Logical Observation Identifier Names and Codes (LOINC®)Users' Guide

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This and other relevant documents and files are available at http://www.regenstrief.org/loinc

List of Files:

Format	File Name
MDB	LOINCDB.MDB
ASCII	LOINCDB.TXT
PDF	LOINCDB.PDF
Word	LOINCManual.doc
PDF	LOINCManual.pdf
	RELMA.exe
Word	RELMAManual.doc
PDF	RELMAManual.pdf
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Preface and Introduction

The LOINC database provides a set of universal names and ID codes for identifying laboratory and clinical test results. ¹ ²The purpose is to facilitate the exchange and pooling of results, such as blood hemoglobin, serum potassium, or vital signs, for clinical care, outcomes management, and research. Currently, many laboratories are using ASTM 1238 or its sister standard, HL7, to send laboratory results electronically from producer laboratories to clinical care systems in hospitals. Most laboratories identify tests in these messages by means of their internal (and idiosyncratic) code values. Receiving medical informatics systems cannot fully "understand" the results they receive unless they either adopt the producer's laboratory codes (which is impossible if they receive results from multiple source laboratories, e.g.; the hospital lab, the local commercial lab, and a nursing home lab), or invest in the work to map each laboratory's code system to their internal code system.³

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

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

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

- 1) Component (analyte) e.g. potassium, hemoglobin, hepatitis C antigen.
- 2) Property measured e.g. a mass concentration, enzyme activity (catalytic rate).
- Timing i.e. whether the measurement is an observation at a moment of time, or an observation integrated over an extended duration of time e.g. 24-hour urine.
- 4) The type of sample e.g. urine; blood.

5) The type of scale — e.g. whether the measurement is quantitative (a true measurement) ordinal (a ranked set of options), nominal (e.g. E. coli; Staphylococcus aureus), or narrative (e.g. dictation results from x-rays).

6) Where relevant, the method used to produce the result or other observation.

It also contains information about the amount, route, and timing of physiologic or pharmacologic challenges (e.g. oral glucose tolerance test, which would be expressed in LOINC as GLUCOSE^1H POST 100 G GLUCOSE PO¹). The LOINC identifiers do not usually include the method in the name for chemistry tests, where tests are more often standardized to normalized methods; they do include methods for most serological tests and coagulation studies. This same principle is usually reflected in the master files of existing laboratories. Of course, the method can always be reported as a separate item of information in a result message regardless of whether it is part of the test name.

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

We used many sources for constructing the database, including the Silver Book from the International Union of Pure and Applied Chemistry (IUPAC) and the International Federation of Clinical Chemistry (IFCC),⁴ textbooks of clinical pathology (e.g. Henry⁵ and Tietz⁶), the expertise and work of the LOINC members, and EUCLIDES. We have also reviewed the master test files of seven sources (Indiana University/Regenstrief, University of Utah, Association of Regional and University Pathologists (ARUP), Mayo Medical Laboratories, LDS Hospital in Salt Lake City, the Department of Veterans Affairs, Quest Diagnostics, and University of Washington). This has been an empirical effort. Our goal is to provide codes that correspond to the concepts in real world laboratories' and clinical departments' master files.

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

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

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

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

The print version of the LOINC database is presented to you as an electronic document grouped by "common sense" categories to make it easier to find general areas of interest. It is divided first into four categories, "lab", "clinical", "attachments" and "surveys". (This split is recorded in Field #35, CLASSTYPE.) The laboratory portion is further divided into the usual categories of chemistry, hematology, serology, microbiology (which includes parasitology and virology), and toxicology. We have separated antibiotic susceptibilities into their own category. The clinical portion of the LOINC database contains entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, pulmonary ventilator management, and other clinical observations. Table 20 (Appendix B) lists these classes in detail. There is nothing sacred about these categories. You will be able to sort the database by whatever class is convenient for your application.

The Regenstrief Institute will maintain this database The LOINC database (which identifies over 34,000 different lab tests and clinical observations), supporting documentation and the RELMA mapping program are all available through the Regenstrief Institute web site. (http://www.regenstrief.org/loinc)

The LOINC databases are available in a number of file formats. In each of them, the first part of the file contains the copyright notice with permission to use the database for any purpose without charge or written permission. We have copyrighted the databases and this document to assure that multiple variants of the codes do not emerge. Having many variants would defeat the purpose of a universal identifier for test results.

LOINC ACCESS database:

The official LOINC database is available as an ACCESS file called LOINC.MDB. It was created using Microsoft Access™ 97.

Since version 2, the LOINC database has been distributed in a Microsoft Access97 database. Microsoft ended most support for Access97 on August 31, 2001 and is dropping all remaining support on January 16, 2004. Therefore, we are beginning the process of converting from Access97 to Access2002. Within the next year or two LOINC and RELMA will be distributed in the new format.

If you just use the RELMA program, this change should be completely transparent. However, if you access the database directly or through some other program, this change may cause incompatibilities. We are hoping that by giving this advance notice, you will be able to avoid any problems. If you would like to discuss this issue with LOINC/RELMA developers, please e-mail us at loinc@regenstrief.org.

LOINC Tab Delimited ASCII:

Each record of the database is on a separate line. Each record is terminated by CR/LF, and each field is delimited with a tab character. Non-null text fields are enclosed in double quotes ("). This is the format you will use if you want to import into your own database. This file contains all of the content of the database and is formatted to be easily imported into a wide variety of database and spreadsheet applications. Unlike the pdf versions, it will always contain all implemented fields.

LOINC PDF file:

This file is formatted to print landscape in a Courier 6 point font and is intended to provide an easily browsed print version. The LOINC records are sorted first by class type (lab or clinical), then by class, and then alphabetically by full LOINC name. The print version does not include all of the LOINC fields and some of the longer fields wrap vertically. The size of the printed page makes it impossible to display all database fields in this file.

The LOINC Users' Guide (this document) is also available both as a PDF or Word 97 file. It explains the structure of the database, its rationale, and the rules we used for naming test results. It is not compressed.

RELMA

In addition to the basic LOINC files, we also produce a Windows-based mapping utility called the Regenstrief LOINC Mapping Assistant (RELMA®). This program is also available for free use

The RELMA package includes the LOINC table in the database plus several large index tables. Zipped, the program and database files exceed 12M, not including the manual. All of the RELMA files will need approximately 90 megabytes of disk space.

RELMA Users' Manual

There is a separate Users' Manual documenting the RELMA program.

All of the above files are available from the LOINC website http://www.regenstrief.org/loinc. They are also distributed on CD.

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

Clem McDonald Stan Huff

Chairman, LOINC Committee
Chairman, Laboratory LOINC Committee
Chairman, Clinical LOINC Committee

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1 Goals

The goal of this project is to create universal identifiers (names and codes) to be used in the context of existing ASTM E1238, HL7, CEN TC251, and DICOM observation report messages employed in the various subdomains of healthcare informatics such as Clinical Laboratory Information Management Systems and Computer-Based Patient Record Systems. Page 5.8 Specifically, we want to create identifiers that can be used as the coded value of the "Observation Identifier" field (# 3) of the OBX segment of an ORU HL7 (HL7 vs. 2.x and vs. 3.9 or ASTM 1238-9410) messages, or in a corresponding field in future versions of these HL7 and DICOM standards. The LOINC codes will be identified in HL7 as code system "LN". The ultimate goal is that these "universal" identifiers, when used in the context of the messaging standards, will allow the exchange of clinical laboratory data between heterogeneous computing environments.

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

We focused our initial effort on creating names for results of reportable tests or clinical measurements rather than requestable batteries, because the issues involved in naming results of tests are less complex than those involved in naming the batteries, but we have also defined codes for some order panels. Note however, that LOINC codes for single tests, reports, and observations are equally suitable for reporting results or ordering them.

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

Short Names

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

The fully specified LOINC name is long and sometimes awkward, so we don't envision it being used as the label for standard clinical reports and have rules for naming orderable results. Over the last 7 years we have had many requests for a universal "short name" that could be used in HL7 messages and, perhaps on delivered reports. In 2002, we introduced our first attempt at the developing of such short names. At this stage we have limited the scope of this effort to laboratory tests with the exception of challenge tests, which have particularly long names that can be difficult to squeeze into a specified limit. The LOINC committee recommended that the short name be no more than 30 characters in length. We recommend these names be sent along with the LOINC code as the 2nd part of the HL7 CE data type in HL7 messages. These short names are unique, but they are subject to change as we develop better algorithms for generating short names.

It is assumed that shorter, more convenient abbreviated names and synonyms will be created and maintained by the local computer system. We have had many requests to create standardized "short" names that could serve as reportable or displayable names, and will consider defining such names as a future project.

1.1 Successes

The LOINC codes have been greeted enthusiastically since they were released to the Internet in April of 1996. Since then we have released thirteen revisions of the LOINC database and it now includes over 30,000 observation concepts. The informatics committee of the College of American Pathologists has endorsed the LOINC codes. The American Clinical Laboratory Association (ACLA), an association of large referral laboratories whose members are responsible for more than 60% of US outpatient laboratory test volume, has recommended LOINC for adoption by its members. Quest Diagnostics (formerly Corning MetPath), LabCorp, and SmithKline Beecham (now part of Quest Diagnostics), three of the largest commercial laboratories in the US, have adopted LOINC as their code system for reportable test results, as has ARUP (Associated Regional and University Pathologists). Mayo Medical Laboratories is currently mapping their tests to LOINC. In addition, the University of Colorado, Intermountain Health Care, Kaiser Permanante, Clarian Health (Indiana University, Methodist Hospital, and Riley Hospital), Partners Healthcare System of Boston (Brigham and Women's and Mass General Hospital), Care Group of Boston, Mayo Medical Group, and the Department of Defense are adopting the LOINC codes for laboratory reporting. All US veterinary medicine laboratories have committed to the use of LOINC.

HMOs such as Empire Blue Cross and Aetna Health Care are also adopting LOINC for internal purposes. Internationally, LOINC has also met success. Geneva, Switzerland, is adopting LOINC for quality assurance mandates. The provinces of Ontario and British Columbia, Canada, are adopting LOINC codes province wide, and Newfoundland is considering following in their footsteps. Most recently, Germany has adopted LOINC for national use.

The LOINC codes have been incorporated into the National Library of Medicine's ULMS. They have been incorporated in HCFA's quality assurance testing pilot programs, and will likely be part of the HIPAA (Health Insurance Portability and Accountability Act) electronic attachments specification. They have been adopted by the Centers for Disease Control and Prevention/Council of State and Territorial Epidemiologists' project for electronically reporting/transmitting communicable disease information^{11, 12} and by NAACCR (North American Association of Central Cancer Registries) for their tumor registry variables.

On March 21, 2003, the United States Departments of Health and Human Services HHS), Defense (DoD) and Veterans Affairs (VA) announced the first set of uniform standards for the electronic exchange of clinical health information to be adopted across the federal government. As part of this, all federal agencies that deal with health care data will adopt laboratory Logical Observation Identifier Name Codes (LOINC) to standardize the electronic exchange of clinical laboratory results.

SNOMED collaboration

LOINC and SNOMED are supporting a collaboration that will ensure a consistent, unambiguous clinical reference terminology that builds upon the strengths of each. The SNOMED Editorial Board and the LOINC Committee have agreed on the following method for linking the SNOMED and LOINC terminologies in a synergistic way and preventing overlap:

• The detailed names of laboratory tests provided by LOINC will all be incorporated into the SNOMED distribution. These codes will retain the full LOINC code (number and check digit) but will include a prefix to identify the SNOMED axis. The LOINC committee will continue to operate independently and have full editorial control over these terms and will continue to distribute them on the Internet at no cost for public use.

• SNOMED will not define laboratory test names that overlap in meaning with fully specified LOINC names. The SNOMED Editorial Board may create hierarchical concepts in the SNOMED P3 (Laboratory Procedures) axis that combine any one or two LOINC relationships. However, if one of the relationships is the LOINC component relationship, SNOMED may **not** combine it with the LOINC system relationship. When the SNOMED Editorial Board has the need to use more than two LOINC relationships, the Editorial Board will work with the LOINC Committee to create a mutually acceptable solution. Any concept in the SNOMED P3 axis that currently does not meet these criteria will be retired and/or given to the LOINC Committee for consideration. LOINC will not define codes for entities that would be stored as values for its observations, including those that are listed as text in the answer field of the LOINC database.

1.2 What is not part of the name

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

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

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

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

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

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

1.3 Scope of this document

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 has 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 (see Section 3.10). Existing LOINC codes could always be used to order the specific tests observation, but prior to 2000 there was no mechanism to use LOINC codes to order a set of observations. We have currently only addressed a group of observations that are either naturally produced as a panel (e.g. urinalysis) or are defined by some national body (e.g. BASIC METABOLIC HCFA 2000 PANEL).

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

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

2 Major "Parts" of a Test/Observation Name

The fully specified name of a test result or clinical observation has five or six main parts including: the name of the component or analyte measured (e.g. glucose, propranolol), the property observed (e.g. substance concentration, mass, volume), the timing of the measurement (e.g. is it over time or momentary), the type of sample (e.g. urine, serum), the scale of measurement (e.g. qualitative vs. quantitative), and where relevant, the method of the measurement (e.g. radioimmunoassay, immune blot). These can be described formally with the following syntax.

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

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

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

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

We used Tietz⁶, Henry⁴, IUPAC³, EUCLIDES¹³, diagnostic microbiology textbooks such as Mahon and Manuselis¹⁴ the American Association of Blood Banking¹⁵, and other sources as well as the expertise of the individuals or the committee to choose preferred names.

Examples of fully specified LOINC names:

SODIUM:SCNC:PT:SER/PLAS:QN

SODIUM:SCNC:PT:UR:QN

SODIUM:SRAT:24H:UR:QN

CREATININE RENAL CLEARANCE: VRAT: 24H: UR: QN

GLUCOSE^2H POST 100 G GLUCOSE PO:MCNC:PT:SER/PLAS:QN

GENTAMICIN^TROUGH:MCNC:PT:SER/PLAS:QN

ABO GROUP: TYPE: PT: BLD DONOR: NOM

BODY TEMPERATURE: TEMP: 8H^MAX: XXX: QN

CHIEF COMPLAINT:FIND:PT:^PATIENT:NAR:REPORTED

PHYSICAL FINDINGS:FIND:PT:ABDOMEN:NAR:OBSERVED

BINOCULAR DISTANCE:LEN:PT:HEAD^FETUS:QN:US.MEASURED

2.1 General naming conventions

2.1.1 Abbreviations in names of component/analyte

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

Table 2: Allowable Abbreviations in Component (analyte) Names			
Abbreviation	Full Name		
AB	Antibody		
AG	Antigen		
DNA	deoxyribonucleic acid		
HIV	human immunodeficiency virus		
HLA	human histocompatibility complex derived antigens		
HTLV 1	human t-cell lymphotropic virus-1		
Igx	immunoglobulins (e.g. IGG for immune globulin G, IGM for		
	immune globulin M)		
NOS	not otherwise specified		
RNA	ribonucleic acid		
RRNA	ribosomal ribonucleic acid		

- 2.1.2 General naming rules for the component (analyte) part of the fully specified name.
- 2.1.2.1 <u>Place the identifier of the substance being measured first</u>. This means "Hepatitis A antibodies (AB)" not "Antibodies, Hepatitis A."
- 2.1.2.2 <u>Use the generic name of a drug</u>, 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 <u>Use full taxonomic name of an organism or virus name</u> (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.

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 Microbiology²⁰. When it includes the name of a virus (e.g. West Nile Virus IgM antibodies), we use the viral name as given by Index Virum¹⁶.

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.

- 2.1.2.5 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.
- 2.1.2.6 Use "platelets," not "thrombocytes."
- 2.1.2.7 Name vitamins by the chemical name. E.g. use thiamine not Vitamin B1, The name containing "Vitamin" will be included as a synonym. This is the only reasonable approach because all vitamins have a chemical name but not all vitamins have a "numbered" vitamin name.
- 2.1.2.8 <u>Always specify whether serology tests measure the antigen or antibody</u>, 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.
- 2.1.2.9 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.
- 2.1.2.10 <u>Use the noun form of the target of the antibody</u>, e.g. Myocardium AB, not Myocardial AB.
- 2.1.2.11 <u>Anion vs. acid</u>: 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.
- 2.1.2.12 <u>Alcohols</u>: Always use the single-word names for alcohols: methanol, not methyl alcohol; ethanol, not ethyl alcohol, and so on.
- 2.1.2.13 Always spell out OH as Hydroxy, or as ol, with no space or hyphen between Hydroxy and the next word.
- 2.1.2.14 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.
- 2.1.2.15 Use pH, not log(H+).
- 2.1.2.16 Whenever possible, the component will contain the scientific names of allergens. NOTE: This is a new convention implemented in January 2002.
- 2.1.2.17 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.
- 2.1.2.18 For drug metabolites, we will use the "nor" form rather than "desmethyl", e.g. for instance nordoxepin not desmethyldoxepin.

2.1.3 Punctuation in analyte names

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

2.1.4 Case insensitivity

All names are case insensitive. We use upper case in the database and our examples, but senders and receivers could 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.

Since some systems are capable of distinguishing upper and lower case, we provide mixed case names in the EXT_CP_SY (Exact Component Synonym) field (Field #32). However, the available character set does not permit direct representation of superscripts; these are recorded in the EXT_CP_SY field as a carat ("^"), e.g. Lu^a.

Table 3: 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.

2.2 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 Class/Subclass

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

If the antibody is from a particular subclass of antibodies specify the subclass (IGM, IGG, IGA, or IGD) e.g. HEPATITIS A VIRUS AB.IGG, HEPATITIS A VIRUS AB.IGM

If more than one species is included in the measurement, all are listed in the subclass, e.g. "MUMPS VIRUS AB.IGG+IGM" with a plus sign (+) to separate the subspecies. There should be no spaces between the plus sign and the words it connects. If two constituents are measured as one quantity, both should be named and the component separated by a plus sign (+), e.g. CYCLOSPORINE+METABOLITES.

2.2.2 Challenge test (2nd subpart)

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

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

where the challenge can be further characterized as

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

An example of a challenge that used all parts would be: ALDOSTERONE^1H POST 25 MG CAPTOPRIL PO The time difference follows the syntax: n<S|M|H|D|W> where n is a number (possibly a decimal); S denotes seconds; M denotes minutes; H denotes hours; D denotes days; and W denotes weeks. The time delay can be preceded by a 'greater than' (>) sign, e.g. >4H. Table 4 lists some possible values for time difference, but any time specification that follows the above syntax would be legal.

In addition to specifying a time elapsed since challenge, the time delay slot can be used to name a clock time when the measurement was taken, e.g. GLUCOSE^10AM SPECIMEN, or to specify the ordering of specimens, e.g. ^1ST SPECIMEN, ^2ND SPECIMEN. Use this syntax to indicate pre- and post-immunization specimens, acute and convalescent specimens, or a series of specimens for which no more detailed information is available.

Table 4: Time Delay Post Challenge					
BS	Baseline (time just before the challenge)				
PEAK	The time post drug dose at which t	he highest drug le	evel is reached (differs by drug)		
TROUGH	The time post drug dose at which t	he lowest drug lev	vel is reached (varies with drug)		
RANDOM	Time from the challenge, or dose n	ot specified (rand	lom)		
n minutes/hours	s/days/weeks/months/etc. after challe	nge begun:			
1M	1 minute post challenge	6H	6 hours post challenge		
2M	2 minutes post challenge	7H	7 hours post challenge		
3M	3 minutes post challenge	8H	8 hours post challenge		
4M	4 minutes post challenge	8H SHIFT	8 hours aligned on nursing shifts		
5M	5 minutes post challenge	12H	12 hours post challenge		
6M	6 minutes post challenge	24H	24 hours post challenge		
7M	7 minutes post challenge	2D	2 days		
8M	8 minutes post challenge	3D	3 days		
9M	9 minutes post challenge	4D	4 days		
10M	10 minutes post challenge	5D	5 days		
15M	15 minutes post challenge	6D	6 days		
20M	20 minutes post challenge	7D	7 days		
25M	25 minutes post challenge	1W	1 week		
30M	30 minutes post challenge	10D	10 days		
1H	1 hour post challenge	2W	2 weeks		
1.5H	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		
3Н	3 hours post challenge	2MO	2 months (60 days) post challenge		
4H	4 hours post challenge	3MO	3 months (90 days) post challenge		
5H	5 hours post challenge				

The second subpart is also used to describe measurements taken at a specified point after the beginning of an ongoing treatment, such as peritoneal dialysis, e.g. CREATININE^12H POST PERITONEAL DIALYSIS. More generally, this syntax can be used to indicate that observations were recorded, e.g. ^POST PARTUM, ^POST SURGERY, or ^POST EDTA THERAPY.

