 1BDBinocular DistanceBORBrachio-Oto-RenalBPCBiparietal CircumferenceBPDBiparietal diameterCDCluster of differentiationCDACongenital dyserythropoietic anaemiaCDBChildhood Disability BenefitscDNAcomplementary DNA	
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BPDBiparietal diameterCDCluster of differentiationCDACongenital dyserythropoietic anaemiaCDBChildhood Disability Benefits	
CD       Cluster of differentiation         CDA       Congenital dyserythropoietic anaemia         CDB       Childhood Disability Benefits	
CDACongenital dyserythropoietic anaemiaCDBChildhood Disability Benefits	
CDB Childhood Disability Benefits	
compromentary Divit	
CFst Calorie Fast	
CHAMPUS Civilian Health and Medical Program of the Uniformed Services	
Cine Cinematographic	
CNR1 Cannabinoid receptor 1	
COC Commission on Cancer	
COPD Chronic Obstructive Pulmonary Disease	
CPT Current Procedural Terminology	
CRL Crown-Rump Length	
CSF Cerebral spinal fluid	
CW Continuous wave	
CyCD22 Cytoplasmic CD22	
DBG Donna Bennett-Goodspeed	
DCIS Ductal carcinoma in situ	
DISIDA Diisopropyliminodiacetic acid	
DRG Diagnostic Related Groups	
DTPA Diethylenetriamine pentaacetate	
Dx Diagnosis	
EBV-LMP Epstein Barr virus – latent membrane protein	
ED Emergency Department	
EDD Estimated Delivery Date	
EEG Electroencephalogra	
EFW Estimated Fetal Weight	
EGD Esophagogastro duodenoscopy	
EKG Electrocardiogram	
EMS Emergency Medical Service(s)	
ENT Ear, Nose Throat	
ERCP Endoscopic Retrograde Cholangiopancreatography	

# Appendix F – Example Acronyms used in LOINC

FL	Femur Length
FLACC	Face Legs Activity Cry Consolability
FNA	Fine needle
FTA	Fetal Trunk Area
GALOP	Gait disorder Autoantibody Late-age Onset Polyneuropathy
GSD	Gestational Sac Diameter
GSL	Gestatonal Sac Length
НС	Head Circumference
HCFA	Health Care Financing Administration
HIV	Human immunodeficiency virus
HIV-SSC	Sign and Symptom Check-List for Persons with HIV
	Disease
HL	Humerus Length
HLA	Human Leukocyte Antigen
HMPAO	Hexamethylpropyleneamine oxime
HTLV	Human T-cell Lymphotrophic Virus
HWL	Height Width Length
ICD	International Classification of Diseases
ICD9	International Classification of Diseases, Ninth Revision
ICD9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification
ICD-O	International Classification of Diseases for Oncology
ID	Intradermal
INR	International normalized ratio
IOD	Inter Ocular Distance
KUB	Kidney-Ureter-Bladder
LHON	Leber hereditary optic neuropathy
LOINC	Logical Observation Identifiers Names and Codes
LVOT	Left Ventricular Outflow Tract
LW	Landsteiner-Wiener
LWT	Length Width Thickness
MAA	Microalbumin aggregate albumin
MEMS	Medication Event Monitoring System
MERSTH	Medical Event Reporting System-Total Health System
MIB-1	Mindbomb homolog 1
MIBG	Metaiodobenzylguanidine
MIC	Minimum inhibitory concentration
MLC	Minimum lethal concentration
MLO	Mediolateral oblique
MMA	Macro aggregate albumin
MVV	Maximum Voluntary Ventilation
NAACCR	North American Association of Central Cancer Registries
Ng	Nasogastric
NPI	National Provider Identifier
OFD	
O L P P D	Occipital-Frontal Diameter
O-I BPD	Occipital-Frontal Diameter Outer to Inner Biparietal Diameter
O-I BPD OmpC	
	Outer to Inner Biparietal Diameter

OOD	Outer Orbital Diameter
PA	Postero-Anterior
PCP	Primary Care Physician
PEG	Polyethylene Glycol
PHO	Patient Health Questionnaire
PISA	Proximal Isovelocity Surface Area
PSR	Peridontal Screening and Recording
PYP	Pyrophosphate
QAM	Quality Audit Marker
QID	Four times a day
RAST	Radioallergosorbent test
RFC	Residual Functional Capacity
RFLP	Restriction fragment length polymorphism
RUG	Resource Utilization Groups
SAB	Streptoavidin-biotin
SBT	Sequence based typing
SC	Sulphur colloid
SCB	Sertoli cell barrier
SCL	Scleroderma
SEER	Surveillance Epidemiology and End Result
TAD	Transverse Abdominal Diameter
ТС	Thoracic Circumference
TCD	Transverse Cerebellar Diameter
TD	Transaxial Diameter
TEC	Tubingen electric campimetry
TID	three times a day
TNM	Tumor, node, metastasis
TORCH	Toxoplasma, Rubella. Cytomegalovirus, Herpes Simplex Virus
TTD	Transverse Thoracic Diameter
TU	Tuberculin Units
VTI	Velocity Time Integral
VWF	von Willebrand Factor

# Appendix G – LOINC Technical Briefs

Technical briefs have been developed for various LOINC terms to clarify either the meaning, current nomenclature, or use case of a given term. The following technical briefs are included in this manual and linked to related LOINC terms in RELMA.

