Logical Observation Identifiers Names and Codes (LOINC®)



Users' Guide

Version 2.72
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For LOINC Version 2.72

loinc.org

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Search the LOINC database of terms using an intuitive, multilingual interface including support for Parts, Answer Lists, and Groups.

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Learn how to access LOINC content programmatically with the LOINC Terminology Server using HL7 $^{\circledR}$ FHIR $^{\circledR}$ API.



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1 - Introduction

LOINC provides a set of universal names and ID codes for identifying laboratory and clinical test results. ^{1,2} LOINC facilitates the exchange and pooling of results, such as blood hemoglobin, serum potassium, or vital signs, for clinical care, outcomes management, and research. LOINC's universal identifiers (names and codes) can be used in the context of order and observation exchanges between information systems that use syntax standards such as HL7³, CEN TC251, ISO TC215, ASTM⁴, and DICOM. 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 that may be sent between a Clinical Laboratory Information Management Systems (LIMS) and Electronic Health Record Systems (EHR).⁵, ⁶ In this way, LOINC codes provide "universal" identifiers that allow the exchange of clinical data between heterogeneous computing environments.

If data producers use only their internal (and idiosyncratic) codes to identify the variables, then receiving medical information systems cannot fully "understand" the results they receive unless they either adopt the producer's codes (which is impossible if information system receives results from multiple sources, or invest in the work to map each producer's coding system to their internal code system. 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. LOINC terms should be of interest to many in the healthcare ecosystem, including hospitals, clinical laboratories, outpatient services, state health departments, governmental health care providers, health IT vendors, diagnostic testing vendors, third-party payers, and organizations responsible for quality assurance and utilization review.

In the beginning, we used many sources as substrate that informed the creation of LOINC, 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 10), the expertise and work of the LOINC members, and EUCLIDES. We 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). From the start, this was an empirical effort with the goal to provide codes that correspond to the concepts in real world laboratories' and clinical departments' master files.

We aim to achieve a level of detail in the definition of a LOINC term that will map one-to-one to the separately reported observations on a clinical laboratory or other clinical system 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. LOINC creates terms both for individual variables (reportable tests or clinical measurements) and collections of such variables. We create terms that represent two kinds of collections: Panels, where the child elements are enumerated, and Documents where the terms represent general information collections whose contents are not explicitly enumerated.

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). LOINC content and associated documentation has been translated into many languages in further support of adoption globally. \$\frac{11}{2}\$

1.1 Acknowledgments

Over the years, LOINC has been supported financially by many organizations and individuals. We are thankful for all of their generous support, which we acknowledge on the <u>LOINC website</u>.

This work was initiated by and is performed under the auspices of the Regenstrief Institute. The content is solely the responsibility of the authors and does not necessarily represent the official views of any of our individual or organizational supporters.

We remain grateful to the late Dr. Henrik Olesen for his very helpful comments and insights about laboratory test coding. Dr. Olesen served as chair of the Commission on Nomenclature for Properties and Units (1989) and member of the joint IUPAC-IFCC Commission on Nomenclature, Properties and Units (1988-1997).

1.2 What is not part of the name

LOINC terms 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 *Fully Specified Name* 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. Therefore, 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 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 non-test measurements that are commonly required to interpret test results and are usually included as part of the report with the laboratory observations. Examples include:

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

The June 2000 release contained our first foray into order sets/batteries. Existing LOINC codes could always be used to order the specific tests observation, but prior to 2000 there was no mechanism to use LOINC codes to order a set of observations.

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

^{4.} ASTM E1238-94. Standard Specification for Transferring Clinical Observations Between Independent Computer Systems. Philadelphia: American Society for Testing Materials; 1994.

^{5.} 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.

^{6.} Dick AS, Steen EB (editors). The computer-based patient record. Washington DC: National Academy Press; 1991.

^{7.} McDonald CJ, Park BH, Blevins L. Grocers, physicians, and electronic data processing. AMA Continuing Medical Education Newsletter 1983;1:5-8.

^{8.} 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.

^{9.} Henry JB. Clinical Diagnosis and Management by Laboratory Methods. Philadelphia: W.B. Saunders; 1994.

^{10.} Burtis CA, Ashwood ER (editors). Tietz Textbook of Clinical Chemistry, 2nd ed. Philadelphia: W.B. Saunders; 1994.

^{11.} 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. ←

2 - Major Parts of a LOINC term

A LOINC term is defined as the combination of the LOINC code and the Fully Specified Name (FSN).

The LOINC code is a unique, permanent identifier. 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.

The FSN is composed of five or six main *Parts*: 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).

The FSN is the combination of the main Parts and the colon character, ":", which acts as a separator:

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



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*.

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 Name

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
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 Scale (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)

In general, abbreviations are not used in the *Component*. For example, we use "total", "fraction", "oxygen", "Alpha", and "Beta" rather than "tot", "frac", "O2", "A-", and "B-". However, there are a few exceptions, such as the commonly used abbreviations shown in Table 2.

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"	mmunoglobulins (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)

- 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.
- 2.1.2.6 When the test measures an antigen to a specific species of organism but cross-reactivity is such that other organisms are identified, the name should be the principal organism that is targeted by the test.
- 2.1.2.7 Avoid "direct" and "indirect" except as parts of synonym names. Avoid "conjugated" and "unconjugated" when a more precise term, such as "glucuronidated" or "albumin-bound" is available.
- 2.1.2.8 Use "platelets", not "thrombocytes."
- 2.1.2.9 Name vitamins by the chemical name. For example, use thiamine not Vitamin B1, The name containing "Vitamin" will be included as a synonym. This is the only reasonable approach because all vitamins have a chemical name but not all vitamins have a "numbered" vitamin name. 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 generally use the "nor" form rather than "desmethyl", e.g., nordoxepin not desmethyldoxepin. When the distinction between specific forms of the compound is important, however, we will make an exception, e.g., O-desmethylvenlafaxine and O-desmethylencainide.
- 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.

Beginning in June 2019 with LOINC version 2.66, we adopted tall man lettering for drugs with similar names based on the list recommended by the Institute for Safe Medication Practices, which includes the list previously published by the U.S. Food and Drug Administration. Tall man lettering uses upper case letters to distinguish key parts of the drug name in order to help visually differentiate similar names, such as cycloSPORINE and cycloSERINE. This format is still case insensitive in that the meaning is the same regardless of the case; however, for senders and receivers that can support mixed case display, the tall man lettering helps draw attention to the discriminating parts of similar names.

Table 3: Example Case Specifying Conventions

Our conventions	Standard mixed case
L little u super little a	Lu ^a
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 <u>Unified Code for Units of Measure (UCUM)</u>, exponents are typically represented using an asterisk (*) or carat (^). However, asterisks and carats both already have defined meanings in 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.

2.1.8 Use of curly braces {} in LOINC names

In <u>Section 2.5</u> we describe 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.

2.2 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.

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 4a: Example Time Delay Post Challenge

Abbr.	Description	
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	Time from the challenge, or dose not specified (random)	

Table 4b: N minutes/hours/days/weeks/months/etc. after challenge begun

Abbr.	Description	Abbr.	Description
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	۸		post	dose		РО
11-Deoxycortisol	٨	2nd specimen	post		XXX challenge	
17-Hydroxyprogesterone	^	6H	post		XXX challenge	
11-Deoxycortisol	۸		post		XXX challenge	
Calcium	۸	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**, ¹⁸ 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	мм	Mucus Membrane
В	Buccal	NS	Nasal
DT	Dental	NG	Nasogastric
EP	Epidural	NP	Nasal Prongs
ET	Endotrachial Tube	NT	Nasotrachial Tube
GTT	Gastronomy Tube	ОР	Ophthalmic
GU	GU Irrigant	ОТ	Otic
IMR	Immerse (Soak) Body Part	отн	Other/Miscellaneous
IA	Intra-arterial	PF	Perfusion
IB	Intrabursal	РО	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
мтн	Mouth/Throat	WND	Wound

Examples:

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

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

2.2.2.1 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:Qn
```

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

Another example would be:

```
Oxygen:PPres:Pt:BldA:Qn
Oxygen inhaled:VRat:Pt:Inhl gas:Qn
```

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. ¹⁹ 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 in qualitative terms. More examples of *Properties* are given in Table 8. The complete set of active LOINC *Properties* is available in the LOINC

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**, **fraction**, and **rate** (see LOINC properties table (Table 8)).

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:Qn

Some measures do not fit the above schema. For instance, IUPAC describes an entitic quantity. This refers to

measure per entity (e.g., cells, receptors, and molecules). Entitic quantities usually have units that include the name of some entity, e.g., red blood cells ("per 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
Barbiturates positive:Prid:Pt:Urine:Nom:Confirm
```



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 a) the actual presence or absence of an analyte, or b) 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>Section 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

Туре	Abbreviation	Description
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

Туре	Abbreviation	Description
	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
	MSCnc	Mass or Substance Concentration
	RelMCnc	*Relative Mass Concentration
	RelMRat	Relative Mass Rate
	ThrMCnc	*Threshold Mass Concentration
	MCncDiff	Difference in Mass Concentration
	MCPctDiff	Percent Difference in Mass Concentration
Substance (Moles/Milliequivalents)	RelSCnc	*Relative Substance Concentration
	Sub	*Substance Amount
	SCnc	*Substance Concentration
	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)
	NCncRange	Number Concentration (count/vol) Range
	NCnt	Number Content = Count/Mass
	NumDiff	Number Difference
	NFr	*Number Fraction
	NFr.DF	Decimal 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
<u> </u>	VRatCnt	Volume Rate Content

Туре	Abbreviation	Description
	VRto	*Volume Ratio
	RelVol	Relative Volume
	RelVRat	Relative Volume Rate
	ArVol	Volume/Area
	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
	TmElpot	Time electrical potential
	TmMCnc	Time mass concentration
	TmStp	Time Stamp—Date and Time
	TmStpRange	Time Stamp Range
	TmSCnc	Time substance concentration
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
	AUC	Area under the curve
	Bib	Bibliographic Citation
	Circ	Circumference
	CircFr	Circumference Fraction
	Class	*Class
	ColorRto	Color Ratio
	Compli	Compliance
	CompliRto	Compliance Ratio

Туре	Abbreviation	Description
	Cmplx	Complex
	Desc	Description
	Diam	Diameter
	Dosage	Dosage
	Elcur	Electrical current
	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
	ExtendedID	Extended ID
	Fcn	Function
	Find	Finding
	FldConduct	Fluid Conductance
	FldResist	Fluid Resistance
	Force	Mechanical Force
	Freq	Frequency
	Geno	Genotype
	Нх	History
	Imp	Impression/interpretation of study
	ID	Identifier
	Instrct	Instructions
	InvLen	Inverse Length
	Inverse VI	Inverse Inspired Volume
	Len	Length
	LenFr	Length Fraction
	LRat	Length Rate
	LenRto	Length Ratio
	LogLenRto	Log Length Ratio
	ArLen	Length/Area
	Likelihood	Likelihood
	Loc	Location
	LogInvPct	Log Inverse Percent
	LogRtoElp	Log Ratio Electrical Potential
	МоМ	Multiple of the Median
	Morph	Morphology
	NumRange	Number Range
	OD	Optical Density

Туре	Abbreviation	Description
	Osmol	*Osmolality
	Osmolarity	Osmolarity
	PctDiff	Percent Difference
	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
	Rden	Relative Density
	RelFldResist	Relative Fluid Resistance
	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
	I .	l
	Visc	Viscosity

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

One can either measure a *Property* at a moment (point) in time or measure it over a time interval and integrate, in the mathematical sense, over time. In the latter case, we aggregate a "series" of physiologic states into a single scalar value that reflects some "average" *Property* measured over the specified time interval. Intervals also have relevance for rate measurements such as excretion (**substance rate** or **mass 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. The complete set of active LOINC *Time Aspects* is available in the LOINC Part File and can be identified because they contain a *PartTypeName* of **TIME**.

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 Description		
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		