The syntax of the second subpart can be specified in various ways to indicate challenges of greater or lesser specificity, corresponding to the amount of detail the lab knows about the challenge specimen. Examples of the range of possibilities include:

Analyte	"A"	Time	"POST"	Amount	Sub/Treat	Route
11-DEOXYCORTISOL	٨	8H	POST	30 MG/KG	METYRAPONE	PO
CORTICOTROPIN	٨	45M	POST	DOSE U/KG	INSULIN	IV
ASCORBATE	٨		POST	DOSE		PO
11-DEOXYCORTISOL	٨	2 ND SPECIMEN	POST		XXX CHALLENGE	
17-HYDROXYPROGESTERONE	٨	6H	POST		XXX CHALLENGE	
11-DEOXYCORTISOL	٨		POST		XXX CHALLENGE	
CALCIUM	٨		POST	12H	CFST	
C PEPTIDE	۸		POST		CFST	

2.2.2.1 Reporting the baseline measure as part of a challenge test

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

GLUCOSE^PRE 100 G GLUCOSE PO

A laboratory could use this same test identifier to identify the baseline result of a 2 h glucose tolerance and a 3 h glucose tolerance, for example.

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

We denote the route of the challenge by HL7 Version 2.3 "abbreviations for medication routes" (Table 5). An oral route of administration would be denoted by "PO," an intravenous route by "IV."

Table 5: Route Abbreviations for Challenge Part					
(from HL7 v.2.3, chapter 4)					
AP	Apply Externally	MM	Mucus Membrane		
В	Buccal	NS	Nasal		
DT	Dental	NG	Nasogastric		
EP	Epidural	NP	Nasal Prongs		
ET	Endotrachial Tube	NT	Nasotrachial Tube		
GTT	Gastronomy Tube	OP	Ophthalmic		
GU	GU Irrigant	OT	Otic		
IMR	Immerse (Soak) Body Part	OTH	Other/Miscellaneous		
IA	Intra-arterial	PF	Perfusion		
IB	Intrabursal	PO	Oral		
IC	Intracardiac	PR	Rectal		
ICN	Intracervical (uterus)	RM	Rebreather Mask		
ID	Intradermal	SD	Soaked Dressing		
IH	Inhalation	SC	Subcutaneous		
IHA	Intrahepatic Artery	SL	Sublingual		
IM	Intramuscular	TP	Topical		
IN	Intranasal	TRA	Tracheostomy		
IO	Intraocular	TD	Transdermal		
IP	Intraperitoneal	TL	Translingual		
IS	Intrasynovial	UR	Urethral		
IT	Intrathecal	VG	Vaginal		
IU	Intrauterine	VM	Ventimask		
IV	Intravenous	WND	Wound		
MTH	Mouth/Throat				

Examples:

GLUCOSE^PRE 100 G GLUCOSE PO:MCNC:PT:SER/PLAS:QN GLUCOSE^30M POST 100 G GLUCOSE PO:MCNC:PT:SER/PLAS:QN GENTAMICIN^TROUGH:MCNC:PT:SER/PLAS:QN

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

2.2.2.2 Physiologic challenges

Some challenges are defined in terms of a physiologic stress, not a dose of a chemical substance. The LOINC names currently cover calorie fasts (no calorie intake), exercise, and fluid restrictions. These challenges are denoted by codes given in Table 6. In the case of such challenges, the syntax also includes the duration of the challenge.

E.g. POST <duration><physiologic challenge>

E.g. TRIGLYCERIDE^POST 12H CFST

	Table 6: Nature of Challenge			
CFST	Calorie fast. No caloric intake (food) for the period specified in the time part of the term, e.g. POST 12H CFST			
EXCZ	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:UR:QN

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

TRIGLYCERIDE^POST 12H CFST:MCNC:PT:SER:QN

Two durations can appear in one specification, e.g.:

CORTISOL^90M POST 0.05-0.15 U INSULIN/KG IV POST 12H CFST:MCNC:PT:SER: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 be 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 U/KG INSULIN IV:MCNC:PT: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:IHG:QN (liters/minute or milliliters/second) OXYGEN INHALED MECHANISM:TYPE:PT:DOSE:NOM (to report kind of delivery mechanism, e.g. nasal cannula)

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

2.2.2.4 Generic challenge specifications

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

Some challenges will be specified fully as described above, e.g. ^30M POST 100 G GLUCOSE PO. We will also include: challenges without the amount specified, e.g. ^30M POST DOSE GLUCOSE; those that specify a time elapsed but not a particular challenge, e.g. ^1H POST XXX CHALLENGE; those that do not specify the exact time but provide ordering information, e.g. ^2ND SPECIMEN POST XXX CHALLENGE; or even more generic, ^POST XXX

CHALLENGE. These latter variants are needed to accommodate challenges that do not fit any common protocol, or referrals to reference laboratories where the study protocol is not reported.

2.2.2.5 Acute and convalescent, pre and post immunization

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

Acute specimen, 1st specimen, pre-immunization specimen:

STREPTOCOCCUS PNEUMONIAE AB.IGG^1ST SPECIMEN:ACNC:PT:SER:QN Convalescent specimen, $2^{\rm nd}$ 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 CREATININE RENAL CLEARANCE^NORMALIZED TO 1.72 BODY SURFACE:VRAT:24H:UR:QN LEUKOCYTES^CORRECTED FOR NUCLEATED ERYTHROCYTES:NCNC:PT: BLD:QN

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

HL7 messaging allows for multiple results for one observation. Some systems, however cannot distinguish separate answers per observation, so they made the test names like organism 1, organism 2 or substance 1, substance 2 to report multiple organisms or substances identified in samples. We do not encourage this type of reporting because that distinction can more clearly be accomplished by using one test name (e.g. organism identified) and the HL7 sub ID to distinguish the multiple organisms/substances. However, we have created a few terms to accommodate systems that bind the distinction into their test names. The fourth subpart of the component name will allow reporting of repeat observations taken at the same time and/or on the same specimen.

Example:

MICROORGANISM IDENTIFIED^^^2:PRID:PT:STL:NOM:STOOL 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 Book⁴. We include most of the relevant IUPAC types of property in Table 7. (See Appendix F for detailed examples.)

Main property categories

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

Substance: Observations reported with moles or milliequivalents in the numerator of their units of measure have properties that begin with the word <u>substance</u>.

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 <u>number</u>, e.g. a white blood cell count reported as number of WBCs divided by volume of blood, would have a property of Number Concentration.

The pharmaceutical industry has the need for laboratory terms that are not specific as to whether the test measures a substance (substance concentration or substance rate) or mass (mass concentration or mass rate). We have created terms with the properties of MSCNC or MSRAT to represent these more general test observations. These will only be displayed in RELMA if the user selects one of two new choices (only MS* prop, all MS* prop) on the LIMIT SEARCH screen.

<u>Category subtypes:</u> Each of the above major property categories has number of derivatives: concentration, content, ratio, fraction, and rate (See Table 7).

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 concentration ratio (MCRTO). 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 (RLTM), a ratio of mass concentrations coming from two different specimens will be relative mass concentrate (RLMCNC), and a ratio of catalytic concentrations from different specimens will have the property of relative catalytic concentrate (RLCCNC).

Fractions: Fractions are ratios of a part over a whole: CREATINE KINASE.MB/CREATINE KINASE.TOTAL, if measured in grams, is a mass fraction. (Fractions are usually reported as percents.)

Rates: A rate is a measure per a time period, e.g. mg/day would be a mass rate (MRAT). Clearances have the property of volume rate, but "Clearance" will be included in analyte name to clarify meaning, e.g. SODIUM RENAL CLEARANCE:VRAT:24H:UR: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.

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

MICROORGANISM IDENTIFIED:PRID:PT:ISLT:NOM:BACTERIAL SUBTYPING BARBITURATES POSITIVE:PRID:PT:UR:NOM:CONFIRM

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

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

Table 7: Kind of		<u> </u>	
a . a=	Enzymatic Activity	1	Other Properties
CACT	*Catalytic Activity	ABS	Absorbance
CCNC	*Catalytic Concentration	ACT	*Activity
CCRTO	Catalytic Concentration Ratio	ANAT	Anatomy
CCNT	*Catalytic Content	ANGLE	Angle
CFR	*Catalytic Fraction	APER	Appearance
CRAT	*Catalytic Rate	ARB	*Arbitrary
CRTO	*Catalytic Ratio	AREA	Area
RLCCNC	Relative Catalytic Concentration	ASPECT	Aspect
	Entitic	BIB	Bibliographic Citation
ENT	*Entitic	CIRC	Circumference
AENT	*Arbitrary Entitic	CLASS	*Class
ENTSUB	*Entitic Substance of Amount	CNST	*Constant
ENTCAT	*Entitic Catalytic Activity	COEF	*Coefficient
ENTLEN	Entitic Catalytic Activity Entitic Length	CMPLX	Complex
ENTMASS	Entitic Length Entitic Mass	CONS	*Consistency
ENTNUM	*Entitic Number		,
		DEN	Density = Mass/Volume
ENTVOL	*Entitic Volume	DEV	Device
		DIFF	*Difference
	Mass	ELAS	Elasticity
MASS	Mass	ELPOT	Electrical Potential (Voltage)
MCNC	*Mass Concentration	ELPOTRAT	Voltage Rate (=Amperage)
MCRTO	Mass Concentration Ratio	ELRES	Electrical Resistance
MCNT	Mass Content	ENGRAT	Power = Energy/Time
MFR	*Mass Fraction	ENGRTO	Energy Ratio
MINC	*Mass Increment	ENRG	Energy
MRAT	Mass Rate	EQL	*Equilibrium
MRTO	Mass Ratio	EQU	Equation
RLMCNC	*Relative Mass Concentration	FCN	Function
THRMCNC	*Threshold Mass Concentration	FIND	Finding
	Counts	FLDCONDUCT	Fluid Conductance
NUM	*Number	FLDRESIST	Fluid Resistance
NARIC	Number Areic (number per area)	FORCE	Mechanical Force
NCNC	*Number Concentration (count/vol)	FREQ	
NCNT	Number Content = Count/Mass	IMP	Frequency
	*Number Fraction		Impression/interpretation of study Identifier
NFR		ID	
NRAT	Number Rate = Count/Time	HX	History
NRTO	Number Ratio	KINV	*Kinematic Viscosity
LNCNC	Log Number Concentration	LEN	Length
Sı	ubstance Amount (Moles/Milliequivalents)	LENRTO	Length Ratio
RLSCNC	*Relative Substance Concentration	LINC	Length Increment
SUB	*Substance Amount	LIQ	*Liquefaction
SCNC	*Substance Concentration	METHOD	Method
SCRTO	*Substance Concentration Ratio	MGFLUX	Magnetic flux
SCNT	*Substance Content	MORPH	Morphology
SCNTR	*Substance Content Rate	MOTIL	Motility
SFR	*Substance Fraction	OD	Optical density
SCNCIN	*Substance Concentration Increment	OSMOL	*Osmolality
SRAT	*Substance Rate	PCT	Percent
SRTO	*Substance Ratio	PRCTL	Percentile
THRSCNC	Threshold Substance Concentration	PRID	Presence or Identity
		PPRES	*Pressure (partial)
	Volumos	PRES	Pressure
VOI	Volumes *Volumes		
VOL	*Volume	PRESSDIFF	Pressure Difference
VCNT	*Volume Content	PRESRTO	Pressure Ratio
VFR	*Volume Fraction	RANGE	Ranges
VRAT	*Volume Rate	RATIO	Ratios
VRTO	*Volume Ratio	RDEN	Relative Density
ADENIDO	Energy/Area	REL	*Relative
ARENRG			
ARRESIS	Resistance/Area	SATFR	*Saturation Fraction
	Resistance/Area Volume/Area	SATFR SHAPE	*Saturation Fraction Shape

Table 7: Kind of Property				
ARVRAT	Volume Rate/Area	SUSC	Susceptibility	
	Arbitrary Unit Measures	TASTE	Taste	
ACNC	Arbitrary Concentration	TEMP	*Temperature	
ACNT	Arbitrary Content	TEMPDF	*Temperature Difference	
AFR	Arbitrary Fraction	TEMPIN	*Temperature Increment	
THRACNC	Threshold Arbitrary Concentration	TXT	Text	
ARAT	Arbitrary Rate	THRESHOLD	*Threshold	
RLACNC	Relative Arbitrary Concentration	TITR	Dilution Factor (Titer)	
	Time	TYPE	Type	
DATE	Date	VEL	*Velocity	
TIME	Time (e.g. seconds)	VELRAT	*Velocity Rate	
TMSTP	Time Stamp Date and Time	VELRTO	*Velocity Ratio	
TRTO	Time Ratio	VISC	Viscosity	
RCRLTM	*Reciprocal Relative Time			
RLTM	*Relative Time			
*Starred items are adopted from the IUPAC Silver Book ³ , non-starred items are extensions.				

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.

The allowed values for non-point time aspect are defined as a syntax exactly like the syntax for the times in challenge tests, e.g. <numeric value><S|M|H|W> The most common one is 24H. Table 8 gives some other examples.

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

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

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

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

Table 8: Duration Categories					
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).				
PROCEDURE DUR	Duration of the procedure (surgery, etc.)				
XXX	Not specified; time will be reported in another part of the electronic message				
* (star)	Life of the "unit." Used for blood products.				
1M	1 minute	7H	7 hours	2W	2 weeks
5M	5 minutes	8H	8 hours	3W	3 weeks
10M	10 minutes	9Н	9 hours	4W	4 weeks
15M	15 minutes	10H	10 hours	1MO	1 month (30 days)
20M	20 minutes	12H	12 hours	2MO	2 months
30M	30 minutes	18H	18 hours	3МО	3 months
45M	45 minutes	24H	24 hours		
90M	90 minutes	72H	72 hours		
1H	1 hour	1D	1 day		
2Н	2 hours	2D	2 days		
2.5H	2½ hours	3D	3 days		
3Н	3 hours	4D	4 days		
4H	4 hours	5D	5 days		
5H	5 hours	6D	6 days		
6Н	6 hours	1W	1 week		

2.4.1Time Aspect Modifier

The second and optional subpart of the time component allows an indication of some subselection 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 9.

Table 9: Time Aspect Modifier Codes				
Time	Definition			
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 the their test names. Chemical tests commonly distinguish between serum, urine, blood, and cerebrospinal fluid. Microbiology cultures tend to distinguish between greater numbers of sources.

The first part of the system field should be coded using the abbreviations listed in Table 10. Since this list was defined for reporting sample type in a field of the HL7/ASTM message that is quite independent of the test/measure name, we do not imply that all such types will find their way into distinct LOINC names. However, when a distinction by type of system *is* required in the name, it should be represented by one of these codes.

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

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

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

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

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

	Table 10: Example Laboratory System/Sample Type Codes				
Abbr.	Name	Abbr.	Name	Abbr.	Name
ABS	Abscess	FIST	Fistula	SKN	Skin
AMN	Amniotic fluid	FLU	Body fluid, unsp	SKM	Skeletal muscle
AMNC	Amniotic fluid cells	FOOD	Food sample	SPRM	Spermatozoa
ANAL	Anus	GAS	Gas	SPT	Sputum
ASP	Aspirate	GAST	Gastric fluid/contents	SPTC	Sputum – coughed
BPH	Basophils	GEN	Genital	SPTT	Sputum - tracheal aspirate
BIFL	Bile fluid	GENC	Genital cervix	STON	Stone (use CALC)
BLDA	Blood arterial	GENF	Genital fluid	STL	Stool = Fecal
BBL	Blood bag	GENL	Genital lochia	SWT	Sweat
BLDC	Blood capillary	GENM	Genital Mucus	SNV	Synovial fluid (Joint fluid)
BLDCO	Blood – cord	GENV	Genital vaginal	TEAR	Tears
BLDMV	Blood- Mixed Venous	HAR	Hair	THRT	Throat
BLDP	Blood – peripheral	IHG	Inhaled Gas	THRB	Thrombocyte (platelet)
BPU	Blood product unit	IT	Intubation tube	TISS	Tissue, unspecified
BLDV	Blood venous	ISLT	Isolate	TISG	Tissue gall bladder
BLD.DOT	Blood filter paper	LAM	Lamella	TLGI	Tissue large intestine
BONE	Bone	WBC	Leukocytes	TLNG	Tissue lung
BRAIN	Brain	LN	Line	TISPL	Tissue placenta
BRTH	Breath (use EXG)	LNA	Line arterial	TSMI	Tissue small intestine
BRO	Bronchial	LNV	Line venous	TISU	Tissue ulcer
BRN	Burn	LIQ	Liquid NOS	TRAC	Trachea
CALC	Calculus (=Stone)	LIVER	Liver	TUB	Tube, unspecified
CDM	Cardiac muscle	LYM	Lymphocytes	ULC	Ulcer
CNL	Cannula	MAC	Macrophages	UMB	Umbilical blood
CTP	Catheter tip	MAR	Marrow (bone)	UMED	Unknown medicine
CSF	Cerebral spinal fluid	MEC	Meconium	URTH	Urethra
CVM	Cervical mucus	MBLD	Menstrual blood	UR	Urine
CVX	Cervix	MLK	Milk	URC	Urine clean catch
COL	Colostrum	MILK	Breast milk	URT	Urine catheter
CNJT	Conjunctiva	NAIL	Nail	URNS	Urine sediment
CUR	Curettage	NOSE	Nose (nasal passage)	USUB	Unknown substance
CRN	Cornea	ORH	Other	VITF	Vitreous Fluid
CYST	Cyst	PAFL	Pancreatic fluid	VOM	Vomitus
DENTIN	Dentin	PAT	Patient	BLD	Whole blood
DIAFP	Peritoneal Dialysis fluid	PEN	Penis	BDY	Whole body
DIAF	Dialysis fluid PCAR Pericardial Fluid		Pericardial Fluid	WAT	Water
DOSE	Dose med or substance PRT Peritoneal fluid /ascites		Peritoneal fluid /ascites	WICK	Wick
DRN	Drain PLC Placenta		WND	Wound	
DUFL	Duodenal fluid	PLAS	Plasma	WNDA	Wound abscess
EAR	Ear	PLB	Plasma bag	WNDE	Wound exudate
EARW	Ear wax (cerumen)	PLR	Pleural fluid (thoracentesis fld)	WNDD	Wound drainage
ELT	Electrode	PMN	Polymorphonuclear neutrophils	XXX	To be specified in another
ENDC	Endocardium	PPP	Platelet poor plasma		part of the message
ENDM	Endometrium	PRP	Platelet rich plasma		
EOS	Eosinophils	PUS	Pus		
RBC	Erythrocytes	SAL	Saliva		
EYE	Eye	SMN	Seminal fluid		
EXG	Exhaled gas (=breath)	SMPLS	Seminal plasma		
FIB	Fibroblasts	SER	Serum		
FLT	Filter				

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

2.5.1 Super system (2nd subpart)

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

Table 11: Super System			
CONTROL	Control		
DONOR	Donor		
BPU	Blood Product Unit (Pack)		
FETUS	Fetus		
POPULATION DISTRIBUTION	Population Distribution		
NEWBORN	Newborn		