- D-Dimer Revisions in LOINC Author: J. Gilbert Hill, MD, PhD
- Cockcroft-Gault formula for estimating creatinine clearance, Schwartz equation for Glomerular Filtration Rate and MDRD formulae Authors: Gilbert Hill, MD, PhD with edits by Clement J McDonald, MD
- Inducible Clindamycin Resistance in Staphylococcus and Streptococcus Author: David Baorto, MD, PhD
- KIR Gene Family Author: David Baorto, MD, PhD
- Oxygen Saturation and LOINC Authors: Gilbert Hill, MD, PhD and Clement J McDonald, MD
- Nomenclature of Salmonella Species, Subspecies, and Serovars Author: David Baorto, MD, PhD
- Segmented Neutrophils versus Polymorphonuclear WBC Author: David Baorto, MD, PhD
- Vitamin D Summary Author: David Baorto, MD, PhD

# *D-DIMER* 2006-11-24

## The Problem:

For many years a test known as "D-dimer" has been used for the assessment of patients with DIC, and more recently, for the exclusion of the diagnosis of DVT or PE. The units used in expressing results are usually ng/mL or ug/L, so that a report might look like:

D-dimer = nn ug/L

or D-dimer = nn ng/mL

Occasionally, this expression is modified to read D-dimer = nn ug/L DDU, (where the DDU stands for D-dimer units)

With time, new test procedures have been developed, in which newer methods of analysis and of preparation of the test standard have led to the use of new "units" in expressing results. With these reagent sets, a report might look like:

D-dimer = xx FEU ug/L

or D-dimer = xx ug FEU/L

or D-dimer = xx ug/L FEU, (where FEU is an acronym for fibrinogen equivalent units)

The location of FEU in the unit is not consistent: some users place the FEU before the "ug", some after the "ug", and some after the "L".

From a clinical perspective, the D-dimer test is potentially of greatest value in ruling out DVT or PE: for results expressed as ng/mL (= ug/L) the exclusion value is generally less than 250; for results expressed as ng/mL FEU, the exclusion value is less than 500, and these values are compatible with a rule-of-thumb conversion published by Biomerieux, July 2003:

600 ng/mL FEU = 300 ng/mL D-dimer.

So ... now we have the use of single name for a test – D-dimer – but with results falling into two separate families. The difference between the two families is that the results differ by a factor of approximately two. This has led to a chaotic situation in the lab, and by extension, to the bedside, a situation in which both laboratory staff and clinicians are confused as to what "D-dimer" is being measured and reported. The world-wide web has dozens of references to the problem, and the CAP has commented frequently, with a series of feature articles in CAP Today (Feb 2000, Jan 2003, April 2005, May 2005, Summer 2005).

In LOINC terms, we have a component representing two different entities, with identical primary attributes (component, property, scale, system, time aspect and scale), differentiated only by method and units, both of which are very weak discriminators.

The fundamental problem is the lack of a useful standard. The International Society on Thrombosis and Haemostasis has had a subcommittee working for more than ten years on D-dimer standardization, without success, and it is said that a seat on the committee comes with retirement benefits. The following figures provide an estimate of the scope of the problem: in a 2004 US (CAP) survey, 59% of labs reported FEU, 41% reported D-DU and 8% did not know the units they were using; in a 2005 Canadian (QMPLS) survey, 68% of labs reported D-DU, 31% reported FEU, and 1% did not know the units they were using.

#### Resolving the Problem

The obvious solution to the problem is to have different names for the two "families" of D-dimer. But what should these names be?

Contributing to the original problem is the unfortunate choice of the acronym FEU, for *fibrinogen equivalent units*. The inclusion of the word "unit" gives the impression that FEU is a unit in the metrological sense, whereas it would be more reasonable to think of it as a unit in the structural sense -e.g., a unit such as glucose in a larger molecule such as starch.

Given this interpretation, FEU may be more closely related to, or equivalent to the "component" (in the LOINCian sense), rather than to the metrological unit. In other words, FEU is the name of what is measured: just as the amount of glucose can be measured in a sample, so can the amount of FEU.

From this it is logical to propose that existing entries in LOINC retain the component name FIBRIN D-DIMER, but that a new entry be created with the name FIBRIN D-DIMER.FEU. In accordance with LOINC naming conventions, a dot (.) separates the analyte name from the "subspecies". This proposed name protects the connection with the D-dimer family, but efficiently separates it as a different entity.

## The fully specified name would be FIBRIN D-DIMER.FEU:MCNC:PT:PPP:QN:EIA

There is at least one precedent in LOINC for this type of component modification – see LOINC 4539-3, Erythrocyte Sedimentation Rate.Zeta.

LOINC	COMPONENT	PROPERTY	EX_US_UNITS	TIME	SYSTEM	SCALE	METHOD
15129-0	FIBRIN D-DIMER	MCNC		PT	PPP	QN	EIA
30240-6	FIBRIN D-DIMER	MCNC	1	PT	PPP	QN	1
3246-6	FIBRIN D-DIMER	ACNC		PT	PPP	QN	EIA
38898-3	FIBRIN D-DIMER	TITR	titer	PT	PPP	QN	
42727-8	FIBRIN D-DIMER	MCNC	ug/L	PT	CSF	QN	LA
7799-0	FIBRIN D-DIMER	ACNC	1	PT	PPP	QN	

The quantitative D-dimer entries in LOINC 2.17 are as follows:

# D-dimer results from American Proficiency Institute 2004 Testing Program

These tables hint at some of the problems associated with the measurement of Ddimer, in particular the inaccuracy and imprecision, but also proved a convenient example of the problem under discussion: Biomerieux pioneered the use of the acronym FEU, but Biomerieux results are shown in the first, ug/L table, rather than the second, ug FEU/mL table.