the content of the presence (uppres) each of the presence (uppres) each of the presence (uppres) each of the section (uppres)	Abbr.	Duration Description		
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No. Political 1H 1 horr 2H 2 hours 25H 2 hours 4H 4 hours 4H 4 hours 6H 6 hours 7H 7 hours 8H 8 hours 10H 9 hours 10H 10 hours 2H 2 hours 2H 4 hours 2D 2 days 3D 3 days 4D 4 days 3D 4 days 3D 3 days 3D 9 days </td <td></td> <td></td>				
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48H 48 hours 72H 72 hours 1D 1 day 2D 2 days 3D 3 days 4D 4 days 5D 5 days 6D 6 days 7D 7 days 14D 14 days 30D 30 days 90D 90 days 100D 100 days 180D 180 days 1W 1 week 2W 2 weeks 3W 3 weeks 4W 4 weeks 1Mo 1 month 2Mo 2 months 3Mo 3 months	18H	18 hours		
72H 72 hours 1D 1 day 2D 2 days 3D 3 days 4D 4 days 5D 5 days 6D 6 days 7D 7 days 14D 14 days 30D 30 days 90D 90 days 100D 100 days 180D 180 days 1W 1 week 2W 2 weeks 3W 3 weeks 4W 4 weeks 1Mo 1 month 2Mo 2 months 3Mo 3 months	24H	24 hours		
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2D 2 days 3D 3 days 4D 4 days 5D 5 days 6D 6 days 7D 7 days 14D 14 days 30D 30 days 90D 90 days 100D 100 days 18D 180 days 1W 1 week 2W 2 weeks 3W 3 weeks 4W 4 weeks 1Mo 1 month 2Mo 2 months 3Mo 3 months	72H	72 hours		
3D 3 days 4D 4 days 5D 5 days 6D 6 days 7D 7 days 14D 14 days 30D 30 days 9DD 90 days 100D 100 days 180D 180 days 1W 1 week 2W 2 weeks 3W 3 weeks 4W 4 weeks 1Mo 1 month 2Mo 2 months 3Mo 3 months	1D	1 day		
4D 4 days 5D 5 days 6D 6 days 7D 7 days 14D 14 days 30D 30 days 90D 90 days 100D 100 days 18DD 180 days 1W 1 week 2W 2 weeks 3W 3 weeks 4W 4 weeks 1Mo 1 month 2Mo 2 months 3Mo 3 months	2D	2 days		
5D 5 days 6D 6 days 7D 7 days 14D 14 days 30D 30 days 90D 90 days 100D 100 days 180D 180 days 1W 1 week 2W 2 weeks 3W 3 weeks 4W 4 weeks 1Mo 1 month 2Mo 2 months 3Mo 3 months	3D	3 days		
6D 6 days 7D 7 days 14D 14 days 30D 30 days 90D 90 days 100D 100 days 180D 180 days 1W 1 week 2W 2 weeks 3W 3 weeks 4W 4 weeks 1Mo 1 month 2Mo 2 months 3Mo 3 months	4D	4 days		
7D 7 days 14D 14 days 30D 30 days 90D 90 days 100D 100 days 180D 180 days 1W 1 week 2W 2 weeks 3W 3 weeks 4W 4 weeks 1Mo 1 month 2Mo 2 months 3Mo 3 months	5D	5 days		
14D 14 days 30D 30 days 90D 90 days 100D 100 days 180D 180 days 1W 1 week 2W 2 weeks 3W 3 weeks 4W 4 weeks 1Mo 1 month 2Mo 2 months 3Mo 3 months	6D	6 days		
30D 30 days 90D 90 days 100D 100 days 180D 180 days 1W 1 week 2W 2 weeks 3W 3 weeks 4W 4 weeks 1Mo 1 month 2Mo 2 months 3Mo 3 months	7D	7 days		
90D 90 days 100D 100 days 180D 180 days 1W 1 week 2W 2 weeks 3W 3 weeks 4W 4 weeks 1Mo 1 month 2Mo 2 months 3Mo 3 months	14D	14 days		
100D 100 days 180D 180 days 1W 1 week 2W 2 weeks 3W 3 weeks 4W 4 weeks 1Mo 1 month 2Mo 2 months 3Mo 3 months	30D	30 days		
180D 180 days 1W 1 week 2W 2 weeks 3W 3 weeks 4W 4 weeks 1Mo 1 month 2Mo 2 months 3Mo 3 months	90D	90 days		
1W 1 week 2W 2 weeks 3W 3 weeks 4W 4 weeks 1Mo 1 month 2Mo 2 months 3Mo 3 months	100D	100 days		
2W 2 weeks 3W 3 weeks 4W 4 weeks 1Mo 1 month 2Mo 2 months 3Mo 3 months	180D	180 days		
3W 3 weeks 4W 4 weeks 1Mo 1 month 2Mo 2 months 3Mo 3 months	1W	1 week		
4W 4 weeks 1Mo 1 month 2Mo 2 months 3Mo 3 months	2W	2 weeks		
1Mo 1 month 2Mo 2 months 3Mo 3 months	3W	3 weeks		
2Mo 2 months 3Mo 3 months	4W	4 weeks		
3Mo 3 months	1Mo	1 month		
	2Mo	2 months		
6Mo 6 months	3Мо	3 months		
	6Мо	6 months		

Abbr.	Duration Description		
12Mo	12 months		
1Y	1 year		
2Y	2 years		
3Y	3 years		
10Y	10 years		
Lifetime	Lifetime		

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.

Example Systems are listed in Table 11. The complete set of active LOINC Systems is available in the LOINC Part File and can be identified because they contain a PartTypeName of SYSTEM.

Laboratories commonly build separate assays in their laboratory information systems (LIS's) for serum, plasma, blood, urine, and cerebrospinal fluid. In addition, they may have a single test that includes all other body fluid specimens. The LOINC System Body fld is intended to reflect this distinction and represents body fluids other than serum, plasma, blood, urine, and cerebrospinal fluid. When LOINC terms with the System Body Fld are used, information about the specific specimen source or body fluid type should also be provided. Keep in mind that in many cases for tests that are run on pleural, peritoneal, synovial, and other types of fluid, LOINC has specific terms to represent these tests, and we encourage you to use the specific terms rather than the Body fld terms when possible.

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 specimen or material is known but recorded elsewhere in the HL7/ASTM message. Yet, using XXX as a System can be problematic (see also Section 2.5.1 - Special issues related to XXX as a System below). XXX and Body fld are different in that Body fld represents a biologic fluid (other than serum, plasma, blood, urine, and cerebrospinal fluid, as stated above), whereas XXX can represent any material, biologic or nonbiologic, solid or 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
Abscess	Abscess
Amnio fld	Amniotic fluid
Anal	Anus
Asp	Aspirate
Bil fld	Bile fluid
BldA	Blood arterial
BldL	Blood bag
BldC	Blood capillary
BldCo	Blood - cord
BldCV	Blood – central venous
BIdMV	Blood - mixed venous
BldP	Blood – peripheral
BldV	Blood venous
Bld.dot	Blood filter paper
Body fld	Body fluid, unsp
Bone	Bone
Brain	Brain
Bronchial	Bronchial
Burn	Burn
Calculus	Calculus (=Stone)
Cnl	Cannula
СТр	Catheter tip
CSF	Cerebral spinal fluid
Cvm	Cervical mucus

Abbr.	Name
Cvx	Cervix
Col	Colostrum
Cnjt	Conjunctiva
Crn	Cornea
Dentin	Dentin
Dial fld	Dialysis fluid
Dose	Dose med or substance
Drain	Drain
Duod fld	Duodenal fluid
Ear	Ear
Endomet	Endometrium
Environmental Specimen	Environmental Specimen
RBC	Erythrocytes
Eye	Eye
Exhl gas	Exhaled gas (breath)
Fibroblasts	Fibroblasts
Fistula	Fistula
Food	Food sample
Gas	Gas
Gast fld	Gastric fluid/contents
Genital	Genital
Genital fld	Genital fluid
Genital loc	Genital lochia
Genital muc	Genital mucus
Hair	Hair
Inhl gas	Inhaled gas
Isolate	Isolate
Isolate.meningitis	Isolate from patient with meningitis
WBC	Leukocytes
Line	Line
Liver	Liver
Resp.lower	Lower respiratory
Lung tiss	Lung tissue
Bone mar	Marrow (bone)
Meconium	Meconium
Milk	Milk
Nail	Nail
Nose	Nose (nasal passage)
Nph	Naspopharynx
Penile vessels	Penile vessels
Penis	Penis
Pericard fld	Pericardial fluid
Periton fld	Peritoneal fluid /ascites
Dial fld prt	Peritoneal dialysis fluid
Oropharyngeal wash	Oropharyngeal wash
Placent	Placenta
Plas	Plasma
Plr fld	Pleural fluid (thoracentesis fld)

Abbr.	Name
РРР	Platelet poor plasma
PRP	Platelet rich plasma
Pus	Pus
RBCCo	Red Blood Cells Cord
Saliva	Saliva
Semen	Seminal fluid
Ser	Serum
Skin	Skin
Sputum	Sputum
Sptt	Sputum - tracheal aspirate
Stool	Stool = Fecal
Sweat	Sweat
Synv fld	Synovial fluid (Joint fluid)
Tear	Tears
Thrt	Throat
Platelets	Thrombocyte (platelet)
Tiss	Tissue, unspecified
TissCo	Umbilical cord tissue
Tigi	Tissue large intestine
Tsmi	Tissue small intestine
Trachea	Trachea
Tube	Tube, unspecified
Ulc	Ulcer
Urethra	Urethra
Urine	Urine
Urine sed	Urine sediment
Unk sub	Unknown substance
Vag	Vagina
Vitr fld	Vitreous Fluid
Vomitus	Vomitus
Bld	Whole blood
Water	Water
Wound	Wound
xxx	See Section 2.5.1

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

2.5.1 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, **Bld/Tiss** and **Body fld**.

Use of **XXX** for the specimen can create problems. Firstly, the reference ranges for measures on a continuous scale change with specimen differences, and most systems depend upon the test code to get to the reference ranges. So

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

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

So, the bottom line is that we won't accept requests for tests with **XXX** specimens without a narrative description of the most common specimen and some sense of the range of specimens for which it is used. We will likely argue for either adding a distinct code for the dominantly common specimen (e.g. **Stool** for **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", "-7.4", "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 (**Qn**).

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 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 (-).

2.6.7 Document (Doc)

The *Scale* of **Doc** represents a collection of information that is either structured or unstructured. Individual LOINC codes are assigned for different collections of information regardless of the format in which they are presented, meaning that the same LOINC code should be used to represent a given document type regardless of whether it is in PDF, text document, JPG, XML, or HTML formats. The difference between **Doc** and **Nar** is that **Nar** represents a single free text result, while **Doc** is used for collections of results reported together, which may include narrative results.



Note

"Narrative reporting" as required by regulatory agencies such as the Office of the National Coordinator for Health Information Technology in the U.S. may be fulfilled by using LOINC terms with *Scale* **Doc** and thus is not only tied to the LOINC **Nar** *Scale*.

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.

A non-exhaustive list of example *Methods* are listed in Table 13. The complete set of active LOINC *Methods* is available in the LOINC Part File and can be identified because they contain a *PartTypeName* of **METHOD**. Further, many *Methods* have descriptions that can be found on the Details Page for that Part. For example, see the details page for LP70657-9 **RPR**.

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 finegrained 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 13: Laboratory Method Type Abbreviations

Method	Abbr.	Comment
Agglutination	Aggl	
Cell binding assay immunofluorescent assay	CBA IFA	Cell binding assays are performed using cells that are engineered to only express the antigen of interest, which increases their specificity compared to traditional immunofluorescent assays.
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 Section 2.7.1 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. Does not include Cell binding assays (see CBA IFA above).
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	МІС	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.

Method	Abbr.	Comment
Virus Neutralization	Neut	Virus neutralization tests, which traditionally relies on live-virus based assays.
Pseudovirus Neutralization	pVNT	Pseudovirus-based neutralization tests
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 *Methods*:

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.

Target amplification followed by probe-based detection (Probe.amp.tar)

Definition: The **Probe.amp.tar** *Method* in LOINC 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.

The **Probe.amp.tar** *Method* is represented as **NAA+probe** in the *Short Name* and **NAA with probe detection** in the *Long Common Name*.

Signal amplification followed by probe-based detection (Probe.amp.sig)

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.

The **Probe.amp.sig** *Method* is represented as **Probe+sig amp** in the *Short Name* and **Probe with signal amplification** in the *Long Common Name*.

Target amplification followed by non-probe based detection (Non-probe.amp.tar)

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.

The **Non-probe**.amp.tar *Method* is represented as **NAA+non-probe** in the *Short Name* and **NAA with non-probe detection** in the *Long Common Name*.

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.

Examples of specific techniques and their corresponding Methods

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

Method Type	Description
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 methodologies that are included in the Probe.amp.tar Method

Method Type	Description
Polymerase chain reaction (PCR) with probe-based 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 methodologies that are included in the Probe.amp.sig Method

Method Type	Description	
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 methodologies that are included in the Non-probe.amp.tar Method

Method Type	Description
-------------	-------------

Method Type	Description		
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.		



Note

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. Immunofluorescent cell binding assays, which use cells that are engineered to express a single antigen of interest, use the *Method* **CBA IFA**. 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 87706-8 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 Oxygen Saturation Technical Brief 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.

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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. 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:

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

3.2.2 Multiple answer reporting

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

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

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

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

3.3 Immunocompetence studies (flow cytometry)

The CD (Cluster of Differentiation) markers in the LOINC database include all of the single markers and the most commonly reported combinations, e.g., CD11C+CD20C+. Most of these are 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::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 <u>Section 3.5</u>.

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

The following table lists *Methods* in drug-susceptibility tests.

Method	Description	
Agar diffusion	Bacterial sensitivity via agar diffusion (Kirby-Bauer)	
MIC	Minimum inhibitory concentration	
MLC	Minimum lethal concentration	
SBT	Serum bactericidal titer	

Method	Description
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 *Systems*:

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 ($\mathbf{Q}\mathbf{n}$), 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.

The following table indicates 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 over-the-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,

```
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

 $\label{lem:methamphetamine} Methamphetamine \ cutoff: MCnc: Pt: Urine: Qn: Confirm$

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)

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:Nom:Confirm
"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. ²³

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 al²⁴ 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.

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 <u>Human Genome Organization (HUGO) Gene Nomenclature Committee's (HGNC) terminology</u> to name the gene(s) and <u>Human Genome Variation Society's (HGVS) syntax</u> to name the variation(s) of interest.

HGVS provides seven types of prefixes to identify the difference types of reference sequences used in naming gene defects as described in the following table. As of LOINC release 2.66, LOINC has terms for the first four (p., c., g., m.).

Designation	Explanation
p	Protein reference sequence based on amino acid (codon) counting.
С	Coding reference sequence based on a transcript that encodes a protein and therefore excludes introns. Since three nucleotides = one codon, these will produce numbers 3x as large as those based on the protein.
g	Genomic reference sequence based on counting from the first nucleotide in the DNA for the gene of interest, as it exists natively in the chromosome with introns included.
m	Mitochondrial reference sequence based on counting from the first nucleotide in the full mitochondrial DNA sequence.
n	Non-coding reference sequence based on a transcript that does not encode a protein.
0	Circular genomic reference sequence, for example, for plasmids or certain viruses.
r	RNA reference 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:

CFTR gene.p.Phe508del:PrThr:Pt:Bld/Tiss:Ord:Molgen

Where we still report variants at the amino acid level, we use the nomenclature for human gene mutations proposed by Beaudet 25 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 the following table.

Amino Acid	1-Letter Symbol	3-Letter Symbol
Alanine	А	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		lle
Leucine	L	Leu
Lysine	К	Lys

Amino Acid	1-Letter Symbol	3-Letter Symbol
Methionine	М	Met
Phenylalanine	F	Phe
Proline	Р	Pro
Serine	S	Ser
Threonine	T	Thr
Tryptophan	W	Trp
Tyrosine	Υ	Tyr
Valine	V	Val
Unknown	Х	

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:

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**). For the LOINC 2.68 release, we added a new Method for Mate pair sequencing. It is unclear at this time whether this new Method produces results that are significantly different from older sequencing methods, and we may update the Method for these terms in the future based on new information.

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 associated observations 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.

3.9.4.4 Inferred phenotype and genotype

Beginning in version 2.66, we have LOINC terms for genotype and phenotype results that are derived from their respective phenotype or genotype analysis. For such concepts we include the word "inferred" in the *Component*. One example is a blood banking panel that is used to report whether or not an RBC antigen is expected to be present in a patient or donor sample based on molecular analysis of the corresponding gene, such as the presence of K Ag based on analysis of the KEL gene, for which the *Component* is **K Ag inferred phenotype**. The reverse example is an assay that reports the genotype for the APOL1 gene based on analysis of apolipoprotein L1 isoforms; for this term, the *Component* is **APOL1 inferred genotype**.

3.9.5 Infectious diseases

For information about molecular genetics in the field of infectious diseases, see <u>Section 3.4.3 - 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 Table 19) 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 (\mathbf{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:

```
\verb|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 Pharmacia²⁶ 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 23797-4:

 $(Acer\ negundo+Quercus\ alba+Ulmus\ americana+Populus\ delto ides+Carya\ pecan)\ Ab. IgE: ACnc: Pt: Ser: Ord: Multidisk and the period of th$

Related name: tx2

There may be more than one type of allergen for each plant. For instance, IgE antibodies can develop towards tree pollen and the fruit of the same tree. Similarly, antibodies exist for grain and for grain pollen. In these cases, the LOINC *Component* will contain the word **POLLEN** to distinguish the pollen allergen from the food allergen. For example, the LOINC term for corn (maize) IgE antibody would be:

```
Zea mays Ab.IgE:ACnc:Pt:Ser:Qn
```

Related names: f8; cultivated corn; maize

Zea mays pollen Ab.IgE:ACnc:Pt:Ser:Qn

Related names: g202: cultivated corn; maize

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
58779-0	Arachis hypogaea recombinant (rAra h) 1 Ab.IgE	Peanut recombinant (rAra h) 1 IgE Ab
58777-4	Arachis hypogaea recombinant (rAra h) 3 Ab.IgE	Peanut recombinant (rAra h) 3 IgE Ab
65769-2	Arachis hypogaea native (nAra h) 1 Ab.IgE	Peanut native (nAra h) 1 IgE Ab
65771-8	Arachis hypogaea native (nAra h) 3 Ab.IgE	Peanut native (nAra h) 3 IgE Ab

^{22.} Walker RH. American Association of Blood Banks Technical Manual. 11th ed. Bethesda, MD: American Association of Blood Banks, 1993. 🗠

^{23.} Antonarakis, SE, and the Nomenclature Working Group. Recommendations for a nomenclature system for human gene mutations. Human Mutation 1998;11:1-3. PubMed: 9450896.