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:ON:COAG
```

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

A AG:ACNC:PT:RBC:ORD A AG:ACNC:PT:RBC^BPU:ORD

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

2.6 Type of Scale (5th part)

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

		Table 12: Type of Scale
Type of	Abbr.	Description
Scale		
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", ">
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 either resistant, intermediate, susceptible or as the mm diameter of the inhibition zone. (Previously named SQN) We discourage the use of ORDQN.
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, e.g. 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	Used for clinical documentation
Set	SET	Used for clinical attachments

Quantitative (QN) identifies scales that can be tied to some physical quantity through a linear equation. This means that if we have two reports for the same quantity one with a value of 5 and the other a value of 10 we know that the two are related in amount through the linear equation Y = aX +b. When the intercept, b, is non-zero, we have a difference scale. (Fahrenheit temperature is a difference scale.) When it is zero we have a ratio scale (Kelvin temperature is a ratio scale). A QN value may be reported as a value for a "continuous" scale, as is the case for serum sodium, or it may be reported from a series of discrete values, as is the case for titers, e.g. 1:16, 1:32.

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

<u>Quantitative/Ordinal (ORDQN)</u>: 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.

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.

Narrative (NAR): Some observations are reported as free text narrative. The content is not drawn

from a formal vocabulary or code system. A dictated present illness would be an example of a scale of narrative (NAR). Many clinical LOINC codes will come in two versions: one for the nominal (coded) version and one for a narrative (free text) version.

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

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

2.7 Type of Method (6th part)

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

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

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

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

Table 13: Method Abbreviations						
Method	Method Abbr. Comment					
AGGLUTINATION	AGGL					
COAGULATION ASSAY	COAG	To distinguish coagulation assays based on clotting methods				
COMPLEMENT FIXATION	CF					
COMPUTERIZED TOMOGRAPHY	CT					
CYTOLOGY STAIN	CYTOSTAIN	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.				
ENZYMATIC ASSAY	ENZY	To distinguish coagulation assays based on enzymatic activity.				
ENZYME IMMUNOASSAY	EIA	Subsumes variants such as ELISA				
FLOCCULATION ASSAY	FLOC					
FLOW CYTOMETRY	FC					
HEMAGGLUTINATION INHIBITION	HAI					
INDIRECT HEMAGGLUTINATION	IHA					
IMMUNE BLOT	IB					
IMMUNE FLUORESCENCE	IF	Encompasses DFA, FA				
LATEX AGGLUTINATION	LA					
LEUKOCYTE HISTAMINE RELEASE	LHR					
MINIMUM INHIBITORY	MIC	Antibiotic susceptibilities				
CONCENTRATION	, a a					
MINIMUM LETHAL CONCENTRATION	MLC	Also called MBC (minimum bactericidal concentration)				
MOLECULAR GENETICS	MOLGEN	General class of methods used to detect genetic attributes on a				
WIGELEGEAR GENETICS	WOLGEN	molecular basis including RFL, PCR and other methods.				
NEUTRALIZATION	NEUT	more and one more meaning in 2,7 or and one meaning.				
RADIOIMMUNOASSAY	RIA					
SERUM BACTERICIDAL TITER	SBT	Determines the serum dilution that is capable of killing microorganisms.				
ULTRASOUND	US					
VISUAL COUNT	VC					

2.7.1 DNA/RNA probes/measures

We distinguish three kinds of DNA probe methods.

- 1. Probe without amplification (PROBE)
- 2. Probe with target amplification (PROBE.AMP.TAR)

See Table 14A for a list of methods that would be identified as PROBE.AMP.TAR in a LOINC method

3. Probe with signal amplification (PROBE.AMP.SIG)

See Table 14B for a list of methods that would be identified as PROBE.AMP.SIG in the method part of the LOINC term.

	Table 14A: Examples of specific methods that would be classed as					
	target amplified DNA/RNA methods (not an exhaustive list)					
PROBE.AMP.TA	AR (includes nucleic acid target amplification and pro	be)				
PCR	Polymerase Chain Reaction	Applies to: DNA, RNA				
		Roche Molecular Systems (thermal cycler)				
		Requires repeated cycles of heating and				
		cooling - each cycle doubles the target				
TMA	Transcription Mediated Amplification	Applies to DNA, RNA				
		Gen-Probe, Inc. (isothermal)				
NASBA	Nucleic Acid Sequence Based Analysis	Applies to RNA, DNA				
		Organon-Tenika Corp (isothermal)				
SDA	Strand Displacement Amplification	Applies to DNA				
		Becton Dickinson (isothermal)				
LAT	Ligation-Activated Transcription					
3SR SR	3 Self-Sustaining Sequence Replication	Applies to RNA, DNA				
		Bartel's Diagnostic (isothermal)				
LCR	Ligase Chain Reaction	Also probe amplification category method				
		Abbott Laboratories (thermal cycler)				
QBR Q-Beta Replicase or probe amplification category		Applies to DNA RNA				
	method	Gene Track Systems. (isothermal)				
Table 14B: F	Examples of specific methods that would be defined in	LOINC as signal amplification methods				
	G (includes nucleic acid signal amplification and prob					
	(
HPA	Hybridization Protection Assay	Applies to RNA				
	•	Gen-Probe Accuprobe				
BdnA	Branched Chain DNA	Applies to DNA, RNA				
		Chiron Corp (isothermal)				
	Hybrid Capture	Applies to				

2.7.2 Immune fluorescence (IF)

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

2.7.3 Immune Stain

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

2.7.4 Enzyme Immune Assay (EIA)

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

2.7.5 Coagulation

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

2.7.6 Stains

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

2.7.7 Clinical measures

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

2.7.8 Imaging studies

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

2.8 Short convenient names

As of the August 2002 release of the LOINC users guide and database we have included a new field in the LOINC database called "SHORTNAME". This field will carry a short, mixed case name for the LOINC concept. We have populated these fields for all laboratory tests, with the exception of the challenge terms that contain too much information to be shortened. Our goal was to produce names no longer than 30 characters in order to fit within the space allocated by most laboratory reporting systems. We strongly suggest including the LOINC short name as the print name for the LOINC code sent in the 2nd component of the HL7 CE data type. In contrast to the formal LOINC name case *is* significant in the LOINC short name. When possible, we have used common acronyms and common names rather than the more formal name rules of the full LOINC name. For example, we used the English names of allergens in the short names rather than the formal Latin species names (in part because they were shorter). The LOINC short names are subject to change in future releases and should not be used as identifying keys in any database.

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

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		0
Finding 3 =	Present		1
Finding 4 =	Absent		0
Finding $5 =$	Absent		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:

<u>Test Name</u>		<u>Value</u>
Escherichia coli	absent	
Staphylococcus aureus		present
Diphtheroids		absent
Streptococcus pneumon	iae	absent
Pseudomonas		present

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

Test Name	<u>Values</u>
Blood culture	Pseudomonas, S. aureus

We bring up these issues to explain why we use a somewhat different data format for some types of tests, and why we sometimes provide for both reporting methods (e.g. HLA blood cell antigen tests) in the LOINC database. When a binary scale is used, the kind of property will usually be arbitrary concentration (ACNC) and the scale ordinal (ORD). 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. ¹⁹ In addition to the antigen or antibody, a modifier would be included in the super-system (the second subfield of the fourth field, system), to indicate whether testing was performed on the patient, donor, or blood pack. Unless explicitly stated, testing is assumed to have been on a material collected from a patient. Additional information about the person identified in the fourth subpart, such as the donor's name or relationship to patient, should be placed in other OBX segments, or comment segments of the message, and would *not* be part of the test name.

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

3.2.1 Panel reporting:

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

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

Measure of serum antibody against type A blood of donor:

A AB:ACNC:PT:SER/PLAS^DONOR:ORD:AGGL RBC

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

A AG:ACNC:PT:RBC^DONOR:ORD:AGGL RBC

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

A AG:ACNC:PT:RBC^BPU:ORD:AGGL RBC

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:BBL:NOM

3.3 Immunocompetence studies (flow cytometry)

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

Two kinds of measures are of interest.

1. The "absolute" number of such cells per cubic millimeter is represented as number concentrations, e.g.:

CELLS.CD16C+CD56+:NCNC:PT:BLD:QN

2. Percent of cells containing the named marker per 100 cells of that type is represented as number fraction, e.g.:

CELLS:CD16C+CD56+/100 CELLS:NFR:PT:BLD:QN

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

Example:

HLA-A1:ACNC:PT:BLD:ORD

3.4 General approach to microbiology results

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

<u>Result Status</u> (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.

<u>Specimen Type</u> (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.

<u>Details of specimen collection</u> 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

DESCRIPTION, IND. 1. ... NOW and the Observation Results fields of the ObA segment

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.)

<u>Descriptions of measurement and culture growth</u> 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

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

MICROSCOPIC OBSERVATION:PRID:PT:XXX:NOM:GRAM STAIN

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

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

The organisms identified in a culture will be sent as result values in OBX segments. A separate table of allowable organism names and/or codes is necessary if these are to be sent as understated results. Euzéby's list of bacterial names²⁰ or some other authoritative source (SNOMED is an appropriate source for these organism concepts) may be used as the standard. While "Throat Culture" is the source of the culture inoculum, it is also a label that indicates what kind of media was inoculated and the other techniques used in the laboratory. So, it is a short hand for a kind of method and such will be recorded as the method part of the name. Thus, "Throat Culture", "Blood Culture", and "Clostridium difficile Culture" all represent labels for how a culture was performed. Examples of names of culture results are:

MICROORGANISM IDENTIFIED:PRID:PT:BLD:NOM:BLOOD CULTURE MICROORGANISM IDENTIFIED:PRID:PT:BRN:NOM:DIRECT BURN CULTURE MICROORGANISM IDENTIFIED:PRID:PT:STL:NOM:STOOL CULTURE

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

MICROSCOPIC OBSERVATION:PRID:PT:XXX:NOM:GRAM STAIN
MICROSCOPIC OBSERVATION:PRID:PT:XXX:NOM:DRY MOUNT
MICROSCOPIC OBSERVATION:PRID:PT:XXX:NOM:INDIA INK PREPARATION
MICROSCOPIC OBSERVATION:PRID:PT:XXX:NOM:TRICHROME STAIN
MICROSCOPIC OBSERVATION:PRID:PT:XXX:NOM:GIEMSA STAIN

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

MICROORGANISM IDENTIFIED:PRID:PT:ISLT:NOM:FUNGAL SUBTYPING

Names for organism-specific cultures:

BRUCELLA SP IDENTIFIED:PRID:PT:BLD:NOM:ORGANISM SPECIFIC CULTURE BORDETELLA PERTUSSIS:ACNC:PT:THRT:ORD:ORGANISM SPECIFIC CULTURE CHLAMYDIA SP IDENTIFIED:PRID:PT:GEN:NOM:ORGANISM SPECIFIC CULTURE LEGIONELLA SP IDENTIFIED:PRID:PT:SPT: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:WND:NOM:ROUTINE FUNGAL CULTURE MICROORGANISM IDENTIFIED:PRID:PT:CSF:NOM:STERILE BODY FLUID CULTURE

Again, the Result Value of these tests would be either organism names or other statements of culture outcome. Table 15 contains valid values of the culture result OBX segment:

Table 15: Example Culture Results

No growth

Gram-positive cocci

Small Gram negative rod

Escherichia coli

Normal flora

Candida albicans

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 ACNC and the scale ordinal (ORD).

3.5 Antimicrobial susceptibilities

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

Antimicrobial susceptibility tests are named according to the generic name of the drug tested and the methodology used in testing, with the property SUSC, with values that are QN, ORD or ORDQN. Thus, appropriate names would be:

AMPICILLIN:SUSC:PT:ISLT:ORDQN:MIC
AMPICILLIN:SUSC:PT:ISLT:ORDQN:AGAR DIFFUSION

TICARCILLIN+CLAVULANATE:SUSC:PT:ISLT:QN:MLC

Table 16 lists methods in drug-susceptibility tests.

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

Methodless codes also exist for each antimicrobial agent.

3.6 Cell counts

Quantitative counts of various entities and cells in blood, urine, CSF, and other body fluids may be performed and reported in one of three ways. Cell counts in blood are often reported as absolute counts per unit volume (property NCNC), or percents of a general cell type, e.g. percent eosinophils, (property 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). E.g. the number of erythrocytes casts per low power field would be reported as:

ERYTHROCYTE CASTS:NARIC:PT:URNS:QN:MICROSCOPY.LIGHT.LPF

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

One other way such entities are reported is as a pure ordinal, e.g. none, few, moderate, loaded. These would be specified as ACNC properties with ordinal scale, e.g.

ERYTHROCYTES:ACNC:PT:SMN: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:LEN:PT:SKN:QN

Where TU means tuberculin units, ID means intradermal, LEN indicates a measure of length (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:

HPLC, EIA, TLC, RIA, GC, and GCMS (rarely) are used for screening.

GCMS, LCMS, GC, and HPLC are used for confirmation.

HPLC	high pressure liquid chromatography
TLC	thin layer chromatography
GC	gas chromatography
EIA	enzyme immune assay
RIA	radioimmune assay
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:

a) Screen for a group of drugs/ toxic substances

```
"X":ACNC:PT:ORD:SYS:SCREEN for the group as a whole (answer = present/absent)

e.g. AMPHETAMINES:ACNC:PT:ORD:UR:SCREEN example answer: "present"
```

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

"X" TESTED FOR:PRID:PT:SYS:NOM:SCREEN

(answers = individual drugs that this screening test could detect, from a fixed list)

- e.g. AMPHETAMINES TESTED FOR:PRID:PT:NOM:UR:SCREEN (nominal) example answer = "amphetamine, methamphetamine, dextroamphetamine, levoamphetamine, pseudoephedrine"
- c) Identify the drugs substances screened for (and perhaps other information). The answer will be a "glob" of narrative text.

"X" TESTED FOR:PRID:PT:SYS:NAR:SCREEN

(answers = individual drugs that this screening test could detect, as a "blob" of text or canned comment)

e.g. AMPHETAMINES TESTED FOR:PRID:PT:NAR:UR:SCREEN (narrative) example answer = "The EMIT urine screen for amphetamines detects amphetamine, methamphetamine, dextroamphetamine, levoamphetamine as indications of methamphetamine abuse. It is also reactive with a component present in over-the-counter nasal decongestant inhalers, and a positive result must be confirmed by a quantitative method that rules out the non-abuse situation"

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

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

"X":ACNC:PT:SYS:ORD:CONFIRM (answers = present/absent)

e.g. AMPHETAMINES:ACNC:PT:UR:ORD:CONFIRM example answer: "present"

e) List of the actual drug/substances confirmed.

"X" POSITIVE:PRID:PT:SYS:NOM:CONFIRM (answers = list of analytes detected)

e.g. AMPHETAMINES POSITIVE:PRID:PT:UR:NOM:CONFIRM example answer: "dextroamphetamine, methamphetamine"

- f) More commonly, confirmatory testing is reported as a set of observations, one to report the presence (or quantitative amount detected) of each analyte in the group.
- g) "X":ACNC:PT:SYS:ORD:CONFIRM
 (answers = present/absent)
 or
 "X":MCNC:PT:SYS:QN:CONFIRM
 (answers = quantitative amount)

e.g.

AMPHETAMINE:ACNC:PT:UR:ORD:CONFIRM [present]
DEXTROAMPHETAMINE:ACNC:PT:UR:ORD:CONFIRM [present]
METHAMPHETAMINE:ACNC:PT:UR:ORD:CONFIRM [present]
LEVOMETHAMPHETAMINE:ACNC:PT:UR:ORD:CONFIRM [present]
PSEUDOEPHEDRINE:ACNC:PT:UR:ORD:CONFIRM [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.

(a) We provide separate LOINC terms for reporting the cutoff levels of a number of commonly abused substances and substance groups.

"X" CUTOFF:MCNC:PT:UR:QN:SCREEN "X" CUTOFF:MCNC:PT:UR:QN:CONFIRM

e.g. AMPHETAMINES CUTOFF:MCNC:PT:UR:QN:SCREEN example answer: "1000 ng/ml" e.g. METHAMPHETAMINE CUTOFF:MCNC:PT:UR:QN:CONFIRM example answer: "500 ng/ml"

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

XXX CUTOFF:MCNC:PT:SYS:QN:SCREEN XXX CUTOFF:MCNC:PT:SYS:QN:CONFIRM

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

"X":ACNC:PT:SYS:ORD:SCREEN>"N"
"X":ACNC:PT:SYS:ORD:CONFIRM>"N"

e.g. AMPHETAMINES:ACNC:PT:UR:ORD:SCREEN>1000 NG/ML example answer: "not detected"

3.8.3 Reporting the method used for screen and confirm

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

"X" SCREEN METHOD:PRID:PT:SYS:NOM:*
"X: CONFIRM METHOD:PRID:PT:SYS:NOM:*

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

AMPHETAMINES:ACNC:PT:ORD:UR:SCREEN [answer = positive]
AMPHETAMINES CUTOFF:MCNC:PT:QN:UR:SCREEN [answer = 1000 ng/ml]
AMPHETAMINES SCREEN METHOD:PRID:PT:UR:NOM [answer = EIA]
AMPHETAMINES POSITIVE:PRID:PT:UR:NOM:CONFIRM [answer = amphetamine, methamphetamine]
AMPHETAMINE CUTOFF:MCNC:PT:UR:QN:CONFIRM [answer = 500 ng/ml]
METHAMPHETAMINE CUTOFF:MCNC:PT:UR:QN:CONFIRM [answer = 500 ng/ml]
AMPHETAMINES CONFIRM METHOD:PRID:PT:UR:NOM:* [answer = GC/MS]

3.8.4 Individual drug/metabolite test results

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

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

a) Individual test screen (ordinal)

METHAMPHETAMINE:ACNC:PT:UR:ORD:SCREEN example answer: "present"

b) Individual test confirm (ordinal)

METHAMPHETAMINE:ACNC:PT:UR:ORD:CONFIRM example answer: "present"

c) Individual test confirm (quantitative)

METHAMPHETAMINE:MCNC:PT:UR: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.

d) 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, 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":ACNC:PT:UR:ORD:SCREEN

"analyte group":ACNC:PT:UR:ORD:CONFIRM

"analyte group":MCNC:PT:UR:QN:CONFIRM

"analyte group" TESTED FOR:PRID:PT:UR:NOM:SCREEN

"analyte group" TESTED FOR:PRID:PT:UR:NAR:SCREEN

"analyte group" POSITIVE:PRID:PT:UR:NOM:CONFIRM

"analyte group" SCREEN METHOD:PRID:PT:UR:NOM:*

"analyte group" CONFIRM METHOD:PRID:PT:UR:NOM:*
```

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

ANALYTE:ACNC:PT:UR:ORD:SCREEN
ANALYTE:ACNC:PT:UR:ORD:CONFIRM
ANALYTE:MCNC:PT:UR:QN:CONFIRM
ANALYTE:MCNC:PT:UR:QN
ANALYTE CUTOFF:MCNC:PT:UR:QN:SCREEN
ANALYTE CUTOFF:MCNC:PT:UR: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.

3.9.2 Terminology

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

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

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

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

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

Forensic testing has special requirements of stringency and often mixes blood antigen testing with RFLP testing. The results are usually reported as a probability.²¹

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

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

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

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

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

Defects in genes can be coded in one of three different nomenclatures as described in Table 17.

Table	Table 17 – Three types of nomenclatures for identifying the location of a genetic defect.			
Designation	Explanation			
р	Identify the defect by codon by counting the amino acids in the protein produced by the gene counting the first amino acid.			
c	Identify the defect by counting nucleotides from the messenger RNA used to produce the protein			

	with intron excluded. These will produce numbers 3x as large as those in the first method.
g	Identify the defect by counting from the first nucleotide in the DNA as it exists as a gene natively in the chromosome with introns included.

3.9.3 General Molecular genetic naming rules

When possible, the LOINC component of a molecular pathologic mutation will be named according to the gene name *and* information about the particular defect (e.g. deleted alanine from position 47). LOINC will resort to the use of the disease name only when the gene has no name and/or the genetic defect is not yet fully specified. We will always include the genetic disease name in the related name field of the database, when the disease is not part of the component; so that users of the database can easily find the LOINC term by the disease name as well.

We use the nomenclature for human gene mutations proposed by Beaudet²² in the component (when the mutation name belongs in the test name) or as an answer when it belongs as an answer. This nomenclature system recommends that missense mutations be named using single letter amino acid (p-notated - not nucleotide) abbreviations. A list of single letter amino acid codes is given in Table 18.

Table 18 – List of single letter amino acid codes					
Amino Acid	Code	Amino Acid	Code		
Alanine	A	Leucine	L		
Arginine	R	Lysine	K		
Asparagine	N	Methionine	M		
Aspartic acid	D	Phenylalanine	F		
Cysteine	C	Proline	P		
Glutamic acid	E	Serine	S		
Glutamine	Q	Threonine	T		
Glycine	G	Tryptophan	W		
Histidine	Н	Tyrosine	Y		
Isoleucine	I	Valine	V		

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 will split this further to accommodate fetal specimens in a later release.

We did not create separate variables for each kind of molecular genetic method, i.e. we will not make up separate variables for measurements done via Southern Blot, PCR, restriction fragment length polymorphism (RFLP) because different methods are only used when they provide the same answer, and the difference is rarely important. Further, a plethora of method variants exists, and we could never hope to keep up with all of these minor variants. Instead, we will use the generic method of MOLGEN (for molecular genetic method) to indicate that a result of the analysis is based on a molecular genetic method rather than some chemical or antigen method.