#### 1. D-dimer (quan) (ug/L)

SAMPLE DQT-01				
Peer Group	# of Labs	Mean	SD	Range
Biomerieux Vidas, Mini/Biomerieux Vidas,				
Mini rgt	22	588.6	50.2	488-689
Coulter (IL) ACL/IL Test D-Dimer	34	301.1	40.8	219-383
Dade Stratus CS/Dade Stratus reagent	14	1036.8	67.2	902-1172
Sysmex CA Series/Dade Advanced D-Dimer	16	761.5	222.9	315-1208
Instrument Groups				
Biomerieux Vidas, Mini	22	588.6	50.2	488-690
Coulter (IL) ACL	34	301.1	40.8	219-383
Dade Stratus CS	14	1036.8	67.2	902-1172
Sysmex CA Series	16	761.5	222.9	315-1208
Reagent Groups				
Biomerieux Vidas, Mini rgt	22	588.6	50.2	488-690
Dade Advanced D-Dimer	17	761.5	222.9	315-1208
Dade Stratus reagent	14	1036.8	67.2	902-1172
IL Test D-Dimer	34	301.1	40.8	219-383
All Participants	97	455.6	225	5-906

#### 2. D-dimer (quan) (ugFEU/mL)

SAMPLE DQT-01		Million and State	Law Street Street	
Peer Group	# of Labs	Mean	SD	Range
Diagnostica Stago STA/Diag. Stago STA Liatest D-DI	12	0.46	0.0699	0.32-0.6
Roche Integra/Roche Tina-Quant	10	0.457	0.1326	0.191-0.723
Instrument Groups				
Diagnostica Stago STA	12	0.46	0.0699	0.32-0.6
Roche Integra	10	0.457	0.1326	0.191-0.723
Reagent Groups				
Diag. Stago STA Liatest D-DI	12	0.46	0.0699	0.32-0.6
Roche Tina-Quant	11	0.4545	0.126	0.202-0.707
All Participants	26	0.4596	0.0968	0.266-0.654

# Cockcroft-Gault formula for estimating creatinine clearance, Schwartz equation for Glomerular Filtration Rate and MDRD formulae

Authors: Gilbert Hill, MD, PhD with edits by Clement J McDonald, MD Written: 11/20/2007

# **1** Estimating creatinine clearance from serum creatinine

# 1.1 Cockcroft-Gault – not adjusted for body surface area (BSA)

The Cockcroft-Gault formula is used to estimate creatinine clearance from age, weight and serum creatinine. The original paper from these two authors was *Prediction of Creatinine Clearance from Serum Creatinine*, Nephron 1976;16:31- 41 hence the name. Note that Creatinine clearance is a *proxy* for Glomerular Filtration Rate (GFR) and some clinical settings describe this as an estimated GFR (see below).

The basic formula without normalization for BSA is represented in the LOINC data base by the following term.

35591-7	Creatinine renal	VRat	Pt	Ser/Plas	Qn	Cockcroft-Gault
	clearance.predicted					formula

And the formula is as follows

$$x = \frac{(140 - age) \times weight}{72 \times creatinine}$$

The equation as shown requires weight to be recorded in kg and creatinine in mg/dL, and is valid for male patients. If the patient is female, the result should be multiplied by 0.85.

Web calculator for creatinine in mg/dL

If the patient's weight is recorded in kg and the creatinine is reported in umol/L then results from the above equation must be multiplied by 1.23 for men and 1.04 in women.

Web calculator for creatinine in umol/L

From http://www.sydpath.stvincents.com.au/other/CalcsCrClCGumol.htm

# 1.2 Cockcroft-Gault – adjusted for body surface area

It is now common practice for the creatinine clearance calculated by the Cockcroft-Gault formula to

be normalized for a body surface area of  $1.73 \text{ m}^2$ .

In particular, the Cockcroft-Gault BSA adjusted formula is used by many pharmacy departments for medication dosage adjustments.

Lonie	Lonve terms for Don adjusted creatinine creatance								
35592-5	Creatinine renal clearance/1.73	VRat	Pt	Ser/Plas	Qn	Cockcroft-Gault			
	sq M.predicted					formula, corrected			
						for BSA			
50380-5	Creatinine renal clearance/1.73	VRat	24H	Ser/Plas	Qn	Cockcroft-Gault			
	sq M.predicted.female					formula, corrected			
						for BSA			
50381-3	Creatinine renal clearance/1.73	VRat	24H	Ser/Plas	Qn	Cockcroft-Gault			
	sq M.predicted.male					formula, corrected			
						for BSA			

LOINC terms for BSA adjusted creatinine clearance

# 2 Direct prediction of GFR

# 2.1 Creatinine-based prediction of GFR

# 2.1.1 Schwartz formula for Pediatrics

The Schwartz formula is used to predict GFR in pediatrics. The original paper by G F Schwartz et al, is *A Simple Estimate of GFR in Children Using Body Length and Plasma Creatinine*, Pediatrics 1976;58:259-263 has become more relevant in the last few years because the MDRD formula (below) is specifically stated NOT to be applicable to patients under 18 years of age. The Schwartz formula depends on age, gender, and body height and serum creatinine. The equation can be stated as follows:

# GFR Calculator for Children

# Schwartz Formula

GFR (mL/min/1.73 m<sup>2</sup>) = k (Height) / Serum Creatinine

 $\mathbf{k} = \mathbf{Constant}$ 

- $\circ$  k = 0.33 in Preemie Infants
- $\circ$  k = 0.45 in Term infants to 1 year old
- $\circ$  k = 0.55 in Children to 13 years
- k = 0.65 in Adolescent males (Not females because of the presumed increase in male muscle mass. The constant remains .55 for females.)

Height in cm

Serum Creatinine in mg/dl

Web calculator for Schwartz Formula

LOINC term for Schwartz formula

Lonie	term for Sent are forman					
50384-7	Glomerular filtration rate/1.73 sq	VRat	24H	Ser/Plas	Qn	Creatinine-based
	M.predicted					formula (Schwartz)

# 2.1.2 MDRD 4 variables

The MDRD 4 variable equation is the principle equation recommended by professional nephrology societies to estimate the GFR. It depends upon serum creatinine, age, gender and race. It also includes a BSA adjustment term of 1.73 - the average body surface area in an adult male. (Equations incorporating height and weight can be used to correct this equation when patients are far from the mean in BSA- but are not routinely used.