^{24.} 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.

^{25.} Beaudet AL, Tsui LC. A suggested nomenclature for designating mutations, Human Mutation 1993;2 (4):245-248. PubMed: 8401532.

^{26.} 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/

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. The following table shows examples of pre-coordinated names.

Table 21: Examples of Pre-Coordinated Names

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

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

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

and

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

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

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

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

4.3 Radiology reports

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 our <u>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 LOINC/RSNA Radiology Playbook User Guide.

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 information on HIPAA Attachments, see the Attachments section of the LOINC website (http://loinc.org/attachments) and respective documents published by the HL7 Payer/Provider Information Exchange (PIE) Work Group.

6 - 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.²⁷ 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."

Possible local terms	Document type codes	
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 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.

Allowed Values:

Part Number	Part Name
LP173387-4	Administrative note
LP173388-2	Against medical advice note
LP173389-0	Agreement
LP412176-2	Controlled substance agreement
LP173390-8	Certificate
LP173391-6	Birth certificate
LP173392-4	Death certificate
LP173393-2	Evaluation of mental and physical incapacity certificate
LP267921-7	Proof of encounter certificate
LP173394-0	Consent
LP173395-7	Abortion consent
LP173396-5	Anesthesia consent
LP267939-9	Blood or blood product transfusion consent
LP173397-3	Hysterectomy consent
LP267417-6	Long-term opioid therapy for pain consent
LP173398-1	Organ donation consent
LP173399-9	Procedure consent
LP173400-5	Release of information consent
LP416139-6	Research study consent
LP173401-3	Sterilization consent
LP173402-1	Surgical operation consent
LP173403-9	Contract
LP193873-9	Driver license
LP173404-7	Health insurance card
LP173405-4	Health insurance-related form
LP173406-2	Health record cover sheet

Part Number	Part Name
LP173407-0	Legal document
LP200113-1	Legal letter
LP416137-0	Portable medical order form
LP173408-8	Power of attorney
LP248740-5	Medical clearance note
LP181089-6	Request
LP181085-4	Prescription request
LP173409-6	Advance directives
LP173410-4	Do not resuscitate
LP173411-2	Rescinded do not resuscitate
LP173411-2 LP173412-0	
	Living will Rescinded advance directive
LP173413-8	
LP200111-5	Checklist
<u>LP267279-0</u>	Discharge checklist
<u>LP173414-6</u>	Diagram
<u>LP173415-3</u>	Flowsheet
LP181112-6	Form
<u>LP204180-6</u>	Mandatory reporting form
<u>LP416138-8</u>	Medical history screening form
LP416137-0	Portable medical order form
LP181116-7	Instructions
LP181119-1	Action plan
<u>LP173754-5</u>	ADHD action plan
LP420133-3	Adrenal insufficiency emergency action plan
LP173755-2	Anaphylaxis action plan
LP173756-0	Asthma action plan
LP173757-8	Autism action plan
LP173758-6	Complex medical conditions action plan
LP173759-4	Cystic fibrosis action plan
LP173765-1	Diabetes type I action plan
LP173766-9	Diabetes type II action plan
LP173760-2	Heart disease action plan
<u>LP173761-0</u>	Inflammatory bowel disease action plan
<u>LP173762-8</u>	Multiple sclerosis action plan
LP173763-6	Muscular dystrophy action plan
LP173764-4	Seizure disorder action plan
LP173118-3	Discharge instructions
LP173417-9	Letter
LP200113-1	Legal letter
<u>LP204161-6</u>	List
<u>LP181534-1</u>	Prescription list
<u>LP173418-7</u>	Note
<u>LP173419-5</u>	Adverse event note
<u>LP173420-3</u>	Alert
LP181207-4	Order
LP416137-0	Portable medical order form
LP181204-1	Prescription
LP181529-1	Prescription for diagnostic or specialist care

Part Number	Part Name
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
LP181231-4	Photographic image
LP173421-1	Report
LP183503-4	Case report
LP183502-6	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.

Allowed Values:

Part Number	Part Name
LP173107-6	Communication
LP173099-5	Conference
LP173109-2	Case conference
LP173110-0	Consultation
LP173111-8	Confirmatory consultation
LP418143-6	Coronavirus Disease 2019 (COVID-19)
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
LP310260-7	Care management
LP173130-8	Crisis intervention

Part Number	Part Name
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
<u>LP173144-9</u>	VA C&P exam.cranial nerves
<u>LP173145-6</u>	VA C&P exam.Cushings syndrome
<u>LP173146-4</u>	VA C&P exam.dental ∨ oral
<u>LP173147-2</u>	VA C&P exam.diabetes mellitus
<u>LP173148-0</u>	VA C&P exam.miscellaneous digestive conditions
<u>LP173149-8</u>	VA C&P exam.ear disease
<u>LP173150-6</u>	VA C&P exam.mental health eating disorders
<u>LP173151-4</u>	VA C&P exam.miscellaneous endocrine diseases
<u>LP173152-2</u>	VA C&P exam.epilepsy ∨ narcolepsy
<u>LP173153-0</u>	VA C&P exam.esophagus ∨ hiatal hernia
<u>LP173168-8</u>	VA C&P exam.extremity joints
<u>LP173154-8</u>	VA C&P exam.eye
<u>LP173155-5</u>	VA C&P exam.feet
<u>LP173156-3</u>	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
LP173163-9	VA C&P exam.hemic disorders
<u>LP173164-7</u>	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
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
<u>LP173172-0</u>	VA C&P exam.mouth ∨ lips ∨ tongue
<u>LP173173-8</u>	VA C&P exam.multiple exam
<u>LP173174-6</u>	VA C&P exam.muscles
<u>LP173175-3</u>	VA C&P exam.miscellaneous neurological disorders
<u>LP173176-1</u>	VA C&P exam.nose ∨ sinus ∨ larynx ∨ pharynx
1	

Part Number	Part Name
<u>LP173177-9</u>	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
<u>LP173184-5</u>	VA C&P exam.miscellaneous respiratory diseases
LP173185-2	VA C&P exam.obstructive ∨ restrictive ∨ interstitial respiratory diseases
<u>LP173186-0</u>	VA C&P exam.scars
<u>LP173187-8</u>	VA C&P exam.sense of smell ∨ taste
LP173188-6	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
LP173198-5	History and physical
<u>LP173199-3</u>	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
LP173204-1	Initial evaluation
<u>LP173205-8</u>	Admission evaluation
LP428833-0	Pain assessment
LP173126-6	Readiness for military duty assessment
LP270301-7	Reevaluation
LP173127-4	Risk assessment and screening
LP173128-2	Fall risk assessment
LP204157-4	Safety issue assessment
<u>LP173192-8</u>	Evaluation and management of a specific problem
<u>LP173193-6</u>	Evaluation and management of anticoagulation
LP173194-4	Evaluation and management of hyperlipidemia
LP173195-1	Evaluation and management of hypertension
LP267443-2	Evaluation and management of radiation exposure
LP173197-7	Evaluation and management of smoking cessation
LP208913-6	Evaluation and management of workers compensation
LP269262-4	Fluid management
LP204160-8	Medical equipment or product
LP173206-6	Plan
LP173209-0	Plan of care
LP173213-2	Progress
LP173211-6	Restraint
LP427038-7	Stroke prevention
<u>LP173214-0</u>	Surgical operation

Part Number	Part Name
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
<u>LP173228-0</u>	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
LP203673-1	Notification
LP203034-6	Admission notification
LP428834-8	Arrival notification
LP428837-1	Departure notification
LP203035-3	Discharge notification
LP204130-1	Visit notification
LP173233-0	Outreach
LP173234-8	Procedure
LP267418-4	Cardiopulmonary resuscitation
LP269244-2	Conscious sedation procedure
<u>LP410764-7</u>	Emergency procedure
LP411573-1	Mechanical circulatory support
<u>LP173235-5</u>	Interventional procedure
<u>LP418371-3</u>	Intubation
LP173236-3	Pathology procedure
LP173237-1	Autopsy
LP421048-2	Quality
LP421047-4	Gaps in care
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.

Allowed Values:

Part Number	Part Name
LP173041-7	Ambulance
LP173042-5	Birthing center
LP173043-3	Emergency department
LP173065-6	Hospital
LP173045-8	Intensive care unit
LP173046-6	Long term care facility
LP173047-4	Custodial care facility
LP173048-2	Nursing facility
LP173049-0	Skilled nursing facility
LP173050-8	Unskilled nursing facility
LP222061-6	Observation unit
LP173051-6	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.

Allowed Values:

Part Number	Part Name
LP263512-8	Addiction medicine
LP172912-0	Addiction psychiatry
LP172915-3	Aerospace medicine
LP345051-9	Allergy
LP172918-7	Anesthesiology
LP172981-5	Pain medicine

Part Number	Part Name							
<u>LP248728-0</u>	Sleep medicine							
<u>LP172919-5</u>	Audiology							
<u>LP172923-7</u>	Chiropractic medicine							
<u>LP172933-6</u>	Critical care medicine							
<u>LP172934-4</u>	Dentistry							
<u>LP172935-1</u>	Dermatology							
<u>LP172924-5</u>	Clinical and laboratory dermatological immunology							
<u>LP172936-9</u>	Dermatopathology							
<u>LP172987-2</u>	Pediatric dermatology							
<u>LP172940-1</u>	Emergency medicine							
<u>LP172957-5</u>	Medical toxicology							
<u>LP172988-0</u>	Pediatric emergency medicine							
<u>LP173027-6</u>	Sports medicine							
<u>LP183499-5</u>	Trauma							
<u>LP265794-0</u>	Polytrauma							
<u>LP173035-9</u>	Undersea and hyperbaric medicine							
<u>LP172942-7</u>	Ethics							
<u>LP176905-0</u>	Exercise physiology							
<u>LP172943-5</u>	Family medicine							
<u>LP172913-8</u>	Adolescent medicine							
<u>LP172947-6</u>	Geriatric medicine							
LP248728-0	Sleep medicine							
<u>LP173027-6</u>	Sports medicine							
<u>LP172894-0</u>	Forensic medicine							
LP172944-3	Forensic psychiatry							
<u>LP172946-8</u>	General medicine							
<u>LP431539-8</u>	Hospice care							
<u>LP345043-6</u>	Immunology							
<u>LP172925-2</u>	Clinical and laboratory immunology							
<u>LP342846-5</u>	Integrative medicine							
<u>LP172911-2</u>	Acupuncture							
<u>LP172952-6</u>	Internal medicine							
<u>LP172913-8</u>	Adolescent medicine							
<u>LP172921-1</u>	Cardiovascular disease							
<u>LP172927-8</u>	Clinical cardiac electrophysiology							
<u>LP269425-7</u>	Heart failure							
<u>LP172953-4</u>	Interventional cardiology							
<u>LP269424-0</u>	Transplant cardiology							
<u>LP172941-9</u>	Endocrinology							
<u>LP172938-5</u>	Diabetology							
LP173032-6	Thyroidology							
LP172945-0	Gastroenterology							
LP172950-0	Hepatology							
<u>LP172947-6</u>	Geriatric medicine							
<u>LP175685-9</u>	Hematology							
<u>LP417851-5</u>	Bone Marrow Transplant							
<u>LP172951-8</u>	Infectious disease							
LP183500-0	HIV							
-								

