LOINC SARS-CoV-2 Term Processing

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LOINC and Health Data Standards
Overview

• Typical LOINC term creation process
• Current queue
• LOINC term processing for Special Use codes
• Recommendations on use of prerelease codes
• SARS-CoV-2 term names
• Mapping to SARS-CoV-2 LOINC codes
Typical term creation process

• New requests are received almost daily from LOINC users
• Processed in the order that they are received
• Turn-around time is 3+ months on average
• New codes are published on the prerelease page (updated monthly)
Submitting New Term Requests

What information we need

The information you provide about your local test/measurement and how it is used is more important than the proposed LOINC name you come up with. Having complete information on what your local test is makes the review process much smoother. It helps us create clear term definitions as well as verifying and enhancing other accessory content, which benefits everyone.

The kinds of information we need does vary a bit depending on the type of content (lab, radiology, document titles, survey questionnaires, etc), so not all items are applicable all of the time.

In order for us to process your request, we need:

- Local test/observation name
- Local order (panel) name
- Description of the test (what it measures, how it is performed, what it is used for, and clinical relevance)
- Name of send out lab (if applicable)
- Name of healthcare organization that stimulated the request for this term (if you are submitting on behalf of someone else)
- Units of measure (for quantitative observations)
- Answer lists (for qualitative observations)
- Sample results, reports (if applicable)
- Package inserts, test kit documentation (if applicable)
- Vendor, instrument, and/or reagent kit used to perform this test (if applicable)
- Description of the project or activity that stimulated the request for this term (e.g. IHE Antepartum Record Profile, Indiana Network for Patient Care health information exchange project, etc)
- Implementation guide (for terms designed for use in the context of a specific messaging implementation guide), or any other documentation you have
- If the request is for a panel, you must indicate the tests that comprise the panel
  - Tell us which tests in the panel already have a LOINC code
  - For any tests in the panel that do not already have a LOINC code, you’ll need to supply all of the above information. These new test terms should be separate request entries in your submission.

New LOINC term request form

Use our new form to submit your next LOINC term request. We welcome your feedback as we continue to improve this new process.
RELMA

RELMA® is the Regenstrief LOINC Mapping Assistant

Regenstrief Institute provides a Windows-based mapping utility called RELMA for searching the LOINC database and mapping local codes to LOINC codes.

Like the LOINC database, this program is available for free.

Download RELMA
Version 7.0

Approved LOINC Submission Templates

<table>
<thead>
<tr>
<th>Basic Submissions</th>
<th>Lab Submissions</th>
<th>Surveys/Forms Submissions</th>
<th>Radiology Submissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use this template if you don’t have RELMA and are requesting new document or report titles, or simple clinical measurements.</td>
<td>Use this template if you don’t have RELMA and are requesting new laboratory tests. (It has an easy way to specify panels too.)</td>
<td>Use this template if you are submitting a survey instrument, form, or data set. (Includes examples and the original forms for reference.)</td>
<td>Use this template if you are submitting requests for new radiology procedure codes. (Includes examples.)</td>
</tr>
</tbody>
</table>

Basic Submission Template
Lab Submission Template
Form Submission Template
Radiology Submission Template

When you’re ready with your submission template, attach your file(s) to an email and send it to: submissions@loinc.org
Submission Queue Stats

LOINC Queue
Last updated 1 day ago

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
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</thead>
<tbody>
<tr>
<td>Requests</td>
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</tr>
<tr>
<td>Requested LOINCs</td>
<td>1,445</td>
</tr>
<tr>
<td>Requested LOINCs Pending Copyright Approval</td>
<td>10</td>
</tr>
<tr>
<td>LOINCs Created Since Last Release</td>
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</table>

Median Turnaround for New Terms
Median turnaround time is based on the last two completed LOINC release cycles plus the current cycle.