#### The following is (taken from NKF MDR web site )

The National Kidney Disease Education Program (NKDEP) of the National Institute of Diabetes and Diseases of the Kidney (NIDDK), National Kidney Foundation (NKF) and American Society of Nephrology (ASN) recommend estimating GFR from serum creatinine using the MDRD Study equation. This equation depends upon the serum creatinine age, gender <u>and</u> race to estimate the GFR and therefore improves upon several of the limitations with the use of serum creatinine alone. The MDRD Study equation has been rigorously developed and validated, and is more accurate than measured creatinine clearance from 24-hour urine collections. The equation is:

# GFR = $186 \text{ x} (PCr)^{-1.154} \text{ x} (age)^{-0.203} \text{ x} (0.742 \text{ if female}) \text{ x} (1.210 \text{ if black})$

GFR is expressed in ml/min/1.73 m<sup>2</sup>. In this equation  $P_{cr}$  serum creatinine must be expressed in mg/dl, and age in years. (Of course other units can be used if the right side of the above equation is multiplied by the appropriate constant). (all taken from NKF web site - http://www.kidney.org/professionals/KLS/gfr.cfm#2

December 04 2006)

Web calculator for MDRD

The glomerular filtration rate predicted by the MDRD formula may be reported in at least 3 ways:

a) All four variables are known and used in the equation. The result would be race and gender adjusted creatinine clearance.

b) Only two variables (serum creatinine and age) are used in the equation. In this circumstance, the report may:

i) include a comment saying – "if patient is black multiple result by 1.21" and/or "if patient is female multiply the result by .742"

or ii) may include two values: N1 if white and N2 if black, and a correction factor for gender: if patient is female multiply the result by .742.

LOUVE codes for WIDRD formatia							
33914-3	Glomerular filtration rate/1.73 sq	VRat	Pt	Ser/Plas	Qn	Creatinine-based	
	M.predicted					formula (MDRD)	
48642-3	Glomerular filtration rate/1.73 sq	VRat	Pt	Ser/Plas	Qn	Creatinine-based	
	M.predicted.non black					formula (MDRD)	
48643-1	Glomerular filtration rate/1.73 sq	VRat	Pt	Ser/Plas	Qn	Creatinine-based	
	M.predicted.black					formula (MDRD)	

#### LOINC codes for MDRD formula

50044-7	Glomerular filtration rate/1.73.	VRat	Pt	Ser/Plas	Qn	Creatinine-based
	sq M.predicted.female					formula (MDRD)

### 2.1.3 MDRD 6 variables

A six variable version of the MDRD exists. This one depends on the patient's serum albumin and serum urea nitrogen values in addition to the MDRD-4 variables, but is not the preferred equation for this estimate.

Where PCr=serum creatinine concentration (mg/dl) (alkaline picrate method); SUN=serum urea nitrogen concentration (mg/dl) (urease method); Alb=serum albumin concentration (g/dl) (bromocresol green method).

Taken from:

Stoves J,Lindley E,Barnfield M,Burniston T, Newstead C. MDRD equation estimates of glomerular filtration rate in potential living kidney donors and renal transplant recipients with impaired graft function.Nephrol Dial Transplant.2002,17: 2036-2037

# 2.2 Cystatin-based prediction of GFR

Although the MDRD equation, based on the measurement of serum creatinine, is the most widely used method for estimating GFR, an alternative, based on the measurement of serum cystatin is claimed to have certain advantages.

Estimating Glomerular Filtration Rate in Kidney Transplantation: A Comparison between Serum Creatinine and Cystatin C-Based Methods, J Am Soc Nephrol 16: 3763–3770, 2005

Web calculator for Cystatin-based GFR

LOINC code for GFR predicted by a cystatin-based formula

50210-4	Glomerular filtra	tion rate/1.73 sq	VRat	Pt	Ser/Plas	Qn	Cystatin-based
	M.predicted						formula

# Inducible Clindamycin Resistance in Staphylococcus and Streptococcus Author: David Baorta, MD, PhD Written: 5/12/2011

#### Macrolide-Lincosamide-Streptogramin B (MLS<sub>b</sub>) Resistance

There is a phenomenon by which the organism can appear to be susceptible to lincosamindes such as clindamycin when tested in vitro, yet exposure to an appropriate macrolide (such as erythromycin) can INDUCE resistance to the clindamycin. This mechanism of resistance involves methylation of the 23S rRNA binding site that is shared by 3 antibiotic classes (macrolides, lincosamides, and group B streptogramins) and prevents their binding to the site and exerting their effect. This resistance mechanism is known (for short) as MLSB.

When one of the erm methylases is produced constitutively, the resistance is constitutive and requires no induction. However, in some cases, the translation of the erm methylase protein is suppressed and is activated only after the binding of a macrolide antibiotic to upstream sequences, which alters the mRNA conformation, allowing it to be translated. Once this occurs, active methylase enzyme is produced which methylates the binding site for all 3 antibiotic classes, potentially preventing the binding of any of these antibiotic classes and inducing co-resistance. Detection of this resistance pattern can be detected phenotypically using disc diffusion (Clindamycin.induced [Susceptibility] by Disk diffusion (KB), 42720-3).

#### The detection of the presence of either the ermA or ermC gene

The methylase enzyme is encoded by one of the erm genes, generally ermA or ermC in staph, ermB in strep. Finding ermA or ermC similarly indicates the possibility for resistance to both erythromycin and clindamycin in Staph (either constitutive or inducible for clinda), so reporting both genes has been combined in some assays to indicate that one of the two has been detected (Bacterial erythromyin+clindamycin resistance (ermA + ermC) genes [Presence] by Probe & target amplification method, 62258-9).