Part Number	Part Name						
<u>LP175686-7</u>	Medical Oncology						
LP172962-5	Nephrology						
LP263511-0	Dialysis						
<u>LP418387-9</u>	Therapeutic apheresis						
LP173015-1	Pulmonary disease						
LP173023-5	Rheumatology						
LP248728-0	Sleep medicine						
LP417852-3	Solid organ transplant						
LP173027-6	Sports medicine						
LP172956-7	Medical genetics						
LP172926-0	Clinical biochemical genetics						
LP172928-6	Clinical cytogenetics						
LP172929-4	Clinical genetics						
LP172930-2	Clinical molecular genetics						
<u>LP172959-1</u>	Molecular genetic pathology						
LP268361-5	Pharmacogenomics						
<u>LP172958-3</u>	Mental health						
<u>LP345044-4</u>	Eating disorders						
<u>LP173011-0</u>	Psychiatry						
LP172912-0	Addiction psychiatry						
<u>LP172922-9</u>	Child and adolescent psychiatry						
LP172944-3	Forensic psychiatry						
<u>LP172948-4</u>	Geriatric psychiatry						
<u>LP173013-6</u>	Psychosomatic medicine						
LP173012-8	Psychology						
LP248501-1	Child and adolescent psychology						
<u>LP248729-8</u>	Neuropsychology						
<u>LP172960-9</u>	Multi-specialty program						
<u>LP345048-5</u>	Aerodigestive medicine						
LP263714-0	Brain injury						
<u>LP420041-8</u>	Breastfeeding						
<u>LP345049-3</u>	Cleft and Craniofacial						
<u>LP345044-4</u>	Eating disorders						
<u>LP417672-5</u>	Medical Aid in Dying						
LP265794-0	Polytrauma						
LP417852-3	Solid organ transplant						
LP172963-3	Neurological surgery						
LP345042-8	Spinal surgery						
LP172964-1	Neurology						
LP263714-0	Brain injury						
LP172931-0	Clinical neurophysiology						
LP248726-4	Epilepsy						
<u>LP172965-8</u>	Neurology neurodevelopmental disabilities						
LP172898-1	Neurology w special qualifications in child neuro						
LP172981-5	Pain medicine						
LP248728-0	Sleep medicine						
LP173038-3	Vascular neurology						
<u>LP172968-2</u>	Nuclear medicine						

Part Number	Part Name
LP172899-9	Nutrition and dietetics
<u>LP345044-4</u>	Eating disorders
LP269243-4	Obesity medicine
<u>LP172971-6</u>	Obstetrics and gynecology
LP221284-5	Gynecology
LP202989-2	Gynecologic oncology
<u>LP172955-9</u>	Maternal and fetal medicine
LP221283-7	Obstetrics
LP173020-1	Reproductive endocrinology and infertility
<u>LP172973-2</u>	Occupational therapy
<u>LP172901-3</u>	Oncology
LP202989-2	Gynecologic oncology
<u>LP175686-7</u>	Medical Oncology
LP172991-4	Pediatric hematology-oncology
LP173016-9	Radiation oncology
<u>LP207940-0</u>	Surgical oncology
LP172974-0	Ophthalmology
LP172975-7	Optometry
LP172902-1	Oral and maxillofacial surgery
LP172978-1	Orthopaedic surgery
LP172977-3	Orthopedic sports medicine
LP345042-8	Spinal surgery
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
LP172984-9	Pathology
LP208907-8	Anatomic pathology
LP172936-9	Dermatopathology
LP208906-0	Clinical pathology
LP172920-3	Blood banking and transfusion medicine
LP418387-9	Therapeutic apheresis
LP208902-9	Chemical pathology
<u>LP208903-7</u>	Molecular genetic pathology Pathology - Medical microbiology
	Pathology - Medical microbiology Toyicologic nathology
LP241974-7	Toxicologic pathology Podiatrics
LP173002-9	Pediatrics Adelegate medicine
LP172913-8	Adolescent medicine
LP345048-5	Aerodigestive medicine
LP172922-9	Child and adolescent psychiatry
LP248501-1	Child and adolescent psychology
<u>LP172937-7</u>	Developmental-behavioral pediatrics
LP172950-0	Hepatology

Part Number	Part Name					
LP172957-5	Medical toxicology					
LP172961-7	Neonatal perinatal medicine					
LP192135-4	Birth defects					
<u>LP172985-6</u>	Pediatric cardiology					
LP172986-4	Pediatric critical care medicine					
LP172987-2	Pediatric dermatology					
<u>LP172989-8</u>	Pediatric endocrinology					
<u>LP172988-0</u>	Pediatric emergency medicine					
LP172990-6	Pediatric gastroenterology					
<u>LP173000-3</u>	Pediatric transplant hepatology					
LP172991-4	Pediatric hematology-oncology					
<u>LP417851-5</u>	Bone Marrow Transplant					
LP172992-2	Pediatric infectious diseases					
LP172993-0	Pediatric nephrology					
<u>LP172994-8</u>	Pediatric otolaryngology					
<u>LP172995-5</u>	Pediatric pulmonology					
<u>LP172996-3</u>	Pediatric radiology					
LP172997-1	Pediatric rehabilitation medicine					
<u>LP172998-9</u>	Pediatric rheumatology					
<u>LP172999-7</u>	Pediatric surgery					
<u>LP248728-0</u>	Sleep medicine					
LP173027-6	Sports medicine					
<u>LP173003-7</u>	Pharmacology					
LP220238-2	Clinical pharmacology					
LP268361-5	Pharmacogenomics					
<u>LP173004-5</u>	Physical medicine and rehabilitation					
LP263714-0	Brain injury					
<u>LP172954-2</u>	Kinesiotherapy					
<u>LP172981-5</u>	Pain medicine					
<u>LP172997-1</u>	Pediatric rehabilitation medicine					
<u>LP265794-0</u>	Polytrauma					
<u>LP173026-8</u>	Spinal cord injury medicine					
<u>LP173040-9</u>	Vocational rehabilitation					
LP173005-2	Physical therapy					
<u>LP173006-0</u>	Plastic surgery					
LP268363-1	Burn management					
LP173007-8	Plastic surgery within the head and neck					
<u>LP173029-2</u>	Surgery of the hand					
LP173008-6	Podiatry					
LP173009-4	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					
<u>LP267441-6</u>	Environmental health					
<u>LP173018-5</u>	Radiology					

Part Number	Part Name						
<u>LP172939-3</u>	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						
<u>LP173025-0</u>	Speech-language pathology						
LP173028-4	Surgery						
LP248500-3	Bariatric surgery						
LP268363-1	Burn management						
<u>LP172932-8</u>	Colon and rectal surgery						
<u>LP172999-7</u>	Pediatric surgery						
LP265794-0	Polytrauma						
LP173029-2	Surgery of the hand						
LP173030-0	Surgical critical care						
LP207940-0	Surgical oncology						
LP173031-8	Thoracic and cardiac surgery						
LP207300-7	Cardiac surgery						
LP173033-4	Transplant surgery						
LP417852-3	Solid organ transplant						
LP183499-5	Trauma						
LP265794-0	Polytrauma						
LP173039-1	Vascular surgery						
LP269976-9	Thromboembolism						
LP173034-2	Tumor board						
LP173036-7	Urology						
LP173001-1	Pediatric urology						
LP248732-2	Womens health						
LP185997-6	Wound care management						
LP268363-1	Burn management						
LP412351-1	Wound, Ostomy, and Continence Care						

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.

Allowed Values:

Part Number	Part Name
LP173066-4	Assistant
LP269965-2	Attending
LP173067-2	Case manager
LP173068-0	Clerk

Part Number	Part Name
LP269966-0	Consultant
LP173069-8	Counselor
LP264605-9	Device
LP269967-8	Fellow
LP412180-4	Healthcare navigator
LP173071-4	Hygienist
LP173072-2	Interdisciplinary
LP173073-0	Team
LP203036-1	Rapid response team
LP269968-6	Intern
LP173074-8	Medical assistant
LP221282-9	Midwife
LP173079-7	Nurse midwife
LP173075-5	Nurse
<u>LP173076-3</u>	CRNA
<u>LP173077-1</u>	Certified nursing assistant
<u>LP173078-9</u>	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
LP269965-2	Attending
LP269966-0	Consultant
LP269967-8	Fellow
LP269968-6	Intern
LP269969-4	Resident
LP173090-4	Physician assistant Physician assistant
LP269969-4	Resident
LP269801-9	Social worker
LP173091-2	Student
LP173092-0	Medical student
LP173093-8	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 in Section 7.4.1).** 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:

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

n 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:

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:

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:

Component	Property	Time	System	Scale	Method	Class
Anesthesia consent	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: 80582-0) 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).

Beginning with LOINC version 2.68, a computable format of the LOINC document ontology hierarchies and the relationships of all ontology parts to LOINC terms has been available in a Web Ontology Language (OWL) format. Since OWL is a standard format for representing ontological information, it is possible to query that knowledge, build visual representations, and make inferences if you have the right tools. The OWL file along with further information can be downloaded at https://loinc.org/document-ontology/owl/.

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.

^{27.} 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

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: 2164-2) 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 Section 10.3.)

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. Note that if a single primary result is being reported, the code for that result should be used for the order rather than a panel code. See Section 12.1.11 for more information.

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.

Historically, LOINC created different codes for panels that contain reflex testing versus those that do not. In May 2020, the Lab LOINC committee decided that going forward, panel names would no longer specify reflex testing. Existing panels that specify reflex testing will be reviewed and updated as appropriate.

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

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):

LOINC_NUM	LOINC Fully Specified Name	Description
24358-4	Hemogram WO platelets panel:-:Pt:Bld:Qn	HCT & HGB & WBC & RBC & Indices
24359-2	Hemogram WO platelets & W manual differential panel :-:Pt:Bld:Qn	Hemogram & Differential Count
<u>24317-0</u>	Hemogram & platelets WO differential panel:- :Pt:Bld:Qn	HCT & HGB & WBC & RBC & Indices & Platelets
<u>24338-6</u>	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-Q	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.
<u> 24339-4</u>	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.
<u>29274-8</u>	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.
29576-6	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). Example of simple order set with terms that are either R or O:

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>24358-4</u>	Hemogram WO platelets panel	-	Pt	Bld	Qn	R/O/C
<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>76069-4</u>	Erythrocytes.hypochromic/100 erythrocytes	NFr	Pt	Bld	Qn	0
<u>76090-0</u>	Erythrocytes.hyperchromic/100 erythrocytes	NFr	Pt	Bld	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).

The following table 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 mustbe 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). Example of an order set that includes terms with R-a conditionality:

<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
<u>1963-8</u>	Bicarbonate	SCnc	Pt	Ser/Plas	Qn	R-a
2028-9	Carbon dioxide	SCnc	Pt	Ser/Plas	Qn	R-a
33037-3	Anion gap	SCnc	Pt	Ser/Plas	Qn	0

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.

LOINC CODE 75881-3

Lupus anticoagulant aPTT, dRVVT and PT screening panel W Reflex

LOINC STATUS

Active

Panel Hier	<u> </u>		
Details for each	th LOINC in Panel LHC-Forms		
			Example UCUM
LOINC	Name	R/O/C Cardinality	
<u>75881-3</u>	Lupus anticoagulant aPTT, dRVVT and PT screening panel W Reflex		
6303-2	dRVVT (LA screen)	R-a	S
93234-3	dRVVT in Platelet poor plasma by Coagulation assaypost heparin neutralization	С	S
<u>15359-3</u>	dRVVT actual/normal (normalized LA screen)	R-a	%
<u>75513-2</u>	dRVVT with 1:1 PNP (LA mix)	Rflx-a	S
<u>75512-4</u>	dRVVT with 1:1 PNP actual/normal (normalized LA mix)	Rflx-a	%
93240-0	$dRVVT\ factor\ substitution\ in\ Platelet\ poor\ plasma\ by\ Coagulation\ assay\immediately\ after\ 1:1\ addition\ of\ normal\ plasma\ and\ heparin\ neutralization$	Rflx-a	S
57838-5	dRVVT W excess phospholipid (LA confirm)	Rflx-a	s
68916-6	dRVVT W excess phospholipid actual/normal (normalized LA confirm)	Rflx-a	%
93238-4	dRVVT excess phospholipid in Platelet poor plasma by Coagulation assaypost heparin neutralization	Rflx-a	s
93239-2	$dRVVT\ excess\ phospholipid\ actual/normal\ in\ Platelet\ poor\ plasma\ by\ Coagulation\ assay\post\ heparin\ neutralization$	Rflx-a	%
75511-6	dRVVT W excess phospholipid percent correction	0	%
50410-0	dRVVT/dRVVT W excess phospholipid (screen to confirm ratio)	0	{ratio}
34571-0	aPTT.lupus sensitive (LA screen)	R-a	s
48022-8	aPTT.lupus sensitive actual/normal (normalized LA screen)	R-a	
93235-0	aPTT.lupus sensitive in Platelet poor plasma by Coagulation assay post heparin neutralization	R-a	s
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	%
75506-6	aPTT.lupus sensitive W excess phospholipid (LA confirm)	Rflx-a	s
75508-2	aPTT.lupus sensitive W excess phospholipid actual/Normal (normalized LA confirm)	Rflx-a	%
93236-8	aPTT.lupus sensitive.excess phospholipid in Platelet poor plasma by Coagulation assaypost heparin neutralization	Rflx-a	S
93237-6	$a \mbox{PTT.lupus sensitive.} excess phospholipid actual/normal in Platelet poor plasma by Coagulation assay $$post heparin neutralization $$$	Rflx-a	%
75884-7	aPTT.lupus sensitive/aPTT.lupus sensitive W excess phospholipid (screen to confirm ratio)	0	{Ratio}
75507-4	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-a	

Details page for three screening test lupus anticoagulant panel, 75881-3

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 enduser 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 Names

In addition to the *Fully Specified Name* (*FSN*), which is the 5 or 6 major Parts of a LOINC term concatenated together using the colon character as a separator, each LOINC term has several different names that have been added as LOINC has evolved. Each of these was created for a different purpose and presently, they are generated programmatically with manual curation in special cases. We began with the *Short Name* and *Long Common Name* in 2002 and 2009, respectively.

Even after creating the *Long Common Name*, we 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 (except for truly duplicate concepts), they are sometimes not the most user-friendly. This is also true for our automatically-generated LOINC *Short Names*. However, mostly what users wished for were 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.

However, we continued to think about how we could create a more "friendly" name and with the input of the LOINC Community, we developed the *Consumer Name* and *Display Name* as described below. We welcome feedback from anyone that has implemented or plans to implement these names.

9.1.1.1 Short Names

In August 2002 we added the *Short Name*, which is a short, mixed case name for the LOINC concept. All laboratory and clinical LOINC terms have a *Short Name*. (Many survey LOINC terms do NOT have a *Short Name*). 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 LOINC *FSN*, 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 *FSN*. 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). 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.

The LOINC Short Names are subject to change and should not be used as identifying keys in any database.

9.1.1.2 Long Common Names

In 2009, after collecting and reviewing display names from several sources, we began releasing the *Long Common Name*. These names are also created by an algorithmic process and are checked for uniqueness. Most abbreviations and acronyms that are used in the LOINC *FSN* 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. Through the LOINC 2.65 release, every LOINC *Long Common Name* was unique. This was true even for deprecated duplicate terms, some of which had additional periods appended to their names in order to make them unique. However, the LOINC Committee recommended that concepts that are truly duplicate (i.e., have the exact same values for each of their major Parts) should have the same *Long Common Name*, and we have implemented this change starting with the LOINC 2.66 release.

