Logical Observation Identifiers Names and Codes (LOINC®)



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Preface

LOINC provides a set of universal names and ID codes for identifying laboratory and clinical test results. 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 1238³ or its sister standard, HL7, 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 information systems cannot fully "understand" the results they receive unless they either adopt the producer's laboratory codes (which is impossible if information 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. 5

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 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.

Forrey AW, McDonald CJ, DeMoor G, Huff, SM, Leavelle D, Leland D, Fiers T, Charles L, Stalling F, Tullis A, et. al. The logical observation identifier names and codes (LOINC) database: A public use set of codes and names for electronic reporting of clinical laboratory results. Clinical Chemistry 1996;42:81-90. [PubMed: 8565239]

² McDonald CJ, Huff SM, Suico JG, Hill G, Leavelle D, Aller R, Forrey A, Mercer K, DeMoor G, Hook J, Williams W, Case J, Maloney P. LOINC, a universal standard for identifying laboratory observations: A 5-Year update. Clinical Chemistry 2003;49:624-633. [PubMed: 12651816]

³ ASTM E1238-94. Standard Specification for Transferring Clinical Observations Between Independent Computer Systems. Philadelphia: American Society for Testing Materials; 1994.

⁴ Health Level Seven. An application protocol for electronic data exchange in healthcare environments. Version 2.3. Ann Arbor, MI: Health Level Seven, Inc.; 1997.

⁵ McDonald CJ, Park BH, Blevins L. Grocers, physicians, and electronic data processing. AMA Continuing Medical Education Newsletter 1983;1:5-8.

- 4. System the type of sample e.g., urine, blood.
- 5. *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. *Method* where relevant, the methodology 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), textbooks of clinical pathology (e.g., Henry and Tietz), the expertise and work of the LOINC members, and EUCLIDES. We have also reviewed the master test files of eight 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 <u>Appendix D</u>.

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

International Union of Pure and Applied Chemistry/International Federation of Clinical Chemistry. The Silver Book: Compendium of terminology and nomenclature of properties in clinical laboratory sciences. Oxford: Blackwell Scientific Publishers; 1995.

⁷ Henry JB. Clinical Diagnosis and Management by Laboratory Methods. Philadelphia: W.B. Saunders; 1994.

⁸ Burtis CA, Ashwood ER (editors). Tietz Textbook of Clinical Chemistry, 2nd ed. Philadelphia: W.B. Saunders; 1994.

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 http://loinc.org/license. The LOINC Table, supporting documentation and supplemental files, and the RELMA® mapping program are all made available by the Regenstrief Institute on the LOINC website (http://loinc.org).

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® database format.

• 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).

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®) 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.

Additionally, Regenstrief provides a web-based search application available at http://search.loinc.org 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 LOINC is to create universal identifiers (names and codes) used in the context of existing HL7, CEN TC251, ISO TC215, ASTM, and DICOM order and observation exchanges employed in the various sub-domains of healthcare informatics, such as Clinical Laboratory Information Management Systems (LIMS) and Electronic Health Record Systems (EHR). Specifically, the identifier can be used as the coded value for an observation in any other standard that uses the observation/observation value paradigm, whether messages, documents, application programming interface (API), etc. For example, LOINC codes are used widely in the OBX segment "Observation Identifier" field (OBX-3) of an ORU HL7 (HL7 version 2.x or ASTM 1238-9410) message. In this way, LOINC codes provide "universal" identifiers that allow the exchange of clinical data between heterogeneous computing environments.

To facilitate this process, each identifier requires a fully specified name created in a standard way. This way, 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 the 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 47,000 users in 166 different countries. LOINC adoption worldwide has steadily accelerated. We are now adding more than 600 new users per month. Many countries have adopted

⁹ McDonald CJ, Tierney WM. Computer-stored medical records. Their future role in medical practice. JAMA. 1988 Jun 17;259(23):3433-40. Review. [PubMed: 3286915]

¹⁰ Dick AS, Steen EB (editors). The computer-based patient record. Washington DC: National Academy Press; 1991.

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 (http://search.loinc.org) now have multilingual searching capabilities. We have described how our approach to translations supports international adoption, and we highlight the work of our international colleagues in a special section on the LOINC website at http://loinc.org/international. We provide a voluntary directory of organizations that have adopted LOINC on our website (http://loinc.org/adopters) 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 guide. 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

Vreeman DJ, Chiaravalloti MT, Hook J, McDonald CJ. Enabling international adoption of LOINC through translation. J Biomed Inform. 2012 Aug;45(4):667-73. doi: 10.1016/j.jbi.2012.01.005. Epub 2012 Jan 21. [PubMed: 22285984]

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. However, such information is reported in separate fields in the HL7 message (e.g., OBX-17 can carry very detailed method information). It is not embedded in the name 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 nontest 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.

The clinical portion of the LOINC database covers tests, measures, and other observations about a patient that can be made without removing a specimen from them. LOINC has codes for observations like vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, pulmonary ventilator management, radiology studies, clinical documents, selected survey instruments (e.g. Glasgow Coma Score, PHQ-9 depression scale, CMS-required patient assessment instruments), and other clinical observations.

1.4 The LOINC code

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 or 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 *Time Aspect* of the measurement (e.g., is it over time or momentary), the type of *System* or 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.

Note

Each attribute of the LOINC Fully Specified Name other than the *Method* should be valued for every active LOINC term. In some cases, such as for panel terms, one or more attribute values may be a dash (-), but none of the primary attributes should have null values other than the *Method*. We have not declared a file specification definition requiring a value for these name fields because they were null for some older, deprecated terms. In the rare case that a new term is released without an attribute value, that term will be deprecated and a new term will be created as a replacement.

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*) 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
"Super System" (patient, donor, blood product unit)	2.5.2
Type of <i>Scale</i> (nominal, ordinal, quantitative)	2.6
Method Type	2.7

We used Tietz, ¹² Henry, ¹³ IUPAC, ¹⁴ EUCLIDES, ¹⁵ diagnostic microbiology textbooks, such as Mahon and Manuselis, ¹⁶ the American Association of Blood Banking, ¹⁷ and other sources as well as the expertise of the individuals or the committee to choose preferred names.

Here are some 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 O2", and so on.

¹² Burtis CA, Ashwood ER, Burns DE (editors). Tietz Textbook of Clinical Chemistry, 5th ed. Philadelphia: W.B. Saunders; 2013.

¹³ Henry JB. Clinical Diagnosis and Management by Laboratory Methods. Philadelphia: W.B. Saunders; 1994.

¹⁴ International Union of Pure and Applied Chemistry/International Federation of Clinical Chemistry. The Silver Book: Compendium of terminology and nomenclature of properties in clinical laboratory sciences. Oxford: Blackwell Scientific Publishers; 1995.

Euclides Foundation International. EUCLIDES Laboratory Investigation Codes. Available from Dr. Georges DeMoor, Euclides Foundation International nv, Excelsioriaan 4A, B-1930, Zaventern, Belgium. Phone: 32 2 720 90 60.

¹⁶ Mahon CR, Manuselis G (editors). Textbook of Diagnostic Microbiology. Philadelphia: W.B. Saunders; 1995.

¹⁷ Walker RH. American Association of Blood Banks Technical Manual. 11th ed. Bethesda, MD: Amer Assoc of Blood Banks, 1993.

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 I	Human t-cell lymphotropic virus-l	
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*. 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. 19
- 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.

Euzéby JP. List of bacterial names with standing in nomenclature: a folder available on the internet. Int J Syst Bacteriol 1997;47:590-592. [PubMed: 9103655]. (List of prokaryotic names with standing in nomenclature. [Update 2008 May 2, cited 2008 June]. Available from: http://www.bacterio.net)

¹⁹ Virus taxonomy: classification and nomenclature of viruses: Ninth Report of the International Committee on Taxonomy of Viruses. (2012) Ed: King, A.M.Q., Adams, M.J., Carstens, E.B. and Lefkowitz, E.J. San Diego: Elsevier Academic Press. Available from: http://www.ictvdb.org/virusTaxonomy.asp

- 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. One exception to this rule is that we will use the widely accepted vitamin name for nutrition intake terms.
- 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 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., nordoxepin not desmethyldoxepin.
- 2.1.2.21 Abbreviate units of time, such as Y for year, D for day, and W for week. This only applies to time as a unit of measure, e.g., in the past 7D, and not when year or day are used to refer to a date or general time construct, e.g., next year.

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 for example, commas will appear in multiple substitutions of alkyl chains per the CAS standard, dashes, asterisks and colons will appear in HLA allele names, colons will appear in the names of some microorganisms, 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 we then changed 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	Lua	
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.

2.1.6 Exponents

We will use the phrase "exp" to indicate an exponent in the *Component*. According to the Unified Code for Units of Measure (UCUM), exponents are typically represented using an asterisk (*) or carat (^). However, asterisks and carats both already have defined meanings in the LOINC. (As described later, asterisks are used in variables that report another specific part of the LOINC name, and carats are used as delimiters of subparts.) For this reason, we use "exp" to avoid ambiguity. For example, the concept "height raised to the power of 2.7" is represented as "height exp 2.7".

2.1.7 Use of the slash (/)

In the *Component*, a slash (/) is used to distinguish between a numerator and a denominator (a.k.a. *Divisor*) for terms that represent fractions or ratios. For example, **Basophils/100 leukocytes** represents the fraction of basophils out of the parent population of 100 leukocytes, and **Lecithin/Sphingomyelin** represents the ratio of lecithin to sphingomyelin. In the *System*, a slash is used as a conjunction and means "or". A common example is **Ser/Plas**, which means that either Serum or Plasma is a suitable specimen for measuring a particular analyte.

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 bioavailable 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 or more constituents are measured as one quantity, each constituent should be named in the *Component* separated by a plus sign, e.g., **Cyclosporine+metabolites** or **Human papilloma virus** 16+18+31+33+35+45+51+52+56 DNA.

If multiple *Analytes* are measured separately, the *Analytes* are separated by an ampersand (&) surrounded by spaces. Two cases that use the ampersand convention are the names of panel terms and impression terms.

The naming of panel terms is described more completely in <u>Section 8</u>, but here we describe its use of ampersand. The enumerated child elements of a panel are each measured individually, so we often use ampersand in the name of the parent term (the panel term), e.g., **ABO & Rh group panel**. This particular example of ABO & Rh group also illustrates how panel terms using ampersand are different than an observation term with ampersand. The **ABO & Rh group panel** is linked to two separate observation codes, one for ABO and another for Rh group, that each carries its own result. An **ABO & Rh group** observation

term would carry a combined (but separately measured) result (e.g. A positive). Either term could be used in ordering, depending on the reporting approach.

Note

In general, we recommend using separate observation terms for results that are measured separately. Older LOINC terms for assays that produce individual results for two or three analytes were sometimes modeled in LOINC as a single term with multiple analytes separated by "&". The Answer List associated with such terms would include answer values combining the results from multiple analytes. Moving forward, only assays that truly produce a single result will be modeled this way; otherwise, a panel will be created with individual child terms for each separate result. The second part of the fully specified

Impression terms may also use 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.

In some cases, panel or impression *Components* contain both a plus sign (+) and an ampersand (&), for example, **Human papilloma virus 16 & 18 & 31+33+35+39+45+51+52+56+58+59+66+68 DNA** impression. In this example, the HPV 16 and HPV 18 impressions are both described separately, as is the impression for the group HPV 31+33+35+39+45+51+52+56+58+59+66+68, which is measured as a single quantity.

2.2.1.2 Divisor

Some *Analytes* contain a *Divisor*, which represents the denominator of a result that is expressed as a fraction or ratio. The numerator does not have a separate name because by default the *Analyte* is the numerator for all terms. In *Analytes* that do have a *Divisor*, the numerator is separated from the *Divisor* by a slash (/). For example, in the *Analyte* **Albumin/Protein.total**, the numerator is **Albumin** and the *Divisor* is **Protein.total**, so that the overall *Analyte* represents albumin as a fraction of the total protein. Similarly, **Albumin/Creatinine** represents the ratio of albumin to creatinine. Note that in the former case, the *Property* would be a type of **Fraction**, since albumin is a type of protein (i.e., albumin represents a fraction of total protein), whereas in the latter, the *Property* would be a type of **Ratio**, because the amount of albumin is being compared to the amount of creatinine, but neither of them is a parent compound of the other.

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 *Challenge* 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 the lowest drug level is reached (varies with drug)		
RANDOM	RANDOM Time from the challenge, or dose not specified (random)		
n minutes/hours/day	s/weeks/months/etc. after challenge begu	ın:	
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	1½ hour (90 min) post challenge	3W	3 weeks
2H	2 hours post challenge	4W	4 weeks
2.5H	2½hours post challenge	1MO	1 month (30 days) post challenge
3H	3 hours post challenge	2MO	2 months (60 days) post challenge
4H	4 hours post challenge	3МО	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**, **^postoperative**, 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	^	2nd specimen	post		XXX challenge			
17-Hydroxyprogesterone	^	6H	post		XXX challenge			
11-Deoxycortisol	^		post		XXX challenge			
Calcium	^	12H	post		CFst			
C peptide	^		post		CFst			

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**,²⁰ 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			
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			
Ю	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			

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

Examples:

```
Glucose^30M post 100 g glucose P0: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.

2.2.2.1 Reporting the baseline measure as part of a Challenge test

Through LOINC release 2.52, we have defined one baseline term for different *Challenge* batteries when the *Challenge* is given by the same dose and route. For example, we define one baseline serum glucose for the 100 gm oral glucose tolerance test regardless of the number of separate measurements defined in the battery:

```
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.

However, the number and variety of challenge terms users have been requesting are growing rapidly. It now appears impractical to create a baseline term for every dose and route combination. Furthermore, baseline measurements are not affected by the subsequent challenge and could in principle be reported simply as the "unadorned" measurement with no named relation to a coming *Challenge*. Therefore, we have created generic baseline "pre challenge" terms, for example, **Glucose^pre XXX challenge**. For these terms, the specifics of the challenge would be reported elsewhere.

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:On
```

Thus we distinguish a drug concentration from the drug dose by means of the *System* (sample), 4th part, of the test name (see <u>Section 2.5</u>). 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
```

Example Units: liters/minute or milliliters/second

```
Oxygen inhaled mechanism:Type:Pt:Dose:Nom
```

Comment: 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. We take this approach in part because there are too many levels of the variables and it is not feasible to represent them all.

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, antibody levels are measured before and after the immunization; similarly, evidence for acute infection is obtained 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. However, some systems 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. We include most of the relevant IUPAC quantitative *Property* types in LOINC. We also have a set of *Properties*, such as **PrThr** (Presence or Threshold), **Type**, **Seq** (nucleotide sequence), and **Loc** (geographic location), that are used for qualitative terms. (See <u>Table 8</u> for more examples.)

2.3.1 Quantitative Properties

2.3.1.1 Main quantitative 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 a number of WBCs divided by volume of blood, would have a *Property* of **number concentration**.

2.3.1.2 Quantitative **Property** category subtypes

Each of the above major *Property* categories has number of derivatives: **concentration**, **content**, **ratio**,

International Union of Pure and Applied Chemistry/International Federation of Clinical Chemistry. The Silver Book: Compendium of terminology and nomenclature of properties in clinical laboratory sciences. Oxford: Blackwell Scientific Publishers; 1995.

fraction, and **rate** (see LOINC properties table (<u>Table 8</u>)).

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 concentration (**RelMCnc**), and a ratio of catalytic concentrations from different specimens will have the property of relative catalytic concentration (**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% O2 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, for example:

Sodium renal clearance: VRat: 24H: Urine: On

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 106 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.

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 (http://search.loinc.org) hide these terms from the search results, but they can be displayed by adjusting the search limit settings in these programs.

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.

Examples:

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

Note

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

2.3.1.2.1 Arbitrary Concentration (ACnc)

ACnc means the number of arbitrary units in a volume (arbitrary concentration). We originally used ACnc as a "temporary" place-holder for observations with ordinal answers. We then transitioned to replacing ACnc with either Pr (for results simply based on whether the *Analyte* is present or not without being determined by a cut off value) or Threshold (for observations reported as "positive" or "negative" based on an internal threshold or cut off). As we updated existing terms with the new model, in many cases it was difficult to definitively know how results were determined. Therefore, as of release 2.56, we are using a single *Property* of PrThr to represent results based on either the presence or absence of an *Analyte* regardless of whether or not it is based on an internal cut off. This change was approved by the Laboratory LOINC Committee in June 2016. The display name will continue to say Presence. All of the existing terms with a *Property* of ACnc, Pr or Threshold and a *Scale* of Ord were updated to have the *Property* PrThr for the 2.56 release. A single term with *Property* ACnt and *Scale* Ord was also updated to have the *Property* PrThr.

Examples:

```
Clonazepam:PrThr:Pt:Ser/Plas:Ord

Hepatitis B virus surface Ag:PrThr:Pt:Ser/Plas:Ord:Confirm

Burkholderia mallei:PrThr:Pt:XXX:Ord:Organism specific culture

VKORC1 gene.c.1173C>T:PrThr:Pt:Bld/Tiss:Ord:Molgen
```

The *Property* of **Prid** will continue to be used when the result is selected from a list of organisms, as described above.

2.3.2 Qualitative Properties

Qualitative *Properties* describe what is being measured for non-quantitative laboratory and clinical concepts. Such *Properties* describe a wide variety of results, such as whether or not an analyte is present, the specific type of analyte detected, a person's address, telephone number, or e-mail address, or a clinical finding. Three of the most common qualitative *Properties* in LOINC are **PrThr**, **Prid**, and **Type**. These specific *Properties* are often confusing to LOINC users, so they are described in more detail in this section.

2.3.2.1 PrThr

The *Property* **PrThr** stands for "Presence or Threshold", meaning either the actual presence or absence of an analyte or that the amount of analyte detected is over some predetermined threshold.

2.3.2.2 Prid

Prid, which stands for "Presence or identity", is used for assays that detect whether or not an analyte of a particular kind is present, and if it is, to identify the specific analyte. One example of an assay that would be

represented by a LOINC term with *Property* **Prid** is a bacterial culture. When a culture is performed, it is not known in advance whether or not any bacteria will be present. Therefore, one possible result for a bacterial culture is "No growth". But if one or more types of bacteria are determined to be present, then the specific identity (e.g. *Staphylococcus aureus*) is determined and reported.

2.3.2.3 Type

The *Property* **Type** is used for assays that identify the specific analyte in cases when the baseline presence of the analyte is known. For example, if an isolate known to contain *Streptococcus pneumoniae* is further analyzed to determine the specific serotype, the serotype assay would have a *Property* of **Type**, not **Prid**, because the presence of the *Streptococcus* is already known.

2.3.3 More examples of LOINC Properties

Correct assignment of *Property* tends to be the most difficult task for new users of LOINC. <u>Chapter 4</u> describes more information about Properties for clinical terms, and <u>Appendix E</u> provides more explanation and many detailed examples.

	Table 8: Example LOINC Properties
Enzymatic 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
EntLogNum	Logarithmic Entitic Number
EntMass	Entitic Mass
EntNum	*Entitic Number
EntVol	*Entitic Volume
EntSub	Entitic Substance
EntSRto	Entitic Substance Ratio
Mass	
Mass	Mass
ArMass	Mass/Area
MCnc	*Mass Concentration
MCncSq	Mass Concentration Squared
MCnt	Mass Content
MDiff	Mass Difference
MFr	*Mass Fraction

MFr.DF	Mass Decimal Fraction		
MFrDiff	Mass Fraction Difference		
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/Milliequ			
RelSCnc	*Relative Substance Concentration		
Sub	*Substance Amount		
SCnc	*Substance Concentration		
SCncSq	Substance Concentration Squared		
SRto	*Substance Ratio		
SCnt	*Substance Content		
SFr	*Substance Fraction		
SFr.DF	Decimal Substance Fraction		
SRat	*Substance Rate		
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		
ArVol	Volume/Area		
	, 5, 5, 1, 5, 4		

ArVRat	Volume Rate/Area		
VFrDiff	Difference in Volume Fraction		
VPctDiff	Percent Volume Difference		
VRtoPctDiff	Percent Volume Ratio Difference		
Time			
ClockTime	Clock Time		
Time	Time Duration		
TimeDif	Difference in Time Duration		
TimeFr	Time Fraction		
TRto	Time Ratio		
TQ2	Timing Quantity 2		
RelTime	*Relative Time		
Date	Date		
DateRange	Date Range		
DtTmRange	Date and Time Range		
TmStp	Time Stamp—Date and Time		
TmStpRange	Time Stamp Range		
Arbitrary			
ACnc	Arbitrary Concentration		
ACnt	Arbitrary Content		
ThrACnc	Threshold Arbitrary Concentration		
ARat	Arbitrary Rate		
LaCnc	Log Arbitrary Concentration		
RelACnc	Relative Arbitrary Concentration		
AFr	Arbitrary Fraction		
Other properties			
Accel	Acceleration		
Addr	Address		
Anat	Anatomy		
Angle	Angle		
Aper	Appearance		
Arb	*Arbitrary		
Area	Area		
ArArea	Area/Area		
AreaFr	Area Fraction		
AreaRto	Area Ratio		
Bib	Bibliographic Citation		
Circ	Circumference		
CircFr	Circumference Fraction		
Class	*Class		
ColorRto	Color Ratio		
Compli	Compliance		
CompliRto	Compliance Ratio		
Cmplx	Complex		
Desc	Description		

Diam	Diameter	
Dosage	Dosage	
Elpot	Electrical Potential (Voltage)	
ElpotRat	Voltage Rate (=Amperage)	
ElpotRto	Electrical Potential Ratio	
EmailAddr	E-mail Address	
ArEnrg	Energy/Area	
EngCnc	Energy Concentration	
EngCnt	Energy Content	
EngDiff	Energy Difference	
EngFr	Energy Fraction	
EngRat	Power = Energy/Time	
RelEngRat	Relative Power	
EngRatFr	Energy Rate Fraction	
EngRto	Energy Ratio	
Enrg	Energy	
Equ	Equation	
Fcn	Function	
Find	Finding	
FldConduct	Fluid Conductance	
FldResist	Fluid Resistance	
Force	Mechanical Force	
Freq	Frequency	
Нх	History	
Imp	Impression/interpretation of study	
ID.	Identifier	
Instrct	Instructions	
InvLen	Inverse Length	
Inverse VI	Inverse Inspired Volume	
Len	Length	
LenFr	Length Fraction	
LenRto	Length Ratio	
LogLenRto	Log Length Ratio	
ArLen	Length/Area	
Likelihood	Likelihood	
Loc	Location	
LogInvPct	Log Inverse Percent	
LogRtoElp	Log Ratio Electrical Potential	
MoM	Multiple of the Median	
Morph	Morphology	
NumRange	Number Range	
OD	Optical Density	
Osmol	*Osmolality	
Osmolarity	Osmolarity	
PctDiff	Percent Difference	
	. C. Conta Direct Cried	

Pn	Person Name		
PrThr	Presence or Threshold		
Prctl	Percentile		
Prid	Presence or Identity		
PPres	*Pressure (partial)		
PPresDiff	Difference in Partial Pressure		
PPresRto	Partial Pressure Ratio		
Pres	Pressure		
PresRat	Pressure Rate		
PressDiff	Difference		
PresRto	Pressure Ratio		
Quintile	Quintile		
Ratio	Ratio		
Range	Range		
RatDiff	Rate Difference		
RelRto	Relative Ratio		
RelSoundInt	Relative Sound Intensity		
Resis	Resistance		
ArResis	Resistance/Area		
SatFr	*Saturation Fraction		
Score	Score		
ScoreDiff	Score Difference		
ScoreRange	Score Range		
Seq	Nucleotide Sequence		
Shape	Shape		
Susc	Susceptibility		
Temp	*Temperature		
TempDiff	Temperature Difference		
Tele	Telephone Number		
Tscore	T Score		
TscoreDiff	T Score Difference		
Txt	Text		
Threshold	*Threshold		
ThreshNum	Threshold Number		
Titr	Dilution Factor (Titer)		
Туре	Туре		
URI	Uniform Resource Identifier		
VCF	Variant Call File		
Vel	*Velocity		
VelRat	Velocity Rate		
VelRto	*Velocity Ratio		
Visc	Viscosity		
Zscore	Z Score		
* = from IUPAC Silver Book	21		

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 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, as are look back periods for survey instruments.

The allowed values for non-point *Time Aspect* are defined as a syntax exactly like the syntax for the times in challenge tests, for example:

<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		
Enctr	Duration of an encounter (hospital stay, visit).		
Episode	Episode		
Gt 1H	Greater than 1 hour		
Ge 1 Hr	Greater than or equal to 1 hour		
Lt 1H	Less than 1 hour		

Procedure dur	Duration of the procedure (surgery, etc.)					
RptPeriod	Reporting period	Reporting period				
XXX	Not specified; time	will be reported in	another part of the electr	onic message		
* (star)	Life of the "unit". U	sed for blood produ	cts.			
Abbr.	Description	Description Abbr. Description Abbr. Description				
1M	1 minute	9H	9 hours	100D	100 days	
5M	5 minutes	10H	10 hours	180D	180 days	
10M	10 minutes	12H	12 hours	1W	1 week	
15M	15 minutes	18H	18 hours	2W	2 weeks	
20M	20 minutes	24H	24 hours	3W	3 weeks	
30M	30 minutes	48H	48 hours	4W	4 weeks	
45M	45 minutes	72H	72 hours	1Mo	1 month	
90M	90 minutes	1D	1 day	2Mo	2 months	
1H	1 hour	2D	2 days	3Мо	3 months	
2H	2 hours	3D	3 days	6Мо	6 months	
2.5H	2.5 hours	4D	4 days	12Mo	12 months	
3H	3 hours	5D	5 days	1Y	1 year	
4H	4 hours	6D	6 days	2Y	2 years	
5H	5 hours	7D	7 days	3Y	3 years	
6H	6 hours	14D	14 days	10Y	10 years	
7H	7 hours	30D	30 days	Lifetime	Lifetime	
8H	8 hours	90D	90 days			

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**^**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 **XXX** in the *System* to identify a material that is unknown or not specified — it could be solid or fluid, for example. **XXX** is also used in the *System* when the material is specified, but recorded elsewhere in the HL7/ASTM message. Yet, using **XXX** as a *System* can be problematic (see also <u>Section 2.5.1 - Special issues related to XXX as a System</u> below).

When should we lump a variety of specimen types under the nonspecific **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 *Component-System* 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**, meaning "either Serum or Plasma". Note that the use of a LOINC code with **Ser/Plas** as the *System* to report the result of a specific manufacturer's assay does not imply that the given assay is approved for use with both serum and plasma specimens; it simply means that the results obtained from testing serum and plasma are clinically equivalent, independent of which assay was used. 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 clinically 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.

As with **Ser** and **Plas**, when testing on various specimens is clinically equivalent and the system for the existing test(s) includes only one or a few of those systems, we will review such tests upon request and update them as appropriate to include the additional system(s). One such example is toxicology testing, in which at least a subset of tests (e.g., confirmatory) can be run on instruments that accept either **Ser**, **Plas** or **Bld** as the specimen, so we may update existing **Ser/Plas** or **Bld** terms to have the *System* **Ser/Plas/Bld** as appropriate.

If the test is run on a combination of specimens (such as a ratio of substance found in **CSF** and **plasma**), the sample types are joined with a "+", for example: **Plas+CSF**, **Ser+CSF**, or **Isolate+Ser**.

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. For example, the

SPM specimen segment of an HL7 message can be used to convey detailed information regarding the type of specimen, where and how it was collected, who collected it, and some basic characteristics of the specimen. Earlier versions of HL7 used OBR-17 as a field to report specimen source.

	Table 11: Example Laboratory System/sample Types				
Abbr.	Name	Abbr.	Name	Abbr.	Name
Abscess	Abscess	Exhl gas	Exhaled gas (breath)	Saliva	Saliva
Amnio fld	Amniotic fluid	Fibroblasts	Fibroblasts	Semen	Seminal fluid
Anal	Anus	Fistula	Fistula	Ser	Serum
Asp	Aspirate	Food	Food sample	Skin	Skin
Bil fld	Bile fluid	Gas	Gas	Sputum	Sputum
BldA	Blood arterial	Gast fld	Gastric fluid/contents	Sptt	Sputum - tracheal aspirate
BldL	Blood bag	Genital	Genital	Stool	Stool = Fecal
BldC	Blood capillary	Genital fld	Genital fluid	Sweat	Sweat
BldCo	Blood – cord	Genital loc	Genital lochia	Synv fld	Synovial fluid (Joint fluid)
BldMV	Blood- mixed Venous	Genital muc	Genital mucus	Tear	Tears
BldP	Blood – peripheral	Hair	Hair	Thrt	Throat
BldV	Blood venous	Inhl gas	Inhaled gas	Platelets	Thrombocyte (platelet)
Bld.dot	Blood filter paper	Isolate	Isolate	Tiss	Tissue, unspecified
Body fld	Body fluid, unsp	Isolate.meningitis	Isolate from patient with meningitis	Tigi	Tissue large intestine
Bone	Bone	WBC	Leukocytes	Tsmi	Tissue small intestine
Brain	Brain	Line	Line	Trachea	Trachea
Bronchial	Bronchial	Liver	Liver	Tube	Tube, unspecified
Burn	Burn	Resp.lower	Lower respiratory	Ulc	Ulcer
Calculus	Calculus (=Stone)	Lung tiss	Lung tissue	Urethra	Urethra
Cnl	Cannula	Bone mar	Marrow (bone)	Urine	Urine
СТр	Catheter tip	Meconium	Meconium	Urine sed	Urine sediment
CSF	Cerebral spinal fluid	Milk	Milk	Unk sub	Unknown substance
Cvm	Cervical mucus	Nail	Nail	Vag	Vagina
Cvx	Cervix	Nose	Nose (nasal passage)	Vitr fld	Vitreous Fluid
Col	Colostrum	Nph	Naspopharynx	Vomitus	Vomitus
Cnjt	Conjunctiva	Penile vessels	Penile vessels	Bld	Whole blood
Crn	Cornea	Penis	Penis	Water	Water
Dentin	Dentin	Pericard fld	Pericardial fluid	Wound	Wound

Dial fld	Dialysis fluid	Periton fld	Peritoneal fluid / ascites		
Dose	Dose med or substance	Dial fld prt	Peritoneal dialysis fluid		
Drain	Drain	Placent	Placenta		
Duod fld	Duodenal fluid	Plas	Plasma	XXX	See section 2.5.1
Ear	Ear	Plr fld	Pleural fluid (thoracentesis fld)		
Endomet	Endometrium	PPP	Platelet poor plasma		
Environmental Specimen	Environmental Specimen	PRP	Platelet rich plasma		
RBC	Erythrocytes	Pus	Pus		
Eye	Eye	RBCCo	Red Blood Cells Cord		

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 Special issues related to XXX as a 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 kind of specimen (insects, road kill, and ingested food) when the material is unknown or specified elsewhere in the HL7/ASTM message. 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 microorganisms 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

Entamoeba 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.