# The KIR Gene Family

Author: David Baorto, MD, PhD Written: 4/17/2011

#### **Clinical Significance**

KIR (Killer cell Immunoglobulin-like **R**eceptor) molecules, a novel category of lymphocyte receptors, are predominantly found on the surface of natural killer (NK) cells. Through their interaction with HLA class I molecules, they modulate NK cell activity, central to the ability of those cells to distinguish between healthy cells and those either infected or transformed. The KIR family of molecules demonstrates extensive diversity at the gene level, stemming from multiple genes as well as multiple alleles. As a result of this polymorphism, KIR genotype is unlikely to be identical between individuals (in a sense similar to their molecular ligand, HLA Class I). The relationship between KIR genotype and disease is beginning to be elucidated, and is likely to interact with HLA. Needless to say it is a growing area, but there is evidence that which KIR genes are expressed in an individual may be related to susceptibility to infections (e.g, HCV, HIV), autoimmune diseases, and certain cancers. Importantly, the success of hematopoietic cell transplantation for some leukemias may be closely tied to KIR type or KIR compatibility, and be an additional predictor (with HLA).

#### Nomenclature of KIR genes and alleles

The KIR genes have been classified under the CD nomenclature as a set of CD158 molecules (CD158a, CD158b, etc.), but the CD names are not commonly used because they do not specifically reflect structure, function and gene polymorphism. The frequently used KIR gene nomenclature is developed by the HUGO Genome Nomenclature committee (HGNC). It includes over 15 genes and is based on molecular structure. They all begin with "KIR", the next digit is the number of Immunoglobulin-like domains, next is "D" for domain, next is a description of the cytoplasmic tail, either "L" for long, "S" for short, or "P" for pseudogenes. The last digit is an integer to distinguish among different KIR genes having that same structure. (e.g. KIR2DL1, KIR2DL2, etc). Different alleles of a KIR gene are named in a fashion similar to that of HLA alleles, with an asterisk following the gene name, followed by digits indicating differences in encoded proteins and non-coding regions.

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Carrington M, Norman P. The KIR Gene Cluster. Bethesda (MD): National Center for Biotechnology Information (US); May 28, 2003. [PMID: <u>NBK10135</u>]

# Oxygen Saturation and LOINC®

#### Authors: Gilbert Hill and Clement J. McDonald Written: 10/19/2007 – Revised: 7/9/2009

(See NCCLS 46-A Blood Gas and pH Analysis and Related Measurements: Approved Guideline.)

#### 1. **Oxygen saturation**

The term "oxygen saturation" is often used to refer to two distinctly different quantities, hemoglobin oxygen saturation (recommended symbol =  $sO_2$ ) and fractional oxyhemoglobin (recommended symbol =  $FO_2$ Hb).

#### 2. NCCLS 46-A defines the two as follows:

#### 2.1 Hemoglobin oxygen saturation

Hemoglobin oxygen saturation = the amount of oxyhemoglobin in blood expressed as a percent of the total amount of hemoglobin **able to bind** oxygen (i.e. oxyhemoglobin ( $O_2Hb$ ) + deoxyhemoglobin (HHb). Note that carboxyhemoglobin (COHb), methemoglobin (MetHb) and Sulfhemoglobin (SulfHb), the so-called dyshemoglobins (dysHb) are unable to bind oxygen, so are not included in the denominator of this fraction

$$sO_2 = 100 \text{ x } O_2\text{Hb}/(O_2\text{Hb} + \text{HHb})$$

More important some instruments, e.g. the pulse oximeter- can not pick up the dyshemoglobins. So they always report sO2

This quantity may be referred to as "oxygen saturation", Terms such as "functional" oxygen saturation or oxygen saturation of "available" or "active" hemoglobin, but NCCLS should not be used to name this quantity...

#### 2.2 Fractional oxyhemoglobin

Fractional oxyhemoglobin = the amount of oxyhemoglobin expressed as a percent of the **total** hemoglobin (where total Hb = O2Hb + HHb + [COHb + MetHb + SulfHb] taken all together O2Hb HHb and the three DysHb's represent the total Hb.

$$FO_2Hb = O_2Hb/tHb$$

A key point here is that it takes a more sophisticated machine to measure Fractional Oxyhemoglobin than sO2.

## 3. When there are no dyshemoglobins present (the usual situation), $sO_2 = FO_2Hb$

## 4. Oxygen saturation obtained by measuring pH and pO2

An "oxygen saturation" can also be obtained by measuring pH and pO2 and substituting the values into an empirical formula for the oxyhemoglobin dissociation curve (Hill equation). However, this calculated approach is prone to many kinds of errors and "oximetry" based on differential spectrophotometry is now the method of choice.

# 5. Three principal classes of oximetry

There are at least three principal classes of oximetry, commonly known as:

Pulse (or transcutaneous) oximetry (sensor attached to body surface) Hemoximetry (sample of blood injected into instrument) Co-oximetry. Historically a Co-oximeter measures Carbon monoxide bound hemoglobin's and the other two dyshemoglobins and could only be done in the laboratory with an injected blood sample Today (2009) most laboratory blood analyzers measure all three dyshemoglobins and are really Co-oximeters, but may not be named as such.

A pulse co-oximeter was placed on the market in 2005 this devise reports the both oxyhemoglobin %, Carbon monoxide %, the Pleth variability index, it also measures each of the dyshemoglobins. So it provides an accurate fractional oxygen saturation as well as information about CO poisoning.

## 6. Instruments used for pulse and hemoximetry

The instruments used for pulse and hemoximetry base results on calculations from readings at two different wavelengths, which means they do not reflect the presence of any dyshemoglobins, and therefore the result they produce will be  $sO_2$  (LOINC component Oxygen saturation = NCCLS hemoglobin oxygen saturation).

# 7. Instruments used for co-oximetry

The instruments used for co-oximetry base results on calculations from readings at four to eight different wavelengths, which means they are able to reflect the presence of any dyshemoglobins, and therefore the result they produce will be  $FO_2Hb$  (LOINC component Oxyhemoglobin/Hemoglobin. total = NCCLS fractional oxyhemoglobin).