114 DAYS
**Submission Queue Details**

Showing 1 to 15 of 28 entries (filtered from 1,647 total entries)

<table>
<thead>
<tr>
<th>Status</th>
<th>Updated</th>
<th>ID</th>
<th>Set</th>
<th>Class</th>
<th>Component</th>
<th>Property</th>
<th>Time</th>
<th>System</th>
<th>Scale</th>
<th>Method</th>
<th>LOINC</th>
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<tbody>
<tr>
<td>Done</td>
<td>2 days ago</td>
<td>45934</td>
<td>5348</td>
<td></td>
<td>SARS-related coronavirus RNA</td>
<td>PrThr</td>
<td>Pt</td>
<td>Respiratory</td>
<td>Ord</td>
<td>Probe.amp.tar</td>
<td>94502-2</td>
</tr>
<tr>
<td>Done</td>
<td>2 days ago</td>
<td>46116</td>
<td>5364</td>
<td></td>
<td>SARS-related coronavirus + MERS coronavirus</td>
<td>PrThr</td>
<td>Pt</td>
<td>Respiratory</td>
<td>Ord</td>
<td>Probe.amp.tar</td>
<td>94532-9</td>
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<tr>
<td>On Hold per LOINC</td>
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<td>5392</td>
<td></td>
<td>SARS coronavirus + SARS coronavirus 2 RNA</td>
<td>PrThr</td>
<td>Pt</td>
<td>Respiratory</td>
<td>Ord</td>
<td>Probe.amp.tar</td>
<td></td>
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<tr>
<td>Done</td>
<td>7 days ago</td>
<td>46159</td>
<td>5373</td>
<td></td>
<td>SARS coronavirus 2 Ab.IgG &amp; IgM panel</td>
<td>-</td>
<td>Pt</td>
<td>$er/Plas</td>
<td>Ord</td>
<td>IA.rapid</td>
<td>94503-8</td>
</tr>
<tr>
<td>Done</td>
<td>7 days ago</td>
<td>46160</td>
<td>5373</td>
<td></td>
<td>SARS coronavirus 2 Ab.IgM</td>
<td>PrThr</td>
<td>Pt</td>
<td>$er/Plas</td>
<td>Ord</td>
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<td>Ord</td>
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<td>Ord</td>
<td>IA</td>
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<td>-</td>
<td>Pt</td>
<td>Respiratory</td>
<td>-</td>
<td>Probe.amp.tar</td>
<td>94533-1</td>
</tr>
</tbody>
</table>

Click here to view details about your term requests (must be logged in)

Search on key words or IDs:

[SARS]
Processing of New Requests

- Initial intake and review of supporting materials
- Questions or requests for additional information sent to submitter if needed
- Loaded into the LOINC submission system
- Each submission and requested term is assigned a unique ID
- Submissions are assigned various statuses (New, Pending, In Process, QA Review, etc.) as they are processed
- All new terms complete QA Review by internal and external reviewers
New Term Attributes

• Parts (Component, Property, etc.)
• Display names
• Answer list
• Example units
• Term & part descriptions
• Synonyms
• Related Codes
• Tags (Special usage)
• Many more, depending on use-case
Special Use Term Requests

• Developed in response to an urgent or emergent situation (e.g. infectious disease outbreak)
• Requests may be initiated by the LOINC team or come from users (labs, manufacturers)
• Expedited (24-48 hour turn-around time)
• Complete QA review
• Published on Prerelease page with Special Usage label
Special Usage Prerelease codes

- Not yet part of an official LOINC release...therefore, not available as a direct download
- You can copy/paste the data from the prerelease page for use in your system
- The terms will be published in the next LOINC release (June).

⚠️ Keep track of updates...
1) Terms may change
2) Additional codes may be added
Special Use LOINC codes

Special Use codes are developed in response to an urgent or emergent situation. These codes are based on the most up-to-date information available at the time of their creation. They have undergone the normal QA terminology process. LOINC supports their use in the unique situation that resulted in their rapid creation. However, be aware that downstream users may not be ready to handle prerelease codes until they are published in an official release.
All Other Prerelease codes

- In general, provided for informational purposes only
- Under development by the LOINC team
- It is possible that they may not be published in the next, or any, public release
- See Section 11.4 of LOINC Users’ Guide for additional information
Current list of prerelease LOINC codes for SARS-CoV-2 testing

https://loinc.org/prerelease/
**Component for SARS-CoV-2 codes**

- Represents the analyte being measured
- Codes that identify the virus
  - Molecular
    - SARS-CoV-2 E gene
    - SARS-CoV-2 RNA
  - Antigen
    - SARS-CoV-2 Ag
- Plus ‘+’ means detects but does not differentiate
  - SARS-CoV-2 IgG+IgM
  - SARS-related CoV+MERS
System for SARS-CoV-2 codes

- **Respiratory**
  - For SARS-CoV-2 RNA assays - primary specimen is respiratory
  - e.g. nasopharyngeal or throat swabs, or sputum
  - If your lab is testing respiratory specimens, **we strongly recommend that you use respiratory-specific LOINC codes**
  - Specimen information should be sent separately in the electronic result message

- **XXX**
  - Implies the specimen is not known or multiple unique specimen types (e.g., respiratory, blood, urine, environmental) may be tested
  - Specimen information is sent separately in the electronic result message
  - For COVID-19 testing, LOINC terms with System **XXX** were created for cases where respiratory, stool, urine, or blood, may be tested now or in the future
System for SARS-CoV-2 codes (Cont.)