2.5.2 Super System (2nd subpart)

The second subpart of the *System* identifies a "super-system" when the source of the specimen is someone or something other than the patient and the result needs to be distinguished from the patient's results because they will be stored together in the patient's record. Examples of *Super Systems* include a blood product unit (**BPU**), a bone marrow donor, or a fetus. The *Super System* is also used when the clinical finding (history, physical) is about someone other than the patient and needs to be distinguished from the patient's findings, for example, a history of diseases in a family member recorded in the patient's chart. When the *Super System* is not included in a name, "patient" is the assumed default value.

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:PrThr:Pt:RBC:Ord

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

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", "7.8912", "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 that could be in many formats (XML, narrative, etc.)
Set	Set	Used for clinical attachments

2.6.1 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). 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.

2.6.2 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 (Ord).

2.6.3 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.

2.6.4 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

²² Stevens SS. Measurement, statistics, and the schemapiric view. Like the faces of Janus, science looks two ways--toward schematics and empirics. Science 1968;161:849-856. [PubMed: 5667519]

²³ Tang YW, Procop GW, Persing DH. Molecular diagnostics of infectious diseases. Clin Chem 1997;11:2021-2038. [PubMed: 9365385]

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.

2.6.5 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.

2.6.6 Multi

We strongly encourage all reporting to be at the most granular level of detail. That is, if three numbers were 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 embedded (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 elements 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. When a LOINC term does include a *Method*, it usually describes a type or class of method and does not make fine-grained distinctions except in special cases.

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 detailed information about the *Method* is irrelevant, but that it is not always useful or practical to bind it to the test name. It is an essential element of the internal quality assurance of laboratories and there are fields for reporting other details about the *Method* in HL7 and CEN TC251 test result messages.

	Table 15. Lar	poratory Method Type Abbreviations
Method	Abbr.	Comment
Agglutination	Aggl	
Coagulation Assay	Coag	To distinguish coagulation assays based on clotting methods that test function/activity from Immune methods that detect the presence of clotting factors and may or may not be functional assays.
Complement-dependent Cytotoxicity	CDC	
Complement Fixation	Comp fix	
Cytology Stain	Cyto stain	The staining method used for pap smears, fine needle aspirates and other cell stains.
DNA Nucleic Acid Probe	Probe	See <u>Section 2.7.1</u> for more information about probes.
Chromogenic/Enzymatic Assay	Chromo	To distinguish coagulation assays based on chromogenic (enzymatic) activity.
Immunoassay	IA	Encompasses all immunoassays with a few exceptions, including Immune Blot and Immune Fluorescence, which were created based on historic usage.
Flocculation Assay	Floc	
Hemagglutination Inhibition	HAI	
Hemagglutination	НА	Encompasses direct and indirect
Immune Blot	IB	Applies to techniques that include electrophoretic or chromatographic separation such that position (size) of the band is part of the assessment
Immune Fluorescence	IF	Encompasses DFA, IFA, FA. Usually applies to cells and smears examined microscopically so that both the "where" and the "what" can be assessed, but can also be used on fluids in a way similar to ELISA.
Latex Agglutination	LA	
Leukocyte Histamine Release	LHR	
Line blot	Line blot	A membrane strip pre-coated with a specific set of antigens in parallel lines that are incubated with antibodies in order to detect the targets of interest.
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	

Rapid Plasma Reagin	RPR	Microscopic flocculation test, using cardiolipin-lecithin-cholesterol antigen with carbon particles.
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.
Vertical Auto Profile	VAP	Developed by Atherotech, Inc.
Visual Count	VC	
Venereal Disease Research Laboratory	VDRL	Microscopic flocculation test

2.7.1 Methods for identifying nucleic acids

We distinguish *Methods* that detect nucleic acid based on two aspects of the assay: whether or not the target nucleic acid is amplified (copied), and how it is detected. We are still working on determining what the most important distinctions are in the variety of nucleic acid detection methods that are used, and may update our *Methods* to reflect these distinctions in the future. As of the 2.63 release, however, we use the following four *Methods*:

1. Probe-based detection without amplification (**Probe**)

Definition: A hybridization probe is a typically a short nucleic acid segment that binds to a complementary nucleic acid sequence that is specific to the target of interest. The probe is typically attached to signaling molecule in such a way that a signal is only generated when the probe binds to the target nucleic acid. In LOINC, the **Probe** method is used for assays that do not include either a nucleic acid amplification or a signal enhancement step.

2. Target amplification followed by probe-based detection (**Probe.amp.tar**), which is represented as **NAA+probe** in the *Short Name* and **NAA with probe detection** in the *Long Common Name*

Definition: The LOINC **Probe.amp.tar***Method* is used for assays that include a nucleic acid amplification step, in which many copies of the nucleic acid sequence(s) of interest are made, followed by detection of the target nucleic acid of interest using a hybridization probe. Nucleic acid amplification can be done using different techniques such as polymerase chain reaction (PCR). The primary difference between the **Probe.amp.tar** and **Non-probe.amp.tar** *Methods* is the technique used for target nucleic acid detection. Note that for historical reasons, this *Method* also includes older techniques for identifying PCR target amplification products, such as gel separation and staining to identify the fragments based on their expected sizes.

3. Signal amplification followed by probe-based detection (**Probe.amp.sig**), which is represented as **Probe+sig amp** in the *Short Name* and **Probe with signal amplification** in the *Long Common Name*

Definition: Probe with signal amplification is a lab method that uses a hybridization probe, which is a typically a short nucleic acid segment that binds to a complementary nucleic acid sequence that is specific to the target of interest, followed by a signal enhancement step, in which the signal that is generated when the probe binds to the target sequence is multiplied so that it is "brighter" and easier to detect. Signal amplification can be done using different techniques, including the branched-chain DNA (bDNA) method. In theory, signal amplification is more sensitive than a probe by itself because it generates a brighter signal per each copy of the target sequence that is present. In LOINC, the **Probe. amp.sig** method is assigned to codes for assays that do not include a nucleic acid amplification step.

4. Target amplification followed by non-probe based detection (Non-probe.amp.tar), which is

represented as **NAA+non-probe** in the *Short Name* and **NAA with non-probe detection** in the *Long Common Name*

Definition: The LOINC **Non-probe.amp.tar** method is used for assays that include a nucleic acid amplification step, in which many copies of the nucleic acid sequence(s) of interest are made, followed by detection of the target nucleic acid of interest using a method other than a hybridization probe, such as melt curve analysis or turbidity measurement. The primary difference between the **Probe.amp.tar** and **Non-probe.amp.tar** *Methods* is the technique used for target nucleic acid detection.

a. Historical information: In LOINC version 2.54, we added a new *Method* for target amplification with melt curve analysis (Melt.amp.tar) to distinguish assays that use melt curves rather than probes for analyte detection. For version 2.56, we replaced Melt.amp.tar with a more encompassing non-probe based *Method* (Non-probe.amp.tar) that is used for PCR assays with non-probe based detection technology, including melt curve analysis, and which still distinguishes from probe-based assays (Probe.amp.tar). The *Method* for the terms originally created with the Melt.amp.tar *Method* was updated to Non-probe.amp.tar for the 2.56 release, and Melt.amp.tar is no longer in use.

The tables below describe specific techniques that are included in each of the four *Methods* described above.

Table 14a: Examples of methodologies that are included in the Probe Method		
DNA probe	A fragment of labeled DNA, usually 100–1000 bases long, which can be used to detect the presence of nucleotide sequences that are complementary to the sequence in the probe.	
RNA probe	A fragment of labeled RNA, usually 100–1000 bases long, which can be used to detect the presence of nucleotide sequences that are complementary to the sequence in the probe.	
Table 14b: Examples of me	thodologies that are included in the Probe.amp.tar Method	
Polymerase chain reaction (PCR) with probebased target detection (e.g., conventional PCR, real-time PCR)	A technique that requires repeated cycles of heating and cooling to double the targeted nucleic acid sequence with each cycle. In conventional PCR, after the amplification is complete, the target is detected using a labeled probe; in real-time PCR, the target is detected using probes during the amplification process.	
PCR with target detection based on gel separation and staining of PCR products	PCR followed by gel separation and staining to identify the fragments based on their expected sizes. This older technique for identifying PCR amplification products is included in Probe.amp.tar for historical reasons.	
Transcription mediated amplification (TMA)	An isothermal technique that uses RNA polymerase and reverse transcriptase enzymes to amplify the targeted nucleic acid sequence.	
Nucleic acid sequence based analysis (NASBA)	An isothermal transcription-based amplification method specifically designed for the detection of RNA targets.	
Strand displacement amplification (SDA)	An isothermal amplification technique that relies on a strand-displacing DNA polymerase.	
Hybridization protection assay (HPA)	A chemiluminescent-based detection assay that uses specific oligonucleotide probes labeled with an acridinium ester (AE) enzyme that emits a chemiluminescent signal when the probe binds to the RNA target.	
Table 14c: Examples of me	thodologies that are included in the Probe.amp.sig Method	
Hybridization protection assay (HPA)	See description above.	
Branched chain DNA (bDNA)	Involves a series of hybridization reactions for the detection of a nucleic acid sequence. bDNA is commonly used for the diagnosis and monitoring of viral and bacterial infections.	
Hybrid capture	Involves nucleic acid hybridization and microplate chemiluminescent detection. A microplate is coated with tagged antibodies that bind nucleic acid hybrids, capturing the hybrid molecules to the microplate.	
Table 14d: Examples of meth	odologies that are included in the Non-probe.amp.tar Method	

Target amplification (e.g., using conventional PCR) with melt curve analysis	Amplification of a targeted nucleic acid sequence using a technique such as conventional PCR, followed by target detection by melt-curve analysis. DNA-binding dyes, such as SYBR Green I, are used to produce a melt-curve profile. The profile is based on the total fluorescence generated from the DNA-binding dye as it binds to melting double-stranded DNA as temperature changes.
Loop-mediated isothermal amplification (LAMP)	An isothermal nucleic acid amplification technique that uses 4-6 primers recognizing 6-8 distinct regions of target DNA. Synthesis is initiated by a strand-displacing DNA polymerase and two of the primers form loop structures to facilitate subsequent rounds of amplification.

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

2.7.2 Immune assays

Immune assays in the LOINC world include a large swath of tests. We have historically lumped together immune assays that detect the linking of antigens and antibodies via special signaling mechanisms, such as EIA, ELISA, chemiluminescence and other similar tests that produce one measure (quantitative or qualitative) of the analyte of interest. We thought of this class of tests as "EIA-like" and in the absence of an existing short acronym to describe their constituents, we borrowed **EIA** to provide this meaning in the *Short Name* and used **Immunoassay** in the *Long Common Name* to signal that this method type was not limited to pure EIA tests. In LOINC version 2.56, we changed the name of the **EIA** *Method* to **IA** (and **EIA.rapid** to **IA.rapid**), in order to mitigate some of the confusion regarding the EIA name. The *Long Common Name* will continue to use **Immunoassay** as it always has, and the *Short Name* will use **IA** rather than **EIA**.

Some immunologic tests have always had their own *Method* type and were never lumped in the category of EIA-Immune assays described above. Immune blot (**IB**) tests, **immune diffusion** and immune based flow cytometry (**FC**) tests have always had specific method names because they are different in that they usually yield multiple related observations.

Immune fluorescence tests (IFA, DFA and ACIF) also have had their own *Method* type, namely **IF**, because they can provide information about the presence or amount of a target analyte AND its location (or pattern) on a smear, tissue slice or cell. LOINC has also assigned distinct method types to some other immunologic tests including **VDRL**, **Latex fixation**, and other kinds of agglutination tests because these were their historic names or they had specialized uses or limits.

We classify peroxidase and all other non-IF immune stains of tissue under the *Method* category **immune stain**.

2.7.3 Immunoblot and Line blot Methods

LOINC has two different *Methods* for **Immunoblot** (**IB**) and **Line blot**. **IB** is used in cellular and molecular biology to identify a specific protein in a complex mixture extracted from cells. Gel electrophoresis separates polypeptide chains (subunits) into bands according to their molecular weight. The bands are transferred onto a membrane and incubated with a primary and secondary antibody to visualize the target subunits. The **Line blot** *Method* is similar in that it utilizes membrane strips that are pre-coated with a specific set of antigens in parallel lines that are incubated with antibodies in order to detect the targets of interest. However, LOINC distinguishes the two *Methods* based on when the electrophoretic/chromatographic separation occurs. In **IB**, the separation occurs in the testing laboratory, whereas in **Line blot**, it occurs during the manufacturing step and not in the testing laboratory.

2.7.4 Coagulation

We distinguish among three kinds of coagulation methods: those that measure the coagulation activity (Coag),

those that measure the coagulation factor via enzyme rate (**Chromo** or enzymatic), and those that measure the amount of the coagulant protein, not its activity. The *Method* that measures the amount of protein was called **Imm** until the 2.58 release, for which it was renamed **IA** to be consistent across laboratory classes.

2.7.5 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

2.7.6 Substrates used to measure enzyme activity

For tests that are measuring enzyme activity using various substrates, the name of the enzyme or enzyme group will be the *Component* and the substrate will be the *Method*:

Mitochondrial respiratory chain enzymes: CCnt: Pt: Fibroblasts: Qn: 1-14C-glutamate substrate

2.7.7 "Detection limit" Methods

In specific instances, including viral load testing, urine albumin measurement and certain hormones (e.g., thyrotropin), we have LOINC codes where the *Method* value is the detection limit for the test. These were primarily created based on industry requests to differentiate tests that have at least an order of magnitude (10x) difference in detection thresholds, because this detection limit information was deemed more important than the specific laboratory method that was used. For example, we have codes for urine albumin with the *Method* **Detection limit** <= **20** mg/L and **Detection limit** <= **1** mg/L, and we also have thyrotropin terms with *Method* **Detection limit** <= **0.05** mIU/L and **Detection limit** <= **0.005** mIU/L. In some cases, the detection limit values are not round numbers, e.g., **Detection limit** <= **3.47** pmol/L. This seemingly odd value of 3.47 pmol/L is the molar equivalent of 1.0 ng/dL.

Based on discussion at the June 2018 Laboratory LOINC Committee meeting, LOINC terms that specify a detection limit in the *Method* are no longer recommended for use, except in a select number of use cases such as thyrotropin and urine albumin. In general, we will not create new terms with such *Methods* because the detection limit is not actually a *Method* but rather a measure of the sensitivity of the test. Instead, we recommend using a more generic code, such as a term with **Probe.amp.tar** as the *Method* for a viral load, and reporting the detection limit separately using LOINC <u>87706-8</u> Laboratory device Detection limit.

2.7.8 "Confirm" Method outside of Drug/Tox

In a few special cases outside of Drug/Tox, we have codes with the *Method* **Confirm**. In each of these instances, the fact that the specific instance of the result is a confirmatory result is deemed more important than the specific laboratory method used to obtain the result. Two such cases include ABO & Rh group typing, and Hepatitis B virus surface antigen testing in pregnant women.

2.7.9 Special issues with Methods for clinical measures

2.7.9.1 Estimated versus measured values

For some kinds of clinical measures we distinguish the *Method* Reported from Estimated and Measured.

For example, reported body weight is the stated weight from a patient or surrogate. Estimated body weight is estimated by an observer, and measured would be the body weight as measured on a scale.

2.7.9.2 Oximetry

Use of **oximetry** as a *Method* can cause confusion. For details see the <u>Oxygen Saturation Technical Brief</u> at the end of this guide, but briefly, oximetry has several specific types, including pulse oximetry, co-oximetry and heme-oximetry. Unfortunately, at one time the word "oximetry" was used interchangeably with "pulse oximetry," which created confusion in LOINC because we have one *Method* called **oximetry** and another called **pulse oximetry**. To avoid ambiguity, as of version 2.54 we deprecated most of the terms with **oximetry** as the *Method*, and moving forward we will continue to review the ones that are remaining and create new terms with the *Method* **pulse oximetry** as needed.

2.7.10 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.).

2.7.10.1 Methods that include imaging modality and calculation

In some cases, the *Method* includes two concepts: the imaging modality and the method of calculation for the specific measure. Through LOINC version 2.50 we used the pattern <imaging modality>.<calculation>, for example, US.2D.Teichholz. This format, however, does not clearly differentiate between the two distinct concepts being represented. This was further complicated by our convention of using a dot (.) to specify the submodality (e.g. 2D). Beginning in LOINC version 2.52, we separated the two concepts with a plus (+) rather than a dot (.), so that US.2D.Teichholz became **US.2D+Calculated by Teichholz method**. We have now updated all existing terms, and are using this format going forward.

2.8 Use of curly braces {} in LOINC names

In <u>Section 2.5</u> we described the use of **XXX** in the *System* when the material is unknown or specified elsewhere in the HL7/ASTM message. In some domains, particularly clinical observations, we have adopted a newer style of notation with curly braces to indicate that the information is provided elsewhere.

For example, LOINC term <u>32491-3</u> represents a deep tendon reflex observation where the anatomic location is not specified in the term name:

Deep tendon reflex:Find:Pt:{Reflex location}:Ord:Observed

Such terms could be used in post-coordinated expressions where the value of "reflex location" is communicated elsewhere. The curly braces notation has the advantage over using **XXX** in some cases because it allows a more precise indication of the set of possible entities to expect for that piece of information. In the reflex example above, saying {reflex location} narrows the expected set of possible values down to those anatomic regions where a muscle tendon reflex can be observed.

We have made use of this notation primarily in the *System* and *Method* part of the name.

2.9 Short 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 40 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.

2.10 Long Common Names

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. In LOINC release 2.54, many of the echocardiography and ophthalmology were updated based on input from DICOM and the National Eye Institute, respectively.

Even after creating the *Long Common Name*, we have continued to receive periodic requests from users to produce "prettier" display names for use in user interfaces, etc. While systematically created LOINC *Long Common Names* can be guaranteed to be unique, they are sometimes not the most user-friendly. This is also true for our automatically-generated LOINC *Short Names*. However, mostly what users wish for are for names that leave out some of the defining attributes of the term (e.g. *Property, Scale*, and "default" specimens in the *System*) because they are unfamiliar to clinicians. This is problematic across all of LOINC because it would create ambiguous and duplicate names. For such reasons, we have always expected that users would link their own local preferred names to LOINC terms for use in reports and displays. Within a given local system context it may be possible to resolve the ambiguities created by names that omit these attributes. For example, if the user display always shows the reported units of measure, then having the *Property* in the display name may not be necessary.

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 <u>Appendix B</u>. 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 *Scale* will be ordinal (**Ord**) and the kind of *Property* will usually be presence (**PrThr**, for results based on the presence/absence of an analyte regardless of whether an internal cut off value is used to determine the ordinal result). 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.²⁴ In addition to the antigen or antibody, a modifier would be included in the super-system (the second subfield of the *System* field), to indicate whether testing was performed on the patient, donor, or blood product. Unless explicitly stated, testing is assumed to have been on a material collected from a patient. Additional information about the person identified in the *System*, such as the donor's name or relationship to patient, should be placed in other OBX or comment segments of the message.

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:PrThr:Pt:Ser/Plas^donor:Ord

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

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

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

Walker RH. American Association of Blood Banks Technical Manual. 11th ed. Bethesda, MD: American Association of Blood Banks, 1993.

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 measuring the number or percent of a population of cells that bear the specific marker(s) of interest, e.g., Cells.CDx. In other cases, the percent of a population of abnormal cells, such as blasts, is measured, for instance, Blasts.CD2 or Abnormal blood cells.CD5. LOINC Components for cells with single markers typically do not include a plus or minus sign after the marker because flow cytometry labs do not report single CD marker-negative results, so when the marker is reported, the plus is implied. In other words, the LOINC Component Cells.CD4 represents the presence of CD4, and we do not have a Cells.CD4- Component, because such a result is not reported. However, when multiple markers per cell are reported, the pluses and minuses are always included, for example:

```
Cells.CD3-CD8-CD57+
```

Two kinds of measures are of interest, as described below.

3.3.1 Number of cells containing the marker

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 marker

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
```

3.3.3 Specifying the parent cell population

Historically, the most common cell marker tests were measuring the marker(s) on a population of lymphocytes, such as CD4+ and CD8+ counts, and the LOINC *Divisor* for the terms representing the number fraction was simply specified as **100** cells, where the fact that the 100 cells are lymphocytes was understood. Over the last several years, cell markers have become more common in the diagnosis and monitoring of a variety of immune deficiencies and hematologic malignancies, and for these tests, the parent cell population may be not necessarily be lymphocytes. In order to fully specify what is being measured, many newer LOINC terms include the cell marker(s) that define the parent population in the *Divisor*. So for example, the following term is used to report the percent of cells that do not express CD4 or CD8 out of a population of cells that express CD3 and T-cell receptor (TCR) alpha and beta:

80699-2 CD4-CD8-/100 CD3+TCR alpha beta+ cells in Blood

However, in some cases, the parent population may vary depending on the clinical context and/or the laboratory, so we also have newer terms that have 100 cells as the Divisor. For these, we recommend reporting the parent cell population using a separate LOINC term, <u>32760-1</u> Cell type in Unspecified specimen.

3.4 Microbiology

3.4.1 Microbiology cultures

The inherent complexity in reporting microbiology culture results presents unique challenges for the goal of standardized observation names.

3.4.1.1 Result status

The 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.

3.4.1.2 Specimen

The 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.)

3.4.1.3 Descriptive results

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

3.4.1.4 Culture results

The organisms identified in a culture will be sent as result values in OBX segments. LOINC provides codes to identify the observation, but not for identifying the names of organisms that would appear as result values (i.e. in OBX-5). SNOMED CT is an appropriate source for these organism concepts.

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.

The LOINC naming model for routine cultures is:

Bacteria identified:Prid:Pt:<specimen>:Nom:Culture

Example names include:

```
Bacteria identified:Prid:Pt:Bld:Nom:Culture

Bacteria identified:Prid:Pt:Burn:Nom:Culture

Bacteria identified:Prid:Pt:Stool:Nom:Culture
```

The LOINC names for cultures are based on the expected observations they generate, e.g. "bacteria identified" or "virus identified". For most routine cultures the users are looking for bacteria. However, in some cases a routine culture may also grow out some fungi like yeasts. Such observations can also be reported under the same test code. But, since the culture would not be optimized for growing out fungi we have a bacteria-focused name.

It is worth emphasizing these culture terms are intended for use as both as orders and observations despite having a more result-oriented name. Furthermore, as a matter of good clinical practice, most laboratories perform susceptibility testing on any significant isolate on a reflex basis. So there is no need for codes that say "culture and sensitivity" because it is implied. Thus, an order for:

17928-3 Bacteria identified in Blood by Aerobe culture

would likely trigger several workflow steps, including bottle blood culture, bacteria isolation, identification, and antimicrobial susceptibility testing.

Note

At the current time, a single code for a routine or organism-specific culture is recommended for reporting the results of the bottle culture, bacterial isolation, and identification. Historically, all of these steps have been included in the laboratory workflow under the "culture" umbrella, and individual results for each step have not been reported to or stored in the patient's record. Susceptibility testing would be reported with separate susceptibility terms as described in Section 3.5.

LOINC names for *Methods* of staining a sample/material directly (where many descriptive observations are possible) include:

```
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:PrThr: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

3.4.2 Properties for culture terms

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 presence (**PrThr**) and the *Scale* ordinal (**Ord**).

3.4.3 Microorganism identification based on nucleic acid targets

PCR-based testing for the presence of microorganisms is becoming more common. Early on, we received requests for and created codes with *Components* such as **Acinetobacter baumannii DNA** or **Influenza virus RNA**. More recently, we have received requests for tests that detect bacteria, viruses, and other pathogens based on a specific genetic target. Thus, LOINC now contains terms with more specific *Components* such as **Clostridium difficile toxin A+B (tcdA+tcdB) genes** and **Zika virus envelope (E) gene**.

As genetic testing continues to evolve, distinguishing the specific analyte (i.e. the genetic target) will be important for understanding the differences between tests, interpreting the results, and guiding further testing. Therefore, we will continue to create new LOINC codes that specify the gene targets, and ask requesters of new LOINC codes to supply this information. This specificity is important for bacterial identification, but also for other pathogens.

3.5 Antimicrobial susceptibilities

The drug susceptibility tests are grouped together in the LOINC database under the *Class* **ABXBACT**. Various agencies, including the FDA and CLSI in the U.S. and EUCAST in Europe, publish guidelines for determining susceptibility of different organisms to different antimicrobials.

In LOINC, 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.

3.5.1 Susceptibility thresholds based on type of infection ("Breakpoints")

In most cases, susceptibility thresholds are the same for a given organism+antibiotic combination regardless of infection site or route of antibiotic administration. However, for some antibiotic+organism combinations, the threshold ("breakpoint") varies based on route of administration and/or type of infection, including meningitis, pneumonia, and urinary tract infection. These are two independent parameters: there are cases where one antibiotic could have multiple different breakpoints depending on the combination of route and type of infection, and others where one antibiotic will have a single breakpoint regardless of route and type of infection. For example, depending on whether or not the patient has suspected meningitis there are two different breakpoints for parenteral penicillin. But, there is a single breakpoint for vancomycin. The susceptibility test itself is carried out exactly the same way regardless of the breakpoint. It is only for the final step of assigning a susceptibility result that the specific breakpoint becomes important. These data are published by the same agencies (FDA, CLSI, EUCAST) that publish the common susceptibility thresholds.

Prior to the 2.58 LOINC release, we specified that the susceptibility threshold was based on a meningitis breakpoint in the *Component*, e.g., **Cefepime.meningitis**. However, the concept really identifies an antimicrobial susceptibility result for a patient with suspected meningitis rather than a susceptibility result for a meningitis form of the antibiotic. Therefore, as of LOINC 2.58, we moved "meningitis" from the *Component* to the *System*: **Isolate.meningitis**. In upcoming releases, we will also be adding codes with the *Systems* **Isolate. pneumonia** and **Isolate.UTI**.

Note that **Isolate.meningitis** (or ".pneumonia", ".UTI") indicates that the particular susceptibility result being reported is for an antibiotic that has a meningitis breakpoint and that the patient is suspected to have meningitis. This does not necessarily mean that a particular patient has meningitis. For the same patient with suspected meningitis, the result for an antibiotic that does not have a published meningitis breakpoint will be reported using a code with **Isolate** as the *System*.

3.5.2 Genotypic resistance testing and predicted susceptibility

Genotypic resistance testing is done to look for genes or gene mutations that confer resistance to a drug or class of drugs. The subtle difference between phenotypic susceptibility and genotypic resistance testing is that susceptibility testing is used to determine whether or not a particular organism's growth is actually inhibited in the presence of an antimicrobial, while testing for resistance mechanisms or genes is used to determine whether or not such genes or mutations are present and to predict whether the organism will be inhibited in the presence of a particular antimicrobial.

Various *Methods* are available to test for the genetic information (e.g., specific resistance genes or nucleotide alterations in native genes) that encodes resistance mechanisms, including **Probe.amp.tar**, **Non-probe. amp.tar**, and **Sequencing**. Until 2018, LOINC bacterial genotypic susceptibility testing terms used the specific *Methods* named above; however, as approved by the Laboratory LOINC Committee in June 2018, moving forward we are recommending using the **Molgen** *Method* for all bacterial molecular resistance testing to obviate

the need to create different terms for different molecular *Methods* (**Probe.amp.tar**, **Sequencing**, etc.). New terms will be created with the *Method* **Molgen**, and terms that were previously created with a *Method* other than **Molgen** will be reviewed and either updated to **Molgen** if not duplicative or the *Status* will be changed to Discouraged.

Historically, susceptibility testing was always phenotypic; it was always performed on an **Isolate**, which is a microorganism from a patient specimen that is grown and isolated on culture media. However, with new molecular techniques, genotypic testing can be performed directly on patient specimens without the pre-step of isolating the organism. Rather than create separate terms for every possible patient specimen that can be tested, the Laboratory LOINC Committee approved an approach in June 2018 to create single terms for each resistance gene or resistance-conferring mutation with the *System* **Isolate/Specimen**. These terms will represent assays that can be done using a traditional isolated colony or on a direct specimen. This approach does NOT imply that every manufacturer's genotypic assay is approved for testing on an isolate or any type of specimen.

Existing terms with **Isolate** or other specific specimens as the *System* will be reviewed and either updated to the same model if not duplicative or the *Status* will be changed to **Discouraged**.

LOINC terms that represent the predicted susceptibility of an organism to a particular antimicrobial based on the presence or absence of resistance genes or resistance-conferring mutations in native genes will contain the drug name or class in the *Component*, **Isolate/Specimen** as the *System*, and **Genotyping** as the *Method*. This model was also approved by the Laboratory LOINC Committee in June 2018.

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 (**Ord**) *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 drugs/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

Terms representing screening for the group as a whole:

```
"X":PrThr:Pt:Ord:{System}:Screen Example answers: present/absent
```

For example,

```
Amphetamines:PrThr:Pt:Urine:Ord:Screen Answer:present
```

Terms to identify the set of drugs/substances screened for by the group test. Here the answer will be a list of discrete drug/substance names or codes:

```
"X" tested for:Prid:Pt:{System}:Nom:Screen

Example answers: individual drugs that this screening test could detect, from a fixed list
```

For example,

```
Amphetamines tested for:Prid:Pt:Urine:Nom:Screen

Answer: amphetamine, methamphetamine, dextroamphetamine, levoamphetamine, pseudoephedrine
```

3.8.1.2 Identify the drugs or substances screened for (and perhaps other information) as narrative

Terms of this format carry answers that are reported as a "glob" of narrative text. 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.

```
"X" tested for:Prid:Pt:{System}:Nar:Screen

Example answers: individual drugs that this screening test could detect, reported as a "blob" of text or canned comment.
```

For example,

```
Amphetamines tested for:Prid:Pt:Urine:Nar:Screen
```

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 overthe-counter nasal decongestant inhalers, and a positive result must be confirmed by a quantitative method that rules out the non-abuse situation.