3.9.4 Infectious Diseases

For most infections disease reporting, the existing LOINC nomenclature (e.g. detecting a particular species of organism by detecting DNA homology) works fine. The word DNA is included as part of the component name and we distinguish the type of method used for detecting the microorganisms (PROBE, PROBE, AMP, TAR, PROBE, AMP, SIG). See the Microbiology

section for more information.

3.9.5 Genetic Diseases

3.9.5.1 DNA diagnostic assays for the detection of specific disease gene mutations.

In most of these cases we require the gene name, the specification of the nomenclature (e.g. p, g, or, c) and the mutation name. A LOINC term that identifies a specific mutation will start with the gene name followed by the specification of the mutation in that mutation using Beaudet's²² syntax. A dot will separate the gene name and the mutation identifier. In general, the form of the component (first part) of the LOINC name will be:

<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 18) at codon #506.

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

F5 GENE.P.R506Q:ARB:PT:BLD/TISS:ORD:MOLGEN
Synonyms = Factor V Leiden, Factor V resistance, APC resistance gene

HFE GENE.P.C282Y:ARB:PT:BLD/TISS:ORD:MOLGEN Synonyms = HLA-H gene, hemochromatosis gene

CFTR GENE.P. F508 DEL :ARB:PT:BLD/TISS:ORD:MOLGEN Synonyms = Cystic Fibrosis Transmembrane Regulator

The scale used for LOINC codes of this type is ORD. Test procedures that identify single mutations use 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". 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
- 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.

3.9.5.2 DNA diagnostic assays for the detection of multiple disease gene mutations (alleles).

Multiple testing can be reported in 4 styles: a single observation for each pair, two separate observations, gene mutation analysis and narrative.

3.9.5.2.1 A separate observation for each pair of genes

This style of reporting is identical to the style used in 3.9.5.1 with each tested mutation having a separate LOINC code. For example:

HFE GENE.P.C282Y:ARB:PT:BLD/TISS:ORD:MOLGEN

HFE GENE.P.H63D:ARB:PT:BLD/TISS:ORD:MOLGEN

3.9.5.2.2 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 = E1, E2, E3, or E4

APOE GENE ALLELE 2:PRID:PT:BLD/TISS:NOM:MOLGEN

Answers = E1, E2, E3, or E4

3.9.5.2.3 Gene Mutation Analysis

This is really an extension of the above case. The general name is <genetic disease> mutation analysis: PRID:PT:BLD/TISS:NOM:MOLGEN. The answers are the names of the genes detected. Examples follow:

CFTR MUTATION ANALYSIS:PRID:PT:BLD/TISS:NOM:MOLGEN Synonyms = Cystic fibrosis transmembrane regulator

BRCA1 MUTATION ANALYSIS: PRID:PT:BLD/TISS:MOLGEN Synonyms = breast cancer risk gene

Answers for these could be "Identifiable Mutation" "Not Identifiable Mutation"

With this type of reporting, a separate observation is usually required to report what alleles or mutations were tested for, so that the person receiving the report will know how to interpret a negative report. In this style of reporting, we may use the disorder name to identify the domain of interest because it covers more than one mutation. The report provides information about multiple possible mutations.

The general form will be <allele class or disease name> TESTED FOR: PRID:PT:BLD/TISS:NOM:MOLGEN.

For example:

CFTR MUTATIONS TESTED FOR: PRID:PT;BLD/TISS:NOM:MOLGEN

The answers could include "Delta F508", "G542X", "R553X", "W1282X", "N1303K", etc.

3.9.5.2.3 Narrative report

In this case, the information is provided as a bulk narrative report like a visit note and without computer accessible structure. We discourage the use of this approach because it is not useful for automatic analysis.

3.9.6 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 name> <trinucleotide> repeats

For example, Huntington disease would be represented as HD GENE.CAG REPEATS

Examples of some fully specified LOINC names are:

FRAXE GENE.CGG REPEATS:ARB:PT:BLD/TISS:ORD:MOLGEN Synonym = Fragile x syndrome

HD GENE.CAG REPEATS:ARB:PT:BLD/TISS:ORD:MOLGEN
Synonym = Huntington Disease, It15, Hd, Huntington Chorea

SPINOCEREBELLAR ATAXIA GENES.CAG REPEATS: ARB:PT:BLD/TISS:ORD:MOLGEN

DMPK GENE.CTG REPEATS:ARB:PT:BLD/TISS:ORD:MOLGEN Synonym = Myotonic Dystrophy

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

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

3.9.7 Hematopathology gene re-arrangement.

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

IMMUNOGLOBULIN HEAVY CHAIN GENE REARRANGEMENTS: ARB:PT:BLD/TISS:ORD:MOLGEN

IMMUNOGLOBULIN KAPPA LIGHT CHAIN GENE REARRANGEMENTS: ARB:PT:BLD/TISS:ORD:MOLGEN

IMMUNOGLOBULIN LAMBDA LIGHT CHAIN GENE REARRANGEMENTS: ARB:PT:BLD/TISS:ORD:MOLGEN

- TCRB GENE REARRANGEMENTS:ARB :PT:BLD/TISS:ORD:MOLGEN Synonym = T cell receptor beta chain
- TCRD GENE REARRANGEMENTS:ARB :PT:BLD/TISS:ORD:MOLGEN Synonym = T cell receptor delta chain
- TCRG GENE REARRANGEMENTS:ARB :PT:BLD/TISS:ORD:MOLGEN Synonym = T cell receptor gamma chain

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

3.9.8 Translocations

Tests to detect gene-specific translocation breakpoints (with known "partner" genes) should be designated as follows:

T(
breakpoint gene 1>,
breakpoint gene 2>)(<gene1>,<gene2>):gene translocation

For example:

- T(9,22) (ABL1,BCR) GENE TRANSLOCATION:ARB:PT:BLD/TISS:ORD:MOLGEN Synonyms = Philadelphia chromosome, BCR1, chronic myeloid leukemia, CML
- T(14,18) (IGH,BCL2) GENE TRANSLOCATION: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) (PML,RAR) GENE TRANSLOCATION:ARB:PT:BLD/TISS:ORD:MOLGEN Synonyms = RAR, promyelocytic leukemia, myelogenous, retinoic acid receptor, acute promyelocytic leukemia, APL

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

CELLS.T(9,22).(ABL1,BCR)/CELLS TOTAL:NRF:PT:BLD/TISS:QN:MOLGEN

If specific partner genes are not known, use:

BCL1 GENE REARRANGEMENTS:ARB:PT:BLD/TISS:ORD:MOLGEN Synonyms = Lymphoma 1

BCL2 GENE REARRANGEMENTS:ARB:PT:BLD/TISS:ORD:MOLGEN Synonyms = Lymphoma 2

The specificity for "major" or "minor" breakpoints should also be designated:

T(9,22) (ABL1,BCR) GENE TRANSLOCATION MAJOR BREAK POINTS: ARB:PT:BLD/TISS:ORD:MOLGEN

T(9,22) (ABL1,BCR) GENE TRANSLOCATION MINOR BREAK POINTS: ARB:PT:BLD/TISS:ORDMOLGEN

3.9.9 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: anatomic and pre-coordinated definitions

3.9.9.1 Atomic style

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

DNA probes used:PRID:PT:Index case^comparison case:NOM: MOLGEN.IDENTITY.TESTING

Population base:PRID:PT:Probes:NOM: MOLGEN.IDENTITY.TESTING

Relationship:TYPE:PT:index case:NOM: MOLGEN.IDENTITY.TESTING Answers = child, victim, suspect

Relationship:TYPE:PT:^comparison case:NOM: MOLGEN.IDENTITY.TESTING
Answers = mother, alleged mother, father, alleged father, evidence
(external to victim)

Confidence of relationship:likelihood:PT:Index case^comparison case:QN: MOLGEN.IDENTITY.TESTING

(this gives the statistical confidence in the conclusion)

Conclusion:IMP:PT:index case ^comparison case:NAR: MOLGEN.IDENTITY.TESTING (this gives summary statement of the conclusion about identity of relatedness)

3.9.9.2 Pre-coordinated definitions alternative

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

- Relationship:likelihood: child^alleged mother:QN: MOLGEN.IDENTITY.TESTING
 Synonyms:= maternity testing
 (gives the likelihood that the alleged mother is the mother of the index child)
- Relationship:likelihood:child^alleged father: MOLGEN.IDENTITY.TESTING
 Synonyms:= paternity testing
 (gives the likelihood that the alleged father is the father of the index child)
- Relationship:likelihood: victim^suspect:QN:MOLGEN.IDENTITY.TESTING (gives the likelihood that the either the genetic material on the victim is that of the suspect)
- Relationship:likelihood: suspect^victim:QN:MOLGEN.IDENTITY.TESTING (gives the likelihood that the genetic material on the suspect is that of the victim)
- Identity:likelihood:Evidence^suspect:QN:MOLGEN.IDENTITY.TESTING (gives the likelihood that the genetic material on the evidence is that of the suspect)
- Identity:likelihood:evidence^victim:QN:MOLGEN.IDENTITY.TESTING (gives the likelihood that the genetic material on the evidence is that of the victim)

3.9.10 Tumor Relation Tumor Genetics

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

N-Myc gene amplification: ENTNUM:PT:BLD/TISS:QN:ORD:MOLGEN

N-Myc gene amplification: ARBENT:PT:BLD/TISS:ORD:MOLGEN Answers = Non-amplified, indeterminant, amplified

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

gene loss

p gene loss:ARB:PT:tumor:ORD:MOLGEN

Answer: gene loss, no gene loss

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

3.11 Allergy Testing

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

For LOINC terms that represent allergen testing, the component is the allergen name plus the type of the antibody (mostly IgE). Most allergens relate to animals, plants or derivatives of such entities. In the past (prior to LOINC vs. 2.04), we used the common name, rather than the scientific name to identify the allergen. However, this approach led to some duplicate term definitions, because two different companies would name the same allergen differently. It also led to ambiguity because two different species of animal or plant would some times 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 Pharmacia²³ that most allergy testing companies reference in their catalogue of testing. We used these codes to identify duplicate and ambiguous LOINC allergy test terms. These Pharmacia codes are also included in the related names field of the database. Second, allergen tests are often reported in two styles: a quantitative raw measure and an ordinal (0-6) severity rank (RAST class). LOINC defines separate terms for each of these reporting styles. For example, the two LOINC codes for reporting IgE antibodies to Japanese Millet are:

ECHINOCHLOA CRUS-GALLI AB.IGE:ACNC:PT:SER:QN ECHINOCHLOA CRUS-GALLI AB.IGE.RAST CLASS:ACNC:PT:SER:ORD

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

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

(ACER NEGUNDO+QUERCUS ALBA+ULMUS AMERICANA+POPULUS DELTOIDES+CARYA PECAN) AB.IGE:ACNC:PT:SER:ORD:MULTIDISK Related name = tx2

There may be more then 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 = Cultivated corn;maize;f8 ZEA MAYS POLLEN AB.IGE:ACNC:PT:SER:QN Related names: Cultivated corn;maize;g202

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. E.g. 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 (3rd part) of the name.

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

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

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

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

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

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

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

Table 19 Subjects covered to date in clinical LOINC

Blood pressure (systolic, diastolic, and mean)

Body height

Body temperature

Body weight (and measures used to estimate ideal body weight)

Cardiac ultrasound (echo) imaging

Cardiac output, resistance, stroke work, ejection fraction, etc.

Circumference of chest, thigh, legs

Critical care measures

Dental

Electrocardiographic measures

Emergency department case reports – CDC DEEDS

Gastrointestinal endoscopy

Heart rate (and character of the pulse wave)

Intake and output

Major headings in operative note

Major headings of 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 is a special case of PRID that identifies anatomic sites.

IMP (impression) is a diagnostic statement, always an interpretation or abstraction of some other observation (a series of test results, an image, or a total patient), and almost always generated by a professional. (We could also consider the EKG cart's automated diagnoses as impressions.) Impressions are used in laboratory

medicine as well as clinical medicine, so you will see them appearing there as well.

FIND Finding is an atomic clinical observation, not a summary statement as an impression. Physical, historical, review of systems and other such observations have a property of Finding. These may have a scale of NOM for coded findings or NAR for findings reported in narrative text.

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 oddball kinds of circumferences for which we have not yet defined a pre-coordinated term.

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 commonest 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.

5 Tumor registry

In collaboration with North American Association of Central Cancer Registries (NAACCR), 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. These are identified by the class TUMRREG.

More detailed guide for implementing these LOINC tumor registry variables within an HL7 message is being developed by NAACCR and collaborators.

6 Claims attachments

See specific RELMA tasks, HIPAA ATTACHMENTS and the respective Claims Attachment books for further details.

7 HL7 LOINC Document Type Vocabulary Domain

This document proposes a set of document type codes. It represents a continuation of Stan Huff and Pavla Frazier's work within LOINC and done by Stan Huff, Bob Dolin, Clem McDonald and representatives

7.1 Use of document type codes in HL7 messages

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

7.2 Relationship with other terminologies

Relationship with LOINC

This is work that has been developed by the LOINC committee and the HL7 document ontology task force. HL7 will use LOINC codes for clinical document codes. It will not develop an independent document code system for clinical documents. At its option, HL7 may choose to limit its domain to a subset of LOINC codes. HL7 can incorporate any LOINC document code into the HL7 domain.

The naming rules in this document only apply to "clinical notes." Within this document we are using the term "clinical note" to have a special meaning. For purposes of this document, a clinical note is a clinical document (as defined by the HL7 CDA Standard) where the documentThe model for what is called "Clinical documents" in this document applies only to documents that are was produced by clinical professionals and trainees either spontaneously (e.g. I write my admitting note) or in response to a request for consultation. These might better be named "Clinical Notes". They 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 are already well covered by existing terms within the LOINC database.

Relationship with HL7 V2.x values

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

- We provide a mapping from LOINC codes to HL7 V2.x document codes.
- The HL7 V3 domain may contain concepts that are not present in the V2.x tables.

Relationship to a reference terminology

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

7.3 **DocumentType components**

In the following synonymy or equivalent terms are designated by parenthesis. Document codes are defined by their component parts:

Kind of Document

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

Allowed values for kind of document:²

- Clinical Note (AKA "Clinical Document"). Documents generated by clinicians as part of patient care, which includes notes written at the initiative of "individual clinic and consulting clinicians." It does not include clinical reports such as, radiology, pathology, and cardiac cath reports that are usually stimulated by a particular order. Clinical documents meet five criteria, as defined in CDA 1.0: wholeness, stewardship, authentication, persistence, and human readability.
- Future work This document only describes the strategy and initial content for clinical documents. Several other document types will be the focus of work during the coming year:
 - Letters
 - Consents
 - Legal documents
 - o Reference documents

Type of Service

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

- Communication
- Evaluation and management
 - o Conference
 - Case conference
 - Consult
 - Confirmatory consultation
 - o Counseling
 - Group counseling
 - Education
 - History & Physical (H & P)
 - Admission history and physical (Admission H & P)
 - Comprehensive history and physical (Comprehensive H & P)
 - Targeted history and physical (Targeted H & P)
 - o Initial evaluation
 - Admission evaluation
 - Admission history and physical (Admission H & P)
 - o Pre-operative evaluation and management
 - Subsequent evaluation
 - Summarization of episode
 - Transfer summarization
 - Discharge summarization
 - Summary of death
 - Transfer of care referral

² The current proposal focuses on clinical notes. While "Consent", "Legal", and

[&]quot;Reference" are a matter for future work and will be further addressed at a later time.

- Supervisory direction
- Telephone encounter
- Interventional Procedure
 - Operative
- Pathology Procedure
 - o Autopsy

Setting

Setting is a modest extension of CMS's (AKA HCFA) coarse definition of settings, which have well defined meanings. Setting is not equivalent to location, which typically has more locally defined (and appropriately so) 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). The CMS settings are on the first level of the hierarchy and synonyms are included in parenthesis.

- Home
 - Assisted Living
 - Home Health Care
- Hospital (Inpatient) Setting
 - o Acute care hospital
 - Hospital Unit
 - Critical Care Unit
 - Emergency Department
 - Observation Ward
 - Rehabilitation hospital
- Nursing Home
 - Skilled Nursing Facility
- Outpatient (Office / Clinic)

Most clinical report names would include a setting (at least at the top level) to avoid confusion between important classes of reports. E.g., 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.

Subject Matter Domain

Characterizes the subject matter domain of a note.

- Anesthesia
- Cardiology
- Case Manager
- Chaplain
- Dentistry
- Diabetology
- Endocrinology
- Gastroenterology
- General Medicine
- General Surgery
- Gynecology
- Multidisciplinary
- Neurosurgery
- Obstetrics

- Oncology
- Ophthalmology (EYE)
- Optometry
- Orthopedics
- Otorhinolaryngology (ENT)
- Pathology
- Pharmacacy
- Physical Medicine
- Plastic Surgery
- Podiatry
- Psychiatry
- Pulmonary
- Thyroidology
- Tumor Board
- Urology
- Veterinary Medicine

Training / Professional Level

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

- Attending
- Case Manager
- Chaplain
- Dental Hygienist
- Dentist
- Fellow
- Intern
- Medical Student
- Nurse
- Nurse Practitioner
- Nursing Student
- Occupational Therapist
- Pharmacist
- Physician *
- Physician Assistant
- Physical Therapist
- Resident
- Respiratory Therapist
- Social Worker
- Sub-intern
- Veterinarian

7.4 Rules for Creating Clinical Notes from Multiple Components

Names for required clinical notes would be constructed by picking entries from at least one of the above four axis.

^{*} Physician subsumes medical physicians and osteopathic physicians.

The LOINC committee will create LOINC codes for all required combinations (not all possible combinations). The simple name would be ordered as follows:

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

(This will be another axis when we extend this document to other kinds of documents.)

Recall that at least one of the four axis and the word "note" is required to define a name. Sample names might be:

- Cardiology note
- Cardiology attending note
- Cardiology attending hospital admission note
- Cardiology nurse hospital admission note
- Cardiology fellow admission note
- Pulmonary note
- Consult note
- Nurse note
- Hospital admission H&P note

7.5 Future Work

We will develop equally specific definitive documents for other kinds of health case associated documents including the following used in the upcoming manual.

- [DRAFT] Legal Medico-legal documents such as advanced directives that are not generated by clinicians, but must be retained as part of the medical record.
- [DRAFT] Letter A clinical document that is intended primarily for person to person communication and secondarily as a report for the patient record. A letter would normally be addressed to a specific person or organization, and would include a date of creation, a salutation, a body, and a signature line. The name for a referral letter (a letter from one provider, either a person or organization, to a second provider that requests that the patient receive services from the second provider) is represented by selecting letter as the kind of document, and referral as the type of service.
- [DRAFT] Reference A documentation of knowledge that is not patient-specific. Examples include library resources, patient education material, clinical practice guidelines, and prescription drug package inserts.

Initial DocumentType Submissions

Each item in the Document Name column will become a value in the DocumentType vocabulary domain. The document name is comprised of the components described above, and shown in the following table.