LOINC will name its components according to the NCCLS recommendation, and apply the corresponding NCCLS synonyms i.e. sO2 and FO2HB to the components, oxygen saturation and Hemoglobin Oxygen fraction, respectively and include the defining equation (see above) for the terms that carry these respective components. We will retain oxygen saturation as a synonym for both sO2 and FO2Hb so that mappers who may not know the official names will still be able to find the terms.

LOINC will use the property of MFR (mass fraction) to identify the property of these terms. There would only be an imperceptible difference between the numerical representation of this quantity as a MFR versus an SFR (substance or molar fraction), By LOINC convention we use MFR rather than SFR in such cases.

Depending upon the naming precision of laboratory, it may be difficult to determine whether a result called an Oxygen saturation is really an sO2 or FO2Hb, The other tests in the panel, and the inclusion of method names in the test order or battery and the source of the term (clinical laboratory, cardiac cath laboratory, respiratory therapy, nursing) all provide guidance for the mapping. But it may be necessary to contact the source to be sure in some cases.

If a battery reports both a fractional oxyhemoglobin and oxygen saturation the situation should be clear. If the method is co-oximetry or the batter includes a separate measure of Carboxyhemoglobin (or any of the other dyshemoglobins) then the will be reporting a fractional oxyhemoglobin. If the method is pulse oximetry- then you have a sO2. Most central and ICU based blood gas measures will produce a fractional oxyhemoglobin.

Finally, in the U.S. these results are almost always reported with units of percent (%), but these results are reported as pure fractions (E.g. 20% becomes 0.2) in some environments.

# Nomenclature of Salmonella Species, Subspecies, and Serovars

Author: David Baorto, MD, PhD Written: 7/9/2011

Salmonella nomenclature is complex and has caused confusion. At the present time, by molecular methods the genus Salmonella is known to have only 2 species: *Salmonella enterica* and *Salmonella bongori*. *Salmonella enterica* is divided into 6 subspecies, each of which is further divided into numerous serovars (or serotypes) based on serological testing of somatic(O) and flagellar(H) antigens. Serovars are then designated by a formulaic concatenation of the antigens, known as the "antigenic formula". The terms "serovar" and "serotype" appear to be used interchangeably, however, there has been a preference expressed for the term "serovar" by the Association of Public Health Laboratories and the World Health Organization (which uses "serovar" in its documentation). As a result, that will be the term used in this document.

A significant number of what are now known to be serovars were originally thought to be distinct species of Salmonella, and those species names became rooted in common clinical usage. As a result, Salmonella nomenclature deviates from that of other bacteria, which, for the most part, do not have common names assigned to serovars. (Even the well-known *E. coli* O157:H7 is known by its antigenic formula.) Salmonella, on the other hand consists of 2579 individual serovars (2007 WHO documentation), about 1400 of which have common names.

Here is where it gets tricky(er). While it would be impractical to eradicate commonly used names for important serovars, formatting is used to indicate that the names are **not** that of **species**, generally by NOT italicizing and instead capitalizing the first letter of the serovar name as follows: "*Salmonella enterica* subsp. *enterica* serovar Typhimurium". Since all the commonly named serovars are in the subspecies enterica, that middle designation can be left off, resulting in the name "*Salmonella enteric* serovar Typhimurium".

# LOINC<sup>®</sup> Terms Associated with Salmonella Serotyping:

#### Salmonella sp identified [Type] in Isolate (59846-6)

This code has one of 7 possible answers to differentiate the 2 species and 6 subspecies in the case of *enterica*. When performed by the CDC, the answer is derived from a series of about 50 biochemical tests and consists of 7 possibilities:

Salmonella enterica subspecies enterica (type I) Salmonella enterica subspecies salamae(type II) Salmonella enterica subspecies arizonae(type IIIa) Salmonella enterica subspecies diarizonae(type IIIb) Salmonella enterica subspecies houtenae(type IV) Salmonella bongori Salmonella enterica subspecies indica(type VI)

## Salmonella sp antigenic formula [Identifier] in Isolate by Agglutination (56475-7)

This code has a discrete set of over 2500 possible answers representing the antigenic formula concatenated from the O and H antigens and sometimes other antigens found by agglutination testing. This code is intended to report only the antigenic formulae of the serovar, not the common name for the serovar.

The format of the antigenic formula generally is expected to contain the subspecies type (I,II,IIIa, etc), then followed by somatic (O) antigens, flagellar (H) phase 1 antigens, flagellar (H) phase 2 antigens, and other antigens separated by a colon. So, a Salmonella type IV (Salmonella enteric subspecies houtenae) with O antigen 43 and H (phase 1) antigens z36, z38 would be reported as "IV 43:z36,z38:-".

# Salmonella sp serovar [Type] in Isolate (65756-9)

This code is intended to report a final answer for the serovar found, thus has an answer list similar in size to 56475-7. It will report the common name for the antigenic formula reported by that code (if there is a common name). If there is no common name, it will report the antigenic formula. In about 90% of cases the antigenic formula reported by 56475-7 will cleanly map to a serovar to report by this code. In the remaining 10% of cases, however, serovars can be further distinguished even in the light of identical antigenic formulas. These distinctions can involve further biochemical testing or sometimes further antigen testing.

# Segmented Neutrophils Versus Polymorphonuclear WBC

#### Author: David Baorto, MD, PhD Written: 4/17/2011

Segmented neutrophils are commonly referred to as polymorphonuclear neutrophils, PMNs, or "polys". Therefore, in common usage the term polymorphonuclear leukocyte (or polymorphonuclear WBC) refers to neutrophils. Caution coding in this area should be applied because there is a usage whereby all granulocytes, including neutrophils, basophils and eosinophils, can be referred to as polymorphonuclear cells" due to the variable shape of their nuclei. Basophils can therefore be referred to as polymorphonuclear basophil (PMB), eosinophils as polymorphonuclear eosinophils (PME), in addition to neutrophils (polymorphonuclear neutrophil, PMN).