9.1.1.3 Display Name

Beginning with LOINC version 2.64, we began publishing *Display Names*, which were developed as a prototype for a more "clinician-friendly" set of names compared to the current LOINC *Short Name*, *Long Common Name*, and *Fully Specified Name*. They are created algorithmically from the manually crafted display text for each *Part* and are generally more concise than the *Long Common Name*. Currently only LOINC Laboratory terms have *Display Names*, though we may add *Display Names* for Clinical terms in the future.

In general, *Display Names* are unique for a given concept; however, in the case of truly duplicate concepts (i.e., have the exact same values for each of their major Parts), the *Display Name* will be the same. Unlike the *Short Name* and *Long Common Name*, the *Display Name* does not include an indicator that a term is deprecated.

Some of the high-level rules used to create the Display Names include:

- *Components* are shortened where possible using common abbreviations and conventions such as including only the first letter of the genus when a Component includes both the genus and species;
- Systems Ser/Plas and ^Patient are implied, and all other Systems are included in parentheses;
 - Exception: for terms with the *Property* **Susc**, the *System* is implied
- For Timing Pt is implied and all other Timing values are specified;
- If the Scale is **Qn**, the Property value is included and Scale is not;
 - Exception 1 for the *Properties* **ACnc** and **Likelihood**, the *Property* is left off and *Scale* is included
 - Exception 2 when the *Component* contains words that make the *Property* redundant, the *Property* is left off
- If the *Scale* is not **Qn**, the *Scale* is included instead of the *Property*;
 - Exception 1 in a few cases (e.g., ID, Imp) where the Property conveys specific information about what result to expect, the *Property* is included
 - \circ Exception 2 **Nom** is implied

9.1.1.4 Consumer Name

The *Consumer Name* was originally hand-crafted for a very small subset of LOINC terms. At its inception, these names were labeled as "experimental". In 2019 we undertook a concerted effort to develop a more comprehensive set of consumer-friendly names, primarily based on the increasing availability of consumer-facing health and wellness apps that take advantage of existing LOINC codes for the underlying data.

Consumer Names are created based on manually crafted consumer name text for each *Part*. In contrast to the other names, this text may represent a more general concept for the defining *Part*. These names do not represent each of the defining *Parts* of a given term, are not unique, and do not include an indicator that a term is deprecated.



Consumer Names are intended for downstream display only and are not intended to be used at any point in the clinical workflow, or for the purpose of mapping local terms to LOINC.

Some of the high-level rules used to create the *Consumer Names* include:

- The specimen is placed at the end of the name and is prefixed by a comma;
- Almost all intravascular specimens are labeled Blood, with a few exceptions such as Dried Blood Spot;
- *Property, Scale,* and *Method* values are mostly excluded. This results in many duplicate *Consumer Names* and is based on the assumption that the result value and/or the units of measure will provide context for the name;
- Abbreviations are not used except in select cases, such as HIV; however, some abbreviations are included in parentheses for education purposes.

The current collection of *Consumer Names* have a "pre production" maturity level and we welcome user feedback about them. Until they reach production status, we plan to release them in a separate file rather than in the existing *Consumer_Name* field in the LOINC table.

9.1.2 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.

9.1.3 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).

9.1.4 Associated observations

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

9.1.5 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.

9.1.6 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 <u>Appendix</u> <u>C</u>). 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 and on details pages. There are details pages for each LOINC answer list, and the answer list also appear as a section of the details pages for LOINC terms they are associated with.

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. Bakken²⁸ 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. 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.²⁹

10.2 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 terms are created for the individual questions/items within an instrument, as well as for the panels/groups of terms representing the hierarchical nature of the instrument. We recognize that standardized assessments have psychometric properties that are essential to their interpretation, and so the data model includes elements such as the actual question text and allow answer options as attributes of the LOINC observation term.

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

LOINC creates terms 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.

10.2.2 Attributes of the LOINC terms for individual questions or variables

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

In order to accommodate inclusion of instruments that are copyrighted by a third party, we have added an external copyright field to the LOINC Table (*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).

10.2.3 Structured answer lists

The questions/items in standardized assessment instruments often have highly specialized, fixed answer lists. As described in <u>Section 9.2</u>, we have created a structured representation of the answer lists for the questions in assessment instruments represented in LOINC.

10.2.4 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.

10.2.5 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:
- 2. **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?"
- 3. **COMPONENT** in the LOINC table. This is the default display. *Else*:
- 4. **SHORTNAME** in the LOINC table. This field contains a short display name (target is 40 characters or less).
- 5. **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

10.2.6 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.

10.2.7 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 7**D** for *Time Aspect* rather than 1**W**)
- 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.

10.2.8 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.

10.3 Assessment content in the LOINC distribution

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 package contains the full

assessment content, including:

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

This content is available for download from the <u>LOINC website</u>. Please see the PanelsAndFormsReadMe.txt file in the LOINC Panels and Forms File for more details. All of the assessment content is also included within the RELMA program.

10.4 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 search functionality in RELMA and on search.loinc.org with links to the CMS assessment item codes that are searchable as "Related Codes". For example, searching "Related Codes: BB0700" will return the LOINC term that represents the CMS assessment item "Expression of ideas and wants".

^{28.} 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. Pubm 11062226.

^{29.} Vreeman DJ, McDonald CJ, Huff SM. LOINC® - A Universal Catalog of Individual Clinical Observations and Uniform Representation of Enumerated Collections. Int J Funct Inform Personal Med. 2010;3(4):273-291. Epub 2011 May 23. PubMed: 22899966. ←

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 Streptococcus pneumoniae serotype nomenclature 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. Another example is when a microorganism genus and/or species are modified based on new knowledge or new sequence information (e.g., Clostridium difficile to Clostridioides difficile). In cases where the microorganism and its testing and disease process are the same but name has changed, LOINC will change the name of the Component and LOINC terms when and if 1) a preponderance of evidence in the literature and 2) a naming authority, such as International Committee on Taxonomy of Viruses (ICTV), supports the change.

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
--------	-------------

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) 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) and should be used both for new mappings and updating existing implementations.

Furthermore, LOINC 2.31 added two new fields:

Status	Description
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 <u>Appendix A</u> 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

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 re-mapping for existing users.

Our general policy is not to make any edits to a term once it is **DEPRECATED**. However, in rare cases we may update one or more names of DEPRECATED terms in order for them to correctly represent the original meaning of the term. For example, in LOINC 2.66, the *Long Common Name* for 26693-2, which has the *Component* **Streptococcus pneumoniae 12f Ab**, was updated from *Deprecated Streptococcus pneumoniae 12 Ab* [Mass/volume] in Serum to Deprecated Streptococcus pneumoniae 12f Ab [Mass/volume] in Serum.

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 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.

11.5 File versioning and naming

Beginning with the June 2018 LOINC release, we implemented a policy on versioning and naming of LOINC release artifacts that was approved by the LOINC Committee. This policy includes approaches to version numbers, major versus minor (or patch) changes, and content versus file structure changes. See the LOINC Versioning page on our website for details.

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.

In Fall 2020, the Laboratory LOINC Committee decided that **an exception to this rule** includes LOINC panels that contain terms that are representative for the type of testing being done but where the specific list of analytes tested may vary across geographic region or laboratory. In this case, it is the reporting laboratory's responsibility to use the set of LOINC codes that are appropriate for reporting the results for the individual tests performed, even if all of those LOINC codes are not included in the LOINC panel. Examples of such panels include:

- Allergen panels that representing testing for individual components within an allergen category, such as 49222-3
 Food allergen panel Serum and 51662-5
 Core respiratory allergens panel Serum
- Autoimmune serology panels that represent testing for autoantibodies associated with a particular category of autoimmune disorders, such as <u>94708-5</u> Encephalopathy autoimmune Ab panel - Cerebral spinal fluid and <u>94712-7</u> Movement disorder autoimmune Ab panel - Cerebral spinal fluid
- Multiplex microbiology panels that represent testing for microorganisms associated with infections of a specific body region, such as <u>88569-9</u> Ocular pathogens panel - Cornea or Conjunctiva Qualitative by NAA with probe detection and <u>92695-6</u> Gastrointestinal bacterial pathogens panel - Stool by NAA with probe detection

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: <u>57698-3</u>) a user could make substitutions as below and still have a comparable panel:

Reference Term	Substitute Term
2093-3Cholesterol [Mass/volume] in Serum or Plasma	14647-2 Cholesterol [Moles/volume] in Serum or Plasma
2571-8 Triglyceride [Mass/volume] in Serum or Plasma	14927-8 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 Panels and reflex (reflexive) testing

LOINC contains a small number of panels specifying the inclusion of reflex (or reflexive) testing. Some of these were created to take the American Medical Association's reflexive CPT codes into account, and some were for very specific testing algorithms as recommended by professional organizations. In May 2020, the Lab LOINC committee decided that going forward, panel names would not specify reflex testing (i.e., the Component will not contain "W

Reflex"), and that existing and future panels that contain the appropriate concepts for the testing being done could serve as reflex panels regardless of the name. We continue to review and update the names and required/optional/conditional elements of existing panels, and we welcome your input regarding panels that need review.

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.

12.1.10 Substitutions related to System

Panel elements with a general System may be replaced with other LOINC terms that only differ by having a **more specific** System. For example, terms with a System of Respiratory.upper may be replaced with LOINC terms with a System of Nph (nasopharynx), Throat, or Nose, and terms with a System of Genital may be replaced with LOINC terms with a System of Vag (vaginal), Cvx (cervix), Urethra, etc. Substitutions with terms that have less specific Systems are NOT allowed; for example, you may not substitute a term with System of Respiratory for a Sputum term.

Substitutions with terms with unrelated Systems are also NOT allowed, such as substituting a LOINC term with System CSF for a term with System Ser/Plas, or substituting a term with System Urine for a term with System Respiratory.

The following table illustrates acceptable substitutions related to System.

Reference Term	Substitute Term
45095-7 Chlamydia trachomatis [Presence] in Genital specimen by Organism specific culture	14463-4 Chlamydia trachomatis [Presence] in Cervix by Organism specific culture
88592-1 Influenza virus B RNA [Presence] in Lower respiratory specimen by NAA with probe detection	76079-3 Influenza virus B RNA [Presence] in Bronchoalveolar lavage by NAA with probe detection

12.1.11 Single primary results

If a single primary result (either measured or derived) is being reported along with secondary results that serve as supportive or interpretive findings, the LOINC code for the primary result should be used as the order code. For example, if the ratio of an analyte to creatinine is the primary result but is report along with the creatinine result, the LOINC term for the ratio should be used as the order and a LOINC panel will not be created. This recommendation was agreed upon by the Laboratory LOINC Committee in March 2021.

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
8048-1	Varicella zoster virus IgM Ab [Units/volume] in Serum	R
<u>8047-3</u>	Varicella zoster virus IgG Ab [Units/volume] in Serum	R

Elements of User-defined Panel

LOINC_NUM	Long Common Name
5404-9	Varicella zoster virus IgM Ab [Units/volume] in Serum by Immunoassay
5403-1	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
20569-0	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	
<u>9643-8</u>	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	Elements of User-defined Panel
2157-6	Creatine kinase [Enzymatic activity/volume] in Serum or Plasma
20569-0	Creatine kinase.MB/Creatine kinase.total in Serum or Plasma
9642-0	Creatine kinase.BB/Creatine kinase.total in Serum or Plasma
9643-8	Creatine kinase.MM/Creatine kinase.total in Serum or Plasma
26020-8	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	
<u>14314-9</u>	Benzoylecgonine [Presence] in Urine by Screen method	R
18282-4	8282-4 Cannabinoids [Presence] in Urine by Screen method R	
19295-5 Opiates [Presence] in Urine by Screen method R		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
14314-9	Benzoylecgonine [Presence] in Urine by Screen method
18282-4	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
41395-5	Collection date of Urine

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 field names listed in bold in LOINC Database Structure section. 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 <u>HL7 FHIR®</u> team, we are working to create a specification for the canonical representation of LOINC in FHIR as a <u>CodeSystem resource</u>. 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 colon-separated aggregate of the six part name) is generally not recommended because they are not as human friendly and contain more instances of 'reserved characters' like "^" and "&", which would need to be properly escaped in the message.

Furthermore, we recommend the simultaneous communication of the sender's local code and local name (in addition to the LOINC code and name) as allowed in the messaging structure to facilitate debugging and detection of mismappings. 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 <u>section on LOINC as a code system</u>, 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).

Note: prior versions of the FHIR standard listed the preferred LOINC pattern as "http://loinc.org/owl". The current version of FHIR has updated that guidance to be consistent with our recommendations in this document.

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/LP148409-8

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

A - LOINC Database Structure

LOINC Table Structure

LOINC_NUM

Type: Text Width: 10

COMPONENT

Type: Text Width: 255

First major axis-component or analyte

PROPERTY

Type: Text Width: 255

Second major axis-property observed (e.g., mass vs. substance)

TIME_ASPCT

Type: Text Width: 255

Third major axis-timing of the measurement (e.g., point in time vs 24 hours)

SYSTEM

Type: Text Width: 255

Fourth major axis-type of specimen or system (e.g., serum vs urine)

SCALE_TYP

Type: Text Width: 255

Fifth major axis-scale of measurement (e.g., qualitative vs. quantitative)

METHOD_TYP

Type: Text Width: 255

Sixth major axis-method of measurement

CLASS

Type: Text Width: 255

An arbitrary classification of the terms for grouping related observations together. The current classifications are listed in Appendix B. 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.

VersionLastChanged

Type: Text Width: 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. Version First Released field.

CHNG_TYPE

Type: Text Width: 255

Change Type Code

DEL = delete (deprecate)

ADD = add

PANEL = addition or removal of child elements or change in the conditionality of child elements in the panel or in sub-panels contained by the panel.

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

DefinitionDescription

Type: Memo Width: N/A

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.

STATUS

Type: Text Width: 255

ACTIVE = Concept is active. Use at will.

TRIAL = Concept is experimental in nature. Use with caution as the concept and associated attributes may change.

DISCOURAGED = Concept is not recommended for current use. New mappings to this concept are discouraged; although existing may mappings may continue to be valid in context. Wherever possible, the superseding concept is indicated in the MAP_TO field in the MAP_TO table (see below) 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 below) and should be used both for new mappings and updating existing implementations.