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

```
"X":PrThr:Pt:{System}:Ord:Confirm Example answers: present/absent
```

For example,

```
Amphetamines:PrThr:Pt:Urine:Ord:Confirm
```

Answer: present

3.8.1.4 List of the actual drug/substances confirmed

```
"X" positive:Prid:Pt:{System}:Nom:Confirm Example answers: a list of analytes detected
```

For example,

```
Amphetamines positive:Prid:Pt:Urine:Nom:Confirm Answer: dextroamphetamine, methamphetamine
```

3.8.1.5 Confirmatory testing reported as a set of observations (more common)

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

```
"X":PrThr:Pt:{System}:Ord:Confirm

Example answers: present/absent

"X":MCnc:Pt:{System}:Qn:Confirm

Example answers: a quantitative amount
```

For example,

or

```
Amphetamine:PrThr:Pt:Urine:Ord:Confirm
Dextroamphetamine:PrThr:Pt:Urine:Ord:Confirm
Methamphetamine:PrThr:Pt:Urine:Ord:Confirm
Levomethamphetamine:PrThr:Pt:Urine:Ord:Confirm
Example answers: present/absent
```

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
Answer:1000 ng/ml

Methamphetamine cutoff:MCnc:Pt:Urine:Qn:Confirm
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

```
"X" cutoff:MCnc:Pt:{System}:Qn:Screen
"X" cutoff:MCnc:Pt:{System}:Qn:Confirm
```

3.8.2.3 For commonly used cutoffs, such as those mandated by regulatory agencies, we provide pre-coordinated terms for reporting a "present/absent" result with the cutoff specified in the *Method* field

```
"X":PrThr:Pt:{System}:Ord:Screen>"N"
"X":PrThr:Pt:{System}:Ord:Confirm>"N"

For example,

Amphetamines:PrThr:Pt:Urine:Ord:Screen>1000 ng/mL
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:{System}:Nom:*
"X" confirm method:Prid:Pt:{System}:Nom:*
```

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

```
Amphetamines:PrThr: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 are typically reported as screens (ordinal), confirms (ordinal) or confirms (quantitative – usually mass or substance concentrations), though some labs also report as screen (quantitative). Ordinal terms for reporting individual substances should always specify a *Method* of **screen** or **confirm**.

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:PrThr:Pt:Urine:Ord:Screen

Example answer: present

3.8.4.2 Individual test screen (quantitative)

Methadone:MCnc:Pt:Urine:Qn:Screen

Example answer: 150 ng/ml

3.8.4.3 Individual test confirm (ordinal)

Methamphetamine:PrThr:Pt:Urine:Ord:Confirm

Example answer: present

3.8.4.4 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.

3.8.4.5 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":PrThr:Pt:Urine:Ord:Screen
"Analyte group":PrThr: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:*
"Analyte group" confirm method:Prid:Pt:Urine:Nom:*
```

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

Analyte:PrThr:Pt:Urine:Ord:Screen Analyte:PrThr: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.²⁵

LOINC term names follow the recommendations and nomenclature of other standards. As molecular genetic testing expands, we are evolving our naming conventions. Existing terms are being reviewed for compatibility with current naming conventions. An overall description of LOINC's approach to naming molecular genetics tests can be found in the Deckard et al²⁶ paper.

3.9.2 Brief review of molecular genetics terminology

For clarity, here we provide a brief introduction to some key genetics terminology. DNA consists of a series of nucleotides, nucleotides encode amino acids, and a string of amino acids forms a protein. There are four types of nucleotides (adenine, guanine, cytosine and thymine), and a sequence of three nucleotides that codes for one amino acid is called a codon. Codons are numbered from the first codon participating in the protein (in humans the codon for Methionine) starting with codon number 1. Locus refers to a specific DNA (or RNA) codon or the corresponding amino acid produced by this codon.

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.

The term "mutation" is usually applied to a genetic variant that causes a functional change in the gene and results in disease. 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.

Antonarakis, SE, and the Nomenclature Working Group. Recommendations for a nomenclature system for human gene mutations. Human Mutation 1998;11:1-3. [PubMed: 9450896]

Deckard J, McDonald CJ, Vreeman DJ. Supporting interoperability of genetic data with LOINC. J Am Med Inform Assoc. 2015 May;22(3):621-7. [PubMed: 25656513]

Alleles refer to different forms of a gene and are distinguished at the phenotype level. The term allele is usually applied to a genetic variant that does not cause a disease.

3.9.3 Background on molecular genetics testing methods

The main laboratory 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 homologies instead of antigen-antibody binding.

DNA chips provide a radical new way to identify DNA and RNA sequences. In the patented AFYMETRIX® 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.

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

3.9.4 General molecular genetics naming rules

LOINC's approach to naming tests makes use of established conventions. For naming genetic tests that target specific genetic variations, LOINC uses the Human Genome Organization (HUGO) Gene Nomenclature Committee's (HGNC) terminology to name the gene(s) and Human Genome Variation Society's (HGVS, http://varnomen.hgvs.org/) syntax to name the variation(s) of interest.

HGVS provides four different levels of naming gene defects 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 introns excluded. Since three nucleotides = one codon, 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 for the gene of interest, as it exists natively in the chromosome with introns included.
m	Identify the defect by counting from the first nucleotide in the full mitochondrial DNA sequence.

The HGVS recommendations have evolved over time. In our early approach, we used the extant protein-based naming convention to get the following name for the commonest mutation causing cystic fibrosis:

```
CFTR gene.p.F508del:PrThr:Pt:Bld/Tiss:Ord:Molgen
```

For clarity's sake, HGVS now prefers the three letter amino acid abbreviations over the single letter amino acid abbreviations we used in the above example.

We embrace 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. Under the current HGVS rules, the above name would be:

Where we still report variants at the amino acid level, we use the nomenclature for human gene mutations proposed by Beaudet²⁷ in the *Component* or in the LOINC 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	Α	Ala
Arginine	R	Arg
Asparagine	N	Asn
Aspartic acid	D	Asp
Cysteine	С	Cys
Glutamic acid	E	Glu
Glutamine	Q	Gln
Pyroglutamic acid	pQ	pGlu
Glycine	G	Gly
Histidine	Н	His
Hydroxyproline, 4(R)-L-	0	Нур
Isoleucine	1	lle
Leucine	L	Leu
Lysine	K	Lys
Methionine	M	Met
Phenylalanine	F	Phe
Proline	P	Pro
Serine	S	Ser
Threonine	Т	Thr
Tryptophan	W	Trp
Tyrosine	Υ	Tyr
Valine	V	Val
Unknown	X	

HGVS has made other changes in naming style. Overall they now prefer describing the variant at the coding DNA level as nucleotide changes rather than at the protein level as amino acid changes. The above cystic fibrosis mutation would have the following coding DNA-based name:

²⁷ Beaudet AL, Tsui LC. A suggested nomenclature for designating mutations. Human Mutation 1993;2 (4) :245-248. [PubMed: 8401532]

```
CFTR gene.c.1521_1523del:PrThr:Pt:Bld/Tiss:Ord:Molgen
```

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 coding DNA naming convention. (Realize, of course, that more than one nucleotide-level variation name can correspond to a single amino acid variation name.)

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 include the genetic disease name in the *RELATEDNAMES2* field of the database when the disease name is not part of the *Component*. This allows users to easily find the LOINC term by the disease name as well.

3.9.4.1 Specimens in molecular genetics

Blood is the most common specimen for molecular pathology studies. Leukocytes, bone marrow, tumors, products of conception and forensic specimens also contain DNA and are important specimens. 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, fixed tissue, and CSF.

3.9.4.2 Methods in molecular genetics

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**).

3.9.4.3 Narrative and document-level reporting in molecular genetics

Bulk narrative reports in molecular pathology are often used to provide results for mutation analyses, without reporting any discrete coded answers. We discourage the use of this approach because it is not useful for automated analyses. Since these kinds of results often include some structured elements, we will use the *Property* **Find** and *Scale* **Doc** beginning with version 2.54. The *Scale* of **Doc** represents a collection of information (e.g. results contained in a report) that are either structured or unstructured. To assist with structured reporting, we will attach to these terms specific <u>associated observations</u> that could be used to send data in a structured format. With this approach, labs will still have the flexibility to send text reports. However, we encourage them to also report key data as structured results using the associated observation variables so that it is more easily understood by computers. We plan to use this model for newly created terms

for molecular pathology tests and are contemplating the best approach for transitioning existing terms to this format over time.

3.9.5 Infectious diseases

For information about molecular genetics in the field of infectious diseases, see <u>Section 3.4.2 - Microorganism</u> <u>identification based on nucleic acid targets</u>.

3.9.6 Genetic conditions

3.9.6.1 Diagnostic assays for mutation analysis

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

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

3.9.6.1.1 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 <u>Table 19</u>) at codon #506.

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

```
F5 gene.p.R506Q:PrThr:Pt:Bld/Tiss:Ord:Molgen

Synonyms: Factor V Leiden, Factor V resistance, APC resistance gene

HFE gene.p.C282Y:PrThr:Pt:Bld/Tiss:Ord:Molgen

Synonyms: HLA-H gene, hemochromatosis gene

CFTR gene.p.F508 del:PrThr: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.

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":

- 1. no mutation (wild type)
- 2. heterozygous mutation (the mutation found in one gene)
- 3. 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.

Both document-level (*Scale* is **Doc**) and ordinal (*Scale* is **Ord**) codes are available in the LOINC database for single variant tests. In cases where more than one variant is tested, a nominal (**Nom**) *Scale* will be used. As mentioned above, we encourage the use of document-level codes for the order and overall result report, which can be used in conjunction with additional LOINC codes for reporting the discrete results.

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
```

3.9.6.1.2 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> targeted gene mutation analysis:Find:Pt:Bld/Tiss:Doc:Molgen
For example:
```

```
CFTR gene mutation analysis:Find:Pt:Bld/Tiss:Doc:Molgen Synonyms: Cystic fibrosis transmembrane regulator

BRCA1 gene mutation analysis:Find:Pt:Bld/Tiss:Doc:Molgen Synonyms: breast cancer risk gene
```

For each such targeted mutation analysis, we recommend reporting the mutations that were tested using an additional LOINC code, such as LOINC 36908-2 (Gene mutations tested for) or gene-specific companion LOINC observation codes 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
```

Example answers: "Delta F508", "G542X", "R553X", "W1282X", "N1303K", etc.

The 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 gene mutation analysis terms could be used for ordering or reporting the results of a given targeted mutation analysis. Both document-level (*Scale* is **Doc**) and nominal (*Scale* is **Nom**) codes are available in the LOINC database. As mentioned above, we encourage the use of document-level codes for the order and overall result report, which can be used in conjunction with additional LOINC codes for reporting the discrete results. Nominal results for such an analyses 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.

3.9.6.1.3 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:Find:Pt:Bld/
Tiss:Doc:Molgen
```

For example:

```
TNFRSF13B gene mutation analysis limited to known familial mutations:Find:Pt:Bld/Tiss:Doc: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.

3.9.6.1.4 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:Find:Pt:Bld/Tiss:Doc: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.

3.9.6.2 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.

3.9.6.3 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**.

```
<disease or gene name>.<trinucleotide> repeats
```

For example, Huntington disease would be represented as follows:

```
HTT gene.CAG repeats
```

Examples of some fully specified LOINC names are:

```
FRAXE gene.CGG repeats:PrThr:Pt:Bld/Tiss:Ord:Molgen

Synonym: Fragile x syndrome

HTT gene.CAG repeats:PrThr:Pt:Bld/Tiss:Ord:Molgen

Synonyms: Huntington Disease, It15, HD, Huntington Chorea

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

DMPK gene.CTG repeats:PrThr:Pt:Bld/Tiss:Ord:Molgen

Synonym: Myotonic Dystrophy
```

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

When the actual number of trinucleotide repeats is reported, the *Property* is entitic number (**EntNum**) and the *Scale* is quantitative (**Qn**), and separate results are reported for each allele. Examples include:

```
HTT gene allele 1.CAG repeats:EntNum:Pt:Bld/Tiss:Qn:Molgen HTT gene allele 2.CAG repeats:EntNum:Pt:Bld/Tiss:Qn:Molgen DMPK gene allele 1.CTG repeats:EntNum:Pt:Bld/Tiss:Qn:Molgen DMPK gene allele 2.CTG repeats:EntNum:Pt:Bld/Tiss:Qn:Molgen
```

3.9.6.4 Hematopathology gene re-arrangement

Immune cells 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 gamma chain

These would be reported as "clonal" or "not clonal".

3.9.6.5 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:PrThr: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 Synonym:Lymphoma 1

BCL2 gene rearrangements:Arb:Pt:Bld/Tiss:Ord:Molgen Synonym:Lymphoma 2
```

3.9.7 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.

3.9.7.1 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
Example Answers: child, victim, suspect
Relationship:Type:Pt:^comparison case:Nom:Molgen.identity.testing
Example Answers: mother, alleged mother, father, alleged father, evidence (external to victim)
```

Confidence of relationship:likelihood:Pt:Index case^comparison case:QN:Molgen.identity.testing

Comment: gives the statistical confidence in the conclusion

Conclusion:Imp:Pt:index case^comparison case:Nar:Molgen.identity.testing Comment: gives a summary statement of the conclusion about identity of relatedness

3.9.7.2 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 **Synonym:** maternity testing

Comment: gives the likelihood that the alleged mother is the mother of the index child

Relationship:likelihood:child^alleged father:Qn:Molgen.identity.testing **Synonym:** paternity testing

Comment: gives the likelihood that the alleged father is the father of the index child

Relationship:likelihood:victim^suspect:Qn:Molgen.identity.testing Comment: gives the likelihood that the genetic material on the victim is that of the suspect

Relationship:likelihood:suspect^victim:Qn:Molgen.identity.testing Comment: gives the likelihood that the genetic material on the suspect is that of the victim

Identity:likelihood:evidence^suspect:Qn:Molgen.identity.testing

Comment: gives the likelihood that the genetic material on the evidence is that of the suspect

Identity:likelihood:evidence^victim:Qn:Molgen.identity.testing

Comment: gives the likelihood that the genetic material on the evidence is that of the victim

3.9.8 Tumor related genetics

Using the models described in this section, LOINC has terms for many genetic tests relevant to cancer, including tests related to tumor suppressor genes (e.g. BRCA1, BRCA2, and p53), oncogenes (e.g. HER2), and more.

3.10 HLA allele and antigen nomenclature

Naming conventions for HLA alleles and antigens are specified by the WHO Nomenclature Committee for Factors of the HLA System. Recommendations for both allele and antigen naming have evolved since the original HLA terms were represented in LOINC. For the LOINC 2.54 release (December 2015), we updated nearly all of the antigen and allele terms to reflect the WHO Nomenclature Committee's latest recommendations. HLA allele and antigen naming conventions are briefly described below; for more details, see http://hla.alleles.org/.

Allele names begin with the "HLA-" prefix and gene name, followed by an asterisk (e.g. "HLA-A* or HLA-DR*") and up to four sets of numbers separated by colons. The first set of digits following the asterisk describes the allele type, which may correspond to the serological antigen number (e.g., "HLA-A*01 corresponds to the antigen **HLA-A1**). The second set of digits is the subtype number, which is assigned in the order in which

the subtype was identified and sequenced. The third and fourth sets of digits describe the specific sequence variations of the subtype, if applicable.

Antigen names also begin with the "HLA-" prefix and specific gene, but antigen names are distinguished from allele names in that the gene name is not followed by an asterisk. For HLA-A, -B, -DQ and -DR, the antigen number immediately follows the gene name, and HLA-C, -D and -DP have a lower case w between the gene name and the antigen number (e.g., **HLA-Cw3**). The lower case w is used to distinguish the C antigens from complement factors and the D and DP antigens as being identified by cellular techniques rather than serological ones. Most antigen names have one set of digits (the antigen number) following the gene name, but in some cases, if an antigen originally identified as a single antigen was later recognized as being two distinct entities, the original, broader antigen number will follow the specific number in parentheses. For example, **HLA-B38(16)** and **HLA-B39(16)**.

3.11 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 version 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 Pharmacia²⁸ that most allergy testing companies reference in their catalog 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. An example of how these tests are represented is shown for LOINC <u>23797-4</u>:

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

Related name: tx2

²⁸ ImmunoCAP Allergens [Internet]. Uppsala(Sweden): ImmunoCAP; c2006 [updated 2007 November 2; cited 2008 June]. Available from: http://www.phadia.com/en-GB/5/Products/ImmunoCAP-Allergens/

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

3.11.1 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 the following:

- 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). If the first 3 letters of the genus and the first letter of the species are not enough to distinguish between two allergens, the second letter of the species name is added (e.g., Prunus avium recombinant (rPru av) 1). Because the content in the parentheses represents the antigen acronym and not the Pharmacia code, the antigen sequence number is purposely placed after the closed parenthesis. 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
<u>58779-0</u>	Arachis hypogaea recombinant (rAra h) 1 Ab.lgE	Peanut recombinant (rAra h) 1 IgE Ab
<u>58777-4</u>	Arachis hypogaea recombinant (rAra h) 3 Ab.IgE	Peanut recombinant (rAra h) 3 IgE Ab

<u>65769-2</u>	Arachis hypogaea native (nAra h) 1 Ab.IgE	Peanut native (nAra h) 1 IgE Ab
<u>65771-8</u>	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*, *Time Aspect*, *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 1 Ab). In the case of clinical terms, the Component usually identifies a particular projection of a three- or four-dimensional space to a measure of a particular feature (e.g., QRS interval, Intrachamber.systolic) of a time changing measure (Heart.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* is **chest**, the *Component* is **circumference at nipple line**, and the *Property* is **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 the 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: Example subjects covered in clinical LOINC
Blood 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
Standardized 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 review of systems and other such observations have a *Property* of **Find**. These may have a *Scale* of **Nom** for coded findings, **Nar** for findings reported in narrative text or **Ord** for ordinal findings.
- **Hx:** Terms representing patient or family history concepts originally had *Components* that began with "History of" and were assigned the **Find** *Property*. As of LOINC version 2.56, these terms were updated to remove "History of" from the *Component* and change the *Property* to **Hx**, which is exactly what this *Property* represents.

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 precoordinated 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

As of the December 2017 LOINC release, we have completed updating all of our radiology content according to the LOINC/RadLex Unified Model, which was developed through <u>our collaboration with the Radiological Society of North America (RSNA)</u>.

You can find information about the unified model at the end of this document, in the <u>Annex - RadLex-LOINC Radiology Playbook User Guide</u>.

The following table provides a reference for how the attributes in the Unified Model correspond to the primary LOINC Parts.

Table 22: Relationship of primary LOINC Parts to Radiology attributes		
Primary Part	Radiology Attribute	
Component 1st part (Analyte)	View Guidance Reason for Exam	
Component 2nd part (Challenge)	Timing Maneuver Pharmaceutical	
System	Anatomy Subject	
Method	Modality	

4.4 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 (http://naaccr.org).

5 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 (http://loinc.org/attachments).

6 LOINC Document Ontology

This section describes our approach to creating a set of document type codes. This work began as a collaboration between the LOINC committee and the HL7 document ontology task force, with initial contributions from Stan Huff, Pavla Frazier, Bob Dolin and Clem McDonald. The background and initial development of the ontology was described by Frazier et al.²⁹ Over time, we have continued to make many refinements to this ontology. In particular, we have received exceptional contributions from colleagues at Columbia University and the U.S. Department of Veterans Affairs.

6.1 Introduction to the use of LOINC document type codes

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 workflow 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

The naming rules in this Document Ontology apply primarily 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.

We must also emphasize that the names constructed in LOINC are based on the expected information content

²⁹ Frazier P, Rossi-Mori A, Dolin RH, Alschuler L, Huff SM. The creation of an ontology of clinical document names. Stud Health Technol Inform. 2001;84(Pt1):94-8. [PubMed: 11604713]

of the document, rather than the document format. This is to say that the same LOINC code would be used to represent a given document type regardless of whether it was in PDF, text document, JPG, XML, or HTML formats – if the information content contained by those documents were the same.

6.2 Relationship to other standards

6.2.1 HL7

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.

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.

6.3 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.

6.3.1 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.

Part Number	Part Name
<u>LP173387-4</u>	Administrative note
LP173388-2	Against medical advice note
LP173389-0	Agreement
LP173390-8	Certificate
LP173391-6	Birth certificate
LP173392-4	Death certificate
LP173393-2	Evaluation of mental and physical incapacity certificate
LP173394-0	Consent

LP173395-7	Abortion consent
<u>LP173396-5</u>	Anesthesia consent
<u>LP173397-3</u>	Hysterectomy consent
LP267417-6	Long-term opioid therapy for pain consent
<u>LP173398-1</u>	Organ donation consent
LP173399-9	Procedure consent
<u>LP173400-5</u>	Release of information consent
LP173401-3	Sterilization consent
LP173402-1	Surgical operation consent
LP173403-9	Contract
LP193873-9	Driver license
LP173404-7	Health insurance card
<u>LP173405-4</u>	Health insurance-related form
<u>LP173406-2</u>	Health record cover sheet
LP173407-0	Legal document
LP200113-1	Legal letter
LP173408-8	Power of attorney
LP248740-5	Medical clearance note
<u>LP181089-6</u>	Request
LP181085-4	Prescription request
<u>LP173409-6</u>	Advance directives
<u>LP173410-4</u>	Do not resuscitate
<u>LP173411-2</u>	Rescinded do not resuscitate
LP173412-0	Living will
<u>LP173413-8</u>	Rescinded advance directive
LP200111-5	Checklist
LP267279-0	Discharge checklist
<u>LP173414-6</u>	Diagram
<u>LP173415-3</u>	Flowsheet
LP181112-6	Form
LP204180-6	Mandatory reporting form
LP181116-7	Instructions
LP181119-1	Action plan
LP173754-5	ADHD action plan
LP173755-2	Anaphylaxis action plan
LP173756-0	Asthma action plan
<u>LP173757-8</u>	Autism action plan
LP173758-6	Complex medical conditions action plan
<u>LP173759-4</u>	Cystic fibrosis action plan
LP173765-1	Diabetes type I action plan
LP173766-9	Diabetes type II action plan
LP173760-2	Heart disease action plan
LP173761-0	Inflammatory bowel disease action plan
LP173762-8	Multiple sclerosis action plan
LP173763-6	Muscular dystrophy action plan
<u> </u>	induction dystrophy action plan

LP173764-4	Seizure disorder action plan
LP173118-3	Discharge instructions
<u>LP173417-9</u>	Letter
LP200113-1	Legal letter
<u>LP204161-6</u>	List
LP181534-1	Prescription list
<u>LP173418-7</u>	Note
<u>LP173419-5</u>	Adverse event note
LP173420-3	Alert
LP181207-4	Order
LP181204-1	Prescription
LP181529-1	Prescription for diagnostic or specialist care
LP181530-9	Prescription for durable medical equipment attachment
LP181190-2	Prescription for eyewear
LP181531-7	Prescription for medical equipment or product
LP181532-5	Prescription for medication
LP181533-3	Prescription for rehabilitation
LP181534-1	Prescription list
LP156982-3	Photographic image
LP173421-1	Report
LP183503-4	Case report
<u>LP183502-6</u>	Registry report

Further explanation of LOINC's use of "Note" (i.e., a Clinical Note, also known as "Clinical Document") versus "Report": In LOINC, a Note is a document generated by a clinician as part of patient care and includes notes written at the initiative of "individual clinic and consulting clinicians." In contrast, a Report is usually generated in response to an order, e.g., radiology, pathology, and cardiac catheterization reports. In general, we will not make two distinct LOINC codes for concepts that have all of the same attributes except that one is a Note and one is a Report. Requests for such pairs of codes (or a request for a note when a report term exists or vice versa) will be reviewed on a case by case basis.

Clinical documents meet five criteria, as defined in CDA 1.0: wholeness, stewardship, authentication, persistence, and human readability.

6.3.2 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 evaluations, consultations, and summaries. The notion of time sequence, e.g., at the beginning (admission) or at the end (discharge), is subsumed in this axis.

Part Number	Part Name
LP173107-6	Communication
LP173099-5	Conference

LP173109-2	Case conference
LP173110-0	Consultation
LP173111-8	Confirmatory consultation
LP173100-1	Counseling
LP173113-4	Group counseling
LP173112-6	Individual counseling
LP173114-2	Daily or end of shift signout
LP173115-9	Diagnostic study
LP173116-7	Inhalation challenge test
LP173117-5	Education
LP173120-9	Discharge teaching
LP173121-7	Preoperative teaching
LP173122-5	Evaluation and management
LP173129-0	Care
LP173130-8	Crisis intervention (psychosocial crisis intervention)
LP263715-7	Suicide prevention
LP173131-6	Disease staging
LP173132-4	Disability examination
LP173133-2	Social security administration compensation examination
LP173134-0	Compensation and pension examination
LP173135-7	VA C&P exam.acromegaly
LP173136-5	VA C&P exam.aid and attendance ∨ housebound
LP173137-3	VA C&P exam.arrhythmias
LP173138-1	VA C&P exam.miscellaneous arteries ∨ veins
LP173139-9	VA C&P exam.audio
LP173140-7	VA C&P exam.bones
LP173105-0	VA C&P exam.bones fractures ∨ bone disease
LP173141-5	VA C&P exam.brain ∨ spinal cord
LP173142-3	VA C&P exam.chronic fatigue syndrome
LP173143-1	VA C&P exam.cold injury protocol
LP173144-9	VA C&P exam.cranial nerves
LP173145-6	VA C&P exam.Cushings syndrome
LP173146-4	VA C&P exam.dental ∨ oral
LP173147-2	VA C&P exam.diabetes mellitus
LP173148-0	VA C&P exam.miscellaneous digestive conditions
LP173149-8	VA C&P exam.ear disease
LP173150-6	VA C&P exam.mental health eating disorders
LP173151-4	VA C&P exam.miscellaneous endocrine diseases
LP173152-2	VA C&P exam.epilepsy ∨ narcolepsy
LP173153-0	VA C&P exam.esophagus ∨ hiatal hernia
LP173168-8	VA C&P exam.extremity joints
LP173154-8	VA C&P exam.eye
LP173155-5	VA C&P exam.feet
LP173156-3	VA C&P exam.fibromyalgia
LP173157-1	VA C&P exam.general medical

LP173158-9	VA C&P exam.genitourinary
LP173159-7	VA C&P exam.disability in gulf war veterans
LP173160-5	VA C&P exam.gynecological conditions ∨ disorders of the breast
LP173161-3	VA C&P exam.hand ∨ thumb ∨ fingers
LP173162-1	VA C&P exam.heart
<u>LP173163-9</u>	VA C&P exam.hemic disorders
LP173164-7	VA C&P exam.HIV-related illness
LP173165-4	VA C&P exam.hypertension
LP173166-2	VA C&P exam.infectious ∨ immune ∨ nutritional disabilities
LP173167-0	VA C&P exam.large ∨ small intestines
<u>LP173168-8</u>	VA C&P exam.extremity joints
LP173169-6	VA C&P exam.liver ∨ gall bladder ∨ pancreas
LP173170-4	VA C&P exam.lymphatic disorders
LP173171-2	VA C&P exam.general mental disorders
LP173172-0	VA C&P exam.mouth ∨ lips ∨ tongue
LP173173-8	VA C&P exam.multiple exam
LP173174-6	VA C&P exam.muscles
LP173175-3	VA C&P exam.miscellaneous neurological disorders
LP173176-1	VA C&P exam.nose ∨ sinus ∨ larynx ∨ pharynx
LP173177-9	VA C&P exam.peripheral nerves
LP173178-7	VA C&P exam.initial evaluation post-traumatic stress disorder
LP173179-5	VA C&P exam.review evaluation post-traumatic stress disorder
LP173180-3	VA C&P exam.prisoner of war protocol
LP173181-1	VA C&P exam.pulmonary tuberculosis ∨ mycobacterial diseases
LP173182-9	VA C&P exam.rectum ∨ anus
LP173183-7	VA C&P exam.residuals of amputations
LP173184-5	VA C&P exam.miscellaneous respiratory diseases
LP173185-2	VA C&P exam.obstructive ∨ restrictive ∨ interstitial respiratory diseases
LP173186-0	VA C&P exam.scars
LP173187-8	VA C&P exam.sense of smell ∨ taste
<u>LP173188-6</u>	VA C&P exam.skin diseases other than scars
LP173106-8	VA C&P exam.social ∨ industrial survey
LP173189-4	VA C&P exam.spine
LP173190-2	VA C&P exam.stomach ∨ duodenum ∨ peritoneal adhesions
LP173191-0	VA C&P exam.thyroid ∨ parathyroid diseases
LP173124-1	Evaluation
LP173123-3	Annual evaluation
LP173125-8	Functional status assessment
LP173204-1	Initial evaluation
LP173205-8	Admission evaluation
LP173200-9	Admission history and physical
LP173126-6	Readiness for military duty assessment
LP173127-4	Risk assessment and screening
LP173128-2	Fall risk assessment
LP204157-4	Safety issue assessment
	<u> </u>

LP173192-8	Evaluation and management of a specific problem
LP173193-6	Evaluation and management of anticoagulation
LP173194-4	Evaluation and management of hyperlipidemia
LP173195-1	Evaluation and management of hypertension
LP173196-9	Evaluation and management of overweight and obesity
LP267443-2	Evaluation and management of radiation exposure
LP173197-7	Evaluation and management of smoking cessation
LP208913-6	Evaluation and management of workers compensation
LP173198-5	History and physical
LP173199-3	Annual history and physical
LP173200-9	Admission history and physical
LP173202-5	Labor and delivery admission history and physical
LP173201-7	Comprehensive history and physical
LP173203-3	Targeted history and physical
LP204160-8	Medical equipment or product
LP173206-6	Plan
LP173209-0	Plan of care
LP173213-2	Progress
<u>LP173211-6</u>	Restraint
LP173214-0	Surgical operation
LP173215-7	Postoperative evaluation and management
LP173216-5	Preoperative evaluation and management
LP173103-5	Summary
LP173218-1	Antepartum summary
LP173221-5	Discharge summary
LP222264-6	Immunization summary
LP173223-1	Labor and delivery summary
LP173222-3	Maternal discharge summary
LP175732-9	Population summary
LP173225-6	Summary of death
LP200117-2	Summary of encounters
LP173224-9	Summary of episode
LP173226-4	Transfer summary
LP189614-3	Weight management summary
LP173227-2	Transplant candidate evaluation
LP173228-0	Transplant donor evaluation
LP173229-8	Well child visit
LP173230-6	Exercise testing
LP263510-2	Immunization
LP204160-8	Medical equipment or product
LP173231-4	Medication management
LP207306-4	Medication administration
LP266264-3	Parenteral therapy
LP173232-2	Medication reconciliation

LP203034-6	Admission notification
LP203035-3	Discharge notification
LP204130-1	Visit notification
LP173233-0	Outreach
<u>LP173234-8</u>	Procedure
LP267418-4	Cardiopulmonary resuscitation
LP173235-5	Interventional procedure
LP173236-3	Pathology procedure
LP173237-1	Autopsy
LP173238-9	Referral
LP173240-5	Respite
LP173104-3	Supervisory
LP173242-1	Triage

6.3.3 Setting

Description: Setting is a modest extension of CMS's 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.