	Short Name	Kind of Documen t	Type of Service	Setting	Training / Professional Level	SubjectMatter Domain	Code Mappings	Comment s
1.	Anesthesia Hospital Pre-op Note	Clinical Note	Pre-operative evaluation and management	Hospital		Anesthesia		

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	Short Name	Kind of Documen t	Type of Service	Setting	Training / Professional Level	SubjectMatter Domain	Code Mappings	Comment s
2.	Attending Outpatient Supervisory Note	Clinical Note	Supervisory direction	Outpatient	Attending physician			
3.	Autopsy Note	Clinical Note	Autopsy				18743-5^LN; AR^HL7027	
4.	Cardiology Attending Outpatient Supervisory Note	Clinical Note	Supervisory direction	Outpatient	Attending physician	Cardiology		
5.	Cardiology Consultation Note	Clinical Note	Consultation			Cardiology		
6.	Cardiology Hospital Admission Note	Clinical Note	Admission history and physical	Hospital		Cardiology		
7.	Cardiology Outpatient Progress Note	Clinical Note	Subsequent visit evaluation	Outpatient		Cardiology		
8.	Case Manager Home Health Care Progress Note	Clinical Note	Subsequent visit evaluation	Home Health Care	Case Manager			
9.	Clinical Encounter Note	Clinical Note	Evaluation and Management					
10.	Comprehensive H&P Note	Clinical Note	Comprehensiv e history and physical					
11.	Conference Note	Clinical Note	Conference evaluations					
12.	Consultation Note	Clinical Note	Consultation					
13.	Critical Care Consultation Note	Clinical Note	Consultation	Critical Care Unit				
14.	Critical Care Progress Note	Clinical Note	Subsequent visit evaluation	Critical Care Unit				
15.	Dental Hygienist Outpatient Progress Note	Clinical Note	Subsequent visit evaluation	Outpatient	Dental hygienist			
	Dentist Outpatient Progress Note	Clinical Note	Subsequent visit evaluation	Outpatient	Dentist			
17.	Diabetology Outpatient Note	Clinical Note	Evaluation and management	Outpatient		Diabetology		
18.	Emergency Department Note	Clinical Note	Evaluation and management	Emergency Department				

	Short Name	Kind of Documen	Type of Service	Setting	Training / Professional Level	SubjectMatter Domain	Code Mappings	Comment
19.	Gastroenterolog y Attending Outpatient Supervisory Note	Clinical Note	Supervisory direction	Outpatient	Attending physician	Gastroenterolog y		
20.	General Medicine Outpatient Consultation Note	Clinical Note	Consultation	Outpatient		General Medicine		
21.	History and Physical Note	Clinical Note	History and Physical					
22.	Home Health Educational Visit Note	Clinical Note	Education procedure	Home Health				
23.	Home Health Initial Evaluation Note	Clinical Note	Initial evaluation	Home Health				
24.	Home Health Progress Note	Clinical Note	Subsequent visit evaluation	Home Health				
25.	Hospital Admission H & P Note	Clinical Note	Admission history and physical	Hospital			28636-9^LN	
26.	Hospital Consultation Note	Clinical Note	Consultation	Hospital			11488-4^LN; CN^HL7027 0	
27.	Hospital Discharge Summary Note	Clinical Note	Discharge Summarization	Hospital				
28.	Hospital Group Counseling Note	Clinical Note	Group counseling	Hospital				
29.	Hospital Progress Note	Clinical Note	Subsequent visit evaluation	Hospital				
	Inpatient Note	Clinical Note	Evaluation and Management	Inpatient				
31.	Interventional Procedure Note	Clinical Note	Interventional Procedure				28570-0^LN; PN^HL70270	
32.	Medical Student Hospital H & P Note	Clinical Note	History & Physical	Hospital	Medical student			
33.	Nurse Telephone Encounter Note	Clinical Note	Telephone encounter		Nurse			
34.	Nursing Home Comprehensive H & P Note	Clinical Note	Comprehensiv e history and physical	Nursing Home			28626-0^LN	
35.	Nursing Home Conference Note	Clinical Note	Conference evaluation	Nursing Home				
	Nursing Home Initial Evaluation Note	Clinical Note	Initial Evaluation	Nursing Home				
37.	Nursing Home Note	Clinical Note	Evaluation and management					

	Short Name	Kind of Documen	Type of Service	Setting	Training / Professional	SubjectMatter Domain	Code Mappings	Comment s
20	0 1 11	t	g : 1		Level			
38.	Operative Note	Clinical Note	Surgical operation					
20	Outpatient	Clinical	Confirmatory	Outpatient			24611-6^LN	
39.	Confirmatory	Note	consultation	Outpatient			24011-0 LIN	
	Consultation	14010	Consultation					
	Note							
40.	Outpatient Initial	Clinical	Initial	Outpatient				
	Evaluation Note	Note	evaluation	1				
41.	Outpatient Note	Clinical	Evaluation and	Outpatient			11516-2^LN	
		Note	management					
42.	Outpatient	Clinical	Surgical	Outpatient			11504-8^LN;	
	Operative Note	Note	operation				OP^HL70270	
43.	Outpatient	Clinical	Subsequent	Outpatient				
	Progress Note	Note	visit evaluation					
44.	Pathology Note	Clinical	Evaluation and			Pathology		
15	Pharmacist	Note Clinical	management	Outrations	D1 : 4			
45.	Outpatient	Note	Subsequent visit evaluation	Outpatient	Pharmacist			
	Progress Note	Note	visit evaluation					
46	Physician	Clinical	Discharge	Hospital	Physician		11490-0^LN;	
	Hospital	Note	summarization	Trospital	11195101011		11.50 0 21.,	
	Discharge							
	Summary Note							
47.	Physician	Clinical	History &	Nursing		Physician		
	Nursing Home	Note	Physical	Home				
	H & P Note	~						
48.	Progress Note	Clinical	Subsequent				11506-3^LN;	
40	Darrahiatur	Note Clinical	visit evaluation Consultation	Hamital		Psychiatry	PR^HL70270	
49.	Psychiatry Hospital	Note	Consultation	Hospital		Psychiatry		
	Consultation	14010						
	Note							
50.	Pulmonary	Clinical	Consultation			Pulmonary		
	Consultation	Note						
	Note							
51.	Summary Note	Clinical	Summarization					
	T 111.0 D	Note	of episode					
52.	Targeted H & P	Clinical	Targeted					
	Note	Note	history and physical					
53	Transfer Referral	Clinical	Transfer of					
55.	Note	Note	care referral					
54.	Transfer	Clinical	Transfer				18761-7^LN;	
	Summary Note	Note	summarization				TS^HL70270	
55.	Over the	Reference						
	Counter Drug	Document						
	Label							
56.	Prescription	Reference						
57	Drug Label Reference	Document						
3/.	Document Document	Reference Document						
	Document	Document	j	İ		<u> </u>	I .	

8 Order Panels (Batteries)

Beginning with version 1.0o, the LOINC database was expanded to include order sets/panels. These have been identified with the word "PANEL" in the component name. Since the property type will vary depending on the panel elements, the second part of the LOINC name may be populated by a dash (-). The scale (5th part of the LOINC name) will be populated by a dash (-) if the panel elements could have different scales.

If a government authority recognizes the order set, it will be indicated in the component name and may include the year that an order set took effect. For example: COMPREHENSIVE METABOLIC HCFA 2000 PANEL.

A new field called **PanelElements** has also been added to the LOINC database. It contains a list of the individual test components included in the order sets. The elements will be accompanied by a panel test flag that will denote the expected appearance of the panel element in the panel when resulted. A panel test flag is always one of three states:

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

Some example order sets:

Fully specified LOINC name	Panel Elements	Flag
24358-4:HEMOGRAM PANEL:-	26464-8:LEUKOCYTES:NCNC:PT:BLD:QN:	R
:PT:BLD:QN	26453-1:ERYTHROCYTES:NCNC:PT:BLD:QN:	R
	718-7:HEMOGLOBIN:MCNC:PT:BLD:QN:	R
	20570-8:HEMATOCRIT:VFR:PT:BLD:QN:	R
	30428-7:MEAN CORPUSCULAR	R
	VOLUME:ENTVOL:PT:RBC:QN:	
	28539-5:ERYTHROCYTE MEAN CORPUSCULAR	R
	HEMOGLOBIN:ENTMASS:PT:RBC:QN:	
	28540-3:ERYTHROCYTE MEAN CORPUSCULAR	R
	HEMOGLOBIN CONCENTRATION:MCNC:PT:RBC:QN:	
	30384-2:ERYTHROCYTE DISTRIBUTION	0
	WIDTH:ENTVOL:PT:RBC:QN:	
24318-8:DIFFERENTIAL PANEL:-	26508-2:NEUTROPHILS.BAND FORM/100	С
:PT:BLD:QN	LEUKOCYTES:NFR:PT:BLD:QN:	
	26507-4:NEUTROPHILS.BAND FORM:NCNC:PT:BLD:QN:	0
	26478-8:LYMPHOCYTES/100	R
	LEUKOCYTES:NFR:PT:BLD:QN:	
	26474-7:LYMPHOCYTES:NCNC:PT:BLD:QN:	0
	26485-3:MONOCYTES/100 LEUKOCYTES:NFR:PT:BLD:QN:	R
	26484-6:MONOCYTES:NCNC:PT:BLD:QN:	
	26450-7:EOSINOPHILS/100	0
	LEUKOCYTES:NFR:PT:BLD:QN:	С
	26449-9:EOSINOPHILS:NCNC:PT:BLD:QN:	0
	30180-4:BASOPHILS/100 LEUKOCYTES:NFR:PT:BLD:QN:	С
	26444-0:BASOPHILS:NCNC:PT:BLD:QN:	0
	26511-6:NEUTROPHILS/100	
	LEUKOCYTES:NFR:PT:BLD:QN:	R
	26464-8:LEUKOCYTES:NCNC:PT:BLD:QN:	0
	26499-4:NEUTROPHILS:NCNC:PT:BLD:QN:	0
	26505-8:NEUTROPHILS.SEGMENTED/100	С
	LEUKOCYTES:NFR:PT:BLD:QN:	0
	30451-9:NEUTROPHILS.SEGMENTED:NCNC:PT:BLD:QN::	

Fully specified LOINC name	Panel Elements	Flag
24326-1:ELECTROLYTES HCFA 98	2028-9:CARBON DIOXIDE:SCNC:PT:SER/PLAS:QN:	R
PANEL:-:PT:SER/PLAS:QN	2075-0:CHLORIDE:SCNC:PT:SER/PLAS:QN:	R
	2823-3:POTASSIUM:SCNC:PT:SER/PLAS:QN:	R
	2951-2:SODIUM:SCNC:PT:SER/PLAS:QN:	R
	10466-1:ANION GAP 3:SCNC:PT:SER/PLAS:QN:	0
	1863-0:ANION GAP 4:SCNC:PT:SER/PLAS:QN:	0

8.1 Goals

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

LOINC codes have been defined for most individual laboratory observations and for many clinical observations, and claims attachments. Obviously, these same LOINC codes can be used to order individual laboratory and clinical observations, as well as to report the LOINC code for Blood Hemoglobin (LOINC # 20504-6) could as easily be used to order a Blood Hemoglobin, as well as to report the result of that test. Pre-existing LOINC codes could also be used to order more complex observations. The Urinary Creatinine Clearance (LOINC # 2164-8) could also be used order code Creatinine Clearance. Since the calculation of creatinine clearance requires two distinct measures (serum creatinine and 24-hour urine creatinine), an order for creatinine clearance implies an order for these two other measures. However, the existing single value LOINC codes could not be used to order many laboratory and clinical procedures that are ordered as a single-named test (battery), such as CBC, urine dipsticks, blood differential count, LDH isoenzymes. Similarly physicians order Blood pressure measures and expect to get (at least) the diastolic blood pressure and the systolic blood pressure. Though these are separate observations, for practical purposes one is never measured without the other.

In this phase of LOINC, we have created LOINC codes for the common "fixed" observation packages. By fixed, we mean that certain kinds of measures will always be part of the battery, and the production of that particular set of measurements is tightly bound to the procedure or instruments that produce the values and or by a government mandate (e.g. LOINC # 24325-3: HEPATIC FUNCTION HCFA 2000 PANEL).

Background on kinds of results found in order sets

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

8.2 Reflex tests

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

8.3 Calculated or derived results

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

8.4 Associated observations

Some sets consist of a set of measures produced by the laboratory and a set of observations obtained by the placer and sent along with the request. For example, placers will usually report the percent inspired O_2 when they request an arterial blood gas and the laboratory reports that value along with the values it measures directly. We call these "associated observations" and count the volumes and times of collection in this category for the purpose of this discussion. We will not define distinct order panels that vary with the number of clinical variables (not measured by the lab) that are included in the report.

8.5 LOINC Rules for representing order panel names

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

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

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

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

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

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

At this first phase we have defined batteries for:

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

Description of some LOINC Panels (Order Set Names):

LOINC_NUM	LOINC Fully Specified Name	<u>Description</u>
24358-4	HEMOGRAM PANEL:-:PT:BLD:QN	HCT & HGB & WBC & RBC & Indices

24359-2	HEMOGRAM & DIFFERENTIAL PANEL :-:PT:BLD:QN	Hemogram & Differential Count
24361-8	HEMOGRAM ,PLATELETS & DIFFERENTIAL PANEL:-:PT;BLD:QN	Hemogram & Differential & Platelets
24317-0	HEMOGRAM & PLATELET PANEL:-:PT:BLD:QN	HCT & HGB & WBC & RBC & Indices & Platelets
24338-6	GAS PANEL:-:PT:BLD:QN	pH & PO2 & PCO2 on blood without specifying whether arterial, venous, or other source. The report would usually include an observation about the inspired O2 sent along with the report. It may include a variety of other patient characteristics sent by the requester and a variety of computed variables
24336-0	GAS PANEL:-:PT:BLDA: QN	pH & PO2 & PCO2 on arterial blood. The report would usually include an observation about the inspired O2 sent along with the report. It may include a variety of other patient characteristics sent by the requester and a variety of computed variables
24339-4	GAS PANEL:-:PT:BLDV:QN	pH & PO2 & PCO2 on venous blood. The report would usually include an observation about the inspired O2 sent along with the report. It may include a variety of other patient characteristics sent by the requester and a variety of computed variables
29274-8	VITAL SIGNS MEASURMENTS:FIND:PT:^PATIENT^MULTI	Diastolic Blood Pressure & Systolic Blood Pressure & Pulse Rate & Respiratory Rate
24357-6	UA DIPSTICK PANEL:-:PT:UR:-	Urinalysis dip stick 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:ISLT:ORDQN	Would include susceptibility results for the antibiotics relevant to the isolates and the kind of culture.

9 Standardized Survey Instruments

The LOINC committee approved inclusion of standardized survey instruments with version 1.0p. The initial corpus includes material from standardized nursing assessment instruments: Home Health Care Classification (HHC), Quality Audit Marker (QAM), Signs and Symptoms Checklist for Persons with HIV (HIV-SSC), Living with HIV and the Omaha System. A detailed description of the methodology for inclusion and evaluation into LOINC and the extensions to the LOINC axes can be found elsewhere (Bakken, S, et al. Evaluation of Clinical LOINC (Logical Identifiers, Names, and Codes) for Terminology Model for Standardized Assessment of Measures, JAMIA, Volume 7, Nov/Dec 2000, p. 529-538.)

LOINC added two new columns to the database to contain the exact survey test question and the survey source and question number. The LOINC class structure was also extended to include the new SURVEY classes that will form the basis for future additional standardized assessment measures from other domains.

Survey instruments (questionnaires) can be stored in the same panel structure. In a survey the individual question corresponds to the test in a test panel. Like a panel, survey instruments can be defined in a nested fashion.

- 1. Survey instruments will require some additional attributes per questions. These will include the literal questions that get asked.
- 2. Node type header, calculated or given
- 3. Sky high

Appendix A - LOINC Database Structure

	Field Name	Туре	Width	Description
1.	LOINC_NUM	Text	7	The unique LOINC Code. This is a numeric code with a mod 10-check digit. (The algorithm for calculating a mod 10-check digit is given in Appendix C.)
2.	COMPONENT	Text	150	Fields 2-7 contain the six parts of the name. The fully specified
3.	PROPERTY	Text	30	name for a given LOINC code would be constructed by printing out
4.	TIME_ASPCT	Text	15	the contents of these fields (2-7), inserting a colon (:) between the
5.	SYSTEM	Text	100	contents of each of these fields.
6.	SCALE TYP	Text	30	contents of each of these fields.
7.	METHOD TYP	Text	50	
8.	RELAT_NMS	Text	254	This field is no longer being maintained. It has been replaced by # 58 RelatedNames2
9.	CLASS	Text	20	An arbitrary classification of the terms for grouping related observations together. The current classifications are listed in Table 20. We present the database sorted by the class field within class type (see field 35). 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. However some of these need more specification.
				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 AB0-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 excludes 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 - Challenge tests.
III	SOURCE	Text	8	This is for our internal use and should be ignored by database users.
11.	EUCLIDE_CD	Text	10	EUCLIDES analyte code. The Euclides code identifies the analyte
1.0	ACTM CD	T '	0	(the first subpart of the first part of the name).
12.	ASTM_CD	Text	9	The ASTM codes apply to only a few of the tests (e.g. cell counts, antibiotic sensitivities). These are the codes included in the appendices of HL7 and ASTM E1238-94. This field is no longer being maintained

	Field Name	Type	Width	Description
13.	IUPAC_CD	Text	8	The IUPAC code identifies the component, kind of property, and
	_			system. Note: Most of the IUPAC codes for chemistry assume the
				component is measured in substance concentration, e.g. moles, while
				most U.S. labs report in mass concentration. We have applied the
				IUPAC code for substance concentration to mass concentration,
				because IUPAC has no code for the mass concentration variant.
14.	DT_LAST_CH	Text	8	Date last changed, in the format YYYYMMDD
	CHNG_REAS	Text	254	Reason term was changed. If a term has been changed, the reason
	_			for the change is detailed here.
16.	CHNG_TYPE	Text	3	Change Type Code. DEL = Delete; ADD = add, NAM = change to
	_			Analyte/Component (field #2); MAJ = change to name field other
				than $\#2 (\#3 - \#7)$; MIN = change to field other than name.
17.	COMMENTS	Text	254	Free-text comments relating to the test result.
18.	ANSWERLIST	Memo	-	The list of answers for results that are reportable from a multiple-
				choice list (e.g. the answers for the term DISPOSITION OF BLOOD
				PACK are GIVEN; PARTIALLY GIVEN; DISCARDED). This
				field provides examples, not required answer lists.
19.	STATUS	Text	3	Deprecated or superseded status indicated by DEL in this field
				(otherwise blank). Used to mark terms as the database evolves.
				LOINC codes will not ever be re-used nor will they be removed from
				the database, they will instead be cross-referenced whenever possible
				to superseding terms in Field 20.
20.	MAP_TO	Text	7	Used when a field has been dropped from the active database (by
	_			entering "DEL" in the Status field) because it has been replaced by
				an updated term. In those cases, Map_To contains the LOINC code
				of the new term that should be used.
21.	SCOPE	Text	20	Not currently used.
22.	SNOWMED_CD	Text	10	SNOMED Code (future versions). Not currently used.
23.	VA_CD	Text	8	VA Code (future versions). Not currently used.
24.	METPATH_CD	Text	10	MetPath Code. Not currently used.
25.	HCFA_CODE	Text	12	HCFA code (future versions). Not currently used.
26.	CDC_CODE	Text	6	Code from CDC Complexity file that maps laboratory tests to the
				instruments used to perform them. These codes are at the analyte
				level, not the test instrument level.
27.	NORM_RANGE	Text	30	Normal Range - Example answers from real tests
28.	EX_US_UNITS	Text	30	Example units used in the US. The terms have been standardized to
				more closely resemble HL7 version 3 units.
29.	IPCC_UNITS	Text	30	Example units used by IUPAC/IFCC (future)
30.	GPI_CD	Text	100	GPI Code. For drugs, this field contains a map to the Medispan GPI
				codes, a hierarchical system of classifying pharmaceutical products.
				In cases where a one-to-one mapping was not possible, all applicable
				GPI codes are contained in this field, separated by semicolons.
31.	REFERENCE	Memo	-	Contains references to medical literature, product announcements, or
				other written sources of information on the test or measurement
				described by the LOINC record.
32.	EXACT_CMP_SY	Text	50	Exact core component synonym: This field contains an exact
				synonym for the "core component" of the LOINC component name.
				We have included the mixed case and "superscript" form of blood
				bank and HLA antigens (e.g. Lu ^a) here. As there is no ASCII
				representation for superscript letters, we use the hat (^) to signify
				superscripts in this field. (e.g. if the core component is represented
				as L LITTLE U LITTLE SUPER A in the LOINC
				component/analyte name field, it is represented in the Exact Core
				Synonym field as Lu^a.)