CONSUMER_NAME

Type: Text Width: 255

An experimental (beta) consumer friendly name for this item. The intent is to provide a test name that health care consumers will recognize.

CLASSTYPE

Type: Number Width: N/A

1=Laboratory class; 2=Clinical class; 3=Claims attachments; 4=Surveys

FORMULA

Type: Memo Width: N/A

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.

EXMPL_ANSWERS

Type: Memo Width: N/A

For some tests and measurements, we have supplied examples of valid answers, such as "1:64", "negative @ 1:16", or "55".

SURVEY_QUEST_TEXT

Type: Memo Width: N/A

Verbatim question from the survey instrument

SURVEY_QUEST_SRC

Type: Text Width: 50

Exact name of the survey instrument and the item/question number

UNITSREQUIRED

Type: Text Width: 1

Y/N field that indicates that units are required when this LOINC is included as an OBX segment in a HIPAA attachment

SUBMITTED_UNITS

Type: Text Width: 30

Units as received from person who requested this LOINC term

RELATEDNAMES2

Type: Memo Width: N/A

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).

SHORTNAME

Type: Text Width: 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.

ORDER_OBS

Type: Text Width: 15

Defines term as order only, observation only, or both. A fourth category, Subset, is used for terms that are subsets of a panel but do not represent a package that is known to be orderable. We have defined them only to make it easier to maintain panels or other sets within the LOINC construct. This field reflects our best approximation of the terms intended use; it is not to be considered normative or a binding resolution.

CDISC_COMMON_TESTS

Type: Text Width: 1

"Y" in this field means that the term is a part of a subset of terms used by CDISC clinical trials.

HL7_FIELD_SUBFIELD_ID

Type: Text Width: 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.

EXTERNAL_COPYRIGHT_NOTICE

Type: Memo Width: N/A

External copyright holders copyright notice for this LOINC code

EXAMPLE_UNITS

Type: Text Width: 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.

LONG_COMMON_NAME

Type: Text Width: 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 tabledriven algorithmic process. Most abbreviations and acronyms that are used in the LOINC database have been fully spelled out in English.

UnitsAndRange

Type: Memo Width: N/A

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".

EXAMPLE_UCUM_UNITS

Type: Text Width: 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.

EXAMPLE_SI_UCUM_UNITS

Type: Text Width: 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.

STATUS_REASON

Type: Text Width: 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.

STATUS_TEXT

Type: Memo Width: N/A

Explanation of concept status in narrative text. This field will be Null for ACTIVE concepts, and optionally populated for terms in other status.

CHANGE_REASON_PUBLIC

Type: Memo Width: N/A

Detailed explanation about special changes to the term over time.

COMMON_TEST_RANK

Type: Number Width: N/A

Ranking of approximately 2000 common tests performed by laboratories in USA.

COMMON_ORDER_RANK

Type: Number Width: N/A

Ranking of approximately 300 common orders performed by laboratories in USA.

COMMON_SI_TEST_RANK

Type: Number Width: N/A

Corresponding SI terms for 2000 common tests performed by laboratories in USA.

HL7_ATTACHMENT_STRUCTURE

Type: Text Width: 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.

EXTERNAL_COPYRIGHT_LINK

Type: Text Width: 255

For terms that have a third party copyright, this field is populated with the COPYRIGHT_ID from the Source Organization table (see below). It links an external copyright statement to a term.

PanelType

Type: Text Width: 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.

AskAtOrderEntry

Type: Text Width: 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.

AssociatedObservations

Type: Text Width: 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.

VersionFirstReleased

Type: Text Width: 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.

ValidHL7AttachmentRequest

Type: Text Width: 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.

DisplayName

Type: Text Width: 255

This field contains a name that is more "clinician-friendly" compared to the current LOINC Short Name, Long Common Name, and Fully Specified Name. It is created algorithmically from the manually crafted display text for each Part and is generally more concise than the Long Common Name.

MapTo Table Structure

LOINC

Type: Text Width: 10

The deprecated term to which the replacement term(s) apply.

MAP_TO

Type: Text Width: 10

A replacement term that is to be used in place of the deprecated or discouraged term.

COMMENT

Type: Memo Width: N/A

Narrative text that explains the rational for using the recommended replacement term.

SourceOrganization Table Structure

ID

Type: Number Width: N/A

A unique numeric identifier for the source. This identifier does not have any meaning outside of LOINC.

COPYRIGHT_ID

Type: Text Width: 255

Used in the LOINC table as a foreign key.

NAME

Type: Text Width: 255

Name of the organization or institution.

COPYRIGHT

Type: Memo Width: N/A

Copyright notice to be displayed for the organization or institution.

TERMS_OF_USE

Type: Memo Width: N/A

Terms of use text for an external source.

URL

Type: Text Width: 255

URL link to the reference.

B - Classes

Clinical Term Classes

Table 32a: Clinical Term Classes

Abbreviation	Clinical Term Class
ADMIN	Administrative
ADMIN.DEMOG	Demographic observations
ADMIN.FACILITY	Facility information
ADMIN.ID	Identification numbers
ADMIN.PATIENT	Patient administrative information
ADMIN.PATIENT.DEMOG	Patient demographics
ADMIN.PATIENT.ID	Patient identification numbers
АРТА	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	Cardiology
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
CLIN.VET	Clinical veterinary
CLINTRIAL	Clinical trials
DENTAL	Dental
DEVICES	Medical devices
DOC.EPSOS	Smart Open Services for European Patients (epSOS) documents
DOC.MISC	Miscellaneous documentation

Abbreviation	Clinical Term Class
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.LASIK	Laser-assisted in situ keratomileusis
EYE.LENSOMETRY	Lensometry
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.SPECULAR MICROSCOPY	Ophthalmology specular microscopy
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	Gastroenterology
H&P.HX	History
H&P.PX	Physical
H&P.SURG PROC	Surgical procedure
HEMODYN.ATOM	Hemodynamics atomic
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

Abbreviation	Clinical Term Class
IEEE Rosetta	IEEE Rosetta
IO.TUBE	Input/Output of tube
IO_IN.ATOM	Input/Output atomic
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
PANELADMIN	Administrative information panel
PANEL.APTA	American Physical Therapy Association panel
PANEL.ART	Antiretroviral therapy order set
PANELBDYTMP	Body temperature order set
PANEL.BP	Blood pressure order set
PANEL.CARDIAC	Cardiology panel
PANEL.CLIN	Clinical NEC (not elsewhere classified) set
PANEL.CLIN.RISK	Clinical risk panel
PANEL.CV	Cardiovascular panel
PANEL.DEVICES	Medical device panel
PANEL.DOC	Document panel
PANELED	Emergency (DEEDS) order set
PANELEYE	Ophthalmology panel
TANGELLE	Opiniumiology paner
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 panel
PANEL.IO	Input/Output panel
PANEL.MEDS	Medication panel
PANEL.NEMSIS	National EMS Information System data set
PANEL.NEONAT	Neonatal measure panel
PANEL.NEURO	Neurology panel
PANEL.NIH.COGNITIVE	NIH Toolbox Cognitive Domain panel
PANEL.NIH.MOTOR	NIH Toolbox Motor Domain panel
PANEL.NIH.SENSORY	NIH Toolbox Sensory Domain panel
PANEL.NUTRITION&DIET	Nutrition and dietetics panel

Abbreviation	Clinical Term Class
PANEL.OB.US	Obstetrical panel
PANEL.ONCO	Oncology panel
PANEL.PATIENT SAFETY	Patient safety order set
PANEL.PHENX	PhenX panel
PANEL.PHR	Personal health record panel
PANEL.PULM	Pulmonary panel
PANEL.RAD	Radiology panel
PANEL.SURG	Surgery panel
PANEL.TRAUMA	Trauma panel
PANEL.TUMRRGT	Tumor registry panel
PANEL.UPDRS	Unified Parkinson's Disease Rating Scale (UPDRS) set
PANEL.US.URO	Urology ultrasound panel
PANEL.VACCIN	Vaccination panel
PANEL.VITALS	Vital signs panel
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

Laboratory Term Classes

Table 32b: Laboratory Term Classes

Abbreviation	Laboratory Term Class
ABXBACT	Antibiotic susceptibilities
ALLERGY	Allergy testing
BLDBK	Blood bank
BLDBK.GENOTYPING	Blood bank genotyping
CELLMARK	Cell markers
CHAL	Challenge tests
CHALROUTINE	Routine challenge tests
CHALSKIN	Skin challenge tests
СНЕМ	Chemistry
COAG	Coagulation study
СҮТО	Cytology

BORDOTON Decident For transmitting control pharmacylahetics) BORDOTON Decident for transmitting control pharmacylahetics) BERT Fertility BERT Fertility BERD MED Pharmacylahetics control HEADELBAR Historia typeanetic report HEADELBAR Historia typeanetic report HEADELBAR Historia typeanetic report HEAD Historia typeanetic report HEAD Historia typeanetic report HEAD Historia typeanetic report HEAD Historia typeanetic report HEADELBAR Historia typeanetic report HEADELBAR Historia typeanetic report MEGICA Historia typeanetic report MEGICA Michitary arbitries MODERATION COUNTY Conceilerance MODERATION COUNTY Conceilerance MODERATION COUNTY Paramacylanical MODERATION	Abbreviation	Laboratory Term Class	
Pett	DRUG/TOX	Drug levels & Toxicology	
IREMODE Hententionsprice counts HEAPPLAR Hententionsprice report HEAPPLAR Clinical cotespensite report HEA HEAR Count of Comment of Papers HEA HEAR Count of County pring an inferon and antibusfore HEA HEAR County order codes MERO HEAR County order codes MICRO Microbiology MICRO Microbiology MICRO Microbiology MICRO Microbiology MICRO Microbiology MICRO Microbiology MICRO ATTEMPTORY Connections or displications MICRO ATTEMPTORY Promocephonics MICRO ATTEMPTORY Promocephonics MICRO ATTEMPTORY Connection or necessarian MICRO ATTEMPTORY Connection or necessarian MICRO ATTEMPTORY Connection or necessarian MICRO ATTEMPT	DRUGDOSE	Drug dose (for transmitting doses for pharmacokinetics)	
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PANELOBS Obstetrics panel PANELPATH Pathology panel	PANEL.MOLPATH	Molecular pathology panel	
PANEL.PATH Pathology panel	PANEL.MOLPATH.PHARMG	Pharmacogenomics panel	
	PANEL.OBS	Obstetrics panel	
PANELSERO Serology panel	PANEL.PATH	Pathology panel	
	PANEL.SERO	Serology panel	

Abbreviation	Laboratory Term Class	
PANEL.SPEC	Specimen set	
PANEL.UA	Urinalysis panel	
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	

Attachment Term Classes

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

Survey Term Classes

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.BADS	Brief Anxiety and Depression Scale set
PANEL.SURVEY.BCAT	Brief Cognitive Assessment Tool 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.BRIEF	BRIEF Health Literacy Screening Tool set
PANEL.SURVEY.CAM	Confusion Assessment Method (CAM) set
PANEL.SURVEY.CARE	Continuity Assessment Record and Evaluation (CARE) set
PANEL.SURVEY.CBS-8	Columbia Behavior Scale for Dementia (CBS-8) set
PANEL.SURVEY.CDC	Centers for Disease Control (CDC) set
PANEL.SURVEY.CESD	Center for Epidemiological Studies Depression (CESD) set
PANEL.SURVEY.CHILD-PUGH	Child-Pugh set
PANEL.SURVEY.CMS	Centers for Medicare & Medicaid Services set
PANEL.SURVEY.CNPI	Checklist of Nonverbal Pain Indicators (CNPI) set
PANEL.SURVEY.COOP	Dartmouth Cooperative Functional Status Test (COOP) set
PANEL.SURVEY.COVID	COVID-19 related surveys
PANEL.SURVEY.COMI	Core Outcome Measures Index (COMI) set
PANEL.SURVEY.CSSRS	Columbia Suicide Severity Rating Scale (CSSRS) set
PANEL.SURVEY.DAST	Drug Abuse Screening Test set
PANEL.SURVEY.DUKE-AD	Duke Anxiety Depression Scale (DUKE-AD) 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 Health 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 Human Services set
PANEL.SURVEY.HITS	HITS Survey 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.LKSS	Lysholm Knee Scoring Scale (LKSS) 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
	Neurological survey set

Abbreviation	Survey Term Class
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.NIDA	National Institute on Drug Abuse 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.NPASS	Neonatal Pain, Agitation and Sedation Scale 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.ORTHOPEDICS	Orthopedic survey panels
PANELSURVEY.PAIN	Pain survey panels
PANEL.SURVEY.PAS	
PANEL.SURVEY.PASII	Patient Activity Scale (PAS) set
	Patient Activity Scale II (PAS-II) set
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.PEG	Pain intensity, Enjoyment of life, General activity (PEG) set
PANEL.SURVEY.PHQ	Patient Health Questionnaire set
PANEL.SURVEY.PNDS	Perioperative Nursing Data Set outcomes panel
PANEL.SURVEY.PRAPARE	Protocol for Responding to and Assessing Patients Assets Risks and Experiences (PRAPARE) set
PANEL.SURVEY.PROMIS	Patient Reported Outcomes Measurement System set
PANEL.SURVEY.PROWL	Patient Reported Outcomes with LASIK sets
PANEL.SURVEY.QAM	Quality Audit Marker set
PANEL.SURVEY.QRDA	Quality Health Reporting Document Architecture set
PANEL.SURVEY.R-OUTCOMES	R-Outcomes set
PANEL.SURVEY.RFC	Residual Functional Capacity set
PANEL.SURVEY.RUDAS	Rowland Universal Dementia Assessment Scale (RUDAS) set
PANEL.SURVEY.RMDQ	Roland Morris Disability Questionnaire set
PANEL.SURVEY.SAMHSA	Substance Abuse and Mental Health Services Administration (SAMHSA) set
PANEL.SURVEY.SDOH	Social determinants of health set
PANEL.SURVEY.SEEK	Safe Environment for Every Kid
PANEL.SURVEY.SKINDEX	Skindex set
PANEL.SURVEY.SLP	Speech-language pathology (SLP) panels
PANEL.SURVEY.SOFA	Sequential Organ Failure Assessment (SOFA) set
PANEL.SURVEY.TAPS	Tobacco, Alcohol, Prescription medications and other Substance panel
PANEL.SURVEY.USSGFHT	United States Surgeon General Family Health Tool (USSGFHT) set
PANEL.SURVEY.WELLRX	WellRX Questionnaire set
PANEL.SURVEY.WIfI	Would Ischemia and Foot Infection 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.BADS	Brief Anxiety and Depression Scale (BADS)