Part Number	Part Name
LP173041-7	Ambulance
<u>LP173042-5</u>	Birthing center
<u>LP173043-3</u>	Emergency department
<u>LP173065-6</u>	Hospital
<u>LP173045-8</u>	Intensive care unit
<u>LP173046-6</u>	Long term care facility
LP173047-4	Custodial care facility
<u>LP173048-2</u>	Nursing facility
<u>LP173049-0</u>	Skilled nursing facility
LP173050-8	Unskilled nursing facility
LP222061-6	Observation unit
<u>LP173051-6</u>	Outpatient
LP266261-9	Adult day care center
LP173052-4	Ambulatory surgical center
LP173053-2	Office
LP173054-0	Outpatient hospital
LP173055-7	Urgent care center

LP173056-5	Patient's home
LP220237-4	Pharmacy
LP248736-3	Recovery room
LP173057-3	Rehabilitation hospital
LP173058-1	Telehealth
LP248737-1	Teleimaging
LP173059-9	Telephone encounter

6.3.4 Subject Matter Domain (SMD)

Description: Characterizes the subject matter domain of a note.

Part Number	Part Name
LP172911-2	Acupuncture
LP263512-8	Addiction medicine
LP172912-0	Addiction psychiatry
LP172915-3	Aerospace medicine
LP172916-1	Allergy and immunology
LP172925-2	Clinical and laboratory immunology
LP172918-7	Anesthesiology
LP172981-5	Pain medicine
<u>LP248728-0</u>	Sleep medicine
LP172919-5	Audiology
LP172923-7	Chiropractic medicine
LP172933-6	Critical care medicine
LP172934-4	Dentistry
LP172935-1	Dermatology
LP172924-5	Clinical and laboratory dermatological immunology
LP172936-9	Dermatopathology
LP172987-2	Pediatric dermatology
LP172940-1	Emergency medicine
LP172957-5	Medical toxicology
LP172988-0	Pediatric emergency medicine
LP173027-6	Sports medicine
LP183499-5	Trauma
LP173035-9	Undersea and hyperbaric medicine
LP172942-7	Ethics
LP176905-0	Exercise physiology
LP172943-5	Family medicine
LP172913-8	Adolescent medicine
LP172947-6	Geriatric medicine
LP248728-0	Sleep medicine
LP173027-6	Sports medicine

LP172894-0	Forensic medicine
LP172944-3	Forensic psychiatry
<u>LP172946-8</u>	General medicine
LP172952-6	Internal medicine
<u>LP172913-8</u>	Adolescent medicine
LP172921-1	Cardiovascular disease
LP172914-6	Advanced heart failure and transplant cardiology
LP172927-8	Clinical cardiac electrophysiology
LP172953-4	Interventional cardiology
LP172941-9	Endocrinology
<u>LP172938-5</u>	Diabetology
<u>LP173032-6</u>	Thyroidology
<u>LP172945-0</u>	Gastroenterology
<u>LP172950-0</u>	Hepatology
<u>LP172947-6</u>	Geriatric medicine
<u>LP175685-9</u>	Hematology
LP172951-8	Infectious disease
LP183500-0	HIV
LP175686-7	Medical oncology
LP172962-5	Nephrology
LP263511-0	Dialysis
LP173015-1	Pulmonary disease
LP173023-5	Rheumatology
LP248728-0	Sleep medicine
<u>LP173027-6</u>	Sports medicine
LP172956-7	Medical genetics
LP172926-0	Clinical biochemical genetics
LP172928-6	Clinical cytogenetics
LP172929-4	Clinical genetics
LP172930-2	Clinical molecular genetics
LP172959-1	Molecular genetic pathology
LP172958-3	Mental health
LP173011-0	Psychiatry
LP172912-0	Addiction psychiatry
LP172922-9	Child and adolescent psychiatry
LP172944-3	Forensic psychiatry
LP172948-4	Geriatric psychiatry
LP173013-6	Psychosomatic medicine
LP173012-8	Psychology
LP248501-1	Child and adolescent psychology
LP248729-8	Neuropsychology
LP172960-9	Multi-specialty program
LP263714-0	Brain injury
LP265794-0	Polytrauma
LP172963-3	Neurological surgery

LP172964-1	Neurology
LP263714-0	Brain injury
LP172931-0	Clinical neurophysiology
LP248726-4	Epilepsy
LP172965-8	Neurology neurodevelopmental disabilities
LP172898-1	Neurology w special qualifications in child neuro
LP172981-5	Pain medicine
LP248728-0	Sleep medicine
LP173038-3	Vascular neurology
LP172968-2	Nuclear medicine
LP172899-9	Nutrition and dietetics
LP172971-6	Obstetrics and gynecology
LP221284-5	Gynecology
LP202989-2	Gynecologic oncology
LP172955-9	Maternal and fetal medicine
LP221283-7	Obstetrics
LP173020-1	Reproductive endocrinology and infertility
LP172973-2	Occupational therapy
LP172901-3	Oncology
LP202989-2	Gynecologic oncology
LP175686-7	Medical oncology
<u>LP172991-4</u>	Pediatric hematology-oncology
<u>LP173016-9</u>	Radiation oncology
<u>LP207940-0</u>	Surgical oncology
<u>LP172974-0</u>	Ophthalmology
<u>LP172975-7</u>	Optometry
LP172902-1	Oral and maxillofacial surgery
LP172978-1	Orthopaedic surgery
LP172977-3	Orthopedic sports medicine
LP173029-2	Surgery of the hand
LP172979-9	Orthotics prosthetics
LP172980-7	Otolaryngology
LP172967-4	Neurotology
LP172994-8	Pediatric otolaryngology
LP173007-8	Plastic surgery within the head and neck
LP248728-0	Sleep medicine
LP172982-3	Palliative care
LP172983-1	Pastoral care
<u>LP172984-9</u>	Pathology
<u>LP208907-8</u>	Anatomic pathology
LP172936-9	Dermatopathology
<u>LP208906-0</u>	Clinical pathology
LP172920-3	Blood banking and transfusion medicine
LP208902-9	Chemical pathology
<u>LP172959-1</u>	Molecular genetic pathology

LP208903-7	Medical microbiology – pathology
LP241974-7	Toxicologic pathology
LP173002-9	Pediatrics
LP172913-8	Adolescent medicine
LP172922-9	Child and adolescent psychiatry
LP248501-1	Child and adolescent psychology
LP172937-7	Developmental-behavioral pediatrics
LP172950-0	Hepatology
<u>LP172957-5</u>	Medical toxicology
LP172961-7	Neonatal perinatal medicine
LP192135-4	Birth defects
LP172985-6	Pediatric cardiology
LP172986-4	Pediatric critical care medicine
LP172987-2	Pediatric dermatology
<u>LP172989-8</u>	Pediatric endocrinology
LP172988-0	Pediatric emergency medicine
LP172990-6	Pediatric gastroenterology
LP173000-3	Pediatric transplant hepatology
LP172991-4	Pediatric hematology-oncology
LP172992-2	Pediatric infectious diseases
LP172993-0	Pediatric nephrology
LP172994-8	Pediatric otolaryngology
LP172995-5	Pediatric pulmonology
LP172996-3	Pediatric radiology
LP172997-1	Pediatric rehabilitation medicine
LP172998-9	Pediatric rheumatology
LP172999-7	Pediatric surgery
LP248728-0	Sleep medicine
LP173027-6	Sports medicine
LP173003-7	Pharmacology
LP220238-2	Clinical pharmacology
<u>LP173004-5</u>	Physical medicine and rehabilitation
LP263714-0	Brain injury
LP172954-2	Kinesiotherapy
LP172981-5	Pain medicine
LP172997-1	Pediatric rehabilitation medicine
<u>LP265794-0</u>	Polytrauma
LP173026-8	Spinal cord injury medicine
LP173040-9	Vocational rehabilitation
LP173005-2	Physical therapy
LP173006-0	Plastic surgery
LP173007-8	Plastic surgery within the head and neck
LP173029-2	Surgery of the hand
LP173008-6	Podiatry
<u>LP173009-4</u>	Preventive medicine

LP172957-5	Medical toxicology
LP172972-4	Occupational medicine
LP173035-9	Undersea and hyperbaric medicine
LP173010-2	Primary care
LP173014-4	Public health
LP204156-6	Community health care
LP267441-6	Environmental health
LP173018-5	Radiology
LP172939-3	Diagnostic radiology
LP172896-5	Interventional radiology
LP172969-0	Nuclear radiology
LP172996-3	Pediatric radiology
LP173016-9	Radiation oncology
LP173017-7	Radiological physics
LP173037-5	Vascular and interventional radiology
LP173019-3	Recreational therapy
LP173021-9	Research
LP173022-7	Respiratory therapy
LP173024-3	Social work
LP173025-0	Speech-language pathology
LP173028-4	Surgery
LP248500-3	Bariatric surgery
LP172932-8	Colon and rectal surgery
LP172999-7	Pediatric surgery
<u>LP265794-0</u>	Polytrauma
LP173029-2	Surgery of the hand
<u>LP173030-0</u>	Surgical critical care
<u>LP207940-0</u>	Surgical oncology
LP173031-8	Thoracic and cardiac surgery
LP207300-7	Cardiac surgery
LP173033-4	Transplant surgery
LP183499-5	Trauma
LP265794-0	Polytrauma
LP173039-1	Vascular surgery
LP173034-2	Tumor board
LP173036-7	Urology
LP173001-1	Pediatric urology
LP248732-2	Womens Health
LP185997-6	Wound care management

6.3.5 Role

Description: Characterizes the training or professional level of the author or the party responsible for the content in the document. The role category is a high-level classification that does not get as detailed as specialty or subspecialty so as to avoid potential overlap with the subject matter domain axis.

Part Number	Part Name
LP173066-4	Assistant
LP173067-2	Case manager
<u>LP173068-0</u>	Clerk
<u>LP173069-8</u>	Counselor
LP264605-9	Device
<u>LP173071-4</u>	Hygienist
LP173072-2	Interdisciplinary
LP173073-0	Team
LP203036-1	Rapid response team
LP173074-8	Medical assistant
LP221282-9	Midwife
LP173079-7	Nurse midwife
LP173075-5	Nurse
LP173076-3	CRNA
LP173077-1	Certified nursing assistant
LP173078-9	Clinical nurse specialist
LP173079-7	Nurse midwife
LP173080-5	Nurse practitioner
LP173081-3	Licensed practical nurse
LP173082-1	Registered nurse
LP173083-9	Patient
LP181523-4	Pharmacist
LP173084-7	Physician*
LP173090-4	Physician assistant Physician assistant
LP173085-4	Physician attending Physician attending
LP173086-2	Physician consulting Physician consulting Physician consulting
<u>LP173087-0</u>	Physician fellow
LP173088-8	Physician intern
<u>LP173089-6</u>	Physician resident Physician resident Physician resident
LP173091-2	Student
LP173092-0	Medical student
<u>LP173093-8</u>	Nursing student
LP173094-6	Technician
LP173095-3	Therapist

Note

* Physician subsumes medical physicians and osteopathic physicians.

6.4 Rules for creating clinical notes from multiple attributes

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 (see exceptions below in <u>Section 7.4.1</u>). 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=""></kind></type>	Find	Pt	<setting></setting>	Doc	<smd>.<role></role></smd>	DOC.ONTOLOGY			

In general, combinations from within an axis are allowed in a term name where they make sense (typically, SMD and Service), but are disallowed where they do not (typically, Role and 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**}. Where neither the SMD nor Role is specified, {**Role**} is used in the *Method* (as of LOINC version 2.54).

LOINC codes for clinical notes designed according to this model and are assigned a *Class* of **DOC**. **ONTOLOGY**. The *Class* name was changed in LOINC version 2.50 from **DOC**. **CLINRPT** to **DOC**. **ONTOLOGY**, a more representative name for all types of documents (not just clinical reports) included in the LOINC Document Ontology.

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	{Role}	DOC.ONTOLOGY				
Note	Find	Pt	Outpatient	Doc	{Role}	DOC.ONTOLOGY				
Admission evaluation note	Find	Pt	{Setting}	Doc	General medicine	DOC.ONTOLOGY				
History and physical note	Find	Pt	{Setting}	Doc	{Role}	DOC.ONTOLOGY				

For every clinical note term we create with a designated Setting, SMD, and/or Role, we will also create a

general "roll-up" term where the Setting, SMD and Role are not specified, i.e. they are defined as {**Setting**} and {**Role**}. The LOINC Committee has agreed not to create a general document code in some cases, including:

- 1. The *Component* contains only one axis value, either a Type of Service or Kind of Document. Such a generic code (absent the other attributes) would violate the current policy to include the Kind of Document plus at least one other axis value.
- 2. The general type of clinical document is not likely to ever exist.

Example LOINC codes that do not have a general clinical note term include:

Table 25. LOINC Code Exceptions to Creating a General Clinical Document Code							
Component Property Time System Scale Method Class							
Anesthesia consent	Find	Pt	{Setting}	Doc	Patient	DOC.ONTOLOGY	
Organ donation consent	Find	Pt	{Setting}	Doc	Patient	DOC.ONTOLOGY	
Health insurance card	Find	Pt	{Setting}	Doc	Patient	DOC.ONTOLOGY	
Triage+Care note	Find	Pt	Emergency department	Doc	Nurse	DOC.ONTOLOGY	
Prescription request	Find	Pt	Pharmacy	Doc	Pharmacist	DOC.ONTOLOGY	

6.4.1 Exceptions to rules for creating clinical notes

As noted above, the current policy for creating clinical notes is to include the Kind of Document plus at least one other axis value. The LOINC Committee has agreed to make exceptions to the Document Ontology rules for cases where only Kind of Document is commonly designated (e.g. **Driver license**).

Example LOINC codes that are approved exceptions containing only a Kind of Document:

Table 26. LOINC Codes with only a Kind of Document						
Component	Property	Time	System	Scale	Method	Class
Administrative note	Find	Pt	{Setting}	Doc	{Role}	DOC.ONTOLOGY
Asthma action plan	Find	Pt	{Setting}	Doc	{Role}	DOC.ONTOLOGY
Birth certificate	Find	Pt	{Setting}	Doc	{Role}	DOC.ONTOLOGY
Case report	Find	Pt	{Setting}	Doc	{Role}	DOC.ONTOLOGY
Death certificate	Find	Pt	{Setting}	Doc	{Role}	DOC.ONTOLOGY
Do not resuscitate	Find	Pt	{Setting}	Doc	{Role}	DOC.ONTOLOGY
Driver license	Find	Pt	{Setting}	Doc	{Role}	DOC.ONTOLOGY
Photographic image	Find	Pt	{Setting}	Doc	{Role}	DOC.ONTOLOGY
Prescription list	Find	Pt	{Setting}	Doc	{Role}	DOC.ONTOLOGY

The LOINC Committee also recognizes the need for terms with only a general Kind of Document (e.g. **Letter**, **Note**, **Report**) designated. We have agreed to create such terms, however, they will have a status of "discouraged" to caution users. If these general terms are used, we strongly recommend that they are used in a post-coordinated manner in conjunction with one of the LOINC terms included in the LOINC Document Ontology associated observations panel (LOINC: <u>80582-0</u>) to carry the relevant attribute specifications.

6.5 Document Ontology content in the LOINC distribution

Beginning with LOINC version 2.44 (June 2013), a delimited text file containing the relationships between clinical document terms (i.e. those within the *Class* of **DOC.ONTOLOGY**) and their associated ontology axis values is available as a separate download from http://loinc.org. The document ontology axis values have been assigned LOINC Part identifiers and classified according to their document ontology axis. This file defines the relationships between a given LOINC term and its ontology axis values through these fields: *LoincNumber*, *PartNumber*, *PartTypeName*, *PartSequenceOrder*, *PartName*. These fields are largely self-explanatory, but of note is that the *PartTypeName* corresponds to the Document Ontology axis, and the *PartSequenceOrder* is relevant for terms that combine axis values from within an axis (see Section 7.4).

6.6 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 care associated documents.

6.7 Proposing new LOINC document terms

New LOINC document type codes can be proposed using the process described in <u>Appendix D</u>. In general, new term proposals that contain allowed combinations of existing axis values will be made expeditiously by Regenstrief staff. Requests for document titles containing new axis values to be added to the ontology will be reviewed by the LOINC committee, and thus their final modeling may take a bit longer.

In LOINC, a **Note** is a document generated by a clinician as part of patient care and includes notes written at the initiative of "individual clinic and consulting clinicians." In contrast, a **Report** is usually generated in response to an order, e.g., radiology, pathology, and cardiac catheterization reports. In general, we will not make two distinct LOINC codes for concepts that have all of the same attributes except that one is a **Note** and one is a **Report**. Requests for such pairs of codes (or a request for a note when a report term exists or vice versa) will be reviewed on a case by case basis.

7 Panels (Batteries)

Beginning with version 1.0, the LOINC database was expanded to include order sets/panels. We use the word "panel" to mean collector terms that contain links to an enumerated set of discrete child elements. Across domains, this generic concept of a collection might be called a battery, form, data set, etc. The same general panel structure in LOINC is used to represent all of these kinds of collections.

7.1 Goals

Our work in creating panels was stimulated by many requests for a standard set of test order codes from medical information system vendors who want to install their systems with a usable starter set of standard codes for common orders. They also want standard codes 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. The same LOINC codes can be used to order individual laboratory and clinical observations, as well as to report the result. For example, a LOINC code for Blood Hemoglobin (LOINC: 718-7) could be used as easily to order the test as to report its result. In HL7 messages, the field where the code is used indicates its role as an order (e.g. OBR-4) or a result observation (OBX-3).

Similarly, pre-existing LOINC codes could also be used to order more complex observations. The LOINC code used to order Urinary Creatinine Clearance (LOINC: <u>2164-2</u>) actually implies an order for two distinct measures (serum creatinine and 24-hour urine creatinine) that are used to calculate the creatinine clearance.

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, and 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" packages of observations. 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, instruments that produce the values, or by a government mandate (e.g., LOINC: 24325-3: Hepatic function HCFA 2000 panel).

Over time, we have evolved our approach to building panels of other observation collections. (For information on using the *ORDER_OBS* field of the LOINC database to help find panels that could be used as orders, see <u>Section 10.3.</u>)

7.2 Types of results found in panels

To understand the rules about how LOINC creates panels and how to map your local panels to LOINC panels, it is important to distinguish among several kinds of "results".

7.2.1 Primary measurements or observations

These observations report key measured results, and may indicate the presence/absence or amount of a substance or organism in the sample. For example, in an electrolytes panel, measured amounts of sodium, potassium, chloride, and bicarbonate would be the primary measures.

7.2.2 Derived observations

These observations are derived from mathematical or logical operations on the primary measurements. For example, in an electrolytes panel, the anion gap is a derived measure that is calculated by subtracting the concentrations of chloride and bicarbonate (anions) from the concentrations of sodium and potassium (cations).

7.2.3 Ask at order entry (AOE) questions and other associated observations

These observations are obtained from the requester as part of the test order and are generally delivered back to the requester as part of the result package. For example, the concentration of inspired oxygen is always an AOE question for blood gas measurements. Similarly, the date of last menstrual period is an AOE question for pap smears.

Other kinds of observations are operationally treated in a similar manner although they may not be "questions" in the literal sense. For example, the volume and times (start, stop, duration) of urine collection are often sent along with the order and back again with the results. We call these "associated observations" and consider them like AOEs for the purpose of this discussion.

7.2.4 Impressions, interpretations, and comments

LOINC defines an impression/interpretation as a summary statement about multiple observations. This kind of summary observation is often included in collections of results sent back to the requester. (Such summary observation terms in LOINC have the *Property* of **Imp**, for impression, in their name).

As an aside, we note that decisions about test results being outside of normal range are best reported with the Interpretation Code (commonly referred to as the "Abnormal flag") field of the HL7 OBX structure and not as a separate interpretation observation.

7.3 LOINC rules for panel names

We use most of the same general LOINC naming rules for panels as we do for individual observations. Here we describe some of the key unique features of panel names.

7.3.1 Component

If a government authority recognizes the panel or order set, we will name such panels with the year that the recognition took effect. For example, LOINC includes the "Comprehensive metabolic 2000 panel".

For panels consisting of more than three 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 or the panel consists of three or less constituents, we will include each of the distinct measured entities separated by ampersand (&) in the *Component*. We may also use a more efficient syntax that implies a repeat of the first part of the name, e.g., Chlamydia Ab IgM & IgG Panel.

In general, LOINC creates different codes for panels that contain reflex testing versus those that do not. Such panels will include **reflex** in the *Component* name, and the general approach is to name the base panel and the kind of test(s) or test panel done as a reflex in the panel name. The reflex test(s) can be a single test, a group of tests, or a test panel.

7.3.2 Property and Scale

Because the *Property* typically varies across the elements of a panel, the *Property* (i.e. the second part of the LOINC name) for the panel term may be populated by a dash (-). Likewise, the *Scale* (5th part of the LOINC name) will be populated by a dash (-) if the panel elements contain different scales.

7.3.3 Time Aspect and System

Because these parts of the LOINC name are typically consistent across the primary measures of a panel, the *Time Aspect* and *System* of a panel name are usually specified with the same conventions that apply to observation terms.

7.3.4 Examples of LOINC Panel names

The following are a few examples of LOINC Panels (Order Set Names):

	Table 27: Examples of LOINC Panel Names (Order Set Names)					
LOINC_NUM	LOINC Fully Specified Name	Description				
<u>24358-4</u>	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				

<u>24357-6</u>	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.
<u>29576-6</u>	Bacterial susceptibility panel:-:Pt:Isolate:OrdQn	Would include susceptibility results for the antibiotics relevant to the isolates and the kind of culture.

7.4 Representing conditionality

Within the LOINC panel structure, we can set an attribute for each element of the panel that denotes whether or not it should be present (conditionality) in the panel when resulted. The primary measures are always required, but the other elements of the panel may have different kinds of conditionality.

The conditionality attribute is visible on the details pages for panel terms under the column "R/O/C" and stored in the *ObservationRequiredInPanel* field of the LOINC panels and forms file (available for download from the LOINC website).

Through version 2.48 of the LOINC database, the conditionality choices were limited to **R** (Required), **O** (Optional) and **C** (Conditional). Examples of simple order sets with terms that are either **R** or **O**:

Table 28: Example Order Sets						
24358-4	Hemogram WO platelets panel	-	Pt	Bld	Qn	R/O/C
<u>26464-8</u>	Leukocytes	NCnc	Pt	Bld	Qn	R
<u>26453-1</u>	Erythrocytes	NCnc	Pt	Bld	Qn	R
<u>718-7</u>	Hemoglobin	MCnc	Pt	Bld	Qn	R
<u>20570-8</u>	Hematocrit	VFr	Pt	Bld	Qn	R
<u>30428-7</u>	Mean corpuscular volume	EntVol	Pt	RBC	Qn	R
<u>28539-5</u>	Erythrocyte mean corpuscular hemoglobin	EntMass	Pt	RBC	Qn	R
<u>28540-3</u>	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
<u>24326-1</u>	Electrolytes 1998 panel	-	Pt	Ser/Plas	Qn	R/O/C
<u>2951-2</u>	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
33037-3	Anion gap	SCnc	Pt	Ser/Plas	Qn	0

Starting with version 2.50 (December 2014), we expanded the choices beyond **R**, **O** and **C** to include **R-a** (Required with alternative), **Rflx** (Reflex) and **Rflx-a** (Reflex with alternative). The expanded choices better accommodate reflex tests, cases in which more than one test could be used to fulfill a given requirement of the panel, and focus the use of **C** (which had previously been used as a "catch-all" for many types).

Table 29 describes the expanded set of conditionality choices.

	Table 29: Options for Term Conditionality within Panels				
Code	Meaning	Discussion / Definition			
R	Required	Means this test must be included.			
R-a	Required with alternatives	Means required but has alternatives. The alternatives will usually be paired, and both will be marked with the R-a code. Results for at least one member of the pair must be included in the panel to satisfy the required condition, but both may be included. The C, conditional, had been used to deal with these cases in the past. The rule for pairing up of the alternatives for a given purpose will be described in a narrative usually in the panel description because the same rule will apply to many pairings in the panel. For example, the LA panel includes lots of coagulation measures and almost all can be reported as an actual time and/or as the ratio of patient time to the normal time. Measures of the same clotting function that differ only by how they are reported would be considered paired alternatives in this panel. More specific pairing rules may also be asserted in the "condition for inclusion" field associated with each item in the panel.			
С	Conditional	Means that the required status of a given variable depends on other factors. This was too much of a waste basket category, which is why we added some new categories to specify what had usually been lumped as conditional.			
0	Optional	Means the variable may be included or not, but whether it is included or not has no bearing on the whether a given set of result represents the given panel. Simple calculations derived from other reported measurements and ask at order entry questions are almost always optional.			
Rflx	Reflex	Means this test will be included in the panel only if it satisfies a reflex condition based on other results in the panel. Such cases had also been lumped under the conditional code in the past. In general, we will not define specific rules for reflexing except in very general terms.			
Rflx-a	Reflex with alternatives	Means that that the test is a reflex but that another test in the panel can serve as an alternate and either or both of these reflex tests can be reported. But if the reflex condition is met, at least one of the alternative pairs must be included. As in the case of R-a, what tests pair up as alternatives will be defined in a narrative in the panel description of the condition for inclusion field.			

If more than one measure can serve as a primary measurement, then both of them will be required with alternatives (**R-a**), and the criteria is that at least one of them must be present. An example would be the absolute count of neutrophils versus the percentage of total white count of neutrophils in a differential blood count – if one is absent the other must be present (of course they are both often reported).

The criteria or explanation for when the tests with **R-a**, **Rflx** and **Rflx-a** should be included in the results for a particular panel can be seen on the comprehensive details page available within RELMA and the online LOINC search application (search.loinc.org).

Note that the conditionality assigned to a term is panel-specific. In other words, a given test may be required in one context and optional in another, which is why both the conditionality and criterion for inclusion only appear in the panel details and not in the individual term details.

We should acknowledge that LOINC includes many panels without the required status having been marked and that the conditional status has not been employed everywhere that it could have been, and that many terms marked as conditional under the previous model probably would be better categorized as required with alternatives, reflex, or reflex with alternative. (We still have LOINC development work to do.)

7.4.1 Lupus anticoagulant testing as an example of complex conditionality

Here we describe lupus anticoagulant testing as a prototype to illustrate the use of conditionality. At the core of lupus anticoagulant testing is a three step process using a given coagulation measure, such as dRVVT. The first is a screening to determine whether a clotting abnormality exists. The second is a mixing study, in which the patient specimen is mixed with pooled normal plasma (PNP) and the same test (e.g. dRVVT) is rerun. This second test is used to evaluate whether the clotting problem is due to a clotting factor deficiency, such as occurs

in Hemophilia. The third is yet another repeat of the same test (e.g. dRVVT) mixed with excess phospholipid – also called the confirmatory test. Lupus anticoagulant is declared present if the addition of excess phospholipid normalizes the result.

There are a number of variations in lupus anticoagulant testing algorithms across laboratories. Some labs do the confirm test second and the mixing study third (if needed). The International Society of Thrombosis and Haemostasis (ISTH) recommends using two clotting tests: dRVVT and aPTT-LA (lupus sensitive), each reflexing to confirm and/or mixing study. However, at least two labs use three screening tests, adding PT to the dRVVT and aPTT-LA, reflex to mixing and confirm studies from these, and add further reflex testing, including thrombin time and from that a reflex to reptilase time. There are also variations in how the results are reported, e.g. as actual clotting times and/or as ratios of the actual time to the time of normal. And some labs define the kind of phospholipid they use for the confirm study, i.e., hexagonal or platelet derived phospholipid.

The lupus anticoagulant panel for three screening tests shown below illustrates a number of issues related to conditionality described above. The three screening tests (dRVVT, aPTT and PT) are all required but can either be reported as the actual result or actual/normal, therefore all six terms are assigned the conditionality **R-a**. The mixing and confirmatory tests as well as thrombin time and reptilase time are only run if any of the screening tests are out of range and when run, can also be report as actual or actual/normal; therefore, all of these terms are assigned **Rflx-a**. The dRVVT and aPTT percent correction and screen to confirm ratio may not be reported by all laboratories and therefore have an **O** status. Finally, the overall interpretation must be reported and so is assigned **R**.

75881-3 Lupus anticoagulant aPTT & dRVVT & PT screening panel W Reflex

LOINC#	LOINC Name	R/O/C	Cardinality	Data Type	Ex. UCUM Units
75881- <u>3</u>	Lupus anticoagulant aPTT & dRVVT & PT screening panel W Reflex		•	•••	
6303-2	dRVVT (LA screen)	R-a			S
15359-3	dRVVT actual/normal (normalized LA screen)	R-a			%
75513-2	dRVVT with 1:1 PNP (LA mix)	Rflx-a			S
75512-4	dRVVT with 1:1 PNP actual/normal (normalized LA mix)	Rflx-a			%
57838-5	dRVVT W excess phospholipid (LA confirm)	Rflx-a			S
68916-6	dRVVT W excess phospholipid actual/normal (normalized LA confirm)	Rflx-a			%
75511-6	dRVVT W excess phospholipid percent correction	0			%
50410-0	dRVVT/dRVVT W excess phospholipid (screen to confirm ratio)	0			
34571-0	aPTT.lupus sensitive (LA screen)	R-a			S
48022-8	aPTT.lupus sensitive actual/normal (normalized LA screen)	R-a			
75510-8	aPTT.lupus sensitive with 1:1 PNP (LA mix)	Rflx-a			S
75509-0	aPTT.lupus sensitive with 1:1 PNP actual/Normal (normalized LA mix)	Rflx-a			%
<u>75506-6</u>	aPTT.lupus sensitive W excess phospholipid (LA confirm)	Rflx-a			S
<u>75508-2</u>	aPTT.lupus sensitive W excess phospholipid actual/Normal (normalized LA confirm)	Rflx-a			%
<u>75884-7</u>	aPTT.lupus sensitive/aPTT.lupus sensitive W excess phospholipid (scree to confirm ratio)	en O			{Ratio}
<u>75507-4</u>	aPTT.lupus sensitive W excess phospholipid percent correction	0			%
5902-2	Prothrombin time (PT)	R-a			S
5894-1	Prothrombin time (PT) actual/Normal	R-a			%
3243-3	Thrombin time	Rflx-a			S
68325-0	Thrombin time actual/Normal	Rflx-a			%
6683-7	Reptilase time	Rflx-a			S
68326-8	Reptilase time actual/Normal	Rflx-a			%
75882-1	Lupus anticoagulant three screening tests W Reflex [interpretation]	R			

Figure 1. Details page for three screening test lupus anticoagulant panel

7.5 Approach to creating and defining distinct panels in LOINC

7.5.1 General approach

The defining characteristics of a LOINC panel term include the enumerated set of child elements and the conditionality of those elements. Thus, users must pay close attention to the full panel structure in order to know whether it is an appropriate representation of their local panel.