	Field Name	Type	Width	Description
33.	MOLAR_MASS	Text	13	Molecular weights: This field contains the molecular weights of chemical moieties when they are provided to us. This release
				contains values kindly contributed by IUPAC.
34	IUPC_ANLT_CD	Text	13	IUPAC analyte code: This field contains the Chemical Abstract
J 1.	TOT C_THVET_CD	TOAL	13	service number or the Enzyme Nomenclature number for the
				chemical components for chemicals and/or enzymes. These were
				also contributed by IUPAC.
35.	CLASSTYPE	Int	2	1=Laboratory class; 2=Clinical class; 3=Claims attachments;
				4=Surveys
36.	FORMULA	Text	255	Regression equation details for many OB.US calculated terms.
37.	MULTUM CD	Text	6	Maps to Multum Inc. database of codes for drugs.
H	DEEDS CD	Text	7	Data Elements for Emergency Department Systems Codes (CDC).
	_			This field contains the DEEDS code value which maps to the LOINC
				code in question.
39.	CSCQ_FRNCH_NM	Text	255	French name for LOINC term. Supplied by Centre Suisse de
				Contrôle de Qualité. This field contains extended characters and will
				not transfer correctly to 7-bit systems
40.	CSCQ_GRMN_NM	Text	255	German name for LOINC term. Supplied by Centre Suisse de
				Contrôle de Qualité. This field contains extended characters and will
				not transfer correctly to 7-bit systems
41.	SPNSH_NM	Text	255	Spanish name for LOINC term. Supplied by Centre Suisse de
				Contrôle de Qualité. This field contains extended characters and will
				not transfer correctly to 7-bit systems
42.	CSCQ_ITLN_NM	Text	255	Italian name for LOINC term. Supplied by Centre Suisse de
				Contrôle de Qualité. This field contains extended characters and will
4.0	and area		20	not transfer correctly to 7-bit systems
43.	SPECIES	Text	20	Codes detailing which non-human species the term applies to. If
1 4 4	EVADI ANGWEDO	M		blank, "human" is assumed.
44.	EXMPL_ANSWERS	Memo	-	For some tests and measurements, we have supplied examples of
				valid answers, such as "1:64", "negative @ 1:16", or "55". This
				differs from the ANSWERLIST field, which details possible choices for nominal scale terms.
15	ACSSYM	Memo		Chemical name synonyms, alternative name synonyms, and chemical
TJ.	ACSSTWI	WICIIIO	_	formulae supplied by the Chemical Abstract Society
46	MOLEID	Text	15	Molecular structure ID, usually CAS number
	BASE NAME	Text	50	Chemical base name from CAS
	FINAL	Text	1	Internal LOINC use field
	GENE ID	Text	20	OMIM (Online Mendelian Inheritance in Man) Names
H	NAACCR ID	Text	20	Maps to North American Association of Central Cancer Registries
	THE TO CITE ID	1 0.10		Identification Number
51.	CODE_TABLE	Text	10	Examples on CR0050 Cancer Registry
	SetRoot	Yes/No	1	Currently used for claims attachments. Yes in this field signifies that
				this record is the root of a set of LOINC codes.
53.	PanelElements	Memo	-	List of individual tests that comprise a panel
	SURVEY_QUEST_TX	Text	255	Verbatim question from the survey instrument
	T			
55.	SURVEY_QUEST_SRC	Text	50	Exact name of the survey instrument and the item/question number
II	UnitsRequired	Text	1	Y/N field that indicates that units are required when this LOINC is
	<u>*</u>			included as an OBX segment in a HIPAA attachment
57.	SUBMITTED_UNITS	Text	30	Example units as submitted by original requester.
	RelatedNames2	Memo	-	This is a new field introduced in version 2.05. It contains synonyms
				for each of the parts of the fully specified LOINC name (component,
1				property, time, system, scale, method). It replaces #8, Relat_NMS.

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Field Name	Type	Width	Description
59. SHORTNAME	Text	40	Introduced in version 2.07, this field is a concatenation of the fully specified LOINC name. The field width may change in a future release.
60. ORDER_OBS	Text	15	Defines term as order only, observation only, or both. A fourth category, Subset, is used for terms that are subsets of a panel but do not represent a package that is known to be orderable we have defined them only to make it easier to maintain panels or other sets within the LOINC construct.

Appendix B - Classes

Table 20: Classes

Clinical Term Classes					
Abbreviation	Clinical Term Class				
BDYCRC.ATOM	Body circumference atomic				
BDYCRC.MOLEC	Body circumference atomic 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.MOLE	Body temperature timed molecular				
BDYWGT.ATOM	Body weight atomic 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.US	Cardiac Ultrasound (was US.ECHO)				
CLIN	Clinical NEC (not elsewhere classified)				
DENTAL	Dental				
DOC.CLINRPT	Clinical report documentation				
DOC.REF	Referral documentation				
DOCUMENT.REGULATORY	Regulatory documentation				
ED	Emergency Department (DEEDS)				
EKG.ATOM	Electrocardiogram atomic				
EKG.IMP	Electrocardiogram impression				
EKG.MEAS	Electrocardiogram measures				
ENDO.GI	Gastrointestinal endoscopy				
EYE	Eye				
EYE.CONTACT_LENS	Ophthalmology Contact Lens				
EYE.GLASSES	Ophthalmology Glasses: Lens Manufacturer (LM) & Prescription				
EYE.HETEROPHORIA	Ophthalmology Heterophoria				
EYE.PX	Ophthalmology Physical Findings				
EYE.REFRACTION	Ophthalmology Refraction				
EYE.RETINAL_RX	Ophthalmology Treatments				
EYE.TONOMETRY	Ophthalmology Tonometry				
EYE.US	Ophthalmology Ultrasound				
EYE.VISUAL_FIELD	Ophthalmology Visual Field				
FUNCTION	Functional status (e.g. Glasgow)				
GEN.US	General Ultrasound				
H&P.HX	History				
H&P.PX	Physical				
H&P.SURG PROC	Surgical procedure				
HEMODYN.ATOM	Hemodynamics anatomic				
HEMODYN.MOLEC	Hemodynamics molecular				
HRTRATE.ATOM	Heart rate atomic				
HRTRATE.MOLEC	Heart rate molecular				
HRTRATE.TIMED.MOL	Heart rate timed molecular				
IO.TUBE	Input/Output of tube				
IO IN.ATOM	Input/Output atomic				
IO IN.MOLEC	Input/Output molecular				
IO IN.SUMMARY	Input/Output inforcedual Input/Output summary				
IO IN.TIMED.MOLEC	Input/Output summary Input/Output timed molecular				
IO IN SALTS+CALS	Input/Output timed inflection Input/Output electrolytes and calories				
IO OUT.ATOM	Input/Output electrolytes and calories Input/Output. Atomic				
IO OUT.MOLEC	Input/Output. Atomic Input/Output. Molecular				
IO_OUT.MOLEC					

Clinical Term Classes			
Abbreviation	Clinical Term Class		
IO_OUT.TIMED.MOLE	Input/Output Timed Molecular		
NEONAT	Neonatal measures		
OB.US	Obstetric ultrasound		
OBGYN	Obstetrics/gynecology		
PANEL.BDYTMP	Body temperature order set		
PANEL.BP	Blood pressure order set		
PANEL.CARDIAC	Cardiac studies order set		
PANEL.FUNCTION	Function order set		
PANEL.H&P	History & physical order set		
PANEL.IO	Input/Output order set		
PANEL.OB.US	Obstetrical ultrasound order set		
PANEL.US.URO	Urology ultrasound order set		
PANEL.VITALS	Vital signs order set		
PATH.PROTOCOLS	Pathology protocols		
PULM	Pulmonary ventilator management		
RAD	Radiology		
RESP.ATOM	Respiration atomic		
RESP.MOLEC	Respiration molecular		
RESP.TIMED.MOLEC	Respiration timed molecular		
SKNFLD.MOLEC	Skinfold measurements molecular		
TUMRRGT	Tumor registry (NAACCR)		
US.URO	Urological ultrasound		
VACCIN	Vaccinations		
VOLUME.MOLEC	Volume (specimens) molecular		

Laboratory Term Classes				
Abbreviation	Laboratory Term Class			
ABXBACT	Antibiotic susceptibility			
ALLERGY	Response to antigens			
BLDBK	Blood bank			
CELLMARK	Cell surface models			
CHAL	Challenge tests			
CHALSKIN	Skin challenge tests			
CHEM	Chemistry			
COAG	Coagulation study			
CYTO	Cytology			
DRUG/TOX	Drug levels and Toxicology			
DRUGDOSE	Drug dose (for transmitting doses for pharmacokinetics)			
FERT	Fertility			
HEM/BC	Hematology (coagulation) and differential count			
HLA	HLA tissue typing antigens			
MICRO	Microbiology			
MISC	Miscellaneous			
MOLPATH	Molecular Pathology			
MOLPATH.DEL	Gene deletion			
MOLPATH.MUT	Gene mutation			
MOLPATH.REARRANGE	Gene rearrangement			
MOLPATH.TRINUC	Gene trinucleotide repeats			
MOLPATH.TRISOMY	Gene chromosome trisomy			
MOLPATH.TRNLOC	Gene translocation			
PANEL.ABXBACT	Susceptibility order set			
PANEL.BLDBK	Blood bank order set			
PANEL.CHAL	Challenge order set	-		
PANEL.CHEM	Chemistry order set	-		
PANEL.COAG	Coagulation order set			
PANEL.DRUG/TOX	Drug levels and Toxicology order set			
PANEL.HEM/BC	Hematology and blood count order set			
PANEL.MICRO	Microbiology order set			
PANEL.OBS	Obstetrics order set			
PANEL.SERO	Serology order set			

Laboratory Term Classes		
Abbreviation	Laboratory Term Class	
PANEL.UA	Urinalysis order set	
PATH	Pathology	
SERO	Serology (antibodies and most antigens except blood bank and infectious agents)	
SPEC	Specimen characteristics	
UA	Urinalysis	

Attachment Term Classes			
Abbreviation	Attachment Term Class		
ATTACH	Attachment		
ATTACH.AMB	Ambulance claims attachment		
ATTACH.CARD	Cardiac attachment		
ATTACH.CLINRPT	Clinical report attachment		
ATTACH.ED	Emergency department attachment		
ATTACH.GI	Gastrointestinal attachment		
ATTACH.LAB	Laboratory claims attachment		
ATTACH.MEDS	Medication attachment		
ATTACH.MODIFIER	Modifier attachment		
ATTACH.OBS	Obstetrics attachment		
ATTACH.REHAB	Rehabilitation attachment		
ATTACH.REHAB.ABUSE	Alcohol/Substance Abuse Rehabilitation attachment		
ATTACH.REHAB.CARDIAC	Cardiac Rehabilitation attachment		
ATTACH.REHAB.NURS	Specialized Nursing attachment		
ATTACH.REHAB.OT	Occupational Therapy attachment		
ATTACH.REHAB.PSYCH	Psychiatric Rehabilitation attachment		
ATTACH.REHAB.PT	Physical Therapy attachment		
ATTACH.REHAB.RT	Respiratory Therapy attachment		
ATTACH.REHAB.SOCIAL	Medical Social Work attachment		
ATTACH.REHAB.SPEECH	Speech Therapy Rehabilitation attachment		
ATTACH.RESP	Respiratory attachment		

Survey Term Classes			
Abbreviation	Survey Term Class		
SURVEY.NURSE.HHCC	Home Health Care Classification Survey		
SURVEY.NURSE.HIV-SSC	Signs and Symptoms Checklist for Persons with HIV Survey		
SURVEY.NURSE.LIV-HIV	Living with HIV Survey		
SURVEY.NURSE.OMAHA	OMAHA Survey		
SURVEY.NURSE.QAM	Quality Audit Marker Survey		

Appendix C - Calculating Mod 10 Check Digits

The algorithm for calculating a Mod 10 check digit is as follows:

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

Appendix D - Procedure for Submitting Additions/Changes to the Database Introduction

The Regenstrief Institute receives two kinds of requests for additions:

- (1) The first kind of request deals with (a) an entirely new kind of measurement, e.g. DNA sequencing or (b) the use of LOINC codes in manners that have not been agreed upon by the LOINC committee, e.g. the definition of terms to accommodate the organism 1, organism 2, etc., structures that are present in many laboratory databases.
- (2) Other requests are variations on observations that are already in the database. E.g. we have a 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. Provided that the requestor followed the rules given below and the number of terms requested at a given time is modest, we will try to respond to these kinds of requests quickly.

The Institute will only be able to respond quickly to such requests if the requestor provides us with clear information about the new terms, as detailed below in Table22, which defines the content that we need to determine whether a submitted code requires a new LOINC code assignment or not. Before sending a request, make sure that you have, at a minimum, provided information about the component, property, timing aspect, system, scale and method. It is also very useful for us to know the units of measure and example results (answers) of the test/observation that is being requested. This information enables us to verify the property, scale, and method.

You have the option of either submitting a file produced solely by you or one generated on your behalf via the RELMA program. Regardless of which option you choose, your submission file must be sent to the Regenstrief Institute in one of three file formats. The preferred format (and the one that RELMA will produce on your behalf) is a Microsoft Access database (mdb). The second format is a tab delimited ASCII file (txt). The final format is a Microsoft Excel spreadsheet (xls). The example file and field descriptions below should aid you in creating a submission file from scratch (without the aid of the RELMA program).

A Few Notes before Proceeding

The terms "addition", "requested term" and "proposed LOINC" are synonymous. All of these terms refer to a concept created by a user that will be or has been submitted to the Regenstrief Institute for consideration as an addition to the LOINC database.

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 methods. Look in the body of this guide for information about the kinds of distinctions that we make.

If you find a test in the database that you believe is wrong, please send us a letter or email (<u>loinc@regenstrief.org</u>) calling attention to the term and the reason you think it is wrong, (e.g. not using the standard nomenclature, typographical error, system of serum when it is only valid when performed on plasma, duplicate of some other concept in the database, etc. We welcome all input from users.

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 requests for submissions that include the system of serum or plasma alone. For most

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

If you are submitting requests for tests or measures that are radically different from those we currently carry, please provide a full description of the test, its purpose, and procedure. (A copy of vendor's test kit descriptive material or a copy from a textbook describing the procedure and its purpose would be very helpful.) We often will require a committee discussion to decide how to represent new subject matter, so response times will be slower.

The requestors also need to supply some evidence that they are familiar with the database and that they are sure the term is not already represented in LOINC. The major work these requests generate is the effort to be sure the observation is not already in the database. We can perform this service if the requestors have done most of this work themselves. For this reason, we request that you identify the LOINC term that is closest to your request and to flag the difference between the requested test and the existing test. That is, when a new observation is only a variation on an old one, use an existing LOINC observation as the template, change the part that is different in the new term and indicate that difference.

An Example Submission and Definition of the Submission File

An example submission (which, because of space limitations, includes columns for only the first few fields) appears below. Real submissions should have columns for all of the items listed in Table 22. Additional details are provided in the sections on creating Access Database and Excel submissions presented later in this appendix.

	Table 21: Example submission									
Row#	Your test	Analyte/Component	Property	Time	System	Scale	Method	Class	Related	Etc
	ID									
1		GLUCOSE^90M POST 50G LACTOSE PO	MCNC	Т	UR	ORD	TEST STRIP	CHAL		
2		COPROPORPHYRIN 1 ISOMER	MRAT	24H	UR	QN		СНЕМ		
3	I98	INDICAN	MRAT	24H	UR	QN		СНЕМ		
4	T51	THYROXINE.FREE	MCNC	PT	UR					

The following table contains a description of the fields contained in the sample submit.mdb file that is installed with RELMA. These fields should be present in the submission file you submit to Regenstrief. Only some of the fields need to be populated with data as noted below.

		Table 2	22a Access F	Field Names for Submissions
Item#	Field Name	Data Type	Size	Description
			(Characters)	
1	S_ROW	LONG	4	Row number of this term in submitter's file.
2	S_LOCAL_CD	TEXT	50	The submitter's local code used to identify the test/observation in the
				submitter's master file.
3	S_COMPO	TEXT	150	Submitter's Analytes/Component. Mandatory. (User Guide 2.2)
4	S_PROP	TEXT	30	Submitter's Kind of Property. Mandatory – but we can help if you provide enough details. (User Guide 23)
5	S_TIME	TEXT	15	Submitter's Time Aspect. Mandatory. (User Guide 2.4)
6	S_SYS	TEXT	100	Submitter's System/Sample Type. Mandatory. (User Guide 2.5)
7	S_SCALE	TEXT	30	Submitter's Type of Scale. Mandatory. (User Guide 2.6)
8	S_METH	TEXT	50	Submitter's Type of Method. If required. (User Guide 2.7)
9	S_REL_NAM	TEXT	254	Submitter's Related Names. Strongly recommended. Common names, acronyms or synonyms.
10	S_LOINC	TEXT	10	Submitter's LOINC number. Strongly recommended. This is the LOINC number that is similar, but not the same as, the submitter's test.
11	S_RESULTS	Memo	-	Submitter's Example Results. Strongly recommended. As reported by your lab.
12	S_UNITS	TEXT	30	Submitter's Example Units. Strongly recommended. As reported by your lab.
13	S SPECIES	TEXT	20	To be used for veterinary term submissions
14	S_ID	TEXT	50	If the submitter includes a reference code ID for each unique submission
	_			to LOINC, record that ID here, and this will be returned with questions or an assigned LOINC number on a returned file
15	S COMMENT	TEXT	254	Comments the submitter may wish to pass to RI when needed.
16	BLANK1	TEXT	50	Placeholder. Do not use
17	BLANK2	TEXT	20	Placeholder. Do not Use
	Table 22	2b Content	Added by Re	genstrief (Fields left blank in submission)
18	RI_REF	TEXT	50	For future use
19	LOINC	TEXT	10	Assigned LOINC code for submitted concept. This may be a new code
				or a pre-existing code.
20	RI_ACTION	TEXT	30	Regenstrief Action Code:
				DONE – term accepted and new code assigned
				DUP – submitted term already exists in LOINC database
				IDUP – submitter submitted same term twice (internal duplicate)
				INFO – more information needed from submitter

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ĺ				HOLD – submission is area not currently being considered
21	RI COMMENT	TEXT	250	RI's comments/questions to submitter.
22	R COMPO	TEXT	150	RI's revised version of submitter's analyte/component
23	R PROP	TEXT	30	RI's revised version of submitter's kind of property
24	R TIME	TEXT	15	RI's revised version of submitter's time aspect
25	R SYS	TEXT	100	RI's revised version of submitter's system/sample type
26	R SCALE	TEXT	30	RI's revised version of submitter's type of scale
27	R METH	TEXT	50	RI's revised version of submitter's type of method
28	R REL NAM	TEXT	254	RI's revised version of submitter's related names
29	R RESULTS	Memo	-	RI's revised version of submitter's results
30	R UNITS	TEXT	30	RI's revised version of submitter's example units
31	R_SPECIES	TEXT	20	RI's revised version of submitter's species
32	R_CLASS	TEXT	20	RI's revised version of class
33	L COMPO	TEXT	150	Formal LOINC name for analyte/component if LOINC number assigned
34	L PROP	TEXT	30	Formal LOINC name for kind of property if LOINC number assigned
35	L TIME	TEXT	15	Formal LOINC name for time aspect if LOINC number assigned
36	L SYS	TEXT	100	Formal LOINC name for system/sample type if LOINC number assigned
37	L SCALE	TEXT	30	Formal LOINC name for type of scale if LOINC number assigned
38	L METH	TEXT	50	Formal LOINC name for type of method if LOINC number assigned
39	L REL NAM	TEXT	254	Formal LOINC name for related names
40	L RESULTS	Memo	-	Formal LOINC name for results
41	L UNITS	TEXT	30	Formal LOINC name for example units
42	L SPECIES	TEXT	20	Formal LOINC name for species
43	L CLASS	TEXT	20	Formal LOINC name for class if LOINC number assigned
		ly for internal	Regenstrief	purposes and should not be of much interest to the submitter:
44	STATUS	TEXT	20	Regenstrief's Status for submitted term
45	ID	TEXT	50	Regenstrief internally assigned ID for the submitter's file. (Internal path
				and filename information.)
46	COMMENT	TEXT	250	Regenstrief's automated comments about the submitted term. These
				identify internal contradictions, automated equivalencing (e.g. serum to
				SER/PLAS).
47	UNIQ	TEXT	150	This lists any words in a concept that are new to the LOINC database.
				These may indicate typo's, mis-statements of words or new words in the
				concepts.
48	DUPS	TEXT	150	These are lists of subsets or near matches for submitted terms. These are
				produced only to assist the submission review process and should not be
				given too much credence.
49	EDIT_CTL	TEXT	10	Regenstrief's Edit Control
	_			

Creating a Submission Using Microsoft Access

A blank Microsoft Access 97 database template named SUBMIT.MDB is included in the RELMA software package. Table 22 above describes the fields in this database. You should be diligent in filling in the first 15 fields of the table for each term in your submission. In Figure 1 below, an example submission is shown as created in Microsoft Access. In the example, the user has opened the submit.mdb template and edited the first 15 fields.

The default path for the template file is:

C:\Program Files\RELMA\submit.mdb

The location on your machine may be different depending on your installation of the RELMA program.