Abbreviation	Survey Term Class
SURVEY.BCAT	Brief Cognitive Assessment Tool (BCAT)
SURVEY.BDI	Beck Depression Inventory (BDI)
SURVEY.BPI	Brief Pain Inventory (BPI)
SURVEY.BRIEF	BRIEF Survey
SURVEY.CARE	Continuity Assessment Record and Evaluation (CARE) survey
SURVEY.CBS-8	Columbia Behavior Scale for Dementia survey
SURVEY.CDC	Centers for Disease Control (CDC) survey
SURVEY.CESD	Center for Epidemiological Studies Depression (CESD) survey
SURVEY.CERNER	Cerner survey
SURVEY.CHILD-PUGH	Child-Pugh survey
SURVEY.CMS	Centers for Medicare & Medicaid Services (CMS) survey
SURVEY.CNPI	Checklist of Nonverbal Pain Indicators survey
SURVEY.COMI	Core Outcome Measures Index (COMI) survey
SURVEY.COOP	Dartmouth Cooperative Functional Status Test (COOP)
SURVEY.COVID	COVID-19 related survey questions
SURVEY.CSSRS	Columbia Suicide Severity Rating Scale (CSSRS)
SURVEY.DAST	Drug Abuse Screening Test (DAST)
SURVEY.DUKE-AD	Duke Anxiety Depression Scale (DUKE-AD)
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.HITS	HITS Survey
SURVEY.howRu	howRu outcomes instrument survey
SURVEY.HWS	Healthy Weight Summary (HWS)
SURVEY.IPAQ	International Physical Activity Questionnaire (IPAQ)
SURVEY.LKSS	Lysholm Knee Scoring Scale survey
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.NEI	National Eye Institue survey
SURVEY.NEURO	Neurological survey
SURVEY.NEUROQ	Quality of Life Outcomes in Neurological Disorders (NeuroQol) survey
SURVEY.NHANES	National Health and Nutrition Examination Survey (NHANES)
SURVEY.NHCS	National Health Care Survey (NHCS)
SURVEY.NIDA	National Institute on Drug Abuse
SURVEY.NIH.EMO	NIH Toolbox Emotion Domain
SURVEY.NIH_TOOLBOX	NIH Toolbox survey
SURVEY.NMMDS	Nursing Management Minimum Data Survey (NMMDS)
SURVEY.NORTON	Norton Scale survey
SURVEY.NPASS	Neonatal Pain, Agitation and Sedation Scale
55	Toolstan Lang, greater and Securior Scale

Abbreviation	Survey Term Class
SURVEY.NSRAS	Neonatal Skin Risk Assessment Scale (NSRAS)
SURVEY.NURSE.HHCC	Home Health Care Classification (HHCC) survey
SURVEY.NURSE.HIV-SSC	Signs and Symptoms Checklist (SSC) for persons living with HIV survey
SURVEY.NURSE.LIV-HIV	Living with HIV survey
SURVEY.NURSE.OMAHA	OMAHA survey
SURVEY.NURSE.QAM	Quality Audit Marker (QAM) survey
SURVEY.OASIS	Outcome and Assessment Information Survey (OASIS)
SURVEY.OPTIMAL	Outpatient Physical Therapy Improvement in Movement and Assessment Log (OPTIMAL)
SURVEY.ORTHOPEDICS	Orthopedics surveys
SURVEY.PAIN	Pain surveys
SURVEY.PAS	Patient Activity Scale (PAS)
SURVEY.PASII	Patient Activity Scale II (PAS-II)
SURVEY.PCORNET	Patient Centered Outcomes Research Network (PCORnet) Common Data Model (CDM)
SURVEY.PEG	Pain intensity, Enjoyment of life, General activity (PEG)
SURVEY.PHQ	Patient Health Questionnaire (PHQ)
SURVEY.PNDS	Perioperative Nursing Data Set (PNDS) survey
SURVEY.PRAPARE	Protocol for Responding to and Assessing Patients Assets Risks and Experiences (PRAPARE)
SURVEY.PROMIS	Patient Reported Outcomes Measurement System (PROMIS) survey
SURVEY.PROWL	Patient Reported Outcomes with LASIK surveys
SURVEY.QRDA	Quality Health Reporting Document Architecture (QRDA) survey
SURVEY.R-OUTCOMES	R-Outcomes survey
SURVEY.RFC	Residual Functional Capacity (RFC) survey
SURVEY.RMDQ	Roland Morris Disability Questionnaire
SURVEY.RUDAS	Rowland Universal Dementia Assessment Scale (RUDAS)
SURVEY.SAMHSA	Substance Abuse and Mental Health Services Administration (SAMHSA) survey
SURVEY.SDOH	Social Determinants of Health
SURVEY.SEEK	Safe Environment for Every Kid
SURVEY.SKINDEX	Skindex
SURVEY.SLP	Speech-language pathology (SLP) surveys
SURVEY.SOFA	Sequential Organ Failure Assessment (SOFA) survey
SURVEY.TAPS	Tobacco, Alcohol, Prescription medications and other Substance tool
SURVEY.USSGFHT	United States Surgeon General Family Health Tool (USSGFHT) survey
SURVEY.WELLRX	WellRX Questionnaire
TIMP	Test of Infant Motor Performance (TIMP) survey

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:

Step 1

Using the number 12345, assign positions to the digits, from right to left.

Example: 1st = 5 2nd = 4 3rd = 3 4th = 2

Step 2

5th = 1

Take the odd digit positions counting from the right (1st, 3rd, 5th, etc.).

Example:

531

Step 3

Multiply by 2.

Example:

1062

Step 4

Take the even digit positions starting from the right (2nd, 4th, etc.).

Example:

42

Step 5

Prepend the results of Step 4 to the results of Step 3.

Example:

421062

Step 6

Add the digits of Step 5 together.

Example:

$$4 + 2 + 1 + 0 + 6 + 2 = 15$$

Step 7

Find the next highest multiple of 10.

Example:

Step 8

Subtract the value of Step 6 from the value of Step 7. Thus, 5 is the Mod 10 check digit for 12345.

Example: 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.

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.

Prior to submitting your request, please check the online <u>LOINC Submissions Queue</u> to see if a similar or equivalent term has already been requested.

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

There are three possible ways to make your request, including: the <u>online request form</u>, RELMA's built in functions, or one of the <u>spreadsheet templates</u> available on the LOINC web site.

For most users, we recommend using the <u>online request form</u>. Regardless of format, we ask that users submit no more than 50 proposed terms at a time.

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)
 - o 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

Online request form

New LOINC terms can be requested directly from the LOINC website using the <u>online request form</u>. The request form can build a set of requested terms by entering the required information for each term and/or by uploading a spreadsheet file with the required fields. Requested terms and supporting information are sent to Regenstrief, and users can review the status of their submissions from the <u>My Submissions</u> section of the LOINC website.

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 from the LOINC website.

Excel file submission

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

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

Please email your submission template and related documents to submissions@loinc.org.

Communication with Regenstrief Institute

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.

You can follow the progress of your requested terms as it progresses through the review process by visiting the LOINC Submissions Queue.

Once the submission process has completed, you will receive files containing your requested codes.

E - Examples for LOINC Property Matching

Content (Cnt)

Like concentration except that volume in the denominator is replaced by mass. By extension:

CCnt

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

24048-1|Alpha galactosidase:CCnt:Pt:Fib:Qn

MCnt

Mass Content, mass of component per unit mass of a sample (System).

9435-9|Isopropanol:MCnt:Pt:Tiss:Qn



Note

All of the heavy metal measurements in hair, nails, and tissue should all be mass contents.

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

NCnt

Number Content, number of component entities per unit mass of a sample (System).

20771-2|Coliform bacteria:NCnt:Pt:Egg:Qn:Viability count



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, ReIMCnc (see below).



Note

If the units of the denominator and numerator are both mass (e.g., mg/g), use MRto: 13706-Z|Amylase/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

Fraction (Fr)

Fraction of component A in a group of entities B, C, Y, N in system 1. By extension:

CFr

Catalytic Fraction

2536-1|Lactate dehydrogenase1/Lactate dehydrogenase.total:CFr:Pt:Ser/Plas:Qn:Electrophoresis 9642-0|Creatine Kinase.BB/Creatine kinase.total:CFr:Pt:Ser/Plas:Qn

NFr

Number Fraction

```
10602-1|Spermatozoa.abnormal head/100 spermatozoa:NFr:Pt:Semen:Qn 764-1|Neutrophils.band form/100 leukocytes:NFr:Pt:Bld:Qn:Manual count
```

MFr

Mass Fraction

```
2614-6|Methemoglobin/Hemoglobin.total:MFr:Pt:Bld:Qn
```

SFr

Substance Fraction

```
30192-9|Acetylcholine receptor modulation Ab/Acetylcholine Ab.total:SFr:Pt:Ser:Qn
```

VFr

Volume Fraction

```
4545-0|Hematocrit:VFr:Pt:Bld:Qn:Spun
```

Ratio (Rto)

Ratio of component A to component B in system 1. By extension:

CRto

Catalytic Ratio (previously Catalytic Concentration Ratio, CCRto)

```
2325-9|Gamma glutamyl transferase/Aspartate aminotransferase:CRto:Pt:Ser/Plas:Qn
```

SRto

Substance Ratio (previously Substance Concentration Ratio, SCRto)

```
2958-7|Sodium/Potassium:SRto:Pt:Sweat:Qn
```

MRto

Mass Ratio (previously Mass Concentration Ratio, MCRto)

2768-0|Phenylalanine/Tyrosine:MRto:Pt:Ser/Plas:Qn

NRto

Number Ratio

11138-5|Myeloid cells/Erythroid cells:NRto:Pt:Bone mar:Qn

VelRto

Velocity Ratio

12022-0|Resistivity index:VelRto:Pt:Uterine artery.right:Qn:Doppler.calculated

VRatRto

Volume Rate Ratio

29462-9|Pulmonic flow/Systemic flow:VRatRto:Pt:Circulatory system.XXX:Qn:US.doppler

Ratio

1811-9|Amylase/Creatinine renal clearance:Ratio:24H:Urine:Qn



Note

CSF/Serum Protein calculation is not a ratio, because the measured components are not in the same system. Its Property type is relative mass concentration, ReIMCnc (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

Relative (Rel)

Relative amount of component A in system 1 compared to system 0. By extension:

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

RelMCnc

Relative Mass Concentration (as noted previously)

```
2858-9|Protein.CSF/Protein.serum:RelMCnc:Pt:Ser+CSF:Qn
3235-9|Coagulation factor XII Ag actual/Normal:RelMCnc:Pt:PPP:Qn:Imm
```

RelTime

Relative time

```
3232-6|Coagulation factor XII activity actual/Normal:RelTime:Pt:PPP:Qn:Coag
```

RelCCnc

Relative Catalytic Concentration

```
28660-9|Plasminogen actual/Normal:RelCCnc:Pt:PPP:Qn:Chromo
```

RelRto

Relative Ratio

```
1756-6|Albumin.CSF/Albumin.SerPl:RelRto:Pt:Ser/Plas+CSF:Qn
```

RelVol

Relative Volume

```
19853-1|Capacity.inspiratory.bs/Capacity.inspiratory.preop:RelVol:Pt:Respiratory system:Qn:Spirometry
```

RelVrat

Relative Volume Rate

 $20161-6 | Voluntary\ ventilation. max ^postbronchodilator / MVV: predicted: RelVRat: Pt: Respiratory\ system: Qnote the content of the cont$

Complex (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.

Arbitrary (Arb)

Arbitrary concentration of items. If we are not measuring the activity of an enzyme then the units of measure and

properties are as follows. Note that U is reserved for catalytic properties (see box below).

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

If the Property is Titr then the Scale is always Qn

For any X Ab or Ag:

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

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)

Nominal (Nom)

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

Intensive Properties	Possible Values (coded)	Property	Scale
ABO Group	A, B, AB, O	Туре	Nom
Surgery (Dis. Summary)	Cholecystectomy, Appendectomy	Prid	Nom

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

Narrative (Nar)

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	Туре	Nar
Surgery (Dis. Summary)	Cholecystectomy	Prid	Nar

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

Impression or Interpretation (Imp)

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:

Evaluation	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:

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

Method versus Property

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).

F - Example Acronyms used in LOINC

The contents of this appendix have been replaced with a new page in the Knowledge Base section of the LOINC website (https://loinc.org/kb/abbreviations/). The new page contains an alphabetical list of the abbreviations and acronyms used across LOINC. It is a work in progress and to date, primarily contains abbreviations/acronyms used in various LOINC Parts, except for Components.

This section will be deleted in a future publication of the LOINC Users' Guide.

G - LOINC Technical Briefs

Technical briefs have been developed for various LOINC terms to clarify either the meaning, current nomenclature, or use case of a given term. The following technical briefs are included in this manual and linked to related LOINC terms in RELMA.

D-Dimer Revisions in LOINC

Author: J. Gilbert Hill, MD, PhD Date Written: 2006-11-24

1 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
```

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
```

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.

2 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 <u>4539-3</u>, 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	1	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	İ
42727-8	FIBRIN D-DIMER	MCNC	ug/L	PT	CSF	QN	LA
7799-0	FIBRIN D-DIMER	ACNC	T T	PT	PPP	QN	

3 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

Choosing the Correct LOINC for Estimated Glomerular Filtration Rate

Author: Laboratory LOINC Committee

Date Written: 2022-01-25

Estimated Glomerular Filtration Rate

The glomerular filtration rate can be estimated based on the concentration of creatinine or cystatin C. Estimates are derived from equations that incorporate demographic variables such as age, sex and race. In August of 2020, the National Kidney Foundation and the American Society of Nephrology established a task force to reassess the inclusion of race. (A Unifying Approach for GFR Estimation: Recommendations of the NKF-ASN Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Disease, DOI: https://doi.org/10.1053/j.ajkd.2021.08.003). The outcome of this task force was the creation of new equations without a race-based variable (New Creatinine-and Cystatin C–Based Equations to Estimate GFR without Race, DOI: 10.1056/NEJMoa2102953). The task force recommends immediate implementation of these new equations in all United States laboratories. The American Association of Clinical Chemistry is publishing guidance on implementation National Kidney Foundation Laboratory Engagement Working Group Recommendations for Implementing the CKD-EPI 2021 Race-Free Equations for Estimated Glomerular Filtration Rate: Practical Guidance for Clinical Laboratories.