When LOINC defines a panel, it will include all of its primary measurements/observations (flagged as required), and will also include commonly reported derived observations (flagged as optional). When laboratories report an interpretation across many observations in a panel, such as the differential count or a serum electrophoresis, the LOINC panel will include an interpretation term specific to that panel (flagged as optional). Likewise, the panel will also contain commonly included AOE variables and other associated observations (flagged as optional).

LOINC will not define distinct panels for different collections that vary only on the optional elements (whether or not there is an interpretation, an additional derived calculation, variables sent along with the request, etc.). As a corollary, users can match their local panels to LOINC panels whether or not their reported results include those optional elements.

During the several years prior to the LOINC 2.56 release, the number of requests for panel terms steadily increased. At the same time, newer laboratory methods have led to the creation of lab kits that could be customized by the end-user in terms of the individual tests that were run. For example, if a kit includes ten different assays, one hospital might implement six while another hospital might implement all ten of the assays. In addition, each version of the kit could potentially have different combinations of tests. Many of our requests were for panels that differed only slightly from existing panels, likely in part due to differences in the aforementioned kit implementation. Going forward, it now appears impractical to create a unique panel for every hospital, laboratory, and test kit. Therefore, at the June 2016 meeting, the Laboratory LOINC Committee agreed upon the following business rules for new panel requests:

7.5.1.1 Panels for test kits

We will make generic panels for groups of tests that are not specific to a particular manufacturer or test kit but that are method- and system-specific. Such panels will not have conditionality or cardinality specified. As test kits evolve over time, additional children may be added, but none will be removed except in limited circumstances. Examples of such panels are:

79381-0 Gastrointestinal pathogens panel - Stool by Probe and target amplification method

82180-1 Meningitis+Encephalitis pathogens DNA and RNA panel - Cerebral spinal fluid by Target amplification with non-probe based detection

7.5.1.2 Panels for individual laboratories and/or hospitals

In general, we will not create new panels for every hospital and laboratory, based on their unique combination of elements. However, we likely will make panels when many hospitals and/or labs use the exact same set of elements.

7.5.1.3 Fully specified panels

We will make panels with conditionality and cardinality details in cases where a specific guideline or standard of care exists, such as the lupus anticoagulant screening panel examples above.

7.5.2 Preference for methodless panel definitions

In most cases, LOINC will not make up different panel terms 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". Thus, as a general approach we tend to create panels with child elements that are methodless.

In special circumstances though, we do create panels of method-specific observations. For example, we have different panels for screen and confirm methods. In such cases, the method specification is the defining characteristic of the panel.

7.5.3 Special cases where enumeration of child elements is not practical

There are special cases where LOINC may define a panel term by a narrative definition because it is not practical to fully enumerate all of the possible child elements and their conditionality.

For example, public health, veterinary medicine, and other laboratories that are not charging Medicare or Medicaid for the tests they perform are not bound by the rules that penalize labs for performing and charging for tests that the practitioner did not explicitly order. This makes creating order panels a little easier.

In the case of public health, the tests performed by a laboratory in response to a request may be chosen from a list of many possible tests, based on information provided by the requester, and the laboratory's judgment. For example, CDC's "Campylobacter, Helicobacter and related organisms identification and subtyping" (CDC-10127) order can include tests that identify the phenotype, the genotype, Penner serotype, PFGE, or AST, and might use multiple test procedures for each of these.

8 Evolving principles for naming collections

8.1 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 how the 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 discrete 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.

8.2 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 an 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". Rather, 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 discrete 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.

8.3 LOINC Scale for collections

Where the Scale for individual elements in a panel vary, the name of the panel term itself will be a dash (-). 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. We are in the process of reviewing our current use of Nar (narrative) or **Nom** (nominal) for general information collections in some portions of the LOINC database and migrating towards broader use of **Doc**. We have already made such changes in some areas, for example Radiology and Molecular Pathology.

9 Additional content in the LOINC distribution

9.1 Additional attributes of LOINC terms

9.1.1 Categorizing LOINC terms as Order, Observation, or Both

LOINC terms can be matched to local test codes that fulfill different roles. For example, a LOINC code can be used to place an order, to report discrete observations, or in some cases a LOINC term can serve in both ways.

The purpose of the ORDER_OBS field in the LOINC database is to provide users with an idea of the intended use of the term by categorizing it as an 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 collection of items that is known to be orderable. Our categorization of a term in this way is not a normative or binding resolution. That is, it is not a definitional attribute of the term. Rather, it represents Regenstrief's best approximation of how the term is used. (If you feel a term should be categorized a different way, please let us know.)

In HL7 messages, the place in the message where the LOINC code is used will indicate what role the LOINC term is fulfilling. If it is in OBX-3, it is being used as an observation. If it is in OBR-4, it is an order.

Examples of each category include:

Order Only

```
34531-4 Blood type and Crossmatch panel - Blood
```

This term represents an order for a type and cross that would never carry an answer (i.e., result value). Panel terms typically fall in the Order only category.

Observation Only

```
51890-2 Factor VIII units given [#]
```

This term is a discrete observation that would carry a result of the number of units given to the patient, but would never be placed as an order for 'Factor VIII Units given'.

Both

```
882-1 ABO and Rh group [Type] in Blood
```

This term could be used to place an order as well as report the result of the test (e.g., A Positive).

9.1.2 Associated observations

In the LOINC Table, a LOINC term can be linked to one or more optional "associated observations" in the

Associated Observation field. Associated observations are additional variables that may be reported along with the primary observation. Within LOINC, we can link primary observation terms to other single LOINC terms or panels containing a set of terms.

There are three main use cases for linking LOINC terms to other associated observations:

- 1. Reporting information related to the primary result that otherwise might be reported using a comment field, such as the volume of urine in a 24-hour urine collection or specimen weight;
- 2. Including key data in a structured, computable format when sending an otherwise unstructured text report or document;
- 3. Identifying the sections and entries from HL7 Clinical Document Architecture (CDA) implementation guides that can be reported with certain LOINC document codes.

Associated observations can be used in conjunction with lab results that are typically sent in an unstructured format, such as genetic testing results. We encourage laboratories to report as much data as they can using the discrete variable LOINC codes so that the data are more directly computable. For example, associated observations linked to a BRCA1 gene targeted mutation analysis may include concepts such as gene identifiers, the reason for genetic testing, genetic sequence variation that was found, genomic reference sequence, and specific version of the coding system that was used to report the results. At the same time, laboratories can still retain the flexibility of sending text reports that can be formatted for readability.

Many LOINC document codes can be used with one or more related HL7 CDA implementation guides (IG). To facilitate identifying which sections (and sometimes entry level codes) may be used with a particular document code, we are working to link a panel of associated observations for each IG.

9.1.3 Ask-at-order-entry (AOE)

Ask-at-order-entry (AOE) observations in LOINC are observations obtained from the requester as part of the test order and generally delivered back to the requester as part of the result package. For example, the concentration of inspired oxygen is always an AOE question for blood gas measurements as well as the date of last menstrual period for pap smears.

Within LOINC, we can connect AOE observations to the primary test using a similar structure as described for associated observations. The linkage between the primary observation and AOE observations is stored in the AskAtOrderEntry field of the LOINC Table. We have not implemented AOE observations extensively yet but have the mechanism in place, and we are working with multiple organizations to target specific domains, including infectious diseases and other public health domains such as lead testing.

9.1.4 Related names

The LOINC database includes a field (RELATEDNAMES2) for related names associated with LOINC terms. We provide these associations as a service to LOINC users to help them find the concepts they are searching for. We often colloquially use the word "synonym" when referring to related names, however, most of the terms in the RELATEDNAMES2 field are not true synonyms. Values in this field may include common names, abbreviations, previous nomenclature, common misspellings, allergen codes, and associated diseases. This information is intended to help users locate relevant concepts, but it may also result in "false-positive" search results due to overlap in the related names associated with different concepts. For example, one of the related names for Influenza is Flu, so searching for Flu will return LOINC codes relevant to Influenza. However, Flu is also associated with Fluid, so the same search for Flu will also return LOINC codes with the System of Body fluid, Amniotic fluid, etc.

9.2 LOINC Answers (LA) and Answer Lists (LL)

Across many domains, the meaning of a particular observation can be best understood in the context of the set of possible answers (result values). For example, 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 the 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 answer lists in LOINC.

We identify the binding of LOINC observation codes to answer lists as "normative", "preferred", or "example".

Normative lists are those specifically defined by a validated instrument or other authoritative source. When using LOINC codes bound to normative answer lists, only answers in the specified set are allowed as result values. Examples of sources for Normative answer lists are PROMIS or the Clinical Pharmacogenetics Implementation Consortium (CPIC).

Preferred lists contain a set of answers that users are strongly encouraged to use. They represent a recommended set, however, in contrast to a Normative list, alternate result values may be used if necessary. Preferred lists may come from a variety of sources, including professional organizations (e.g., American Physical Therapy Association), device manufacturers, and government (e.g., Centers for Diseases Control and Prevention, National Eye Institute).

Example lists are meant to be illustrative of possible result values. Users can also think of them as a starter set to which they may add or subtract depending on their use case. Many of the Example answer lists are in the lab domain, where different labs may report similar results in a variety of ways, such as "Positive", "Present", "Detected", "Abnormal" or "Out of range" but for which we have a single Example answer list.

Starting in the version 2.61 release, we have created a mechanism by which a single LOINC term may be linked to multiple answer lists with different binding strengths defined in the context of a given panel. For example, if two different survey instruments have the exact same question with two different answer lists, rather than making two different codes with different *Methods*, we now have the ability, within the context of a panel, to attach a different answer list to the same question. We will only use this mechanism when the meaning of the observation is the same across panels. If the observations represent different questions, we will make different codes. We will apply this format to new terms moving forward and plan to update existing terms over time.

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 and we do not reproduce those lists within the LOINC structure. Answer lists that are not enumerated within LOINC are flagged to indicate that they are externally defined. We record the answer list OID (whether assigned by Regenstrief or another organization) and optionally a URL pointing to the 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.

LOINC answer lists are also assigned a non-semantic identifier with a "LL" prefix and a mod-10 check digit (see Appendix C). LOINC answer lists are available for viewing in the RELMA program, on details pages, and are also contained in the LOINC Panels and Forms file that is part of the LOINC distribution. Only answer lists for LOINC terms that are contained within panels are available in the Panel and Forms file.

Beginning with LOINC version 2.61, answer lists (and answers) are also available in the Answer artifact, which is a separate download from the LOINC website. This file includes two tables: one includes all of the Answer lists (including information about each list as well as the answer strings it contains) that are associated with LOINC

terms in the current release, and the second contains links between all of the LOINC terms that have answer lists and those lists. Please see the AnswerFile_Readme.txt document included in the AnswerFile for more information.

9.2.1 Null flavors in LOINC Answer lists

It is often necessary to indicate that a valid result value is not present. For example, a question on a questionnaire might have a set of response choices and then one choice at the end like "unknown", "not applicable", "not available", etc. In HL7 standards, these kinds of response values are called **null flavors** (see https://www.hl7. org/fhir/v3/NullFlavor/index.html).

There are two techniques for communicating a null flavor. In version 3 messaging, there is a dedicated nullFlavor attribute that is available for every observation, so these choices are not part of the actual answer list. In version 2 messaging and FHIR, the convention includes the specific allowed null flavors within the choices of the answer set. We can see advantages to both approaches.

Within LOINC, we do not want to make different answer lists that vary only by the inclusion or exclusion of certain null flavors. This is true even for **Normative** answer lists. Thus, our policy is to add specific null flavors as entries in the answer list where we are aware of their relevance. But, any LOINC answer list (including **Normative** lists) can be extended or limited by null flavors without violating the intended conformance that is specified through the binding. So, if a Normative answer list included an "unknown" answer choice, LOINC would not create a separate code for the same observation with "not available" in the answer list instead of "unknown". From the perspective of conformance to the LOINC meaning, users are also free to make such substitutions, insertions, or exclusions of null flavor(s) in the answer list.

9.3 LOINC Parts and Part hierarchies

In order to support several key aspects of development, Regenstrief has created LOINC parts, which are a coded representation of a value for a dimension used to specify a LOINC term. LOINC parts support the translation of LOINC terms into other languages, easy linking of synonyms across many terms, the creation of hierarchies to group related LOINC terms, and several other functions.

Individual LOINC parts are assigned a non-semantic identifier with a LP prefix and a mod-10 check digit.

The intended use of the LOINC parts and LOINC part hierarchies are to organize or be constituents of LOINC terms. As described in the LOINC license, they are not intended for use as a "standalone" terminology nor apart from LOINC terms.

Furthermore, LOINC parts and LOINC part hierarchies are not strictly managed under the same policies (e.g. concept orientation, concept permanence) as are LOINC terms.

9.3.1 Part distribution

Beginning with LOINC version 2.61, we are releasing a Part artifact as a separate download from the LOINC website. This file includes three tables: one includes all of the Parts associated with all of the LOINC terms in the current release, the second contains links between LOINC terms and their parts, and the third has mappings between a subset of Parts and related codes from external standard terminologies such as SNOMED CT. Please see the PartFile_Readme.txt document included in the PartFile for more information.

9.4 Descriptions

LOINC contains two types of descriptions, one at the Part level and one at the term level. Descriptions are attached to parts when the information is specific to the part, such as Component or Method, and they are attached to the term when the information applies to the term as a whole and not to any individual part of the term. For example, the Component part Glucose is associated with a description for the carbohydrate glucose, while the following term description describes the Peritoneal Equilibration Test, which applies to the combination of Glucose, Overnight dwell and Peritoneal dialysis fluid:

79264-8 Glucose [Moles/volume] in Peritoneal dialysis fluid --overnight dwell

A Peritoneal Equilibration Test (PET) is used to assess transport properties of the peritoneal membrane in patients undergoing peritoneal dialysis. Patients arrive at the dialysis unit in the morning with their overnight dwell fluid still in the abdomen. The overnight fluid is completely drained and sampled for testing. In the classic PET, 2000 ml of a 2.27% glucose solution is instilled and peritoneal dialysis is begun. Ten ml samples are drawn at time 0, 2, and 4 hours to measure creatinine, urea, and glucose. The PET assesses the rate of solute equilibration between peritoneal capillary blood and dialysate based on the ratio of the solute concentrations in dialysate and plasma (D/P). PET results are used to adjust various aspects of a patient's peritoneal dialysis regimen, including dwell time, number of exchanges, and dialysis volume and composition. [PubMed: 7474677]

9.5 LOINC Table Core

Beginning with LOINC version 2.61, we are providing an artifact called LoincTableCore that is available as a separate download from the LOINC website. The purpose of this core table is to provide essential LOINC content in a format that is more stable over the long-run. The core table contains all of the LOINC terms that are in the complete table (i.e., the same number of rows), but a subset of the fields (i.e., different number of columns). The fields included in the core table are ones that are both crucial for defining each LOINC term and whose structure is not likely to change in the short-term. We are providing this format in order to make it easier for implementers to update to the latest LOINC release without having to make changes to their database structure. However, depending on their use case, some implementers may still need to refer to the complete LOINC table in order to find all of the relevant information.

9.6 LOINC groups

Beginning with LOINC version 2.61, we are providing an artifact called *Groups* that is available as a separate download from the LOINC website. The goal of the LOINC groups project is to create a flexible, extensible, and computable mechanism for rolling up groups of LOINC codes for various purposes. Representative use cases include aggregating data for displaying on a flowsheet within an EHR system, retrieving data for quality measure reporting, and collecting data for research. This is a work in progress and the contents of the file and the groupings MUST be validated by users prior to implementation in any aspect of clinical care. Please see the GroupFile_Readme.txt document contained in the GroupFile for more information.

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. Bakken³⁰ 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. 31

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

Bakken S, et al. Evaluation of Clinical LOINC (Logical Identifiers, Names, and Codes) for Terminology Model for Standardized Assessment of Measures. JAMIA 7:2000; 529-538. [PubMed: 11062226]

Vreeman DJ, McDonald CJ, Huff SM. LOINC® - A Universal Catalog of Individual Clinical Observations and Uniform Representation of 31 Enumerated Collections. Int J Funct Inform Personal Med. 2010;3(4):273-291. Epub 2011 May 23. [PubMed: 22899966]

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

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 guestions 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 (EXTERNAL_COPYRIGHT_NOTICE). 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. As described in Section 9.2, we have created a structured representation of the answer lists for the questions in assessment instruments represented in LOINC.

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 lookback 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:

1. **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**. We have also used the DISPLAY_ NAME_FOR_FORM field in cases where minor edits in question text (e.g. referring to the subject as "patient" versus "resident") vary by form but do not have a significant change in question meaning.

If the question or variable is from a survey:

- **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?"
- **COMPONENT** in the LOINC table. This is the default display.

Else:

- **SHORTNAME** in the LOINC table. This field contains a short display name (target is 40 characters or less).
- **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 Long Common Name and Consumer Name. These additional names may be useful in some contexts for these items, but 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 the 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. 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.

10.3.7 Time Aspect (3rd part) for a question or variable

Beginning with the June 2015 LOINC release, the Time Aspect for survey questions that include a lookback period specify that lookback period as the Time rather than using Pt. This change was approved by the LOINC Clinical Committee at the February 2015 Clinical LOINC meeting and will apply to all new terms moving forward.

At the August 2015 Clinical LOINC meeting, further naming conventions were approved. These conventions include:

- Using the exact timing given in a validated survey question as the *Time Aspect* value (i.e., for questions with a 7-day lookback period, using 7D for Time Aspect rather than 1W)
- Adding **Lifetime** as a possible *Time Aspect* value
- For questions with a lookback range, using the longer end of the range for *Time Aspect* (e.g., if the question asks "In the last 2-6 months...", the *Time Aspect* value will be **6Mo**).

As of LOINC version 2.54, nearly all of the existing survey instrument terms that include a lookback period have an updated Time Aspect part, and we will continue to make these changes moving forward for any terms that were not updated for the 2.54 release.

10.3.8 Form Information

Assessment instruments often contain additional text either preceding or following an item to guide users in completing the form or provide additional context about the item. LOINC uses two fields, form CodingInstructions and Context, to represent this information.

When the text gives details about completing the form, for example, "Enter 88 if patient does not answer or is unable to respond", that text is represented as form CodingInstructions.

When the text provides additional explanation or description, it is typically represented as Context. For example, along with an item recoding the number of stage 2 pressure ulcers a patient has, the form may display a clinical explanation of what a stage 2 ulcer is: "Stage 2: Partial thickness loss of dermis presenting as a shallow open ulcer with a red or pink wound bed, without slough. May also present as an intact or open/ruptured blister." Such text is represented as Context.

These form-specific attributes are displayed on the LOINC details pages and are present in the LOINC Panels and Forms File.

10.4 Assessment content in the LOINC distribution

All of the assessment content is included within the RELMA program. 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 called the LOINC Panels and Forms File. 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
- 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.

10.5 In-progress updates through our collaboration with CMS on post acute care assessments

Through a collaboration with Centers for Medicare and Medicaid Services (CMS), we are updating the current LOINC representation of CMS Long-term Post Acute Care (LTPAC) assessments and creating new LOINC representations for CMS PAC assessments not currently represented in LOINC. The work includes the Nursing Home Minimum Data Set (MDS), Long-term Care Hospital CARE Data Set (LCDS), In-Patient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI), and the Home Health Outcome and Assessment Information Set (OASIS).

Our work on this content began in August 2016, and starting with LOINC version 2.63 (December 2017), new and updated content represents current versions of all four CMS LTPAC assessments. As we continue to collaborate with CMS, we plan to release the LOINC representation for each new version of these assessments prior to its CMS final publication date so that the LOINC content will be available for implementation at the time of final publication.

In undertaking this work, the LOINC Committee agreed to adopt a unified Method of CMS Assessment across all instruments, rather than having a Method specific to the assessment instrument that was first modeled in LOINC. This change encourages and facilitates re-use of assessment variables across instruments where appropriate.

We have also enhanced the RELMA program with links to the CMS assessment item codes that are searchable as "Related Codes". For example, searching "RelatedCodes: BB0700" in RELMA will return the LOINC term that represents the CMS assessment item "Expression of ideas and wants".

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. Subsequently, we converted the few Danish serotype identifiers to their corresponding U.S. serotype identifiers. Even more recently, when we found out that the Danish nomenclature is, in fact, the one that is commonly used both internationally as well as in the U.S., and that the numbers assigned to serogroups and serotypes identified over the last several years made our existing terms ambiguous and confusing, we did a thorough review of our existing terms. As described in more detail in the <u>Streptococcus pneumoniae serotype nomenclature</u> technical brief, we deprecated all of the terms that were ambiguous and mapped them to new terms. In addition, we updated the names for the ones ones that were not ambiguous, because 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 often, 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:

Status	Description
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 mappings may continue to be valid in context. Wherever possible, the superseding concept is indicated in the MAP_TO field of the MapTo Table (see Appendix A , Table 31b) 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 MapTo Table (see Appendix A, Table 31b) 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 statuses 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 statuses.

Our initial implementation of these new concept status values in LOINC 2.31 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 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 MapTo 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 MapTo 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 31b for information about the MapTo table.

In rare cases, we have had to "undeprecate" **DEPRECATED** terms when upon further, very careful review, we discovered that the concepts are, in fact, valid. Such terms will revert back to a STATUS of ACTIVE but can be identified by the value **UNDEL** in the *Chng_Type* field. We have chosen to undeprecate the codes in such rare cases (instead of making new terms) because **DEPRECATED** terms continue to be included in the LOINC database, and some users may continue to use such concepts or have historical data associated with those codes. If we were to create new codes for the same concept, different users could potentially use different codes to identify the exact same data.

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.

11.4 Publication of LOINC codes in advance of official releases

Supported by the LOINC Committee, Regenstrief has had a long-standing policy of returning new LOINC codes to those who made the request (i.e. the submitter) as soon as the LOINC term passes our internal QA processes rather than waiting for the next official release. The LOINC Committee has also approved Regenstrief's publication of the new codes on a special page of the LOINC website after they pass internal QA but in advance of the next official release. It is understood that providing these codes back to the requestor and listing them on the LOINC website is done for informational purposes only, with the additional caveat that the concept could change prior to inclusion in a public release.

The public should not be expected to have adopted such "pre-released" LOINC codes until they appear in a formal release. Yet, such an approach is valuable because it facilitates the inclusion of new codes in implementation guides and other documents and systems that have their own, often lengthy, development cycles.

12 Recommendations for best practices in using and mapping to LOINC

12.1 Business rules for users mapping their local panels to **LOINC** panels

Through discussion with the ACLA, the S&I Framework aLOINC Order Code Initiative, and others, the LOINC Committee has vetted a set of business rules to help LOINC users understand how to compare their panels to a LOINC panel. These rules help clarify what variation is allowed within the LOINC panel definition that still constitutes a "match" for their panel. In these rules, we use "element" to mean a child LOINC that is a member of the panel definition.

12.1.1 Must contain all of the required elements

To establish equivalence (e.g. for mapping), a user panel must contain all of the required elements of a LOINC panel. Some of the other business rules define allowable substitutions, but the general rule is that all required elements must be present in the user panel.

12.1.2 No extra primary measurements

A user panel cannot be considered equivalent to a LOINC panel term if it contains additional primary measured tests that are not part of the LOINC panel definition.

12.1.3 Optional elements are optional

A user panel can be considered equivalent to a LOINC panel term whether or not it contains the elements marked as optional in the LOINC panel definition.

12.1.4 Substitutions related to Method

Panel elements that do not contain a *Method* specification (i.e. the *Type of Method* part is null) can be treated as a "representative" term that a user could replace with another LOINC term that differed only by specification of Method.

For example, LOINC contains an adenovirus panel:

55160-6 Adenovirus IgG and IgM panel - Serum

with two elements that lack *Method* specification:

```
13914-7 Adenovirus IgG Ab [Units/volume] in Serum
5042-7 Adenovirus IgM Ab [Units/volume] in Serum
```

If a user had a local panel that was similar but had instead mapped to terms that specified the Method of EIA, they may wonder whether their panel was equivalent to the panel in LOINC. Using this business rule, the answer is yes. Either or both of the methodless LOINC panel elements could be replaced by these method-specific LOINC terms that are equivalent on the other attributes:

```
51822-5 Adenovirus IgG Ab [Units/volume] in Serum by Immunoassay
51823-3 Adenovirus IgM Ab [Units/volume] in Serum by Immunoassay
```

However, when a panel element measures an analyte by a particular method, then the LOINC term reported for that analyte would have to be done by that method. Neither replacement by a methodless term nor by a different method would be allowed.

12.1.5 Substitutions for mass versus substance Properties

LOINC defines different terms that distinguish between mass-based and substance-based (moles/ milliequivalents) measures for a single analyte. Different jurisdictions vary in whether they favor reporting in mass units (e.g. mg/dL) or molar units (e.g. mmol/L) for certain analytes.

In order to promote the international reuse of panels, the LOINC Committee has agreed (at its June 2015 meeting) to allow users to substitute panel elements that a) agree on all other LOINC parts, and b) contain an analogous molar Property to a reference element with a mass Property or vice versa.

To illustrate, panel element terms with the *Property* of mass concentration (**MCnc**) could be replaced by substance concentration (SCnc) terms, mass rate (MRat) terms could be replaced by substance rate (SRat), terms etc. For example, in the Lipid panel with direct LDL - Serum or Plasma (LOINC: 57698-3) a user could make substitutions as below and still have a comparable panel:

Reference term:	<u>2093-3</u>	Cholesterol [Mass/volume] in Serum or Plasma
Substitute term:	14647-2	Cholesterol [Moles/volume] in Serum or Plasma
Reference term:	<u>2571-8</u>	Triglyceride [Mass/volume] in Serum or Plasma
Substitute term:	<u>14927-8</u>	Triglyceride [Moles/volume] in Serum or Plasma

And so forth.

12.1.6 No substitutions of quantitative for qualitative (and vice versa)

A quantitative panel element (e.g. one that has a Scale of **Qn**) cannot be replaced by a qualitative term (e.g. one that has a Scale of **Ord**) and have the panel be considered equivalent. Likewise, qualitative terms cannot be replaced by quantitative terms in the panel definition.

12.1.7 Pay attention to reflex elements

LOINC defines different panels for testing that has reflex elements from ones that do not. Thus, users must be aware of the test(s) done as a reflex both in their local panels and in the LOINC definition. The reflex test(s) can be a single test, a group of tests, or a test panel. A user panel is comparable to the LOINC panel if the specification

12.1.8 Special case of differential counts (including conventions for not reporting zero counts)

Panels, like blood differential counts and urinalyses, for which zero counts (e.g. for the % of blast cells) are usually not reported explicitly present a special case. These are included in the panel definition but are marked as conditional (C) to signal that under some circumstances (e.g., when they have a value of zero), they are not reported. Differential counts present another problem in that a given cell type could be reported as a fraction of the total WBC and/or as an absolute count, so both species are included in the panel for differential counts, but as discussed above, both are not required in the report.

12.1.9 Panels with only narrative definitions of the elements they should contain

As described above, in certain special cases, such as public health and veterinary testing, LOINC may define a panel term by a narrative definition rather than enumerating the set of child elements. In such cases, the user must read the definition and use their professional judgment as to whether or not their local panel is comparable to the LOINC panel.

12.2 Examples of applying the business rules for users mapping their local panels to LOINC panels

12.2.1 Comparison Panel: Varicella zoster virus IgG and IgM panel - Serum (LOINC: 45063-5)

This user-defined panel is considered comparable since the component tests are the same and it is acceptable to use method- specific LOINC codes for panels defined with methodless LOINC codes.

Elements of LOINC Panel				
LOINC_NUM	Long Common Name	R/O/C		
<u>8048-1</u>	Varicella zoster virus IgM Ab [Units/volume] in Serum	R		
8047-3	Varicella zoster virus IgG Ab [Units/volume] in Serum	R		

Elements of User-defined Panel				
LOINC_NUM	Long Common Name			
<u>5404-9</u>	Varicella zoster virus IgM Ab [Units/volume] in Serum by Immunoassay			
<u>5403-1</u>	Varicella zoster virus IgG Ab [Units/volume] in Serum by Immunoassay			

12.2.2 Comparison Panel: Creatine kinase panel - Serum or Plasma (LOINC: 24335-**2**)

This user-defined panel is not considered to be comparable since it includes two additional measured components that are not in the LOINC Panel.

Note

The inclusion of an Optional component in the LOINC Panel does not have a bearing on the comparability of the user-defined panel.

Elements of LOINC Panel			
LOINC_NUM	Long Common Name	R/O/C	
<u>2157-6</u>	Creatine kinase [Enzymatic activity/volume] in Serum or Plasma	R	
<u>20569-0</u>	Creatine kinase.MB/Creatine kinase.total in Serum or Plasma	R	
<u>9642-0</u>	Creatine kinase.BB/Creatine kinase.total in Serum or Plasma	R	
9643-8	Creatine kinase.MM/Creatine kinase.total in Serum or Plasma	R	
<u>5912-1</u>	Creatine kinase isoenzymes [interpretation] in Serum or Plasma	0	

Elements of User-defined Panel			
LOINC_NUM	Long Common Name		
<u>2157-6</u>	Creatine kinase [Enzymatic activity/volume] in Serum or Plasma		
20569-0	Creatine kinase.MB/Creatine kinase.total in Serum or Plasma		
<u>9642-0</u>	Creatine kinase.BB/Creatine kinase.total in Serum or Plasma		
<u>9643-8</u>	Creatine kinase.MM/Creatine kinase.total in Serum or Plasma		
<u>26020-8</u>	Creatine Kinase.macromolecular type 2/Creatine kinase.total in Serum or Plasma		
26019-0	Creatine Kinase.macromolecular type 1/Creatine kinase.total in Serum or Plasma		

12.2.3 Comparison Panel: Drugs of abuse 5 panel - Urine by Screen method (LOINC: 65750-2)

This user-defined panel is considered to be comparable since the components use the same method-specific LOINC terms and the additional test is a non-measured component (i.e., it is a variable provided by the requester that is echoed back with the results).