Refer to the following Wikipedia page for more information: <u>http://en.wikipedia.org/wiki/Granulocyte</u>

## Vitamin D

#### Author: David Baorto, MD, PhD Written: 2/19/2011

#### **General Summary**

Vitamin D is a prohormone that is involved in calcium and phosphate homeostasis, bone formation, and immune regulation. The determination of vitamin D is complex because it is not a single component, but has 2 major forms, each of which has several metabolic stages leading to an active end product. Vitamin D3, also known as cholecalciferol, is the form that occurs naturally in humans and is produced in the skin of vertebrates from 7-dehydrocholesterol exposed to UV B radiation from the sun. Vitamin D3 can also be obtained from certain dietary animal products and supplementation. Vitamin D2, also known as ergocalciferol, is introduced into humans primarily by commercial supplementation. It is produced by UV irradiation of ergosterol, a substance that occurs in yeast, molds and certain plants.

Despite their distinct origins, both vitamin D2 and D3 share similar chemical structure, metabolic activation in humans, and presumably bioactivity as well, although the literature suggests that vitamin D2 is biologically inferior. Their structures differ only by a side chain, and the starting forms of both in humans, cholecalciferol and ergocalciferol, are hormonally inactive. Both undergo hydroxylation to 25-hydroxyvitamin D(2 or 3) in the liver, followed by further conversion to the active hormone, 1,25-dihydroxyvitamin D(2 or 3) in the kidney (or the placenta during pregnancy). 25-hydroxyvitamin D3 is also known as calcidiol, while the active form 1,25-dihydroxyvitamin D3 is also known as calcitriol. It is more difficult to find trivial name forms for the vitamin D2 group, although IUPAC recommends ercalcitriol for the active form of D2 (See nomenclature table).

"Vitamin D" based Name	Trivial Name	
Vitamin D2	ergocalciferol	
Vitamin D3	cholecalciferol	
25-Hydroxyvitamin D2	-none found-	
25-Hydroxyvitamin D3	calcidiol	
1,25-dihydroxyvitamin D2	ercalcitriol	
1,25-dihydroxyvitamin D3	calcitriol	

Measurement of the vitamin D parent compound, whether D3 or D2, has limited clinical value because, with a half-life of about 1 day, the value reflects mostly recent sun exposure or intake (there may be a utility in assessing absorption from the gut). Vitamin D status is generally determined by measuring the intermediate 25-hydroxyvitamin D form, the major circulating form with a half-life of 2-3 weeks. Whether there is a value to distinguishing the relative contribution of 25-hydroxyvitamin D2 compared to D3 depends on the objective. Understanding vitamin D status generally requires a total number; however, the need to assess response to supplementation with vitamin D2, for example, may be helped with distinct reports on both forms. The active hormone, 1,25-dihydroxyvitamin D (2 or 3), has a short half-life of 4 - 6 hours, and its concentration is tightly regulated. This makes it a poor candidate for assessing nutritional vitamin D status, although its measurement has utility in differential diagnosis of hyper and hypocalcemia and bone and mineral disorders.

An alternative metabolism pathway in the kidney yields a 24,25-dihydroxyvitamin D form. This is the most prevalent dihydroxylated metabolite in circulation, but (unlike the 1,25-dihydroxyvitamin D forms), it is not hormonally active. The physiological role of 24,25-dihydroxyvitamin D is unclear, although it

has been suggested that the active hormone may self-modulate by shunting toward this pathway.

#### Specific Parts

#### Vitamin D3

Vitamin D plays important roles in maintaining calcium and phosphate levels, and in immune regulation, but its determination is complex due to multiple metabolic intermediates and 2 major forms. Vitamin D3, also known as cholecalciferol, is the parent compound of one of the 2 major families of vitamin D (D2 and D3). Vitamin D3 is the form of vitamin D that is endogenously produced in the skin of vertebrates (including humans) upon exposure to sunlight (specifically UV B). It can also be obtained from dietary animal products, or dietary supplements. Vitamin D3, whether produced endogenously or ingested, is a prohormone form that is not active until further metabolism first to 25-hydroxyvitamin D3 (in the liver), then finally to 1,25-hydroxyvitamin D3 (in the kidney or placenta) . Measurement of the vitamin D parent compound, whether D3 or D2, has limited clinical value because, with a half-life of about 1 day, the value reflects mostly recent sun exposure or intake (there may be a utility in assessing absorption from the gut). Vitamin D status is generally determined by measuring the intermediate 25-hydroxyvitamin D form, the major circulating form with a half-life of 2-3 weeks. The need to assess response to supplementation with vitamin D2, for example, may be helped with distinct reports on both forms.

#### Vitamin D2

Vitamin D plays important roles in maintaining calcium and phosphate levels, and in immune regulation, but its determination is complex due to multiple metabolic intermediates and 2 major forms. Vitamin D2, also known as ergocalciferol, is the parent compound of one of the 2 major families of vitamin D (D2 and D3). Vitamin D2 is the form of vitamin D that is not endogenously produced in the skin. It is produced upon UV radiation of ergosterol, which occurs in molds, yeast, and certain plants, and its major introduction into humans is via commercial supplementation. Vitamin D2 is a prohormone form that is not active until further metabolism first to 25-hydroxyvitamin D2 (in the liver), then finally to 1,25-hydroxyvitamin D2 (in the kidney or placenta) . Measurement of the vitamin D parent compound, whether D3 or D2, has limited clinical value because, with a half-life of about 1 day, the value reflects mostly recent sun exposure or intake (there may be a utility in assessing absorption from the gut). Vitamin D status is generally determined by measuring the intermediate 25-hydroxyvitamin D form, the major circulating form with a half-life of 2-3 weeks. The need to assess response to supplementation with vitamin D2, for example, may be helped with distinct reports on both forms.