New equations

LOINC terms for the new equations refer either to the creatinine-based formula or the creatinine and cystatin C-based formula. To preserve historical integrity in medical records, it is advisable to create a new result field within the laboratory information system (LIS) when a calculation has changed. Distinct result fields allow for correct LOINC term(s) to be applied over time. The new test result will need to be mapped to a new LOINC code, depending on the type of formula used, the creatinine-only 2021 CKD formula or the creatinine-and-cystatin 2021 CKD formula.

LOINC Code	Component	Property	Timing	System	Scale	Method	Short Name
98979-8	Glomerular filtration rate/1.73 sq M.predicted	ArVRat	Pt	Ser/Plas/Bld	Qn	Creatinine-based formula (CKD- EPI 2021)	eGFRcr SerPIBId CKD-EPI 2021
<u>98980-6</u>	Glomerular filtration rate/1.73 sq M.predicted	ArVRat	Pt	Ser/Plas/Bld	Qn	Creatinine and Cystatin C-based formula (CKD-EPI 2)	eGFRcr-cys SerPIBId CKD-EPI 2021

Mapping Guidance

Consult with the clinical chemist, medical director, or pathologist to determine if the lab is using one of the equations recommended by the National Kidney Foundation-American Society of Nephrology Task Force in 2021, or an earlier equation.

If transitioning to the new 2021 calculations, note there are separate equations for male and female patients that need to be implemented. The same LOINC code is applied regardless of which sex-based equation is used to generate the result. Laboratories need to build each male and female equation within their LIS and validate per their accreditation requirements. Many LISs can support multiple equations (such as in this case) and apply the result value to a single laboratory result component. A new test result needs to be built within the LIS, EHR and any other information systems receiving the new calculated result values.

Laboratory processes will be similar to transitioning to a new test kit or method and similar laboratory compendium, LIS and interface updates. Changes need to be communicated to end users so updates can be made in their systems and communicated to all those using the results from the new eGFR formulas accordingly. Clinical decision making may be impacted as well.

While LOINC does not have a specific code for reporting the exact equation used to calculate eGFR, it may be appropriate for labs to transmit this information as part of the information contained in the result comment field. The individual laboratory should determine whether it is better to include the equation, or the author(s) of the equation, to identify the method used to perform the eGFR calculation.

Earlier equations

The LOINC terms for eGFR with a specimen type of Ser/Plas/Bld are distinguished by the COMPONENT and METHOD attributes. The Committee acknowledges metabolic panel elements (Na, K, Glucose, etc) may use LOINC terms of Ser/Plas specimens alongside an eGFR term with specimen of Ser/Plas/Bld.

Existing LOINC content for this type of testing may be updated to have a status of discouraged to help guide users to the current NKF-ASN recommended equations. Please review the definition for the discouraged status in section 11.2 Classification of LOINC term status of the LOINC Users' Guide to better understand how the status value should be used in identifying the correct LOINC code based on the mapping use case.

Component attributes

- Is the patient value normalized by a standard 1.73 sq M body surface area? Use component of Glomerular filtration rate/1.73 sq M.predicted
- Is the result specific to a patient's race (black/non black) or sex (female/male)? Note the new 2021 calculations have separate male/female calculations but there is only one LOINC term. Past methodology had separate LOINCs.

Method attributes

- Which equation does the laboratory use?
- Schwartz formula for Pediatrics The original paper by G.F. Schwartz, et al, 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 Modification of Diet in Renal Disease (MDRD) formula below is specifically NOT applicable to patients under 18 years of age. The Schwartz formula depends on age, sex, and body height and serum creatinine. The Schwartz method LOINC uses the component attribute of Glomerular filtration rate.predicted

LOINC Code	Component	Property	Timing	System	Scale	Method
50384-7	Glomerular filtration rate/1.73 sq M.predicted	ArVRat	PT	Ser/Plas/Bld	Qn	Creatinine-based formula (Schwartz)

• MDRD (4 or 6 variable) Modification of Diet in Renal Disease - 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

LOINC Code	Component	Property	Timing	System	Scale	Method
33914-3	Glomerular filtration rate/1.73 sq M.predicted	ArVRat	Pt	Ser/Plas	Qn	Creatinine-based formula (MDRD)
48642-3	Glomerular filtration rate/1.73 sq M.predicted.non black	ArVRat	Pt	Ser/Plas/Bld	Qn	Creatinine-based formula (MDRD)
48643-1	Glomerular filtration rate/1.73 sq M.predicted.black	ArVRat	Pt	Ser/Plas/Bld	Qn	Creatinine-based formula (MDRD)
50044-7	Glomerular filtration rate/1.73 sq M.predicted.female	ArVRat	Pt	Ser/Plas/Bld	Qn	Creatinine-based formula (MDRD)

• Cystatin-based - 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. This study demonstrates a comparison between the cystatin C-based prediction equations of Le Bricon, Filler, Hoek, and Larsson with the conventional creatinine-based equations of MDRD, Cockcroft-Gault, Nankivell, Walser, Jelliffe, and Mawer. Importantly, the Filler equation and, to a lesser degree, the Le Bricon equation performed well at GFR values both above and below 60 ml/min per 1.73 m2.

LOINC Code	Component	Property	Timing	System	Scale	Method
<u>50210-4</u>	Glomerular filtration rate/1.73 sq M.predicted	ArVRat	Pt	Ser/Plas/Bld	Qn	Cystatin-based formula

Inducible Clindamycin Resistance in Staphylococcus and Streptococcus

Author: David Baorto, MD, PhD Date Written: 2011-05-12

1 Macrolide-Lincosamide-Streptogramin B (MLS_b) 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).

2 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 (Erythromyin+clindamycin resistance ermA + ermC genes [Presence] by Molecular method, 62258-9).

KIR Gene Family

Author: David Baorto, MD, PhD

Written: 2011-04-17

1 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).

2 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.

3 References

Marsh S G, Parham P, Dupont B, Geraghty D E, Trowsdale J, Middleton D, Vilches C, Carrington M, Witt C, Guethlein L A, Shilling H, Garcia C A, Hsu K C, Wain H. Killer-cell immunoglobulin-like receptor (KIR) nomenclature report, 2002. Immunogenetics 2003; 55(4):220-226. PubMed: 12838378.

Parham P. MHC class I molecules and KIRs in human history, health and survival. Nat Rev Immunol. 2005; 5(3):201-214. PubMed: 15719024.

Oxygen Saturation and LOINC

Authors: Gilbert Hill, MD and Clement J. McDonald, MD

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

1 Oxygen saturation

The term "oxygen saturation" is often used to refer to two distinctly different quantities, hemoglobin oxygen saturation (recommended symbol = $_s_O_2$) and fractional oxyhemoglobin (recommended symbol = $_F_O_2$ Hb).

2 NCCLS 46-A defines the two as follows:

2.1 Hemoglobin oxygen saturation

Hemoglobin oxygen saturation = the amount of oxyhemoglobin in blood expressed as a percent of the total amount of hemoglobin **able to bind** oxygen (i.e., oxyhemoglobin (O_2Hb) + deoxyhemoglobin (HHb). Note that carboxyhemoglobin (COHb), methemoglobin (MetHb) and Sulfhemoglobin (SulfHb), the so-called dyshemoglobins (dysHb) are unable to bind oxygen, so are not included in the denominator of this fraction:

 $_sO_2 = 100 \times O_2Hb/(O_2Hb + HHb)$

More important some instruments, e.g., the pulse oximeter, cannot pick up the dyshemoglobins. So they always report sO_2 .

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 = O_2 Hb + HHb + [COHb + MetHb + SulfHb] taken all together O_2 Hb HHb and the three DysHb's represent the total Hb.

 $_FO_2Hb = O_2Hb/tHb$

A key point here is that it takes a more sophisticated machine to measure Fractional Oxyhemoglobin than sO2.

3 When there are no dyshemoglobins present (the usual situation), $sO_2 = FO_2Hb$

4 Oxygen saturation obtained by measuring pH and pO₂

An "oxygen saturation" can also be obtained by measuring pH and pO_2 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 _s_O₂ (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 $_{\rm F}$ O₂Hb (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., sO_2 and FO_2 Hb 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 sO_2 and FO_2 Hb 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 sO_2 or FO_2Hb . 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".

1 LOINC Terms associated with Salmonella Serotyping

1.1 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)

1.2 Salmonella sp antigenic formula [Identifier] in Isolate by Agglutination (<u>56475-</u>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:-".

1.3 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

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1 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.

2 Specific parts

2.1 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.

2.2 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.

2.3 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.

2.4 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.

2.5 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:

- FTI = TT4(ug/ml) x T3 uptake (%)/100
 - This has sometimes been noted leaving off the division by 100, but not in practice: FTI = TT4(ug/ml) x T3 uptake(%).
- FTI = TT4(ug/ml) x (T3 uptake patient/T3 uptake control) (ratio)
 - 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.
- FTI = TT4(ug/ml) / T uptake units (ratio)
 - Here "T uptake units" is ratio of patient to reference serum levels of thyroxine binding globulin (TBG).

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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 unit-less.
- 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

Danish serotype number	U.S. serotype number Vaccine(s) that include this strain		
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	

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H - LOINC Committee

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

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

- Laboratory LOINC Committee
- Clinical LOINC Committee
 - o Nursing Subcommittee
 - o 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.org/committee.

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
 - Anatomic Location.Laterality.Presence
 - o Anatomic Location.Laterality
- View
 - o View.Aggregation
 - o View.View Type
- Timing
- Maneuver
 - Maneuver.Maneuver Type
- Pharmaceutical
 - o Pharmaceutical.Substance Given
 - o Pharmaceutical.Route
- Reason for Exam
- Guidance
 - o Guidance for.Presence
 - Guidance for.Approach

- o Guidance for.Action
- 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

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 imageguided 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**. 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.
- 4. 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.
- 8. Because there is no DICOM modality code for DEXA, **DXA** will be adopted as the *Modality* code.
- 9. 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}

3.3 Allowed Modality/Subtype Combinations

- CT
 - o CT.angio
 - o CT.scanogram
 - o CT.densitometry
 - o CT.perfusion
 - o CT.portable
 - o CT.cone beam
- DXA
 - o DXA.densitometry
- MG
 - $\circ \ MG. tomosynthesis\\$
 - o MG.stereotactic
- MR
 - o MR.angio
 - o MR.functional
 - o MR.spectroscopy
 - o MR.perfusion
 - o MR.tractography
- NM
 - o NM.dosimetry
 - o NM.SPECT
 - o NM.SPECT+CT
- PT
 - o PT.perfusion
 - \circ PT+CT
- RF
 - o RF.angio
 - o RF.video
 - o RF.portable
- US
 - o US.densitometry
 - o US.Doppler

- o US.portable
- o US.A-scan
- US.elastography
- XR
 - XR.tomography
 - o XR.portable
 - o XR.slot radiography
- {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 sub-attributes, 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 - 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:

```
Views AP + lateral
```

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 definitions section, 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:

```
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
- Delayed
- Runoff

9 Reason For Exam

9.1 Definitions

Reason for exam is used to describe a clinical indication or a purpose for the study when this information affects how the procedure is performed. 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**). We will not create separate terms for the same procedure with different reasons if the actual procedure is the same regardless of the clinical indication or purpose.

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

Example	Example	<reason(s)></reason(s)>	
XR	Eye	Foreign body	
MG	Breast	Diagnostic	

Example	Example	<reason(s)></reason(s)>	
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.

Specific definitions for certain actions and interventions:

- **Aspiration**: withdrawal of fluid with a device that is removed at the end of the procedure
- Drainage: withdrawal of fluid with a device that is left in place at the end of the procedure
- Thoracentesis: drainage of fluid with placement of chest tube
- **Arthrocentesis**: aspiration of fluid from a joint space (this does not include aspiration of soft tissue surrounding the joint)

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 pre-coordinated 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*.

10.2.3.1 Aspiration and Drainage

We have adopted the American College of Radiology and American Medical Association's definitions of **aspiration** and **drainage** as described above. Based on those definitions, any term that specifies drainage will also specify placement of a drainage catheter and vice versa, as follows:

Guidance for drainage + placement of drainage catheter

Terms that specify chest tube placement are not required to also specify drainage because chest tube placement can be done without draining fluid, such as for patients with a pneumothorax.

10.2.3.2 Injection and Nerve block

For terms that specify a nerve or set of nerves as the *Anatomic focus*, such as **Peripheral nerve** or **Celiac plexus**, the *Action* should be **Nerve block**. For those that have a more generic focus such as **Spine.lumbar**, then **Injection** may be used.

10.2.4 Guidance for. Object

The *Object* sub-attribute specifies the target of the Action and can represent a variety of concepts, including a device that is being manipulated, a biological substance, or a pathologic lesion. Examples include: **Drainage catheter**, **Nephrostomy tube**, **CSF**, **Calculus**, **Abscess**.

Note that the *Object* sub-attribute is optional. Some procedures will specify an *Action* as well as an *Object*, while others may only specify an *Action*. For example:

Guidance for aspiration

Beginning with LOINC version 2.66, the LOINC/Radlex Committee agreed upon a constrained list of values for the *Object* associated with the **Aspiration** and **Drainage** *Actions* in order to prevent an explosion of terms for very similar concepts that are sometimes difficult to distinguish. This list contains the concepts listed below. Requests for new, more specific values will be considered by the Committee on a case-by-case basis.

- Fluid
- Abscess
- Hematoma
- Cyst
- CSF
- Amniotic fluid
- Urine

The Committee also decided that **Drainage catheter** will be the preferred *Object* for the **Placement** *Action*, but specific named catheters such as **Chest tube** and **Nephrostomy tube** will also be allowed.

10.2.4.1 Relationship between Anatomic Location and Guidance for. Object

For most procedures, 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*.

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

Example	<anatomic loc=""></anatomic>	<approach></approach>	<action></action>	<object></object>
ст	Liver	Percutaneous	Biopsy	

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

 $^{1. \ \}underline{\text{http://dicom.nema.org/Dicom/News/oct2013/docs_oct2013/sup121_pc.pdf}, Accessed \ 14 \ May \ 2016. \underline{\hookleftarrow}$

^{2.} http://dicom.nema.org/medical/dicom/current/output/pdf/part03.pdf, Accessed 14 May 2016.