Elements of LOINC Panel				
LOINC_NUM	Long Common Name	R/O/C		
<u>19261-7</u>	Amphetamines [Presence] in Urine by Screen method	R		
14314-9	Benzoylecgonine [Presence] in Urine by Screen method	R		
<u>18282-4</u>	Cannabinoids [Presence] in Urine by Screen method	R		
<u>19295-5</u>	Opiates [Presence] in Urine by Screen method	R		
<u>19659-2</u>	Phencyclidine [Presence] in Urine by Screen method	R		

Elements of User-defined Panel			
LOINC_NUM	Long Common Name		
<u>19261-7</u>	Amphetamines [Presence] in Urine by Screen method		
<u>14314-9</u>	Benzoylecgonine [Presence] in Urine by Screen method		
<u>18282-4</u>	Cannabinoids [Presence] in Urine by Screen method		
<u>19295-5</u>	Opiates [Presence] in Urine by Screen method		
<u>19659-2</u>	Phencyclidine [Presence] in Urine by Screen method		

12.3 Querying LOINC and creating intensional value set definitions based on LOINC database structure

Specifications that contain queries meant to be run on the LOINC distribution or that contain intensional value set definitions should be expressed with the LOINC attributes contained in Appendix A - LOINC Database Structure. (In JSON representations such as HL7's FHIR, the LOINC attribute serves as the key in an object's property definition. Not to be confused with the LOINC notion of *Property*, in JSON, a key-value pair is often referred to as a property). The available LOINC attributes are the items listed in the Field Name column of that table. Unless Regenstrief publishes a definitive specification otherwise (see discussion of canonical LOINC representation in FHIR below), these names, and their spellings, are the official attribute names. For example, specifying the set of LOINC terms with a scale of document would reference the LOINC attribute SCALE_TYP and its value of **DOC**.

In addition, for LOINC codes that are part of the Document Ontology or those that are radiology procedure codes, there are additional attributes that may be used in attribute-based Value Set Definition components. All attributes will have string values that may be used for the attribute (property) value part of the definition. Some will also have coded identifiers (e.g. LOINC Part codes) that can be used in addition to the string.

For Document Ontology:

- Document.Kind
- Document.TypeOfService
- Document.Setting
- Document.Role
- Document.SubjectMatterDomain

These Document Ontology attributes are currently published in the accessory Document Ontology File (available as a separate download from the LOINC website), and will likely be extended in the future. They will always be the unique values in the PartTypeName field of the Document Ontology File. Starting with the LOINC version 2.61, these are also published in the LOINC Part File artifact (also available as a separate download).

For Radiology:

- Rad.Guidance for.Presence
- Rad.Guidance for.Approach
- Rad.Guidance for.Action
- Rad.Guidance for.Object
- Rad.View.Aggregation
- Rad. View. View type
- Rad.Reason for Exam

- Rad.Maneuver.Maneuver type
- Rad.Timing
- Rad.Pharmaceutical.Substance Given
- Rad.Pharmaceutical.Route
- Rad. Anatomic Location. Region Imaged
- Rad. Anatomic Location. Laterality. Presence
- Rad. Anatomic Location. Laterality
- Rad. Anatomic Location. Imaging Focus
- Rad.Modality.Modality type
- Rad.Modality.Modality subtype
- Rad.Subject

These radiology attributes are published in the PartTypeName field of both the LOINC/RSNA Radiology Playbook File and the LOINC Part File. Both of these artifacts are available as a separate download from the LOINC website.

12.3.1 Canonical representation of LOINC as a FHIR CodeSystem

Together with the HL7 FHIR® team, we are working to create a specification for the canonical representation of LOINC in FHIR as a CodeSystem resource. This is a work in progress. An initial draft of that specification is available at https://loinc.org/fhir/loinc.xml.

This specification is specific to HL7 FHIR®, and it's definitions of the LOINC attributes would supercede the general guidance about names for attributes (properties) given above. For example, in the canonical representation for FHIR, the radiology LOINC attribute Rad. View. Aggregation will be named closer to the conventions for FHIR-style property names as "rad-view-aggregation".

12.4 The Code System for identifiers assigned by LOINC

All of the identifiers assigned by LOINC, including LOINC codes, Part codes (i.e. LP* codes), Answer codes (i.e. LA* codes), Answer List codes (i.e. LL* codes), and Group codes (i.e. LG codes) collectively belong to the LOINC code system. Depending on your technology or application, you may identify the code system in different ways. For example, in HL7 Version 2 it would typically be the abbreviation "LN", in CDA documents it would be an OID (2.16.840.1.113883.6.1), and in FHIR it would be the URI "http://loinc.org".

12.5 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).

Regenstrief and the LOINC Committee assert that best practice is to send the Long Common Name to accompany the LOINC code in messaging. The Long Common Name is complete, unambiguous, and the most understandable LOINC description for human readers.

We recognize that there may still be some information systems today that are not able to accommodate the character length of the Long Common Name. We strongly recommend updating such systems to accommodate longer names. The LOINC Short Name is smaller in size, but not very human friendly and is not populated for all LOINC terms. (We are working to improve on both of these issues). Using the Fully-Specified Name (e.g. a colonseparated 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. Laboratory local codes are often required to be sent by the performing laboratory to meet CLIA (U.S) and laboratory accreditation regulatory requirements in many countries.

It is also worth noting that use of the Long Common Name in messaging does not dictate which test name is displayed in user interfaces to clinicians. There are often regulatory requirements and/or local policies that influence what is shown to clinicians. Many of the implementations around the world using LOINC have a local "interface name" that users see. LOINC is working in the background.

12.6 Updating to new versions of LOINC

At the December 2015 Lab LOINC Committee meeting. Regenstrief and the LOINC Committee approved the following best practice:

We recommend that users update to the current version of LOINC within 90 days of its publication.

12.7 Using URIs to identify LOINC artifacts

In the context of RDF, OWL, and other technologies, URIs are the expected type of identifiers. Some LOINC users have asked for an approved convention for referring to LOINC-created identifiers (e.g. LOINC codes, LOINC Answer List Codes, LOINC Answer String Codes, etc). Here we describe approved patterns for use. Please note that this is an active area of discussion.

12.7.1 Using a URI to identify LOINC as a code system

In HL7 FHIR®, code systems are identified by URIs. As described in the section on LOINC as a code system, the recommended URI for this purpose is:

http://loinc.org

12.7.2 Using a URI to identify LOINC concepts as resources in RDF

The subject of an RDF statement is a uniform resource identifier (URI), or a blank node. After discussion at the Clinical LOINC Committee meeting in August 2015, we agreed to the following patterns:

For LOINC Terms:

http://loinc.org/rdf/{LOINC code}

e.g., http://loinc.org/rdf/2352-3

For LOINC Parts:

http://loinc.org/rdf/{LOINC Part code}

e.g., http://loinc.org/rdf/LP6990-8

In our current platform, URLs of these patterns resolve to the concept details pages (as used by search.loinc.org and RELMA).

The current version of the FHIR standard notes that the preferred LOINC pattern is http://loinc.org/owl. We are in discussion with the FHIR community about a preferred approach.

12.7.3 Using a URI to identify LOINC concepts as a value set

In some contexts, LOINC Parts, LOINC Answer Lists, and LOINC Groups represent value sets. LOINC represents the Multiaxial Hierarchy as a tree where LOINC Parts comprise all of the branches in the and LOINC terms comprise all of the leaf nodes. LOINC Answer Lists represent collections of coded concepts that can be used as response values to LOINC terms. LOINC Groups aggregate a set of LOINC terms that share certain characteristics. In these cases, LOINC defines an implicit value set associated with the code (e.g. a LP* code, a LL* code, or an LG* code).

Here we define a convention to make explicit when you are referring to these entities as either a) a code in the terminology or b) the implicit value set associated with the code.

When referencing the code itself, follow the usual pattern of referencing identifiers from the LOINC code system.

When referencing the implicit value set, use this pattern for the value set identifier as a URI: http://loinc.org/vs/{id}

For LOINC Parts:

http://loinc.org/vs/{LOINC Part code}

e.g., http://loinc.org/vs/LP52960-9

For LOINC Answer Lists:

http://loinc.org/vs/{LOINC Answer List code}

e.g., http://loinc.org/vs/LL715-4

For LOINC Groups:

http://loinc.org/vs/{LOINC Group code}

e.g., http://loinc.org/vs/LG9568-9

Appendix A LOINC Database Structure

Table 31a: LOINC Table Structure				
Field Name	Туре	Width	Description	
1. LOINC_NUM	Text	10	The unique LOINC Code is a string in the format of nnnnnnnnnnnnnnnnnnnnnnnnnnnnnnnnnnn	
2. COMPONENT	Text	255	First major axis-component or analyte	
3. PROPERTY	Text	255	Second major axis-property observed (e.g., mass vs. substance)	
4. TIME_ASPCT	Text	255	Third major axis-timing of the measurement (e.g., point in time vs 24 hours)	
5. SYSTEM	Text	255	Fourth major axis-type of specimen or system (e.g., serum vs urine)	
6. SCALE_TYP	Text	255	Fifth major axis-scale of measurement (e.g., qualitative vs. quantitative)	
7. METHOD_TYP	Text	255	Sixth major axis-method of measurement	
8. CLASS	Text	255	An arbitrary classification of the terms for grouping related observations together. The current classifications are listed in Table 32. 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. VersionLastChanged	Text	255	The LOINC version number in which the record has last changed. For records that have never been updated after their release, this field will contain the same value as the loinc.VersionFirstReleased field.	
10. CHNG_TYPE	Text	255	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	

11. DefinitionDescription	Memo	-	Narrative text that describes the LOINC term taken as a whole (i.e., taking all of the parts of the term together) or relays information specific to the term, such as the context in which the term was requested or its clinical utility.
			ACTIVE = Concept is active. Use at will.
			TRIAL = Concept is experimental in nature. Use with caution as the concept and associated attributes may change.
12. STATUS	Text	255	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 31b) 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 31b) and should be used both for new mappings and updating existing implementations.
13. 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.
14. CLASSTYPE	Number	-	1=Laboratory class; 2=Clinical class; 3=Claims attachments; 4=Surveys
15. FORMULA	Memo	-	Contains the formula in human readable form, for calculating the value of any measure that is based on an algebraic or other formula except those for which the component expresses the formula. So Sodium/creatinine does not need a formula, but Free T3 index does.
16. SPECIES	Text	20	Codes detailing which non-human species the term applies to. If blank, "human" is assumed.
17. EXMPL_ANSWERS	Memo	-	For some tests and measurements, we have supplied examples of valid answers, such as "1:64", "negative @ 1:16", or "55".
18. SURVEY_QUEST_TEXT	Memo	-	Verbatim question from the survey instrument
19. SURVEY_QUEST_SRC	Text	50	Exact name of the survey instrument and the item/question number
20. 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
21. SUBMITTED_UNITS	Text	30	Units as received from person who requested this LOINC term
22. RELATEDNAMES2	Memo	-	This field was 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).
23. SHORTNAME	Text	255	Introduced in version 2.07, this field contains the short form of the LOINC name and is created via a table-driven algorithmic process. The short name often includes abbreviations and acronyms.

			Defines term as order only, observation only, or both. A
24. ORDER_OBS	Text	15	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. This field reflects our best approximation of the terms intended use; it is not to be considered normative or a binding resolution.
25. 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.
26. 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.
27. EXTERNAL_COPYRIGHT_NOTICE	Memo	-	External copyright holders copyright notice for this LOINC code
28. 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.
29. LONG_COMMON_NAME	Text	255	This field contains the LOINC name 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.
30. UnitsAndRange	Memo	-	Units of measure (expressed using UCUM units) and normal ranges 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 a colon (:) and sets of unit:normal range pairs are separated by a semi-colon (;). Syntax for the normal range includes square brackets, which mean that the number adjacent to the bracket is included, and parentheses, which means that the number itself is not included. For example, [2,4] means "two to four", while [2,4) means "two to less than four" and (2,4) means "between two and four but does not include two and four".
31. 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 Work Group.
32. EXAMPLE_UCUM_UNITS	Text	255	The Unified Code for Units of Measure (UCUM) is a code system intended to include all units of measures being contemporarily used in international science, engineering, and business. (www.unitsofmeasure.org) This field contains example units of measures for this term expressed as UCUM units.

33. EXAMPLE_SI_UCUM_UNITS	Text	255	The Unified Code for Units of Measure (UCUM) is a code system intended to include all units of measures being contemporarily used in international science, engineering, and business. (www.unitsofmeasure.org) This field contains example units of measures for this term expressed as SI UCUM units.
34. 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.
35. 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.
36. CHANGE_REASON_PUBLIC	Memo	-	Detailed explanation about special changes to the term over time.
37. COMMON_TEST_RANK	Number	-	Ranking of approximately 2000 common tests performed by laboratories in USA.
38. COMMON_ORDER_RANK	Number	-	Ranking of approximately 300 common orders performed by laboratories in USA.
39. COMMON_SI_TEST_RANK	Number	-	Corresponding SI terms for 2000 common tests performed by laboratories in USA
40. HL7_ATTACHMENT_STRUCTURE	Text	15	This field will be populated in collaboration with the HL7 Attachments Work Group as described in the HL7 Attachment Specification: Supplement to Consolidated CDA Templated Guide. As of Version 2.58, the text will either be "IG exists" (previously STRUCTURED) or "No IG exists" (previously UNSTRUCTURED) for relevant terms. The "IG exists" terms are those that have clinically-relevant HL7 implementation guides that use the U.S. Realm Header. The "No IG exists" terms are those approved by the HL7 Attachments WG for transmission using the Unstructured Document template of the C-CDA.
41. EXTERNAL_COPYRIGHT_LINK	Text	255	For terms that have a third party copyright, this field is populated with the COPYRIGHT_ID from the Source Organization table (see Table 31c below). It links a external copyright statement to a term.
42. PanelType	Text	50	Describes a panel as a "Convenience group", "Organizer", or "Panel". A "Panel" is an enumerated set of terms that are used together in direct clinical care. The package would typically be thought of as a single orderable item that contains a set of reported observations. A "Convenience group" is an enumerated set of terms used for a common purpose, but not typically orderable as a single unit. An "Organizer" is a subpanel (i.e., a child) within another panel that is only used to group together a set of terms, but is not an independently used entity. They often represent a header in a form, or serve as a navigation concept.
43. AskAtOrderEntry	Text	255	A multi-valued, semicolon delimited list of LOINC codes that represent optional Ask at Order Entry (AOE) observations for a clinical observation or laboratory test. A LOINC term in this field may represent a single AOE observation or a panel containing several AOE observations.

44. AssociatedObservations	Text	255	A multi-valued, semicolon delimited list of LOINC codes that represent optional associated observation(s) for a clinical observation or laboratory test. A LOINC term in this field may represent a single associated observation or panel containing several associated observations.
45. Version First Released	Text	255	The LOINC version number in which the record was first released. For oldest records where the version released number is known, this field will be null.
46. ValidHL7AttachmentRequest	Text	50	A value of 'Y' in this field indicates that this LOINC code can be sent by a payer as part of an HL7 attachment request for additional information.

Table 31b: MapTo 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 31c: SourceOrganization Table Structure			
Field Name	Туре	Width	Description
1. COPYRIGHT_ID	Text	255	Used in the LOINC table as a foreign key.
2. NAME	Text	255	Name of the organization or institution.
3. COPYRIGHT	Memo	-	Copyright notice to be displayed for the organization or institution.
4. TERMS_OF_USE	Memo	-	Terms of use text for an external source.
5. URL	Text	255	URL link to the reference.

Appendix B Classes

Table 32a: Clinical Term Classes		
Abbreviation	Clinical Term Class	
ADMIN	Administrative	
ADMIN.DEMOG	Demographic observations	
APTA	American Physical Therapy Association	
ART	Antiretroviral therapy	
AUDIO	Audiology	
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.PROC	Cardiac procedures	
CARD.RISK	Cardiac Risk Scales Framingham	
CARD.US	Cardiac ultrasound (was US.ECHO)	
CARD.US.DICOM	DICOM Simplified Adult Echo Report concepts	
CARDIO-PULM	Cardiopulmonary	
CLIN	Clinical NEC (not elsewhere classified)	
CLIN.RISK	Clinical Risk	
CLINTRIAL	Clinical trails	
DENTAL	Dental	
DEVICES	Medical devices	
DOC.EPSOS	Smart Open Services for European Patients (epSOS) documents	
DOC.MISC	Miscellaneous documentation	
DOC.ONTOLOGY	Document Ontology	
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.ANGIO.NEI	NEI eyeGENE's angiography concepts
EYE.CONTACT_LENS	Ophthalmology contact lens
EYE.EOG.NEI	NEI eyeGENE's electrooculogram concepts
EYE.ERG.NEI	NEI eyeGENE's electroretinogram concepts
EYE.GLASSES	Ophthalmology glasses: Lens manufacturer (LM) & Prescription
EYE.HETEROPHORIA	Ophthalmology heterophoria
EYE.HX.NEI	NEI eyeGENE's eye history concepts
EYE.OCT	Ophthalmology Optical Coherence Tomography (OCT)
EYE.OCT.NEI	NEI eyeGENE's optical coherence tomography concepts
EYE.PX	Ophthalmology physical findings
EYE.PX.NEI	NEI eyeGENE's eye physical exam concepts
EYE.REFRACTION	Ophthalmology refraction
EYE.REFRACTION.NEI	NEI eyeGENE's refraction concepts
EYE.RETINAL_RX	Ophthalmology treatments
EYE.SLITLAMP.NEI	NEI eyeGENE's slit lamp biomicroscopy concepts
EYE.TONOMETRY	Ophthalmology tonometry
EYE.TONOMETRY.NEI	NEI eyeGENE's tonometry concepts
EYE.US	Ophthalmology ultrasound
EYE.VISUAL_FIELD	Ophthalmology visual field
EYE.VISUAL_FIELD.NEI	NEI eyeGENE's visual field concepts
FUNCTION	Functional status (e.g., Glasgow)
GEN.US	General ultrasound
GI	Gastrointestinal
H&P.HX	History
H&P.PX	Physical
H&P.SURG PROC	Surgical procedure
HEMODYN.ATOM	Hemodynamics anatomic
HEMODYN.MOLEC	Hemodynamics molecular
HL7.CCDA	HL7 Consolidated Clinical Document Architecture
HRTRATE.ATOM	Heart rate atomic
HRTRATE.MOLEC	Heart rate molecular
HRTRATE.PSTN.MOLEC	Heart rate positional molecular
HRTRATE.TIMED.MOL	Heart rate timed molecular
IEEE Rosetta	IEEE Rosetta
IO.TUBE	Input/Output of tube
IO_IN.ATOM	Input/Output atomic
	I The state of the

IO_IN.INFUS	Infusion pump intake measures
IO_IN.MOLEC	Input/Output molecular
IO_IN.SUMMARY	Input/Output summary
IO_IN.TIMED.MOLEC	Input/Output timed molecular
IO_IN_SALTS+CALS	Input/Output electrolytes and calories
IO_OUT.ATOM	Input/Output atomic
IO_OUT.MOLEC	Input/Output molecular
IO_OUT.TIMED.MOLE	Input/Output timed molecular
MEDS	Medications
NEMSIS	National EMS Information System data
NEONAT	Neonatology variables
NEURO	Neurology
NIH.COGNITIVE	NIH Toolbox Cognitive Domain
NIH.MOTOR	NIH Toolbox Motor Domain
NIH.SENSORY	NIH Toolbox Sensory Domain
NUTRITION&DIETETICS	Nutrition and Dietetics
OB.US	Obstetric ultrasound
OBGYN	Obstetric/Gynecology
ONCOLOGY	Oncology
PANEL.ADMIN	Administrative information panel
PANEL.APTA	American Physical Therapy Association panel
PANEL.ART	Antiretroviral therapy order set
PANEL.BDYTMP	Body temperature order set
PANEL.BP	Blood pressure order set
PANEL.CARDIAC	Cardiac studies order set
PANEL.CLIN	Clinical NEC (not elsewhere classified) set
PANEL.CLIN.RISK	Clinical risk panel
PANEL.CV	Cardiovascular order set
PANEL.DEVICES	Medical devices order set
PANEL.DOC	Documents panels
PANEL.ED	Emergency (DEEDS) order set
PANEL.EYE	Ophthalmology panels
PANEL.FUNCTION	Function order set
PANEL.H&P	History & Physical order set
PANEL.HL7.CCDA	HL7 Consolidated Clinical Document Architecture set
PANEL.IEEE ROSETTA	IEEE Rosetta panels
PANEL.IO	Input/Output order set
PANEL.MEDS	Medications panels
PANEL.NEMSIS	National EMS Information System data set
PANEL.NEONAT	Neonatal measures order set
PANEL.NIH.COGNITIVE	NIH Toolbox Cognitive Domain panels
PANEL.NIH.MOTOR	NIH Toolbox Motor Domain panels
PANEL.NIH.SENSORY	NIH Toolbox Sensory Domain panels
PANEL.NUTRITION&DIET	Nutrition and dietetics panel
PANEL.OB.US	Obstetrical order set

PANEL.ONCO	Oncology 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.SURG	Surgery panel
PANEL.TRAUMA	Trauma panel
PANEL.TUMRRGT	Tumor registry order set
PANEL.UPDRS	Unified Parkinson's Disease Rating Scale (UPDRS) 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
SURG	Surgery
TRAUMA	Trauma
TRNSPLNT.ORGAN	Organ transplant
TUMRRGT	Tumor registry (NAACCR)
UPDRS	Unified Parkinson's Disease Rating Scale (UPDRS)
US.URO	Urological ultrasound
VACCIN	Vaccinations
VOLUME.MOLEC	Volume (specimen) molecular

Table 32b: Laboratory Term Classes		
Abbreviation	Laboratory Term Class	
ABXBACT	Antibiotic susceptibilities	
ALLERGY	Response to antigens	
BLDBK	Blood bank	
CELLMARK	Cell surface models	
CHAL	Challenge tests	
CHAL.ROUTINE	Routine challenge tests	
CHALSKIN	Skin challenge tests	
CHEM	Chemistry	
COAG	Coagulation study	
СҮТО	Cytology	
DRUG/TOX	Drug levels & Toxicology	

DRUGDOSE	Drug dose (for transmitting doses for pharmacokinetics)
FERT	Fertility
HEM/BC	Hematology (coagulation) differential count
H&P.HX.LAB	History for laboratory studies
HL7.CYTOGEN	Clinical cytogenetic report
HL7.GENETICS	Clinical genetic report
HLA	HLA tissue typing antigens and antibodies
HNA	Human neutrophil alloantigens
HPA	HPA typing
LABORDERS	Laboratory order codes
MICRO	Microbiology
MISC	Miscellaneous
MOLPATH	Molecular pathology
MOLPATH.DELDUP	Gene deletions or duplications
MOLPATH.INV	Gene inversion
MOLPATH.MISC	Gene miscellaneous
MOLPATH.MUT	Gene mutation
MOLPATH.NUCREPEAT	Nucleotide repeats
MOLPATH.PHARMG	Pharmacogenomics
MOLPATH.REARRANGE	Gene rearrangement
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.HNA	HNA 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.HISTO	Histology
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 32c: 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.PERIODONTAL	Periodontal 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		
PANEL.ATTACH.MOD	Modifier attachment panel		

Table 32d: Survey Term Classes		
Abbreviation	Survey Term Class	
PANEL.SURVEY.AAOS American Academy of Orthopaedic Surgeons		

PANEL.SURVEY.ACT	Asthma Control Test (ACT) set		
PANEL.SURVEY.ADVAULT	ADVault survey set		
PANEL.SURVEY.AHRQ	Agency for Healthcare Research and Quality (AHRQ) survey set		
PANEL.SURVEY.ALSFRSR	ALS Functional Rating Scale - Revised set		
PANEL.SURVEY.AMNART	American National Adult Reading Test (AmNART) set		
PANEL.SURVEY.BIMS	Brief Interview for Mental Health Status (BIMS) set		
PANEL.SURVEY.BDI	Beck Depression Inventory (BDI) set		
PANEL.SURVEY.BPI	Brief Pain Inventory (BPI) 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.CESD	Center for Epidemiological Studies Depression (CESD) set		
PANEL.SURVEY.CMS	Centers for Medicare & Medicaid Services set		
PANEL.SURVEY.COOP	Dartmouth Cooperative Functional Status Test (COOP) set		
PANEL.SURVEY.DAST	Drug Abuse Screening Test 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.GPCOG	General Practitioner Assessment of Cognition (GPCOG) set		
PANEL.SURVEY.HABC	Healthy Aging Brain Care (HABC) set		
PANEL.SURVEY.HAQ	Health Assessment Questionnaire (HAQ) set		
PANEL.SURVEY.HARK	Humiliation, Afraid, Rape, and Kick (HARK) 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.IPAQ	International Physical Activity Questionnaire (IPAQ) 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.MLHFQ	Minnesota Living with Heart Failure Questionnaire (MLHFQ) set		
PANEL.SURVEY.MTLHLTH	Mental Health survey set		
PANEL.SURVEY.NEURO	Neurological survey set		
PANEL.SURVEY.NEUROQ	Quality of Life Outcomes in Neurological Disorders (NeuroQol) set		
PANEL.SURVEY.NHANES	National Health and Nutrition Examination Survey (NHANES) set		
PANEL.SURVEY.NIH.EMO	NIH Toolbox Emotion Domain panels		
PANEL.SURVEY.NMMDS	Nursing Management Minimum Data set		
PANEL.SURVEY.NORTON	Norton Scale survey set		
PANEL.SURVEY.NSRAS	Neonatal Skin Risk Assessment Scale survey		
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.PAS	Patient Activity Scale (PAS) set		
PANEL.SURVEY.PASII	Patient Activity Scale II (PAS-II) set		
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PANEL.SURVEY.PCORI	Patient-Centered Outcomes Research Institute (PCORI) set		
PANEL.SURVEY.PCORNET	Patient Centered Outcomes Research Network (PCORnet) Common Data Model (CDM) 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.SAMHSA	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.ACT	Asthma Control Test (ACT)		
SURVEY.ADHD	Attention Deficit Hyperactivity Disorder (ADHD)		
SURVEY.ADVAULT	ADVault survey		
SURVEY.AHRQ	Agency for Healthcare Research and Quality (AHRQ) survey		
SURVEY.ALSFRSR	ALS Functional Rating Scale - Revised		
SURVEY.AMNART	American National Adult Reading Test (AmNART)		
SURVEY.BDI	Beck Depression Inventory (BDI)		
SURVEY.BPI	Brief Pain Inventory (BPI)		
SURVEY.CARE	Continuity Assessment Record and Evaluation (CARE) survey		
SURVEY.CDC	Centers for Disease Control (CDC) survey		
SURVEY.CESD	Center for Epidemiological Studies Depression (CESD) survey		
SURVEY.CERNER	Cerner survey		
SURVEY.CMS	Centers for Medicare & Medicaid Services (CMS) survey		
SURVEY.COOP	Dartmouth Cooperative Functional Status Test (COOP)		
SURVEY.DAST	Drug Abuse Screening Test (DAST)		
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.GPCOG	General Practitioner Assessment of Cognition (GPCOG)		
SURVEY.HABC	Healthy Aging Brain Care (HABC) survey		
SURVEY.HAQ	Health Assessment Questionnaire (HAQ)		
SURVEY.HARK	Humiliation, Afraid, Rape, and Kick (HARK)		
SURVEY.HHS	Department of Health and Human Services (HHS) survey		
SURVEY.howRU	howRU outcomes instrument survey		
SURVEY.HWS	Healthy Weight Summary (HWS)		
SURVEY.IPAQ	International Physical Activity Questionnaire (IPAQ)		
SURVEY.MDS	Minimum Data Set (MDS) for Nursing Home Resident Assessment and Care Screening survey		
SURVEY.MFS	Morse Fall Scale (MFS) survey		
SURVEY.MISC	Miscellaneous survey		
SURVEY.MLHFQ	Minnesota Living with Heart Failure Questionnaire (MLHFQ)		
SURVEY.MTLHLTH	Mental Health survey		
SURVEY.NEURO	Neurological survey		
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Quality of Life Outcomes in Neurological Disorders (NeuroQol) survey		
National Health and Nutrition Examination Survey (NHANES)		
National Health Care Survey (NHCS)		
NIH Toolbox Emotion Domain		
NIH Toolbox survey		
Nursing Management Minimum Data Survey (NMMDS)		
Norton Scale survey		
Neonatal Skin Risk Assessment Scale (NSRAS)		
Home Health Care Classification (HHCC) survey		
Signs and Symptoms Checklist (SSC) for persons living with HIV survey		
Living with HIV survey		
OMAHA survey		
Quality Audit Marker (QAM) survey		
Outcome and Assessment Information Survey (OASIS)		
Outpatient Physical Therapy Improvement in Movement and Assessment Log (OPTIMAL)		
Patient Activity Scale (PAS)		
Patient Activity Scale II (PAS-II)		
Patient Centered Outcomes Research Network (PCORnet) Common Data Model (CDM)		
Patient Health Questionnaire (PHQ)		
Patient Reported Outcomes Measurement System (PROMIS) survey		
Quality Health Reporting Document Architecture (QRDA) survey		
Residual Functional Capacity (RFC) survey		
Substance Abuse and Mental Health Services Administration (SAMHSA) survey		
United States Surgeon General Family Health Tool (USSGFHT) survey		
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 or 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. A list of information required for a submission is provided below.

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.

Please check the LOINC website pre-release page, "What's Coming in the Next Release", to see if there is a similar new term prior to submitting your request.

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 requesters 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. If not RELMA, then you must use one of the templates available on the LOINC web site:

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

The preferred method for submitting proposed LOINCs is using RELMA's built-in functionality. See the section titled "RELMA Submission" below or review the RELMA manual for more details.

Required information

The set of information required for a particular submission depends on the content of the request. In order for us to process your request, we need:

- Local test/observation name
- Local order (panel) name
- Name of send out lab (if applicable)
- Name of healthcare organization that stimulated the request for this term (if you are submitting on behalf of someone else)
- Description of the test
 - For laboratory tests and clinical measurements, the description should indicate what is measured, how it is performed, and how it is used clinically (e.g., what conditions does it diagnose, monitor, screen for, etc.).
 - For other kinds of clinical terms, such as clinical documents, the description should indicate the expected information content that would be sent as the result value (i.e., what kinds of information this document or report contains).

- Units of measure (for quantitative observations)
- Answer lists (for qualitative observations) (both normal and abnormal answers)
- Sample results, reports (if applicable)
- If the request is for a panel, the request should include the tests that comprise the panel. Whether or not each test already has a LOINC code should be included, and for any tests that do not already have a code, all of the above information for each individual test should be provided.
- Package inserts, test kit documentation (if applicable)
- Vendor, instrument, and/or reagent kit used to perform this test (if applicable)
- 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.)
- Implementation guide (for terms designed for use in the context of a specific messaging implementation guide)
- Original survey form (for questionnaires or survey content)
 - If you are requesting survey terms, we recommend that you find out whether the terms are copyrighted and let us know this information when you submit your request. It would be especially helpful and would facilitate processing for you to contact the copyright-holder prior to submission to find out whether they would be willing to give permission to represent the copyrighted content in LOINC, and then include their contact information with your submission so that we can follow up directly with them.
 - Occasionally copyright-holders are only willing to grant time-limited permission or grant permission but at a cost, and in such cases, we will not create the requested content because we cannot agree to these terms.
- Any other documentation that may assist us in creating the requested codes

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 download the RELMA Manual here: http://loinc.org/downloads/files/ RELMAManual.pdf.