- Ser/Plas
  - Serum or plasma
  - Generally used for serology (antibody) testing
- Additional LOINC codes with more specific Systems may be created
  - Respiratory → Upper, Lower, Nph, etc.
  - Urine
Method for SARS-CoV-2 codes

- Probe.amp.tar
  - Nucleic acid amplification of a target (=amp.tar) with probe-based detection (=Probe)
  - As of March 2020, almost all assays use this method

- IA & IA.Rapid
  - As of March 2020, all of the existing antibody and antigen tests in LOINC are based on immunoassays (IA). Serology testing is not yet widely available.
  - “Rapid” in LOINC = <60 minutes to complete test
Property/Scale for SARS-CoV-2 codes

• **PrThr/Ord → Ordinal**
  
  94500-6  SARS coronavirus 2 RNA : PrThr: Pt : Respiratory: Ord: Probe.amp.tar
  
  LCN: SARS coronavirus 2 RNA [Presence] in Respiratory specimen by NAA with probe detection
  
  Ex. results: Positive, Presumptive positive, Negative, Invalid

• **ThreshNum/Qn → Quantitative**
  
  
  LCN: SARS coronavirus 2 N gene [Cycle Threshold #] in Unspecified specimen by NAA using primer-probe set N1 (CDC assay)
  
  Ex. result: >30 Ct

• **Dash (¬) → Panel (battery)**
  
  94531-1  SARS coronavirus 2 RNA panel : - : Pt : Respiratory: - : Probe.amp.tar
  
  LCN: SARS coronavirus 2 RNA panel - Respiratory specimen by NAA with probe detection
SARS-CoV-2 Panel codes

- ONLY used for test orders (batteries) and NOT for reporting results
- Panel codes have the word "panel" in the Component and a dash ("-") for the Property
- They contain a collection of LOINC codes that are used to report the results for each individual test.

RT-PCR battery/panel codes
- LOINC 94531-1 (respiratory specimens)
- LOINC 94306-8 (unspecified specimens)

IgG and IgM antibody (serology) battery/panel codes
- LOINC 94503-0 (qualitative results)
- LOINC 94504-8 (quantitative results)
Mapping to LOINC

1) We strongly recommend that you find out which test kit your laboratory is using
2) Contact the lab or manufacturer to determine which codes are most appropriate
3) Determine what is being measured/reported (Component)
4) Determine specimens tested (System)
5) Determine what results are reported (Property/Scale)
6) Determine the method of analysis (Method)

Most common code for mapping:

94500-6 SARS coronavirus 2 RNA [Presence] in Respiratory specimen by NAA with probe detection

Ex. results: Positive, Presumptive positive, Negative, Invalid
More tips...

- Panel LOINC codes are only for orders and should NOT be mapped to a single test/result.
- If your lab is running a single test, the same non-panel LOINC can be used for the order and result.
- **Human Coronavirus terms** are NOT the same as SARS-related CoV terms.
  - Common cause of wintertime respiratory infections
  - Often part of respiratory panels and done in addition to Influenza testing
  - Will not detect SARS-CoV-2 since the target is not common
- Tests that detect **SARS-CoV** are different from tests for SARS-CoV-2.
Effect of COVID-19 on New Term Requests

- Routine submission processing has slowed
- SARS-CoV-2 term requests take priority
- Median turn-around time includes SARS-CoV-2 terms, so actual time may be longer for usual, routine requests
Legal stuff - LOINC License

No cost use
Worldwide
Commercial or non-commercial purposes
Encourages translation
One major prohibition...

**CANNOT** use any licensed material to develop or propagate a different standard for orders or observations.

http://loinc.org/license
More information is available on loinc.org

SARS-CoV-2 Information/FAQ page