#### 25-Hydroxyvitamin D, 25-Hydroxyvitamin D2, and 25-Hydroxyvitamin D3

The 25-hydroxyvitamin D intermediate is the major circulating metabolite of vitamin D with a half-life of 2-3 weeks, and it is the most useful measure of vitamin D status. The determination of vitamin D is complex due to multiple metabolic intermediates and 2 major forms, vitamin D2 and D3. The lack of specification of the form generally indicates that both are included. Vitamin D3 is the form of vitamin D that is endogenously produced in the skin of vertebrates (including humans) upon exposure to sunlight (specifically UV B), whereas vitamin D2 is produced upon UV radiation of ergosterol, which occurs in molds, yeast, and certain plants, and its major introduction into humans is via commercial supplementation, although both D3 and D2 can be included as supplements. The 25-hydroxyvitamin D metabolites of both forms (also known as calcidiol in the case of D3) are produced in the liver from the corresponding parent compound. Whether there is a value to distinguishing the relative contribution of 25-hydroxyvitamin D2 compared to D3 depends on the objective. Understanding vitamin D status

generally requires a total number; however, the need to assess response to supplementation with vitamin D2, for example, and other specific cases, may be helped with a distinct reports on both forms.

#### 1,25-Hydroxyvitamin D, 1, 25-Hydroxyvitamin D2, and 1, 25-Hydroxyvitamin D3

1,25-hydroxyvitamin D is the physiologically active form of vitamin D. When metabolically activated to this form, vitamin D plays important roles in maintaining calcium and phosphate levels, and in immune regulation. It increases intestinal absorption of calcium and phosphorus, and in concert with parathyroid hormone increases bone resorption. There are 2 major forms of vitamin D, each of which can be activated to a 1,25-dihydroxy form (also known as calcitriol in the case of D3 and ercalcitriol in the case of D2). Vitamin D3 is the form of vitamin D that is endogenously produced in the skin of vertebrates (including humans) upon exposure to sunlight (specifically UV B). It can also be obtained from dietary animal products, or dietary supplements. Vitamin D2 is the form of vitamin D that is not endogenously produced in the skin. It is produced upon UV radiation of ergosterol, which occurs in molds, yeast, and certain plants, and its major introduction into humans is via commercial supplementation. Vitamin D, whether produced endogenously or ingested, is a prohormone form that is not active until further metabolism first to 25 hydroxyvitamin D3 (in the liver), then finally to the active 1,25 hydroxyvitamin D3 (in the kidney or placenta). The active hormone, 1,25-dihydroxyvitamin D (2 or 3), has a short half-life of 4-6 hours, and its concentration is tightly regulated. This makes it a poor candidate for assessing nutritional vitamin D status, although its measurement has utility in differential diagnosis of hyper and hypocalcemia and bone and mineral disorders.

#### 24,25-Dihydroxyvitamin D3

24,25-dihydroxyvitamin D3 is a compound which is closely related to 1,25-dihydroxyvitamin D3, the active form of vitamin D3, but (like vitamin D3 itself and 25-hydroxyvitamin D3) is inactive as a hormone. It is produced from 25-hydroxyvitamin D3 by alternative metabolic pathway in the kidney. The physiological role of 24,25-dihydroxyvitamin D is unclear, although it has been suggested that the active hormone may self-modulate by shunting toward this pathway.

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# **Appendix H - LOINC Committee Members**

#### Name

Ray Aller John Baenziger Suzanne Bakken Pam Banning Rita Barsoum James Barthel Dean Bidgood Bruce Bray James Campbell Jim Case Jim Cimino Lori Carey Robert Dolin James K Fleming Arden Forrey **Bill Francis** Pavla Frazier Alan Golichowski Barry Gordon Brian Griffin Gil Hill Stan Huff Cindy Johns William (Bill) Karitis Ted Klein Jeff Lamothe Lee Min Lau Diane Leland Pat Maloney Doug Martin Susan Matney Ken McCaslin Clem McDonald Kathy Mercer Deirdre O'Neill Judy Ozbolt Dan Pollock **Rick Press** Christine Raine Angelo Rossi Mori Jon Rosenblatt Shawn Shakib

John Stelling

Steve Steindel

Anders Thurin

Wavne Tracv

Larry West

Pat Wilson

Daniel Vreeman

Thomas White

Warren Williams

Jeff Suico

#### Organization

University Southern California Pathology Indiana University Hospital Columbia School of Nursing 3M Kaiser Permanente H. Lee Moffitt Cancer Center Duke Medical Center University of Utah University of Nebraska California Veterinary Diag Labs Columbia Presbyterian Med Center Canada Health Infoway Mayo Foundation Laboratory Corp of America University of Washington Augilent Technologies University of Utah Indiana Univ. Dept. of Medicine **C/NET Solutions Ouest Diagnostics** Hospital for Sick Children Intermountain Health Care LabCorp Department of Defense, U.S. Navy Klein Consulting, Inc USAF 3M HIS Riley Hospital for Children **Ouest Diagnostics** Roudebush VA Medical Center Intermountain Health Care Quest Diagnostics NLM Lister Hill National Center for **Biomedical Communications Regenstrief Institute** National Medical Services Association Vanderbilt University Centers for Disease Control Oregon Health Sciences University Parners Healthcare, Inc. Instituto Tecnologie Biomediche Mayo Medical Laboratories 3M HIS World Health Organization CDC Eli Lilly & Co. University Hospital Health Patterns, LLC Regenstrief Institute/IUSOM **ARUP** Laboratories New York State Office of Mental Health CDC 3M HIS

Location

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