Excel file submission

If you are not using RELMA for submission, please use one of the templates provided on our website:

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

Other formats (e.g., distributed database fields, exported internal/local formats) will not be accepted.

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:

CC	Catalytic Content, catalytic activity of a component per unit mass of a sample (System).
CCnt	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:

	Catalytic Fraction
CFr	<pre>2536-1 Lactatedehydrogenase1/Lactatedehydrogenase.total:CFr:Pt:Ser/ Plas:Qn:Electrophoresis 9642-0 Creatine Kinase.BB/Creatine kinase.total:CFr:Pt:Ser/Plas:Qn</pre>
	Number Fraction
NFr	<pre>10602-1 Spermatozoa.abnormal head/100 spermatozoa:NFr:Pt:Semen:Qn 764-1 Neutrophils.band form/100 leukocytes:NFr:Pt:Bld:Qn:Manual count</pre>
MFr	Mass Fraction
IVIFI	2614-6 Methemoglobin/Hemoglobin.total:MFr:Pt:Bld:Qn
	Substance Fraction
SFr	30192-9 Acetylcholine receptor modulation Ab/Acetylcholine Ab.total:SFr:Pt:Ser:Qn
VFr	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	
	Volume Rate Ratio	
VRatRto	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.

	Relative Mass Concentration (as noted previously)
RelMCnc	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
	Relative Volume Rate
RelVrat	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

Note

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

Possible Values	Property	Scale
U/mL, Units/mL, etc.	CCnc	Qn
U/gm, Units/gm, etc.	CCnt	Qn
U/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	e Values Property Scale	
<1:2, 1:4, 1:8	Titr	Qn

8. For Any X Ab or Ag:

Possible Values	Property	Scale
Neg, Indeterminate, Pos	PrThr	Ord
1+, 2+, 3+	PrThr	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**.

Intensive Properties	Possible Values (coded)	Property	Scale
Organism Identified	E. coli, S. aureus, etc	Prid	Nom
ABO Group	A, B, AB, O	Type	Nom
Surgery (Dis. Summary)	Cholecystectomy, Appendectomy	Prid	Nom

Extensive Properties	Possible Values (coded)	Property	Scale
Urine Color	Amber, straw, etc.	Туре	Nom

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 the scale will be **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**.

Intensive Properties	Possible Values (coded)	Property	Scale
Organism Identified	E. coli, S. aureus, etc	Prid	Nar
ABO Group	A, B, AB, O	Type	Nar
Surgery (Dis. Summary)	Cholecystectomy	Prid	Nar

Extensive Properties	Possible Values (coded)	Property	Scale
Urine Color	Amber, straw, etc.	Туре	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:

	Possible Values (text)	Property	Scale
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. 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).

Appendix F Example Acronyms used in LOINC

Table 33: Example Acronyms used in LOINC		
Acronym	Meaning	
AC	Abdominal Circumference	
ADL	Activities of Daily Living	
AE	Anion Exchange protein	
AP	Anterio-Posterior	
APAD	AnteroPosterior Diameter of the Abdomen	
AUT	Automated Ultrasound Testing	
B2GP1	Beta 2 Glycoprotein 1	
BD	Binocular Distance	
BOR	Brachio-Oto-Renal	
BPC	Biparietal Circumference	
BPD	Biparietal diameter	
CD	Cluster of differentiation	
CDA	Congenital dyserythropoietic anaemia	
CDB	Childhood Disability Benefits	
cDNA	complementary DNA	
CFst	Calorie Fast	
CHAMPUS	Civilian Health and Medical Program of the Uniformed Services	
Cine	Cinematographic	
CMS	Centers for Medicaid and Medicare Services	
CNR1	Cannabinoid receptor 1	
сос	Commission on Cancer	
COPD	Chronic Obstructive Pulmonary Disease	
СРТ	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	Full and ADAL and Date
EDD	Estimated Delivery Date
EEG	Electroencephalogram
EFW	Estimated Fetal Weight
EGD	Esophagogastro duodenoscopy
EKG	Electrocardiogram
EMS	Emergency Medical Service(s)
ENT	Ear, Nose Throat
ERCP	Endoscopic Retrograde Cholangiopancreatography
FL	Femur Length
FLACC	Face Legs Activity Cry Consolability
FNA	Fine Needle Aspirates
FTA	Fetal Trunk Area
GALOP	Gait disorder Autoantibody Late-age Onset Polyneuropathy
GSD	Gestational Sac Diameter
GSL	Gestational Sac Length
HC	Head Circumference
HIV	Human immunodeficiency virus
HIV-SSC	Sign and Symptom Check-List for Persons with HIV Disease
HL	Humerus Length
HLA	Human Leukocyte Antigen
НМРАО	Hexamethylpropyleneamine oxime
HTLV	Human T-cell Lymphotropic 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	I also as leave distance and is a second and the control of the co
	Leber hereditary optic neuropathy
LOINC	Logical Observation Identifiers Names and Codes
LOINC	
	Logical Observation Identifiers Names and Codes
LVOT	Logical Observation Identifiers Names and Codes Left Ventricular Outflow Tract
LVOT LW	Logical Observation Identifiers Names and Codes Left Ventricular Outflow Tract Landsteiner-Wiener
LVOT LW LWT	Logical Observation Identifiers Names and Codes Left Ventricular Outflow Tract Landsteiner-Wiener Length Width Thickness
LVOT LW LWT MAA	Logical Observation Identifiers Names and Codes Left Ventricular Outflow Tract Landsteiner-Wiener Length Width Thickness Microalbumin aggregate albumin
LVOT LW LWT MAA MEMS	Logical Observation Identifiers Names and Codes Left Ventricular Outflow Tract Landsteiner-Wiener Length Width Thickness Microalbumin aggregate albumin Medication Event Monitoring System
LVOT LW LWT MAA MEMS MERSTH	Logical Observation Identifiers Names and Codes Left Ventricular Outflow Tract Landsteiner-Wiener Length Width Thickness Microalbumin aggregate albumin Medication Event Monitoring System Medical Event Reporting System-Total Health System
LVOT LW LWT MAA MEMS MERSTH MIB-1	Logical Observation Identifiers Names and Codes Left Ventricular Outflow Tract Landsteiner-Wiener Length Width Thickness Microalbumin aggregate albumin Medication Event Monitoring System Medical Event Reporting System-Total Health System Mindbomb homolog 1 Metaiodobenzylguanidine
LVOT LW LWT MAA MEMS MERSTH MIB-1 MIBG	Logical Observation Identifiers Names and Codes Left Ventricular Outflow Tract Landsteiner-Wiener Length Width Thickness Microalbumin aggregate albumin Medication Event Monitoring System Medical Event Reporting System-Total Health System Mindbomb homolog 1
LVOT LW LWT MAA MEMS MERSTH MIB-1 MIBG MIC MLC	Logical Observation Identifiers Names and Codes Left Ventricular Outflow Tract Landsteiner-Wiener Length Width Thickness Microalbumin aggregate albumin Medication Event Monitoring System Medical Event Reporting System-Total Health System Mindbomb homolog 1 Metaiodobenzylguanidine Minimum inhibitory concentration Minimum lethal concentration
LVOT LW LWT MAA MEMS MERSTH MIB-1 MIBG MIC	Logical Observation Identifiers Names and Codes Left Ventricular Outflow Tract Landsteiner-Wiener Length Width Thickness Microalbumin aggregate albumin Medication Event Monitoring System Medical Event Reporting System-Total Health System Mindbomb homolog 1 Metaiodobenzylguanidine Minimum inhibitory concentration

MVV	Maximum Voluntary Ventilation
NAACCR	North American Association of Central Cancer Registries
Ng	Nasogastric
NPI	National Provider Identifier
OFD	Occipital-Frontal Diameter
O-I BPD	Outer to Inner Biparietal Diameter
OmpC	Outer membrane porin of E coli
O-O BPD	Outer to Outer Biparietal Diameter
O-O TD	Outer to Outer Tympanum Diameter
OOD	Outer Orbital Diameter
PA	Postero-Anterior
PCP	Primary Care Physician
PEG	Polyethylene Glycol
PHQ	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
TC	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**
- Cockcroft-Gault formula for estimating creatinine clearance, Schwartz equation for Glomerular Filtration Rate and MDRD formulae
- Inducible Clindamycin Resistance in Staphylococcus and Streptococcus
- **KIR Gene Family**
- Oxygen Saturation and LOINC®
- Nomenclature of Salmonella Species, Subspecies, and Serovars
- Segmented Neutrophils Versus Polymorphonuclear WBC
- Vitamin D
- Free Thyroxine Index Variants
- Streptococcus pneumoniae serotype nomenclature

D-Dimer Revisions in LOINC

Author: J. Gilbert Hill, MD, PhD

Date Written: 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 \text{ ng/mL FEU} = 300 \text{ 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.

The quantitative D-dimer entries in LOINC 2.17 are as follows:

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		PT	PPP	QN	Ì
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		PT	PPP	QN	

D-dimer results from American Proficiency Institute 2004 Testing Program

These tables hint at some of the problems associated with the measurement of D-dimer, 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				
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

Date Written: 2007-11-20

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 renai clearance.predicted VRat Pt Ser/Plas Qn Cockcroft-Gault formula	35591-7	Creatinine renal clearance.predicted	VRat	Pt	Ser/Plas	Qn	Cockcroft-Gault 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 m2.

In particular, the Cockcroft-Gault BSA adjusted formula is used by many pharmacy departments for medication dosage adjustments.

	LOINC terms for BSA adjusted creatinine clearance											
<u>35592-5</u>	Creatinine renal clearance/1.73 sq M.predicted	VRat	Pt	Ser/Plas	Qn	Cockcroft-Gault formula, corrected for BSA						
<u>50380-5</u>	Creatinine renal clearance/1.73 sq M.predicted.female	VRat	24H	Ser/Plas	Qn	Cockcroft-Gault formula, corrected for BSA						
50381-3	Creatinine renal clearance/1.73 sq M.predicted.male	VRat	24H	Ser/Plas	Qn	Cockcroft-Gault formula, corrected for BSA						

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, sex, and body height and serum creatinine. The equation can be stated as follows:

GFR Calculator for Children

Schwartz Formula

GFR (mL/min/1.73 m2) = k (Height) / Serum Creatinine

- k = Constant
 - k = 0.33 in Preemie Infants
 - k = 0.45 in Term infants to 1 year old
 - 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									
50384-7	Glomerular filtration rate/1.73 sq M.predicted	VRat	24H	Ser/Plas	Qn	Creatinine-based 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, sex 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 they are not routinely used.)

The following was taken from NKF MDR web site on December 4, 2006 (http://www.kidney.org/professionals/ KLS/gfr.cfm#2):

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, sex and 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 x (PCr)-1.154 x (age)-0.203 x (0.742 if female) x (1.210 if black)

GFR is expressed in ml/min/1.73 m2. In this equation Pcr 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 -

Web calculator for MDRD

The glomerular filtration rate predicted by the MDRD formula may be reported in at least three ways:

- All four variables are known and used in the equation. The result would be race and sex adjusted creatinine clearance.
- Only two variables (serum creatinine and age) are used in the equation. In this circumstance, the report may:
 - include a comment saying "if patient is black, multiply result by 1.21" and/or "if patient is female, multiply the result by .742", or
 - may include two values: N1 if white and N2 if black, and a correction factor for sex: if patient is female, multiply the result by .742.

	LOINC codes for MDRD formula									
33914-3	Glomerular filtration rate/1.73 sq M.predicted	VRat	Pt	Ser/Plas	Qn	Creatinine-based formula (MDRD)				
48642-3	Glomerular filtration rate/1.73 sq M.predicted.non black	VRat	Pt	Ser/Plas	Qn	Creatinine-based formula (MDRD)				
48643-1	Glomerular filtration rate/1.73 sq M.predicted. black	VRat	Pt	Ser/Plas	Qn	Creatinine-based formula (MDRD)				
50044-7	Glomerular filtration rate/1.73 sq M.predicted. female	VRat	Pt	Ser/Plas	Qn	Creatinine-based 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.

MDRD-GFR (ml/min/1.73 m²)
=
$$170 \times [PCr]^{-0.999} \times [age]^{-0.176} \times [0.762 \text{ if patient is female}] \times [1.180 \text{ if patient is black}] \times [SUN]^{-0.170} \times [Alb]^{+0.318}$$

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										
<u>50210-4</u>	Glomerular filtration rate/1.73 sq M.predicted	VRat	Pt	Ser/Plas	Qn	Cystatin-based formula				

Inducible Clindamycin Resistance in Staphylococcus and **Streptococcus**

Author: David Baorto, MD, PhD

Date Written: 2011-05-12

Macrolide-Lincosamide-Streptogramin B (MLSb) 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, <u>62258-9</u>).

KIR Gene Family

Author: David Baorto, MD, PhD

Written: 2011-04-17

Clinical significance

KIR (Killer cell Immunoglobulin-like Receptor) 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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Oxygen Saturation and LOINC®

Authors: Gilbert Hill and Clement J. McDonald

Date Written: 2007-10-19 - Revised: 2009-07-09

(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 = sO2) and fractional oxyhemoglobin (recommended symbol = FO2Hb).

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 (O2Hb) + 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:

 $sO2 = 100 \times O2Hb/(O2Hb + HHb)$

More important some instruments, e.g., the pulse oximeter, cannot 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.

FO2Hb = O2Hb/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), sO2 =FO2Hb

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 hemoglobins and the other two dyshemoglobins and could only be done in the laboratory with an injected blood sample. Today (i.e., 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 device reports the oxyhemoglobin %, Carbon monoxide %, and 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 sO2 (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 FO2Hb (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, then the situation should be clear. If the method is co-oximetry or the battery includes a separate measure of Carboxyhemoglobin (or any of the other dyshemoglobins), then it will be reporting a fractional oxyhemoglobin. If the method is pulse oximetry, then you have an 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

Date Written: 2011-07-09

Salmonella nomenclature is complex and has caused confusion. At the present time, by molecular methods the genus Salmonella is known to have only two species: Salmonella enterica and Salmonella bongori. Salmonella enterica is divided into six 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® Terms associated with Salmonella Serotyping

Salmonella sp identified [Type] in Isolate (59846-6)

This code has one of seven possible answers to differentiate the two species and six 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 seven 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

Date Written: 2011-04-17

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: http://en.wikipedia.org/wiki/Granulocyte.

Vitamin D

Author: David Baorto, MD, PhD

Date Written: 2011-02-19

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 two 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 one 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 two major forms. Vitamin D3, also known as cholecalciferol, is the parent compound of one of the two 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 one 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 two major forms. Vitamin D2, also known as ergocalciferol, is the parent compound of one of the two 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 two 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 two 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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Free Thyroxine Index Variants

Author: David Baorto, MD, PhD

Date Written: January 2012

Although direct measurement of the free hormones has recently become more prevalent, the older methods to estimate free hormone levels by deriving an index still persist. The index methods involve adjusting the total thyroid hormone concentration (TT4) for the thyroid binding capacity of the serum (T3 uptake or thyroid binding globulin TBG) to yield an indicator or estimate of the free hormone level, free thyroxine index (FTI). Over time and across labs this calculation has been and is done in different ways, yielding different results sometimes with different properties. This is mostly due to distinctions in what is known as "T uptake". Here are some variations:

- 1. $FTI = TT4(ug/ml) \times T3 \text{ uptake } (\%)/100$
 - This has sometimes been noted leaving off the division by 100, but not in practice: $FTI = TT4(ug/ml) \times T3 \text{ uptake}(\%).$
- 2. $FTI = TT4(ug/ml) \times (T3 \text{ uptake patient/}T3 \text{ uptake control}) \text{ (ratio)}$
 - a. Here, "T3 uptake" used in the calculation is actually the thyroid hormone binding ratio noted throughout the literature (**THBR**), the ratio of patient to reference serum values of T3 uptake.
- 3. FTI = TT4(ug/ml) / T uptake units (ratio)
 - a. Here "T uptake units" is ratio of patient to reference serum levels of thyroxine binding globulin (TBG).

Notes

- In variation 1, the uptake is a %, while in variations 2 and 3 the uptake is a unit-less ratio normalized to control, known in the literature as the thyroid hormone binding ratio (THBR).
- Variation 1 is apparently the reporting approach used by Mayo, ARUP, and LabCorp and many hospital labs (such as one large NY hospital). It adjusts the total T4 by a T3 uptake % (approximate range 25-40%), and yields FTI values often in the approximate range of 1 to 5 (adults) and is reported as unitless.
- Variation 2 is apparently the reporting approach used by Quest Diagnostics-Nichols and some hospital labs (such as another large NY hospital), and variation 3 apparently the primary method used by Abbott Axsym (although values can be converted).
- Variations 2 and 3 both adjust the total T4 (TT4) by a ratio referenced to a control value of 1, so FTI numerically is in the approximate range of TT4 concentration 5 – 12 (adults). While it is usually reported as unit-less, there is a case that it is really an adjusted TT4 concentration, and in fact the Abbott AxSym package insert (variation 3 above) notes units of ug/dl for its calculated FTI value.
- THBR is a normalized T3 uptake which represents how much labeled T3 did NOT find a binding site in patient serum, meaning it is the INVERSE of available binding sites. Conversely, in the AxSYM method "T uptake units" is a control normalized ratio of TBG, a measure proportional to the binding sites. This may account for why one MULTIPLIES and the other DIVIDES by the ratio. The TBG is not the only thyroid hormone binding protein, another distinction between 2 and 3.
- Historically T3 instead of T4 has been more commonly used as the tracer in uptake assays for practical

reasons. T3 has a lower affinity for TBG, so more would be available to be taken up by the scavenger and easier to count. With non-isotopic techniques, this may be less of an issue, and it has been suggested that T4 uptake would be more appropriate to adjust TT4 concentration. T4 uptake assays do exist.

Streptococcus pneumoniae serotype nomenclature

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Date written: May 2017

Streptococcus pneumoniae is an important human pathogen whose virulence is based primarily on its polysaccharide capsule, which protects it by shielding it from the immune system. Over time, study of the polysaccharide capsule has identified multiple serogroups and serotypes. Serotypes are defined based on the chemical structure and immunologic properties of the polysaccharide, and each serogroup contains one or more serotypes that elicit the same antibody response.

Over time, two parallel serotype naming systems arose, one in the U.S. and one in Denmark. Initially in LOINC, our intent was to create terms based on the U.S. serotype number, but that was not clearly stated in the Component. Over time, as the number of serotypes that have been identified increased in number and were assigned new serogroup, U.S. serotype, and Danish serotype numbers, many of our existing terms became ambiguous because the number in the *Component* could potentially represent any of the three. More recently, it has come to our attention that the Danish naming system is the one that has been widely adopted, including in the U.S.

Beginning with the June 2017 release, LOINC adopted the Danish numbering system in the Component for all pneumococcal terms and explicitly include the words "Danish serotype" in the Component. To that end, we deprecated any existing term that could be ambiguous as to whether the number in the Component referred to the serogroup, U.S. serotype, or Danish serotype, and mapped it to a new term for the corresponding Danish serotype (assuming that the original term was, indeed, created to represent the U.S. serotype as stated above). For existing terms in which the existing Component could only represent the U.S. serotype (i.e., there are no corresponding serogroups or Danish serotypes with the same number), we updated the Component to the corresponding Danish serotype.

In the RELATEDNAMES2 field, we have included the corresponding U.S. serotype number for each of the Danish serotypes, as well as information about whether each serotype is included in each of the 23-valent polysaccharide vaccine (PPSV23), 13-valent pneumococcal conjugate vaccine (PCV13), or 7-valent pneumococcal conjugate vaccine (PCV7), respectively. This same information is also provided in the following table, though please note that the table does not contain every identified serotype, only the ones for which LOINC codes exist.

Danish serotype number	U.S. serotype number	Vaccine(s) that include this strain	
1	1	PCV13, PPSV23	
2	2	PPSV23	
3	3	PCV13, PPSV23	
4	4	PCV7, PCV13, PPSV23	
5	5	PCV13, PPSV23	
6A	6	PCV13	
6B	26	PCV7, PCV13, PPSV23	
7A	7		
7F	51	PCV13, PPSV23	
8	8	PPSV23	
9N	9	PPSV23	
9V	68	PCV7, PCV13, PPSV23	
10A	34	PPSV23	
11A	43	PPSV23	

12F	12	PPSV23	
14	14	PCV7, PCV13, PPSV23	
15B	54	PPSV23	
16F	16		
17F	17	PPSV23	
18C	56	PCV7, PCV13, PPSV23	
18F	18		
19A	57	PCV13, PPSV23	
19B	58		
19F	19	PCV7, PCV13, PPSV23	
20A	20		
22F	22	PPV23	
23A	46		
23F	23	PCV7, PCV13, PPSV23	
33F	70	PPSV23	

References

Geno K A, Gilbert G L, Song J Y, Skovsted I C, Klugman K P, Jones C, Konradsen H B, Nahm M H. Pneumococcal capsules and their types: past, present, and future. Clinical Microbiology Reviews 2015; 28(3):871-899. [PubMed: <u>26085553</u>]

Appendix H LOINC Committee Members

As secretariat, Regenstrief Institute has adopted a new, lightweight structure and governance principles for the LOINC Committee. These principles were unanimously approved by the LOINC Clinical Committee at the September 2017 meeting and by the LOINC Laboratory Committee at the December 2017 meeting.

The LOINC Committee is comprised of the members of its composite committees:

- Laboratory LOINC Committee
- Clinical LOINC Committee
 - Nursing Subcommittee
 - **Document Ontology Subcommittee**
- LOINC/RadLex Committee

Interested parties may formally apply for inclusion in one or more of the composite committees as an individual, organization, Standards Development Organization (SDO), or international affiliate. The application form and membership requirements are available on the LOINC website at loinc.org/committee. We welcome applications for new members who meet the qualifications. Committee membership remains free of charge.

A roster of LOINC Committee members is available on the LOINC website at loinc.og/committee.

Annex LOINC/RSNA Radiology Playbook User Guide

1 Introduction

Welcome to the LOINC/RSNA Radiology Playbook User Guide. This work is the result of a multi-year collaboration between Regenstrief Institute and the Radiological Society of North America (RSNA), supported by the National Institute of Biomedical Imaging and Bioengineering (NIBIB). The participants have developed a model that combines and unifies the useful aspects of LOINC Radiology and the RSNA RadLex Playbook. Both of these terminology initiatives are designed to represent concepts of radiology orderables and results and their attributes.

Each term in the unified Playbook model has a name (a.k.a. description), and takes on a number of attributes. This guide is intended to describe the semantics, syntax, and proper usage of those attributes. Within the terminology, these attributes are used as building blocks to construct several types of standard names, including a fully specified name, long name, and short name.

A list of the Playbook attributes is shown below. Attributes are organized according to attribute groups, consisting of the major bullet headings below, and by more specific sub-attributes, shown in the minor bullets below and denoted by a dot after the attribute group, such as *Pharmaceutical.Route*.

- Modality
 - o Modality.Modality Type
 - o Modality.Modality Subtype
- Anatomic Location
 - o Anatomic Location.Region Imaged
 - o Anatomic Location.Imaging Focus
 - o Anatomic Location.Laterality.Presence
 - o Anatomic Location.Laterality
- View
 - o View.Aggregation
 - o View.View type
- Timing
- Maneuver
 - o Maneuver.Maneuver Type

- Pharmaceutical
 - o Pharmaceutical.Substance Given
 - Pharmaceutical.Route
- Reason for Exam
- Guidance
 - o Guidance for.Presence
 - o Guidance for.Approach
 - o Guidance for.Action
 - o Guidance for.Object
- Subject

The chapters that follow provide a guide to the usage of each of the above attributes.

1.1 Codes and workflows

Radiology procedure codes impact a variety of workflows in the health care enterprise, including ordering, scheduling, billing, protocol specification, image acquisition, and image interpretation, among others. In each case, the codes serve specific purposes in identifying imaging exams. While there is a great deal of overlap between these workflows, there are also important differences. For example, radiology billing is often concerned with a less detailed description of an imaging exam, while the radiology ordering process often involves more information about the requested study.

The Playbook work has been primarily focused on addressing the needs of the radiology ordering workflow. The semantic model described in this document is intended principally to characterize radiology "orderables." This then raises the question of what constitutes an orderable exam, an issue which is complicated by several factors. First, different institutions may expose different levels of granularity at the point of radiology order entry. While one may consider "CT abdomen / pelvis with contrast" to be an appropriate option in an order entry system, another institution may wish to provide the choice "CT abdomen / pelvis with contrast, liver mass." Second, in certain circumstances, what is actually done to satisfy an imaging request may not match the ordered procedure precisely. For example, image-guided interventions often entail procedural modifications at the time of the exam. In such cases, modified or additional orderables may be entered, even though these may not have been exposed in the clinical ordering interface. Third, some institutions have separate orderable codes for interpretations of studies performed at outside institutions ("interpretation only").

The model aims to allow for the type of variation described above, so as to broadly fulfill the needs of radiology ordering workflows at a variety of institutions. We discussed the concept of "interpretation only" and decided not to create a duplicate set of orderables for the interpretations of outside films. Instead, we created a single LOINC code, 86371-2 Study Interpretation of outside study, that can be used with the primary study code to report whether the study being interpreted was performed at an outside institution. Regarding the technical factors in image acquisition, related work at a more granular level is being done by the DICOM Standards Committee. 1

http://dicom.nema.org/Dicom/News/oct2013/docs_oct2013/sup121_pc.pdf, Accessed 14 May 2016.

2 Syntax

2.1 Operators

The model uses several logical operators (".", "+", ">", "&", "()", "&&") to express combinations of atoms.

2.1.1 "." (Dot)

Used to specify refinement of a given attribute or attribute component. For example, the dot operator may be used with the *Imaging focus* component of the *Anatomic Location* attribute to specify a more granular focus (e.g. **Ribs.lower**). For modality subtypes, it is used to indicate a certain type of imaging technique (e.g. "**CT.angio**").

2.1.2 "+" (Plus)

Used to combine atoms, such as Anatomy atoms or View atoms, with AND semantics.

2.1.3 ">" (Greater than)

Used exclusively to separate the Region Imaged from the anatomic Imaging Focus.

2.1.4 "&" (Ampersand)

Used to separate *Region imaged* and *Imaging focus* pairs when more than one anatomic location across more than one region is imaged. May alternatively be used as a low-precedence AND, such as in the *Timing* attribute **WO & W**, which has a combined "before and after" notation.

2.1.5 "^" (Carat)

Used primarily to separate the *Maneuver* attribute from the *View* attribute.

2.1.6 "()" (Parentheses)

Used to indicate bindings between *Maneuver* and *View* values when more than one *View.Aggregation* and/or *View. View Type* exists and the maneuver(s) only applies to a subset of the *View* values.

2.1.7 "&&" (Double ampersand)

Used to indicate parallelism in cases where the relationships between values across multiple attributes needs to be specified. In earlier versions the "&" was used for parallelism, but since we started using "&" to separate *Region imaged* and *Imaging focus* pairs, we created a new delimiter for parallelism in order to distinguish the two concepts.

2.1.8 Precedence

Operator precedence, from greatest to least is as follows: ".", "+", ">", "&", "\", "()", "&&"

2.2 Parallelism

In selected circumstances, it is necessary to specify multiple values for two or more specific attributes or components. In such cases, the correspondences between values across attributes or components may be modeled by maintaining a consistent ordering of values. For example, a radiographic exam of the ribs often includes a radiograph of the chest. The specific views may include an AP view of the chest, and an oblique view of the ribs. Multiplicity of the Anatomic Location attribute as well as the View attribute is modeled using parallelism and the "&&" operator. That is, with Anatomic Location Chest && Ribs and View AP && Oblique the appropriate correspondence between Chest and AP as well as between Ribs and Oblique is maintained by virtue of the relative positions of the atoms (i.e., both **Chest** and **AP** are listed first in their respective attributes).

3 Modality

3.1 Definitions

Modality is used to represent the device used to acquire imaging information. Modalities consist predominantly of a subset of the two-letter DICOM modality codes. DICOM modality codes are listed in PS3.3, Section C.7.3.1.1.1 in the 2016 release of the DICOM standard. In addition, the *Modality* code {Imaging modality} is used to indicate image-guided procedures for which the specific type of imaging is not explicitly modeled.

A Modality subtype may be listed, separated by a ".", to signify a particularly common or evocative configuration of the modality.

Note that when such *Modality subtypes* are specified, the given type of technique is *included* in a study, although this does not necessarily imply that the study consists *exclusively* of that subtype of imaging. For example, an exam with Modality and subtype US.doppler does not mean that only Doppler imaging was performed. On the other hand, XR.portable generally does indicate that only portable images were obtained.

3.2 Usage Notes

- 1. Subtype angio: This Subtype is used for procedures designed to give angiographic images of the vessels (either blood or lymphatic vessels). This should not be used for **US**; **Doppler** should be used instead. Angio is not a synonym for contrast administration because some angiographic MR studies do not require intravenous contrast administration.
- 2. Mammography **tomosynthesis** *Subtype*: This *Subtype*, also known as digital breast tomography (DBT), is a type of digital mammography that is distinct from the concept of **full field digital**. **MG**. tomosynthesis is used for 3-dimensional imaging, while typical digital mammography is 2-dimensional. Digital 2D mammograms may also be reconstructed into 3D images, but these would not be classified under MG.tomosynthesis.
- 3. Obsolete mammography subtypes: We originally included MG.analog and MG.full field digital (FFD) in the list of allowed MG Subtypes to specify analog mammography and digital mammography, respectively, while **MG** without a *Subtype* signified a procedure that could be done with digital or analog equipment. However, given that over the past several years digital mammography has become standard practice, we recommend that moving forward, FFD does not need to be specified as a subtype of MG.

http://dicom.nema.org/medical/dicom/current/output/pdf/part03.pdf, Accessed 14 May 2016.