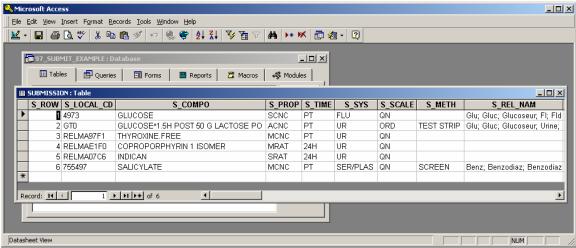


Figure 1 – Example Submission Created with Microsoft Access 97

Creating a Submission Using Microsoft Excel

If you choose to create your submission using Microsoft Excel, you must use the field names as specified in Table 22. Figure 2 below shows an example of what an Excel submission would look like. Please note that the first row contains the field names specified in Table 22.

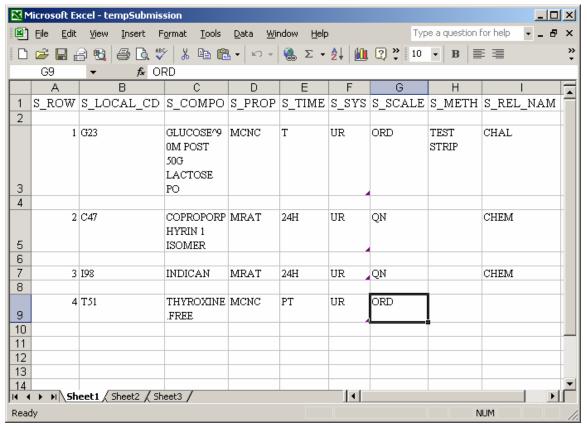


Figure 2 – An Example Excel Submission (first 9 fields only)

CAUTION: Please take note of the field size indicated in Table 22. Upon receipt of your submission, we will copy the submission data into a Microsoft Access database as defined above in Table 22. If the cells in your Excel submission contain too many characters, some data may be lost in the conversion process.

Creating a Submission Using a Tab-Delimited ASCII Text File

If you choose to send your submission in a tab-delimited ASCII text file format, please use the following format:

S_ROW|S_LOCAL_CD|S_COMPO|S_PROP|S_TIME|S_SYS|S_SCALE|S_METH|S_REL_NAM|S_LOINC|S RESULTS|S UNITS|S ID|S SPECIES|S COMMENT<CRLF>

Each field is separated from the other by a Tab character. That is, each vertical bar above would actually be a Tab character (i.e. an ASCII 9). A carriage-return/line-feed pair (i.e. the <CRLF> above) terminates each line. Therefore, each <CRLF>-terminated line in the ASCII file becomes a submission record. Note that the field lengths presented in Table 22 still apply to ASCII file submissions because upon receipt of your submission we copy the ASCII file data you submit into an Access database of the form described above.

Using the previous example, one line might appear as:

1|G23|GLUCOSE^90m POST 50g LACTOSE PO|MCNC|PT|UR|ORD|TEST STRIP|||6762-9||MG/DL|||

where the vertical bars represent the Tab character. Notice that two vertical bars appear between "TEST STRIP" and "6762-9". In this example, this means that the related names field is empty (i.e. a null field value). The example also shows that fields S_RESULTS, S_ID, and S_COMMENT are also empty. Without the empty field, the field information would get out of sync and it would appear that the related names for this submission were actually the closest LOINC number for the submission (i.e. "6762-9"). Therefore, the ordering of the fields and the use of the Tab character to delimit the fields is very important.

In Figure 3 below, an example submission file is shown with the actual tab characters in lieu of the vertical bars used above as illustrations. Please note that the first row contains the field names described in Table 22. Also note that the tab characters are invisible to the human eye and make the text appear chaotic (this is one reason we recommend the use of Microsoft Access for the creation of submission files).

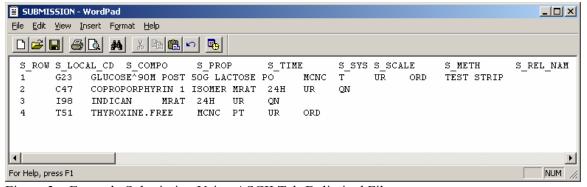


Figure 3 – Example Submission Using ASCII Tab-Delimited File

Generating a Submission Using RELMA

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.

Because there are two kinds of requests for additions, there are two methods for creating them. The first method is to start from scratch, typing or choosing from a list each part of the requested term. The second method is to start with an existing LOINC term and modify one (or more) part of that term to create a unique variation not found anywhere else in the LOINC database. We recommend the second method because it will save you time (you won't have to choose each constituent part of the requested term by hand) and it will expedite the process by providing additional information beyond the first six parts of the requested term.

Starting from a Blank Slate

To start from scratch, choose "Propose a LOINC" from the File menu on the welcome screen. If you are viewing the mapping screen, you can either choose the same menu option from the File menu or click on the "Propose LOINC" button located above the results grid (see Table 22) when the results grid is empty (i.e. there are no LOINC records in the grid).

Starting from an Existing LOINC

To modify an existing LOINC term, you must begin from the mapping screen. After you execute a search, highlight one of the LOINC terms displayed in the results grid. Now you may choose the "Propose a LOINC" option from the File menu, click on the "Propose LOINC" button OR you may right-click your mouse and choose the "Propose LOINC" option from the dropdown menu. See the "Proposing a LOINC using an existing LOINC" section below for more details.

After performing one of the methods described above, you should see a form very similar to the one in Figure 4.

Overview of the Propose LOINC Form Unique code Information assigned to from a local e a LOINC each term in your proposed formation below to deate a proposed LOINC code for submission to the Regenstrief Institute. When you have finished making changes, current working ave and exit or propose another LOINC. Required fields are designated in red. LOINC Local Code ocal Name B-4): Test (OBX-3): 4973 ICOSE FLD QN Working Set: HOSPITAL A The term's SENT - 09/24/2003 Similar LOINC: 2344-0 Reference #: Glucose Fld-mCnc current status LOINC Part Record and explain new part here Analyte: GLUCOSE • ▼ Suffix: Divisor: ▾ Challenge: ▼ Comment Adjustment: ▼ explaining Red change made 4th Subpart: ▼ indicates to existing Property: SCNC ▼ Changed property because we measure in different units. required LOINC Time: PT • field Timing Modifier: ▼ System: FLU ▼ Super System: ▾ Scale: QN \blacksquare Method: ▼ Units: Sample results ecies: Example Answers (Results) C Answer List go here Answers: ٠ ٠ Related Names: Glu; Gluc; Glucoseur; Fl; Fld; BF; Fluid; Body fluid ۸ Move backwards one record Comments: Click button Move to save forwards one changes. record H | | **M** 3 of 9 <u>N</u>ew <u>S</u>ave E<u>x</u>it

Figure 4 – The Propose LOINC Form

After the form displayed in Figure 4 above is loaded, you should edit the parts (the fields on the left side of the dividing line) so they equal the values you wish to exist in the proposed term. Add comments in fields on the right side of the dividing line as necessary to explain the changes or values you enter. Once you have finished creating the proposed LOINC, click the "Save" button. This will save the proposed term to your local computer and make it available for submission later.

NOTE: The fields highlighted in red are required for all proposed LOINCs as specified in Table 22. A requested term cannot be saved for submission unless it contains data in each of the required fields.

To enter another proposed LOINC, click the "New" button. To view other requested terms you have previously created, click the left and right arrow buttons located in the bottom left corner of the form. To close the form, click on the "Exit" button located in the bottom right corner of the form.

Details of the Propose LOINC Form

The following sections describe individual areas of the Propose LOINC form. Each section provides an explanation of the area in question and instructions on how to enter data in that part of the form.

The Local Code Section

Local Code Local Name

Battery (OBR-4):

Test (OBX-3): 4973 GLUCOSE FLD QN

Working Set: HOSPITAL A

Figure 5 – The Local Code Section

This is the name of the working set from which the local code came. When creating a term, this is the current

The local code section displays the details of a term within a working set that served as the model for the requested term. In Figure 5 above, the user was unable to find a valid LOINC to which he could map his local code of 4973 (GLUCOSE FLD QN) in the HOSPITAL A working set, so he chose to request such a term. When the form opened, his local code information was copied onto the Propose LOINC form, and it will be transmitted along with the proposed LOINC when he submits the term. Please make sure that when local code data is present it relates to the requested term. The local code information helps the Regenstrief Institute better understand the need for your requested term.

The local code section cannot be edited. To edit a local code, you must do so using other parts of the RELMA program.

NOTE: The local code section will only contain data if the user opens the Propose LOINC form while viewing the mapping screen and a local code from the current working set is displayed on the screen. If a local code is not visible when the user proposes a new LOINC, a local code will be automatically generated of the form "RELMA####" where the # sign represents either a number or letter.

The Similar LOINC Section



Figure 6 – The Similar LOINC Section

The similar LOINC section contains the LOINC number and the shortname of the LOINC term that is the closest match to the proposed LOINC. Because the LOINC database strives to contain a unique collection of concepts, it is important that each proposed LOINC be unique from any existing LOINC term. By providing a similar LOINC, you assist the Regenstrief Institute to ensure the addition you are requesting is unique.

Like the local code section, the similar LOINC section cannot be edited. The section is populated from information on the mapping screen at the time the requested term is created. To make sure this data is copied, make sure an existing LOINC code is highlighted in the results grid before choosing to propose a LOINC. This is shown below in the "Propose a LOINC using an existing LOINC" section.

The Reference Number

Above, in Figure 6, to the right of the similar LOINC information you will notice a box labeled "Reference #." In this box you can provide a unique reference identification number for each requested term that you create. These reference numbers will be transmitted along with the proposed LOINCs they reference. The staff at the Institute can then use these numbers in correspondence with you regarding specific terms in your submission, and these numbers will be returned with your requested LOINCs after the submission process has been completed.

The Status Field

Displayed above in both Figure 4 and Figure 6 is the status field. This field displays information telling the user the term has been submitted and on what date the term was last submitted. It is possible to submit terms multiple times, but this is not recommended.

NOTE: Once submitted, a term cannot be edited. If you edit a previously submitted term, a new term will be created. This may seem confusing, but this behavior ensures that if a proposed LOINC is submitted twice it can easily be identified as a duplicate of a previously submitted term.

The Parts of a Proposed LOINC Term

Each LOINC is composed of multiple parts. To propose an addition to the LOINC database, you must specify the parts that compose the new term. The left column labeled "LOINC Part" contains spaces for entering data for the various parts of a LOINC term. A description and examples of these parts are provided by placing the mouse above of the textbox (the rectangular box with an arrow pointing downward on the far right side). Additional description and discussion is provided in the LOINC Users' Guide.

NOTE: You must enter text into the parts labeled in red. These are required as specified in Table 22.

These textboxes appear to be standard Windows dropdown controls, and indeed they behave very similarly to dropdown controls. However, many of these textbox controls contain LOINC hierarchies, so their behavior is slightly different than the standard controls used in RELMA and other Windows applications.

You can switch between textboxes using the TAB key like you do in other Windows applications, but pressing the RETURN (ENTER) button causes a slightly different behavior. Instead of moving to the next textbox, pressing the return (enter) key takes the text you entered in the box and conducts a search for that text. If the text is found, a list of words and phrases containing the text entered is displayed on the screen. This is accomplished by the control "dropping down" or "dropping up" on the screen as shown in figures Figure 7 and Figure 8.

Once the control has "dropped down" or "dropped up" you can click using the left mouse button on one of the search results. Clicking in this manner will select one of the search results, and the selected item's LOINC value will be copied into the textbox where you entered your text. **You can also click on items in the list or hierarchy without performing a search.** The item's LOINC value may differ from the value displayed in the "dropped down" or "dropped up" portion of the textbox control. This behavior is caused by the use of abbreviations and synonyms in the LOINC database. Figure 8 below show that while the user clicked on the word "Blood" in the system tree, the text "BLD" was copied into the System part textbox of the proposed LOINC.

NOTE: To search for blood in the system tree, the user could have typed either "bld" or "blood." The system textbox control does not return the exact same set of search results for both strings, but it does return the string "Blood" for each search. Synonyms may not always work, so users may have to try more than one search to find the exact string they wish to use as a part for the requested term they are creating.

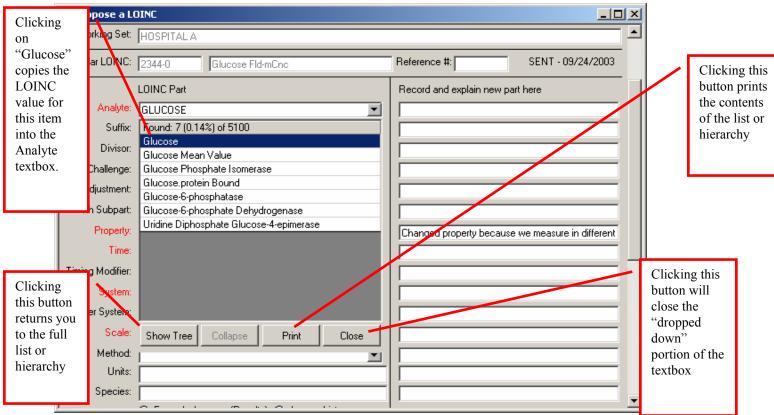


Figure 7 – Propose LOINC form showing Analyte textbox "dropped down"

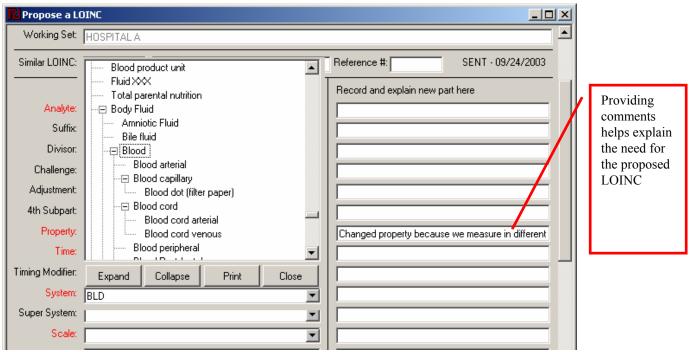


Figure 8 – Propose LOINC form showing System textbox "dropped up"

Providing Comments

Providing comments is not required but highly recommended. Comments allow the staff at Regenstrief who process submissions to understand why your organization is requesting the term(s) submitted. Comments are

especially important when you are requesting new parts (new properties, new systems, etc) because the staff at Regenstrief needs to understand the definition of the new parts and ensure that they are not synonyms of existing parts. If the staff does not understand your request, your submission may take longer as they search for definitions and enter into a dialogue with you to better understand the nature of your request. Please help us process your terms in the most efficient way possible by providing comments.

Example Answers and Answer Lists

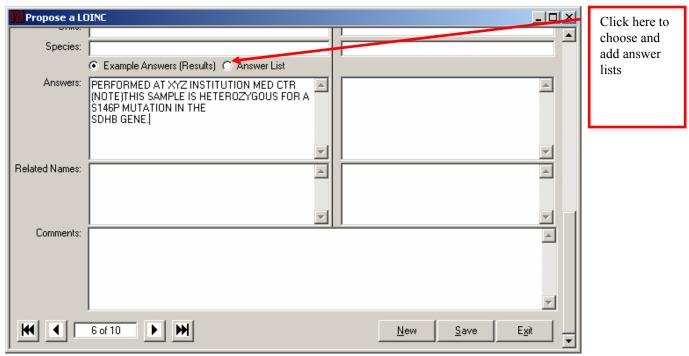


Figure 9 – Example answers (sample results)

Because additional information helps the staff at Regenstrief understand better the nature of your requests, providing example answers or sample results provides the context and output of your requested test(s). You may include anything from a short description like in the figure above or a long block of text from an HL7 message. Any and all information you can provide will be helpful to those who evaluate your requests.

NOTE: When including HL7 messages as sample results, please be sure to remove patient identifying information.

Sometimes your tests will have answers that come from answer lists defined in your information systems. Providing the answers for these lists is just as helpful as including HL7 messages as sample results. The form provides a mechanism by which you can define answer lists. To define a list, first click on the round circle labeled "Answer List" shown in Figure 9. This will change the form so it displays a dropdown textbox with a list of available answer lists. Also displayed is a button labeled "New Answer List." Clicking this button will display the form shown in Figure 11.

Enter the information for the new answer list then click the "Save/Exit" button. This will return you to the "Propose LOINC" form and the newly defined answer list should be selected for the requested term.

Click this

button to

define a new

answer list

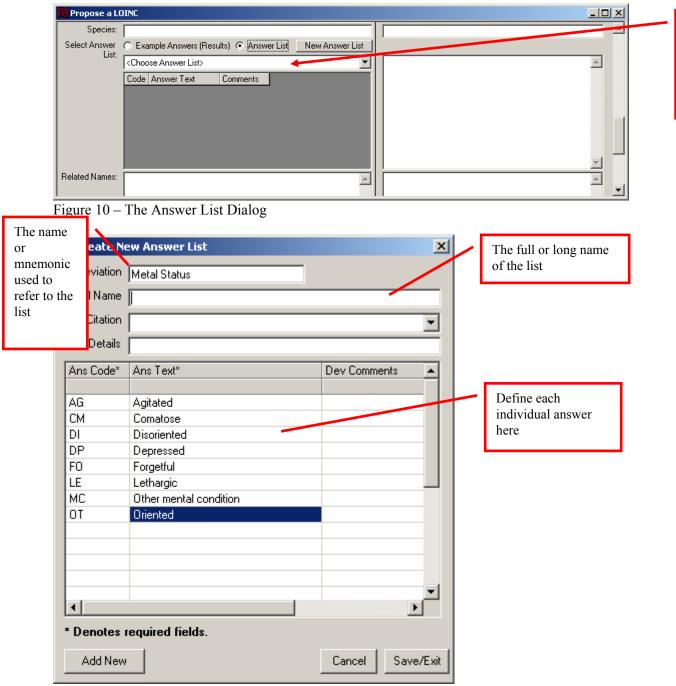


Figure 11 – Defining a new answer list

Proposing a LOINC using an Existing LOINC

To propose a new LOINC term using an existing LOINC as a base from which you may start editing, open the mapping screen. From the mapping screen, conduct a search to find the LOINC that is the closest match to the term you wish to request. Highlight the closest match term by clicking once with the left mouse button and then click the "Propose LOINC" button. An example is shown below.

- Step 1 Conduct search on mapping screen
- Step 2 Highlight LOINC term that best matches the term you wish to propose
- Step 3 Click the "Propose LOINC" button to request a term

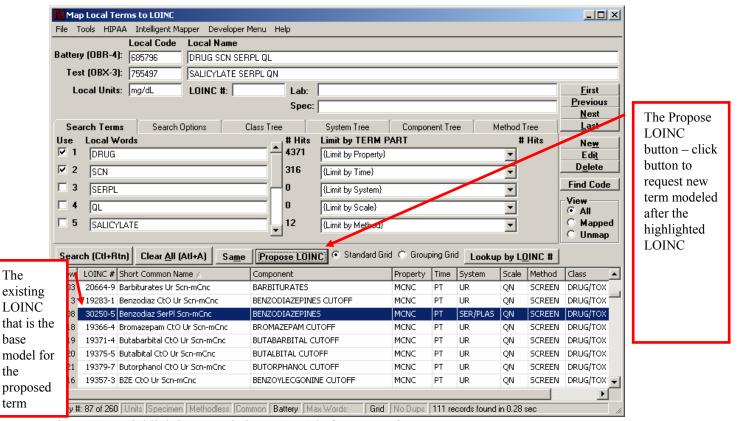


Figure 12 – Highlighting an existing LOINC before proposing a new one

In the example above, the user has conducted a search to map his local term (SALICYLATE SERPL QN) to a LOINC code and come up empty. While there are many drug screens, there exists no LOINC term for a Salicylate drug screen. The user selects the nearest match in the results grid (30250-5) then presses the Propose LOINC button. The user next sees the Propose LOINC form shown below in XXX.