- Instead, the generic MG LOINC codes should be used for 2D mammography, which in most cases will be digital images but may also include analog images.
- CR (computed radiography) vs DX (digital radiography) vs RG (radiographic imaging/conventional film screen): XR will be adopted generically to signify orders for planar radiography. When the images are acquired, the imaging modality may wish to insert a more specific modality code in the DICOM files.
- 5. **Doppler** Subtype vs DICOM modality codes DD (duplex Doppler) and CD (color flow Doppler): **US. Doppler** will be used as the attribute of the orderable procedure. When the images are acquired, the imaging modality may wish to insert a more specific modality code in the DICOM files.
- 6. **Portable** indicates whether the device is movable or whether the patient will come to the radiology department for imaging.
- 7. **SPECT** will be represented as a *Modality subtype* of the **NM** *Modality* (**NM.SPECT**) rather than using ST, the DICOM modality code for SPECT.
- Because there is no DICOM modality code for DEXA, **DXA** will be adopted as the *Modality* code.
- When an imaging study involves more than one imaging *Modality*, "+" is used to concatenate the two Modalities, such as PT+CT or NM.SPECT+CT. The Modality listed first corresponds to the departmental area where the device is typically located. E.g., PT+CT, not CT+PT
- 10. For studies with two *Modalities* that have separate attributes and are performed consecutively (e.g., RF Upper GI with XR abdomen), "&&" is used in the harmonized model and in LOINC to separate the values of each attribute, including Modality, to maintain parallelism across attributes, e.g., XR && RF. However, note that in the Radiology Lexicon (RadLex) imaging modality hierarchy, such Modalities that are commonly performed consecutively are represented as a single entity under the combined modalities node using a "+", e.g., XR+RF.
- 11. Precedence of operators is ".", "+", "&&" (the other delimiters are not used in the *Modality* attribute).
- 12. The **perfusion** *Modality subtype* indicates the study is intended to measure tissue perfusion; if the study is designed to image the vessels, use the **angio** *Modality subtype*.
- 13. 3D is an image processing step, and can be performed on images from a variety of modalities. Its use is discouraged. If adopted locally, it may be used as shown in Reason for Exam section.
- 14. Modality (Imaging modality) is used to refer to image-guided procedures, where the particular type of imaging used is not specified in the orderable. For example, liver biopsies may be performed under ultrasound or CT guidance, although the particular modality used may be at the discretion of the operator. In such cases, {Imaging modality} indicates that the order is modality-agnostic.

3.3 Allowed Modality/Subtype Combinations

- CT
 - CT.angio
 - CT.scanogram
 - CT.densitometry
 - CT.perfusion
 - CT.portable

- DXA
 - o DXA.densitometry
- MG
 - o MG.tomosynthesis
 - o MG.stereotactic
- MR
 - o MR.angio
 - o MR.functional
 - o MR.spectroscopy
- NM
 - o NM.dosimetry
 - o NM.SPECT
 - o NM.SPECT+CT
- PT
 - o PT.perfusion
 - o PT+CT
- RF
 - o RF.angio
 - o RF.video
 - o RF.portable
- US
 - o US.densitometry
 - o US.Doppler
 - o US.portable
- XR
 - o XR.tomography
 - o XR.portable
- {Imaging modality}

4 Anatomic Location

This chapter describes how anatomic terms are used to identify the body region and anatomic focus of imaging. It also specifies the syntax to be used when more than one anatomy term applies to a given exam code, and delineates how laterality should be specified when necessary.

4.1 Definitions

The Anatomic Location attribute specifies the body part or body region that is imaged and includes the subattributes, Region Imaged and Imaging Focus. The most specific anatomic structure should be specified. Multiple Anatomic Locations may be specified using the syntax specified below and should be specified only when necessary to distinguish the code from other codes. Anatomic Location terms are generally drawn from the RadLex anatomic hierarchy.

Region imaged is used in two ways. First, as a coarse-grained descriptor of the area imaged and a grouper for finding related imaging exams; or, it is used just as a grouper. For example, when an abdominal CT focuses on the liver, it images the abdomen as a whole and also would be a relevant comparison for other abdominal CT exams (e.g., renal CT), thus making abdomen a coarse-grained descriptor as well as a grouper. Similarly, a head CT focusing on the brain may also be a relevant comparison for other head CT exams (e.g., orbit CT), making it both a descriptor and grouper. Alternatively, for most studies with Upper extremity or Lower extremity as the Region imaged and a specific Imaging focus, such as Wrist or Knee, the Region imaged is a grouper only, because the entire extremity is typically not imaged.

Imaging focus is defined as a more fine-grained descriptor of the specific target structure of an imaging exam. In many areas, the focus should be a specific organ. For example, in the Region imaged Abdomen, the Imaging focus might be Liver, Pancreas, Adrenal gland, Kidney, etc. In other areas, the Imaging focus will simply be a more specific area within a given region. For example, in the Region imaged Upper extremity, the Imaging focus might be Shoulder, Upper arm, Elbow, Forearm, Wrist, Hand, etc.

Our goals are to populate both the Region imaged and Imaging focus sub-attributes for all terms, except where the Region Imaged is the focus of the study (see Section 4.2.1). We will also constrain Region Imaged to the following short list of regions:

- Head
- Neck
- Chest
- **Breast**
- **Abdomen**
- **Pelvis**
- **Extremity**
- Upper extremity
- Lower extremity
- Whole body (used when the *Imaging focus* exists throughout the body and is being imaged in its entirety, such as **Bones** or **Bone marrow**)
- Unspecified (represented in LOINC as XXX, used when the Imaging focus exists in multiple parts of the body but only one specific instance is being imaged, such as a **Blood vessel**)

Pathologic entities may not serve as an anatomic location (e.g., renal tumor). If there is a need to specify a pathologic entity to distinguish to exam codes, the pathologic entity should be specified with the *Reason for Exam* attribute or *Guidance for.Object* sub-attribute.

4.2 Syntax and Modeling Principles

The syntax used to describe the *Anatomic Location* attribute is as follows:

```
<body region imaged> ">" <imaging focus>
```

For example, for an abdominal CT with a focus on the liver, the Anatomic Location would be specified as:

Abdomen>Liver

4.2.1 Specifying Region(s) imaged without an Imaging focus

If there is a single anatomic context associated with a code, it should be specified as <body region imaged> without an <imaging focus>, for example, for an abdominal CT, the *Anatomic Location* would be specified as:

Abdomen

When multiple regions are imaged without an imaging focus, such as CT of the head and neck, the two regions are separated by a "+":

Head+Neck

4.2.2 Imaging foci that cross body regions

Certain *Imaging foci* cross multiple body regions, such as **Pharynx**, which is included in both the **Head** and **Neck** *Imaging regions*. In this case, the regions will be separated by a "+" as follows:

Head+Neck>Pharynx

4.2.3 Specifying multiple Anatomic locations

When more than one *Anatomic location* is imaged, where each location has a different *Region imaged* and *Imaging focus* pair, they are separated by an "&" according to the syntax:

```
<body region imaged A> ">" <imaging focus A> "&" <body region imaged B> ">" <imaging focus B>
```

For example, a study of the chest and abdomen focused on the lung and liver would be specified as follows:

Chest>Lung & Abdomen>Liver

4.2.4 Broad region combined with a specific focus

In other situations, a specific *Imaging focus* in one *Region imaged* may be imaged at the same time as a different *Region imaged* without a focus. Consider an MRI examination of the face and neck. **Face** is an *Imaging focus* of the *Region imaged* **Head**. **Neck** is an additional *Region imaged*. In such situations, the lower precedence of the "&"

compared to the ">" operator is used to combine these areas as follows:

Head>Face & Neck

4.2.5 Specifying terms without an anatomic location

In some cases, such as fluoroscopic guidance codes, a specific *Anatomic Location* may not be relevant, in which case we use the general unspecified *Region imaged*.

4.2.6 Parallelism

In rare instances, a complex study may require parallelism to model correctly. In this instance, a double ampersand is used to separate the elements of the study. For example, a study that consists of PA and lateral views of the chest plus 4 oblique views of the right ribs could be represented as with the following *Anatomic location* and *Views*

Chest && Chest>Ribs.Right

Views 2 PA+Lateral && Views 4 Right oblique

4.2.7 Operator precedence

The precedence of operators is ".", "+", ">","&","&&". For example:

Head+Neck > Pharynx

is equivalent to

(Head+Neck)> Pharynx

4.2.8 Region imaged as grouper +/- coarse-grained descriptor

The nature of the study should make it clear whether the *Region imaged* is functioning as both a coarse-grained descriptor of the area imaged and a grouper or as a grouper only. The following are additional guidelines to help users make that determination:

- 1. In general, when the *Region imaged* is the **Head**, **Neck**, **Chest**, **Abdomen** or **Pelvis**, it is both a coarse-grained descriptor and a grouper;
- 2. For spine studies, the *Region imaged* is typically a grouper only (this is an exception to rule #1). For example, a C-spine exam will have the *Anatomic location* specified as **Neck>Spine.cervical**, but typically the exam would focus on the spine and not include general imaging of the neck;
- 3. When the *Region imaged* is **Upper extremity** or **Lower extremity**, it typically functions as a grouper only.

4.2.9 Laterality

Many exams require laterality to be specified in order to be performed. These exams will be signified with an *Anatomic Location.Laterality.Presence* attribute set to **True**. For terms with *Laterality.Presence* = **True**, the *Laterality*

attribute must not be null. Valid values of the Laterality attribute are:

- Left
- Right
- Bilateral
- Unilateral
- Unspecified

The recommended practice is to specify one of **Left**, **Right**, or **Bilateral** for *Anatomic Location.Laterality* whenever *Anatomic Location.Laterality.Presence* = **True**. If the *Laterality.Presence* attribute is **False**, the *Laterality* attribute must be null. Laterality applies to the most specific anatomic part associated with the exam code.

4.2.10 Subject

Some exams are relevant only to a Fetus or a Gestation. This distinction will be represented when necessary by the *Subject* attribute.

4.2.11 Ectopic Anatomy

Ectopic anatomy, such as a transplanted kidney, if needed to distinguish an exam code, should be specified as a *Reason for Exam*, not as an *Anatomic Location*. *Anatomic Location* corresponds to where the transplanted kidney is located, e.g., Pelvis.

4.2.12 Anatomic terminology in the extremities

In the upper extremity, the term **Upper arm** is preferred over the term "arm." Even though these are technically equivalent, the redundancy of **Upper arm** provides for greater clarity. **Upper arm** is also preferred over "humerus" for this area, as the latter is bone-specific and could be construed as excluding soft tissues. Similarly, in the lower extremity, **Lower leg** is preferred over "leg," "calf" and "tibia / fibula."

4.2.13 Singular vs. Plural

The singular form of an anatomic structure is typically used, except in a few specific cases that primarily apply to vasculature, as noted below.

4.2.14 Singular vs. Plural in the context of Vasculature

For the set of vessels associated with a particular region, organ or a specific group of vessels, we use the plural "Vessels", "Veins" and "Arteries" to mean "set of", for example, **Adrenal vessels** or **Cerebral arteries**. One use case for such pre-coordination is angiography, for example, CT angiography of the renal vessels would have the following *Anatomic Location*:

Abdomen>Renal vessels

The plural form does not imply laterality, which is still specified using the *Laterality* attribute (see <u>4.2.9</u> - <u>Laterality</u>). For example, **Abdomen>Renal vessels.right** means the set of renal vessels supplying the right kidney.

Specific named vessels use the singular form, e.g., Femoral vein and Superior mesenteric artery.

When vessels in an extremity are imaged for a specific reason, such as varicose vein treatment, and there are different CPT codes for treatment of a single vessel and treatment of multiple vessels, we use the plural form to mean multiple and also created a singular form to represent treatment of a single vessel even though that vessel is not named, i.e., **Extremity veins** and **Extremity vein**.

5 View

This chapter describes the *View* attribute, which is used to indicate the orientation of the patient in the image. This may reflect a combination of patient position and x-ray beam direction, or may alternatively be captured in a named, or eponymous, *View*. While this most commonly refers to radiography (e.g. a lateral radiograph of the chest), it may also be used with other modalities (e.g. prone CT of the chest, or an RF.angio study of the abdominal aorta with runoff views). Attribute values such as **Runoff** and **Perfusion** indicate that these views are included in the study but do not imply that the study is limited to only these views. **Portable** is specified as part of the *Modality* attribute rather than the *View*.

In many instances, the *View* attribute will not be specified at all (e.g. MRI of the brain) in the Playbook model. However, note that in the LOINC model, the Component part of all radiology terms specifies the type of image acquired based on the modality: **Views** for **XR**, **MG**, and **NM**, and **Multisection** for **MR**, **CT**, **US**, **NM.SPECT**, **PT**, and **XR.tomography**.

5.1 Definitions

The View attribute includes optional sub-attributes, including Aggregation and View type.

The *Aggregation* component is used to describe the extent of the imaging performed, whether in quantitative terms (e.g., **3 or more views**) or subjective terms (e.g., **Complete**). The use of "Follow-up" as a value of the *Aggregation* attribute is replaced by the value **Limited**.

View type is used to name specific views, such as **Lateral** or **Prone**. View type is an indicator of the orientation of the patient in an image, often carrying an implication of passive positioning (i.e. positioning which is not unduly onerous for the patient). This may reflect a combination of patient position and imaging direction (e.g. x-ray beam direction), and may be captured in a named or eponymous term (e.g. **Norgaard view**). The positioning involved in view types is designed to permit visualization of specific anatomic targets or particular orientations (e.g. open mouth odontoid view, swimmer's view). Note that this positioning is usually not passive in the strict sense (i.e. performed by someone else), but rather passive in the sense that it is neither onerous for the patient, nor intended as a challenge to the patient. We considered creating a separate attribute for patient position, however, given that relatively few terms would include this attribute, we decided to include it within the *View type*.

5.2 Syntax

The syntax used to describe the *View* attribute is as follows:

<Aggregation> <View type>

For example, for a cervical spine X-ray with AP and lateral views, the View would be specified as:

5.2.1 Aggregation

As stated above, the *Aggregation* attribute is optional and, when included, specifies the extent of imaging performed in qualitative or quantitative terms. Qualitative descriptors include concepts such as **Limited**, **Complete**, and **Multiple days**. Quantitative aggregation values can specify a fixed number or range of views. The syntax for representing greater than or equal to and less than or equal to a specific number of views is "GE <#>" and "LE <#>, respectively. All of the following are examples of *Aggregation*:

```
Views multiple areas
Views 2 or 3
Views GE 5
```

When the number of views is specified for a bilateral exam, the number refers to the number of views per side (e.g., XR Knee Bilateral 2 Views specifies 2 views of each knee)

5.2.2 View type

In studies that specify a *View type*, one or more values can be specified, separated by a "+". For example:

```
View lateral
Views PA + lateral
Views PA + lateral + R-oblique + L-oblique
```

5.2.2.1 Eponymous view types

Eponymous views imply patient position and beam direction, as well as anatomic focus. Anatomic focus will continue to be specified separately as described in the previous chapter, recognizing this redundancy.

5.2.2.2 Laterality in the view

Laterality may optionally be specified in certain views (e.g., "Lateral," "Right lateral" or "Left lateral"). The laterality specified in this case indicates patient position relative to the beam, not the side of the patient being imaged, and is thus independent of the *Anatomic Location.Laterality* sub-attribute.

5.2.3 Specifying Aggregation and View type

In many cases, both an *Aggregation* and one or more *View type* values are specified. If the *Aggregation* value includes the specified *View types*, the two values will not be separated by a delimiter. However, if the *View types* are in addition to the number of views specified in the *Aggregation* value, the two values are separated by a "+".

For example, 2 views including an oblique view is represented as:

```
Views 2 oblique
```

And 2 views and an additional oblique view is given by:

```
Views 2 + oblique
```

5.2.4 Parallelism

Sometimes, parallelism is required to show which attributes are associated with which views. As described earlier, the double ampersand ("&&") is used to show parallelism. For example, an exam that includes a PA view of the chest and at least three rib views would be modeled with the following *View* and *Anatomic location* attributes:

```
Views GE 3 && View PA Chest>Ribs && Chest
```

That is, the atoms **Chest>Ribs** and **Views GE 3** form one group, and **Chest** and **View PA** another group. Note that this parallelism relies on a consistent ordering of atoms to maintain proper groupings.

6 Timing

The *Timing/Existence* attribute may be used in conjunction with both the *Maneuver and Pharmaceutical* attributes. This attribute specifies the existence of a *Maneuver* or a *Pharmaceutical*, or, in some cases, the existence of one *Maneuver* (or *Pharmaceutical*) and the absence of another, for example, views of the thoracolumbar spine without and with lateral bending.

The *Timing/Existence* attribute can be either simultaneous:

WO

W

A combined "before and after" notation that denotes separate sets of images:

```
WO & W
```

Or describing an image taken at a specified time after administration of the pharmaceutical:

```
48H post
```

7 Maneuver

7.1 Definitions

Maneuvers relate to a challenge presented to a patient, often with the goal of elucidating or testing some dynamic aspect of anatomy or physiology. Maneuvers often carry an implication of patient exertion (e.g. Valsalva maneuver), although some maneuvers do not involve patient exertion (e.g. pharmacologic cardiac stress). *Timing/Existence* specifies the existence of that *Maneuver*, or, in some cases, the existence of one *Maneuver* and the absence of another. For example, flexion and extension views of the cervical spine are used to detect instability as indicated by changes in spinal alignment. Similarly, views of the thoracolumbar spine

without and with lateral bending may be done to evaluate scoliosis. Inspiratory and expiratory maneuvers as part of chest imaging may be used to evaluate the lungs. *Maneuvers* may occur in pairs (e.g. **Flexion** and **Extension**). As above, these factors distinguish maneuvers from patient actions used purely to gain a desired perspective. For example, the cross-table lateral radiograph of the hip requires the patient to be lying supine with the contralateral leg bent and raised, though the purpose of this is to obtain a lateral angle on the hip rather than to test stability or dynamic change. In such cases, the patient position is embodied in the named *View type* (e.g. **Danelius Miller**) as described in the *View* <u>definitions section</u>, rather than with a maneuver.

In general, *Maneuver* values, when included, are specified together with a *Timing* attribute value, such as **W** or **WO**, similar to Pharmaceuticals as defined in the next chapter. If no maneuver is specified, it is assumed that the patient is at rest.

7.2 Syntax

Maneuvers are separated from the View attribute by "^" (a carat or a "hat"). By default, the specified Maneuver(s) applies to all of the Aggregation and View types preceding the carat, and vice versa. For example, in the first example below, **W standing** applies to the **Lateral** View, and in the second, to both the **AP** and **Lateral** Views. In the third, **Standing** and **Flexion** both apply to the **PA** View:

```
View lateral^W standing
View AP+lateral^W standing
Views PA^W standing+W flexion
```

7.2.1 Maneuvers that only apply to a subset of the Aggregation and/or View types

In some cases, a given *Maneuver* or set of *Maneuvers* will only apply to some of the *Aggregation* or *View types* that are specified. In such cases, parentheses are used to indicate which *Aggregation* or *View type(s)* the *Maneuver* is related to. For example, a study that includes 2 views plus one or more unspecified views with standing is given by:

```
(Views 2) + (views^W standing)
```

A more complicated example is a study that has two sets of *Maneuvers*, each of which is related to a different *View type*:

```
(Views AP^W R-bending + W L-bending) + (view lateral^W flexion + W extension)
```

8 Pharmaceutical

8.1 Definitions

The *Pharmaceutical* attribute specifies the presence or absence of chemical agents relevant to the imaging procedure. We use this attribute to specify administered contrast agents, radiopharmaceuticals, medications, or other clinically important agents and challenges during the imaging procedure.

8.2 Syntax

The syntax used to describe the *Pharmaceutical* attribute specifies several optional components:

```
<timing/existence><substance given><route>
```

Only the components required for specifying the pharmaceutical at a clinically important level are included in the attribute value.

8.3 Examples

Using this syntax, a common contrast specification of without then with IV contrast would be denoted:

```
WO & W contrast IV
```

In other cases, the time delay is a key component:

```
48H post contrast PO
```

8.4 Specifying more than one pharmaceutical

The syntax above can also be used to specify more than one pharmaceutical that may be influence the imaged physiology. For example, a nuclear medicine cardiac stress test may involve administration of a radiopharmaceutical and a stress agent such as **Adenosine**, **Dobutamine**, or **Regadenoson**. The attribute value list will contain only single pharmaceuticals. We specify multiple instances of the *Pharmaceutical* attribute by combining them with "+":

```
W adenosine + W radionuclide IV
W dipyridamole + W Tc-99m Sestamibi
```

8.5 Usage Notes

Some pharmaceuticals will be more fully specified than others. For example, some may specify the specific substance:

```
W Tc-99m Sestamibi IV
```

whereas others name a more generic class:

```
W radionuclide IV
```

W anesthesia

8.5.1 Preference for Generic Names

We use the generic name of a pharmaceutical, not the brand name, e.g., **Tc-99m Sestamibi**, not Cardiolite. We will usually include the brand or trade names as synonyms. In rare cases, we use the brand name when a generic form does not exist (e.g., **Theraspheres**).

8.5.2 Route

Where possible, we denote the *Route* of administration by abbreviations for medication routes (Table 6 of the LOINC Users' Guide). An oral route of administration would be denoted by **PO**, an intravenous route by **IV**.

8.5.3 Intra versus Via

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 an anatomic space, and this space is what is visualized in the study. For example:
- W contrast intra lymphatic
- We use **via** when the contrast injected goes through a device or anatomic space into the separate anatomic space being visualized. For example:
- W contrast via catheter
- W contrast via urethra

8.5.4 Existence versus Absence

The *Existence* component of the pharmaceutical attribute allows specification of whether or not the imaging occurs in the presence of the agent where existence is denoted **W**, **WO**, or **WO** & **W**. The existence of **WO** & **W** denotes separate images, without and with the pharmaceutical.

8.5.5 Relationship to View. Maneuver sub-attribute

Like the physical maneuvers described in the section on the *View* attribute, pharmaceutical agents are also intended to test a dynamic aspect of the anatomy, with similarities in how these are modeled. In some cases, an exam may use one or the other that are intended to produce a similar anatomic response (e.g., **W exercise** or **W adenosine**). Where needed, they can also be used together as different attributes of the overall term model. For example, in defecography, both a maneuver and contrast are specified:

W contrast PR & during defecation

8.6 Issues

- [Decision: YES] LOINC to change order (WO then W) pattern
- [Decision: NO] Should the existence convention be changed to the more redundant but more clear full expression:
 - o WO contrast IV & W contrast IV
- [Decision: NO] Should the combination pharmaceuticals be items in the attribute value list?
- Is there a more up to date specification of Routes? Not really. FHIR uses this same table. Some were added in 2.3.1

- [Decision: YES] Should we remove the amount sub-attribute?
- Intra articular -> IS (Intrasynovial)
- We will use quotes for keeping together separate words within an attribute. We'll look for naming conventions to eliminate the need for this. We will convert WO & W to WO&W.
- Include the Modifiers from Views:
 - o Deprecate usage of "1 phase" in LOINC (it is implied unless stated as 3 phase)
 - o 3 Phase
 - o 30M post
 - o 45M post
 - o Delayed
 - o Runoff

9 Reason For Exam

9.1 Definitions

Reason for exam is used to describe a clinical indication or a purpose for the study. This may refer to a patient diagnosis, a clinical indication, a clinical status (e.g., **Post op**), an intended measurement, altered anatomy (e.g., **Endograft**), or some other indicator of the purpose of the exam (e.g. **Screening**).

The terms **Diagnostic** and **Screening** are used as values of the *Reason for exam* attribute, and these are potentially confusing for two reasons. First, diagnostic is often thought of as complementary to screening, in which case the terms refer to the patient's clinical status (i.e., asymptomatic patients undergo screening exams, whereas symptomatic patients undergo diagnostic exams). However, diagnostic is also frequently used in the context of mammography, in which case it is an indicator of the views to be obtained (specifically, that additional non-standard views may be performed), not an indicator of the patient's symptom status. In both cases, diagnostic refers to an exam being performed for the purpose of further work-up. Here we have chosen to model these terms as part of the *Reason for exam* semantics, rather than the *View* semantics.

Second, the question of screening and diagnostic exams "for what" may be another source of confusion. Here, we take the position that the answer is typically understood: Screening mammography screens for breast cancer; screening colonography screens for colon cancer. Further, note that the use of the terms **Diagnostic** and **Screening** is intended to be limited to those exams where these are needed to distinguish from some other type of study.

We also use the *Reason for exam* attribute to distinguish studies that are primarily done in the pediatric domain. For example, the codes for bilateral hip ultrasound and cranial ultrasound both have the *Reason for exam* specified as **For pediatrics**.

We do not create separate codes with pediatrics as the *Reason for exam* in cases where the same study is commonly done in both the adult and pediatric population. For example, "Head CT" will be used for both pediatric and adult studies.

Also note that **3D post processing** is included here as a value of the *Reason for exam* attribute. This refers to image rendering done after image acquisition. Some facilities bill for such renderings, which may be used for surgical planning or other purposes. As a result, these renderings (at least sometimes) constitute an end-product of the exam, and we have thereby chosen to model such processing as a reason for performing the exam. While 3D post processing may also be used simply as a diagnostic tool in image interpretation (and thus not technically a reason for performing the study), we have elected to simply model any description of 3D post processing here.

9.2 Examples

		<reason(s)></reason(s)>
XR	Eye	Foreign body
MG	Breast	Diagnostic
MG	Breast	Diagnostic + Call back
US		Pregnancy + Less than 14 weeks
US		Multiple gestation + Greater than 14 weeks
NM	Stomach	Liquid gastric emptying
СТ	Heart	Calcium score

9.3 Notes

- 1. 10/17/14: Values removed "mass," "obstruction," "patency," "pre op"
- 2. 10/17/14: Values added "intra op," "endograft"
- 3. 10/17/14: "Twin pregnancy" replaced with "multiple gestation."
- 4. "Call back" is only to be used in relation to mammography.

10 Guidance

10.1 Definitions

The *Guidance* attribute is used to describe image-guided interventions. Such procedures may range from the very general (e.g., "CT guided needle placement") to the very specific (e.g., "fluoroscopy guided lumbar vertebroplasty, with bone biopsy, additional level").

We recommend using these image-guided intervention terms to represent both the imaging part of the procedure and the intervention itself, so for example, the term for "CT guided needle placement" would be used to order and report both the CT guidance as well as the placement of the needle. If there are use cases for which separate codes are necessary for each of the two aspects, we will determine how best to model those individual concepts, but until we receive feedback from users about such use cases, we will continue to recommend using a single code for both the imaging and the action.

Imaging guidance for procedures is modeled with three sub-attributes:

<Approach> <Action> <Object>

Approach refers to the primary route of access used, such as **Percutaneous**, **Transcatheter**, or **Transhepatic**. Action indicates the intervention performed, such as **Biopsy**, **Aspiration**, or **Ablation**. Object is used to specify the target of the action, such as **Mass**, **Abscess** or **Cyst**. For complex procedures, operators may be used to combine instances of the *Guidance* attribute.

10.2 Usage Notes

10.2.1 Guidance for. Presence

Image-guided intervention codes are signified with a *Guidance for.Presence* attribute value of **Guidance**. This attribute is primarily used as an indicator that one or more of the *Guidance for.Approach*, *Guidance for.Action*, and *Guidance for.Object* attributes will be valued.

10.2.2 Guidance for. Approach

The *Approach* sub-attribute will generally be included in the formal code specification. For some procedures like fluid aspiration or biopsy, the percutaneous route is the "default" and often assumed route. Local procedure names will often not include the word "percutaneous" in the name. For purposes of modeling, we will include **Percutaneous** in the attribute specification. But, to avoid extraneous "clutter", the display name for the precoordinated term will only include the approach if we have two variants, one with percutaneous and one with some other route.

In some cases, "percutaneous" may be part of the overall route used for a procedure (e.g., "percutaneous transhepatic"). In such cases, the primary, or most evocative, route will be used (e.g., **Transhepatic**).

10.2.3 Guidance for. Action

The Action sub-attribute will generally be required to adequately specify an image-guided procedure. Examples include: Placement of; Replacement/Exchange of; Removal of; Repositioning of; Retrieval of; Infusion of; Injection of; Localization of; Check of.

For the *Actions* **biopsy** and **aspiration**, in most cases the type of device used (e.g., needle, fine needle, core needle) does not need to be specified in the procedure name. Therefore, for most terms that include the **biopsy** or **aspiration** *Actions*, we will not include information about the device. In those select cases where a particular type of device is used for a specific purpose, however, we will include the device-specific information in this sub-attribute. For example, percutaneous aspiration of fluid using a fine needle is performed in order to obtain a specimen for cytologic examination, so for this context we will make terms that have **aspiration.fine needle** as the *Action*.

10.2.4 Anatomic Location and Guidance for. Object

For a given procedure, the body region or organ of interest is specified outside of the *Guidance* attribute, using the *Anatomic Location* attribute. On the other hand, when there is a specific site of pathology targeted by an intervention, this is modeled using the *Guidance for.Object* sub-attribute. The expectation is that when normal anatomic specifiers such as **Liver** or **Abdomen** are used, these are modeled using *Anatomic Location*. When a site of disease such as **Mass** or **Abscess** is described, this is modeled using *Guidance for.Object*. Alternatively, the object of a procedure may be a device (e.g., **Central venous catheter**) or substance (e.g., **fluid** or **CSF**).

Note that the *Object* sub-attribute is optional. Some procedures will not specify a particular pathologic lesion

(e.g., "CT guided liver biopsy") whereas others will (e.g., "CT guided liver mass biopsy"). In some cases, neither *Anatomic Location* nor *Guidance for.Object* will be specified (e.g., "US guided fine needle aspiration").

10.2.5 Modality attribute

The *Guidance* attribute will generally be used in conjunction with the *Modality* attribute. Recall that the modality code **{Imaging modality}** is used for image-guided procedures where the particular imaging modality is not specified (e.g., "image guided liver biopsy").

10.2.6 Specifying more than one procedure

Although uncommon, the syntax above can also be used to specify more than one procedure by repeating the triplet of sub-attributes (remember, only the *Action* sub-attribute is required).

As defined in the Syntax section (2.1), use of "+" to join two procedures means logical conjunction (i.e., both procedures were done).

For example:

Guidance for cholangioscopy+removal of calculus

10.3 Examples

	<anatomic loc=""></anatomic>	<approach></approach>	<action></action>	<object></object>
СТ	Liver	Percutaneous	Biopsy	
СТ	Liver	Percutaneous	Biopsy	Mass
{Imaging modality}		Percutaneous	Placement	Drain
{Imaging modality}		Percutaneous	Drainage	Abscess
{Imaging modality}	Gallbladder	Transhepatic	Placement	Drain
US		Percutaneous	Placement	Non-tunneled CVC
{Imaging modality}		Percutaneous	Biopsy	
US	Pleural space	Percutaneous	Drainage	
US	Thyroid	Percutaneous	Aspiration	Fluid
{Imaging modality}		Percutaneous	Exchange	Gastrojejunal tube

11 Subject

11.1 Definitions

The *Subject* attribute is intended for use when there is a need to distinguish between the patient associated with an imaging study, and the target of the study. This situation may occur for pregnant patients undergoing prenatal imaging exams. The potential for multiple gestation further motivates the need for the *Subject* attribute, as an exam may be targeted at a particular one of multiple fetuses. The *Subject* attribute may also be used in cases of surgical specimens, such as specimen radiographs at lumpectomy.