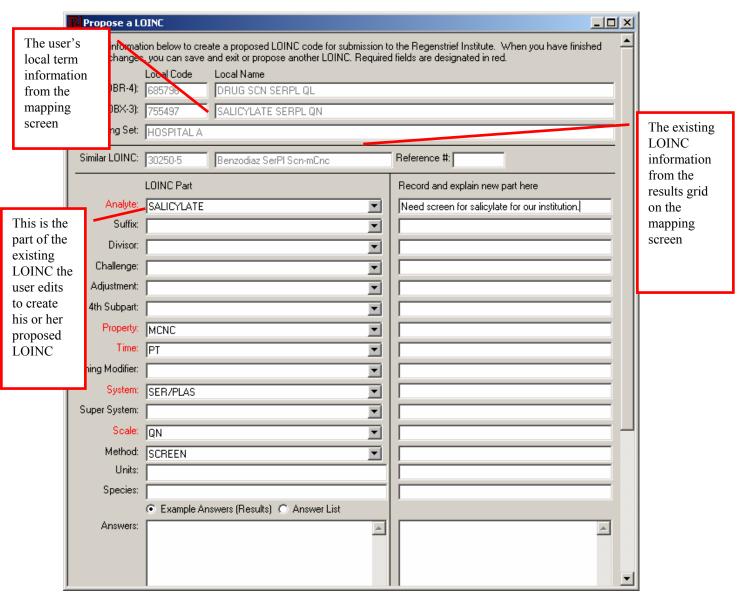
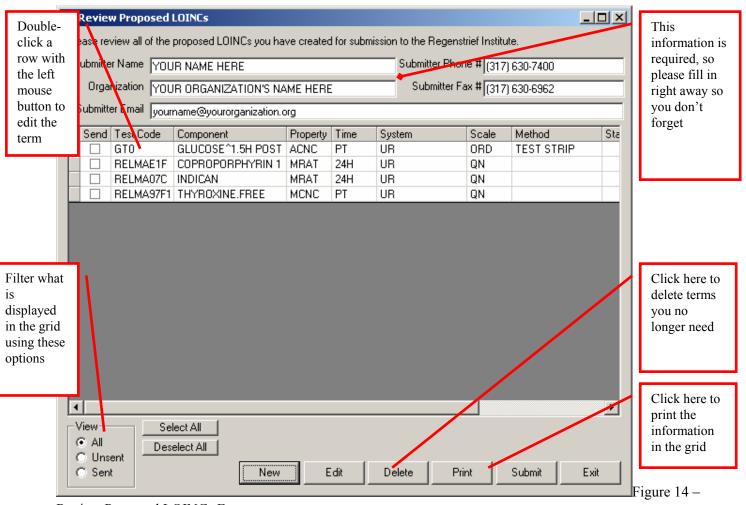


Figure 13 – Proposing a LOINC based on an existing one.

After pressing the "Propose LOINC" button, the Propose LOINC form opens and the information from the mapping screen is copied into the various sections of the form. The user may then edit the part or parts of the existing term in order to create the unique concept he or she wishes to propose.

Reviewing Submission Terms in RELMA

Once you have entered one or more proposed LOINCs using the methods described above, you may wish to review the terms you've created and prepare them for submission. Choosing the "Review Proposed LOINCs" from the File menu on either the welcome or mapping screen will bring up a form similar to the one shown in Figure 14 below.



Review Proposed LOINCs Form

Before you can submit your proposed LOINCs, it is required that you provide your name, organization name, and contact information (phone, fax and email) so that a staff member at Regenstrief may contact you regarding your submission if necessary. Once provided on the form, this information will be saved and loaded each time you run the RELMA program, so it is recommended that you enter this information the first time you view the form.

Loaded into the grid in the center of the form are key pieces of the requested terms you have created using the methods described in the previous sections of this users' manual. The column labeled "Send" contains a checkbox that you can use to select groups of proposed LOINCs you desire to submit to Regenstrief. The column labeled "Test Code" represents a local code from your system that this proposed LOINC is based on. Some codes will have the prefix "RELMA." These codes were generated by the RELMA program when no local code information was available (i.e. you started the requested term from scratch or did not have a working set term showing on the mapping screen). The next set of columns in the grid represents the six parts of your proposed LOINC. These fields should help you identify and distinguish between the many terms you might create. The final fields in the grid help you distinguish between those codes you have previously submitted and those you have not yet submitted.

Of course, you can filter the grid to display only non-submitted or only submitted terms by choosing a different value for the "View" box in the bottom left-hand corner of the form.

To create a new proposed LOINC from scratch, click on the "New" button. To edit a requested term, highlight the term in the grid by clicking on it with the left mouse button then click on the "Edit" button. You can permanently delete one or more proposed LOINCs by first highlighting them using the mouse then clicking the "Delete" button. Clicking on the "Print" button allows you to print the items currently displayed in the grid. See instructions below when using the "Submit" button. The "Exit" button closes the form and returns you to either the welcome or mapping screen.

Submitting a Submission File Using RELMA

To submit terms created and reviewed using the methods described in the previous sections of this appendix, follow the steps outlined below. Users need only to choose which terms they wish to submit, click the submit button then send the file created by RELMA either via email or snail mail to the staff at Regenstrief.

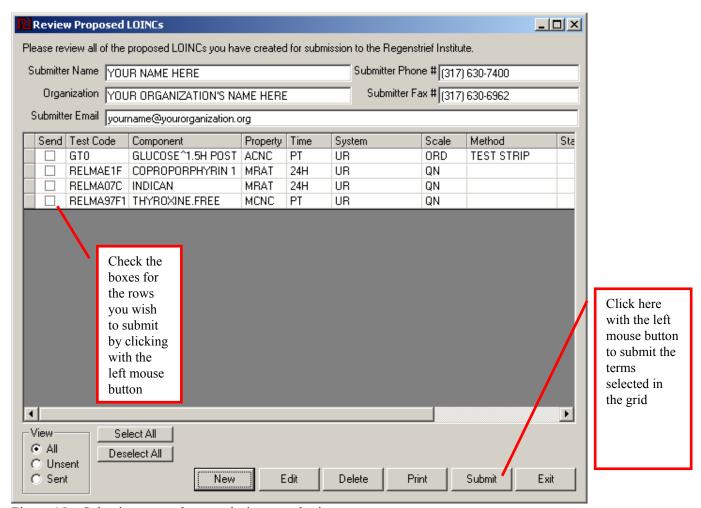


Figure 15 – Selecting terms the user desires to submit

1. Select the terms you wish to submit. To do this, use the left mouse button and click on the "Send" column of the grid to change the checkbox value from blank to a checkmark. To select all terms previously unsent, you may click on the "Select All" button below the grid on the left side of the form. To deselect all terms, you may click on the "Deselect All" button below the grid on the left side of the form. Terms previously sent will have a status of "SENT." Be careful when selecting terms because while you are allowed to submit the same term more than once this practice is not recommended. Sending large batches that contain previously requested terms may slow down the submission process.

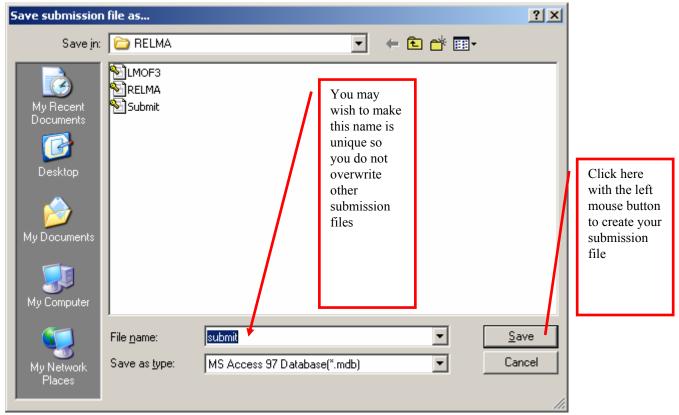


Figure 16 – Windows Common Dialog box used to create LOINC submission files

2. Once you have selected the terms you wish to submit, click on the "Submit" button. Doing this will bring up a Windows Common Dialog box (displayed above as Figure 16) which will prompt you for the location and name of the submission file you are creating. **Remember the name and location of this file**. The default name and location is "C:\Program Files\RELMA\submit.mdb". Once you have entered a name and location for the file, click the "Save" button.



Figure 17 – Message displayed after submission file has been created

3. RELMA will now take the selected proposed LOINCs and create a submission file with the name and location provided by you in step 2. This may take a few moments if you have a lot of terms to submit. Be patient. Once the file has been created, RELMA will display a message similar to the one shown in Figure 17. The message instructs you to email the file to kmercer@regenstrief.org. This is the final step in the process. If you do not have access to email, you may copy this file on a CD or floppy disk and mail it to:

Kathy Mercer Regenstrief Institute, RG5 1050 Wishard Blvd. Indianapolis, IN 46205 Once your file has been received, you should receive a confirmation email and the submission process will be underway. You may receive communication from Regenstrief with requests for further information if required. Once the submission process has completed, you will receive your file back with the additional fields described in Table 22b.

Appendix E - LOINC Printed Report Description

Due to size restrictions, the pdf version of the database contains only some of the database fields. Table 23 shows the fields that appear on the printed version.

Table 23: Columns Appearing on Printed Reports

Status

Class

LOINC Number

Map To

Analyte/Component Name

Type of Property

Time Aspect

System/Specimen

Type of Scale

Method

Related Names 2

Exact Core Component Synonym

Date Last Changed

Reason for Change

Answer List

EUCLIDES Code

IUPAC Analyte Code

Molar Mass

Appendix F - Examples for LOINC Property Matching

1. Content (CNT). Like concentration except that *volume* in the denominator is replaced by *mass*. By extension:

CCNT Catalytic Content, catalytic activity of a component per unit mass of a sample (system). 24048-1|ALPHA GALACTOSIDASE:CCNT:PT:FIB:QN

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

9435-9|ISOPROPANOL:MCNT:PT:TISS:QN

Note: All of the heavy metal measurements in hair, nails, and tissue should all be mass contents. 8157-0|ARSENIC:MCNT:PT:NAIL:QN

NCNT Number Content, number of component entities per unit mass of a sample (system). 20711-2|COLIFORM BACTERIA: NCNT:PT:EGG:QN:VIABILITY COUNT

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

CFR Catalytic Fraction

2536-1|LACTATE DEHYDROGENASE.FRACTION 1/LACTATE

DEHYDROGENASE.TOTAL:CFR:PT:SER:QN

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:SMN:QN 764-1|NEUTROPHILS BAND FORM/100 LEUKOCYTES:NFR:PT:BLD:QN:MANUAL COUNT

MFR Mass Fraction

2614-6|METHEMOGLOBIN/HEMOGLOBIN.TOTAL:MFR:PT:BLD:QN

SFR Substance Fraction

4546-8|HEMOGLOBIN A/HEMOGLOBIN.TOTAL:SFR:PT:BLD:QN

VRFVolume fraction.

4545-0|HEMATOCRIT:VFR:PT:BLD:QN:SPUN

3. Ratio (**RTO**). Ratio of component A to component B in system 1. By extension:

CCRTO Catalytic Concentration Ratio

2325-9|GAMMA GLUTAMYL TRANSFERASE/ASPARTATE AMINO TRANSFERASE :CCRTO:PT:SER:QN

SCRTO Substance Concentration Ratio

2958-7|SODIUM/POTASSIUM:SCRTO:PT:SWT:QN

MCRTO Mass Concentration Ratio

2768-0|PHENYLALANINE/TYROSINE:MCRTO:PT:SER:QN

NRTO Number Ratio

11138-5|MYELOID CELLS/THYROID CELLS:NRTO:PT:MAR:QN

TRTO Time Ratio

6302-4|COAGULATION TISSUE FACTOR INDUCED. NORMAL/ACTUAL:TRTO:PT: PPP^PATIENT:ON

VELRTO Velocity Ratio

12022-0|RESISTIVITY INDEX:VELRTO:PT: UTERINE ARTERY.RIGHT^PATIENT:

DOPPLER.CALCULATED

VRATRTO Volume Rate Ratio

20294-5|PULMONIC FLOW/SYSTEMIC FLOW:VRATRTO:PT:CIRCULATORY SYSTEM.XXX:QN

VRTO Volume Ratio

8819-5|EJECTION FRACTION:VRTO:PT:HEART.VENTRICLE.RIGHT:QN:MRI

RATIO

1811-9|AMYLASE/CREATININE RENAL CLEARANCE:24H:UR: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, RLMCNC (see below).

Note:

If the units of the denominator and numerator are both mass (e.g. mg/g), use MCRTO 13719-0|CARNITINE/CREATININE:MCRTO:PT:UR:QN

If the units of the denominator and numerator are both substance (e.g. mmol/mol) use SCRTO

22695-1|CARNITINE/CREATININE:SCRTO:PT:UR:QN

If the units of the denominator and numerator are different (mmol/g), use RATIO

17866-5|CARNITINE/CREATININE:RATIO:PT:UR:QN

4. Relative (REL/RL). 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.

RLMCNC Relative Mass Concentration (as noted previously)

2858-9|PROTEIN CSF/PROTEIN SERUM:RLMCNC:PT:CSF+SER:QN

3235-9|COAGULATION FACTOR XII AG ACTUAL/NORMAL:RLMCNC:PT:PPP:QN:IMM

RLTM Relative time

3232-6|COAGULATION FACTOR XII ACTIVITY ACTUAL/NORMAL:RLTM:PT:PPP:QN:COAG

RLCCNC Relative Catalytic Concentration

28660-9|PLASMINOGEN ACTUAL/NORMAL:RLCCNC:PT:PPP:QN:ENZY

RELRTO Relative Ratio

20450-3|ALPHA-1-FETOPROTEIN MULTIPLE OF THE

MEDIAN:RELRTO:PT:SER:QN:CALCULATED

RELVOL Relative Volume

19853-1|CAPACITY.INSPIRATORY.BS/CAPACITY.INSPIRATORY.PREOP:RELVOL:PT:

(EIA units)

RESPIRATORY SYSTEM: QN: SPIROMETRY

RELVRAT Relative Volume Rate 2016-6|VOLUNTARY VENTILATION.MAX^POST BRONCHODILATOR/MVV PREDICTED:RELVRAT:PT:RESPIRATORY SYSTEM:QN

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

Possible Values	Property	<u>Scale</u>
Units, International Units, IU	ARB	QN
Units/ml, IU/ml, etc.	ACNC	QN
Units/gm, IU/gm, etc.	ACNT	QN
Unit/min, IU/24hr, etc.	ARAT	QN
Unitless (Patient/Control)	AFR	QN

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

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

Possible Values	Property	Scale
Units, International Units, IU	CRB	QN
IU/ml, Units/ml, etc.	CCNC	QN
IU/gm, Units/gm, etc.	CCNT	QN
IU/24hr, Unit/min, etc.	CRAT	QN
Unitless (Patient/Control)	CFR	QN

7. If the property is TITR then the scale is always QN.

For any X AB or AG

Possible Values	Property	<u>Scale</u>
<1:2, 1:4, 1:8	TITR	QN

8. For:

Any X AB or AG

Possible Values	Property	<u>Scale</u>
Neg, Indeterminate, Pos	ACNC	ORD
1+, 2+, 3+,	ACNC	ORD
<1:2, 1:4, 1:8	TITR	QN
Neg, 1:4, 1:8,	TITR	QN
Neg, 0.90,	ACNC	QN

9. For any intensive evaluation whose value comes from a finite set of unranked (independent) coded items the property will be PRID (or TYPE) and scale NOM. For extensive measures whose value comes from a finite set of unranked coded items, the property will be the extensive property, and the scale will be NOM.

Intensive Properties	Possible Values (coded)	Property	Scale
Organism Identified	E. coli, S. aureus, etc.	PRID	NOM
ABO Group	A, B, AB, O	PRID	NOM
Surgery (Dis. Summary)	Cholecystectomy, Appendectomy	PRID	NOM
Extensive Properties	Possible Values (coded)	Property	Scale
Urine Color	Amber, straw, etc.	COLOR	NOM
Urine Turbidity	Hazy, cloudy, opaque	TURBIDITY	NOM

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

Intensive Properties	Possible Values (text)	Property	Scale
Organism Identified	E. coli, S. aureus, etc.	PRID	NAR
ABO Group	A, B, AB, O	PRID	NAR
Surgery (Dis. Summary)Cholecystectomy	PRID	NAR
Extensive Properties	Possible Values (text)	Property	Scale
Urine Color	Amber, straw, etc.	COLOR	NAR
Urine Turbidity	Hazy, cloudy, opaque	TURBIDITY	NAR

11. IMP is used to represent the property when the evaluation is a mental abstraction based on one a collection of measurements and or data. For example, if several measurements are made relative to immunoglobin levels in SERUM and CSF in a myasthenia gravis panel, and if by examining all of the evidence a pathologist decided that this pattern of findings represented active disease (which could be represented as a coded value), the result of the pathologist thought process would be represented as:

	Possible Values (text)	Property	Scale
Myasthenia Evaluation	No disease, chronic disease	IMP	NOM

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

Myasthenia Evaluation No disease, chronic disease IMP NAR

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

>ml/min/sqM. A sibling to ml/min/sqM should be ml/min/1.73sqM.

Appendix G - LOINC COMMITTEE MEMBERS

Name	Organization	City, State/Prov, Country
Ray Aller	Integrated Regional Laboratories	Snellville, GA
John Baenziger	Indiana University Hospital,	Indianapolis, IN
Suzanne Bakken	Columbia School of Nursing	New York, NY
Pam Banning	3M	West Linn, OR
Rita Barsoum	Kaiser Permanente	Pasadena, CA
James Barthel	H. Lee Moffitt Cancer Ctr	Tampa, FL
Harold Beckala	Mayo Medical Laboratories	Rochester, MN
Dean Bidgood	Duke Medical Center	Durham, NC
Bruce Bray	University of Utah	Salt Lake City, UT
James Campbell	University of Nebraska	Omaha, NE
Jim Case	California Veterinary Diag Labs	Davis, CA
Jim Cimino	Columbia Presbyterian Med Center	New York, NY
Ronda Crist	ARUP Laboratories	Salt Lake City, UT
Robert Dolin	Mayo Foundation	Rochester, MN
James K Fleming	Laboratory Corp of America	Burlington, NC
Arden Forrey	University of Washington	Seattle, WA
Bill Francis	Augilent Technologies	Andover, MA
Pavla Frazier	University of Utah	Salt Lake City, UT
Andy Gajda	Clinical Laboratory Consultation	Killaloe, ON, Canada
Alan Golichowski	Indiana Univ. Dept. of Medicine	Indianapolis, IN
Barry Gordon	C/NET Solutions	Berkeley, CA
Brian Griffin	Quest Diagnostics	Rutherford, NJ
Gil Hill	Hospital for Sick Children	Toronto, ON, Canada
Stan Huff	Intermountain Health Care	Salt Lake City, UT
William (Bill) Karitis	Department of Defence, U.S. Navy	Onley, MD
Jeff Lamothe	USAF	Biloxi, MS
Dennis Leavelle	Mayo Medical Laboratories	Rochester, MN
Lee Min Lau	3M HIS	Salt Lake City, UT
Diane Leland	Riley Hospital for Children	Indianapolis, IN
Pat Maloney	Quest Diagnostics	Teterboro, NJ
Doug Martin	Roudebush VA Medical Center	Indianapolis, IN

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Susan Matney	Intermountain Health Care	Salt Lake City, UT
Ken McCaslin	Quest Diagnostics	Collegeville, PA
Clem McDonald	Regenstrief Institute/IUSM	Indianapolis, IN
Kathy Mercer	Regenstrief Institute	Indianapolis, IN
Deirdre O'Neill	National Medical Services Assoc	Willow Grove, PA
Judy Ozbolt	Vanderbilt University	Nashville, TN
Dan Pollock	Centers for Disease Control	Atlanta, GA
Rick Press	Oregon Health Sciences University	Portland, OR
Christine Raine	Parners Healthcare, Inc.	Brookline, MA
Angelo Rossi Mori	Instituto Tecnologie Biomediche	Rome, Italy
Margie Scott	Central AR VA Healthcare System	Little Rock, AR
Shawn Shakib	3M HIS	Salt Lake City, UT
John Stelling	World Health Organization	Geneva, Switzerland
Steve Steindel	CDC	Atlanta, GA
Jeff Suico	Eli Lilly & Co.	Indianapolis, IN
Anders Thurin	University Hospital	Linkoping, Sweden
Wayne Tracy	Health Patterns, LLC	Overland Park, KS
Alex Tuszynski	Strategic Healthcare Group (VA)	Washington, DC
Margaret Vaughn	Partners HealthCare System, Inc.	Boston, MA
Larry West	ARUP Laboratories	Salt Lake City, UT
Thomas White	New York State Office of Mental Health	New York, NY
Warren Williams	CDC and Prevention	Atlanta, GA
Pat Wilson	3M HIS	Salt Lake City, UT

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