Dear State and Local Public Health Laboratory Directors,

This communication provides an updated set of informatics-related FAQs and additional guidance to support PHL-to-CDC COVID-19 data messaging work. Updates include:

- Message Validation Guidance
- Updated COVID-19 terminology and encoding guidelines
- Updated HL7 sample messages

For informatics related technical assistance needs, please contact APHL’s Help Desk at informatics.support@aphl.org. For all other questions, please contact APHL at eoc@aphl.org.

Thank you,
Scott

Scott J. Becker, MS
Executive Director
240.485.2747
scott.becker@aphl.org
@scottjbecker
COVID-19 messages do not require re-validation due to the removal of ‘SARS-like CoV N’ target, however, please read the following details:

1) PHLs that have already passed HL7 test message validation and are in production:
   - If reporting COVID-19 targets, do not include ‘SARS-like CoV N’ (N3) PCR target and/or CT target. If reporting ONLY conclusions, and no targets, the overall conclusion and reporting algorithm does not change.

2) PHLs in progress with HL7 test message validation:
   - You can opt to continue with current test message validation or opt to update test messages with the removal of SARS-like CoV N (N3) target.

3) PHLs that have not begun HL7 test message validation:
   - PHLs utilizing PHLIP that have not started test message validation should refer to the table below to submit test messages through a test/staging route for validation with CDC.

<table>
<thead>
<tr>
<th>2019 nCoV_N1</th>
<th>2019 nCoV_N2</th>
<th>RNase_P</th>
<th>Report Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detected</td>
<td>Detected</td>
<td>Detected</td>
<td>Detected OR Not detected</td>
</tr>
<tr>
<td>If only one or two of the targets are detected</td>
<td>Detected OR Not detected</td>
<td>Inconclusive</td>
<td></td>
</tr>
<tr>
<td>Not detected</td>
<td>Not detected</td>
<td>Detected</td>
<td>Not detected</td>
</tr>
<tr>
<td>Not detected</td>
<td>Not detected</td>
<td>Not detected</td>
<td>Specimen unsatisfactory for evaluation</td>
</tr>
</tbody>
</table>

Updated COVID-19 Terminology and encoding guidelines

The COVID-19 encoding guidelines have been revised to reflect the new terminology. You can also find this terminology at https://loinc.org/prerelease/ for support.

Updated COVID-19 sample messages

APHL has updated the eight (8) test message scenarios to support data exchange work (4 for HL7 2.5.1 and 4 for HL7 2.3.1). Please be sure to use the correct HL7 version sample messages when developing your test messages. Sample message can be found at:
### Technical Assistance (TA) Requests and Help Desk

**Can I request Informatics Technical Assistance?**
Yes, APHL can provide technical assistance in the following areas:
- Standardized terminology/vocabulary
- Data integration
- HL7 message generation
- Message Transport
- General COVID-19 Informatics questions

**How do I request Technical Assistance?**
- If your PHL has not completed the 2-question assessment, please do so before submitting a TA request.
- If your PHL has not requested COVID-19 TA to date, please open a new APHL's Help Desk ticket outlining your TA needs and include COVID-19 Technical Assistance Request in the subject line.
- If your PHL has already submitted a TA request through the Informatics Help Desk, please respond to the initial Help Desk ticket thread with your updated or new TA request.

### Testing and Validating COVID-19 Messages

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>How do I send my HL7 test messages?</td>
<td>PHLs will send COVID-19 HL7 messages in the same data stream as your current Public Health Laboratory Interoperability Project (PHLIP) data (HL7 2.3.1 or 2.5.1), however, test messages <strong>MUST</strong> be successfully validated by the CDC COVID-19 messaging leads in order to receive approval to migrate to production. As such, all test messages must be sent from a <strong>Staging Environment, not Production.</strong> If you cannot meet these requirements, please open an Informatics Help Desk ticket or respond to an existing COVID-19 TA request with additional questions or issues.</td>
</tr>
<tr>
<td>May I send a single message to see if my transport is set up correctly?</td>
<td>Yes, please send your test transport message with the contents “Hello World.” The “Hello World” helps us know that the message was intentionally sent and no further action is needed.</td>
</tr>
</tbody>
</table>
**Do we need to notify anyone when I send the test messages?**

Yes- Anytime that you send test messages through Staging, please alert APHL by responding to an already open COVID-19 Help Desk ticket or opening a new ticket entitled **COVID-19 Message Validation** that includes:

- The message count
- Date/time the messages were sent.

The APHL team will follow up with CDC and a response will be returned as soon as possible.

**How will I know I am ready to send COVID-19 in production?**

The Technical Assistance team will respond to the already open APHL Informatics Help Desk ticket with CDC’s approval and instructions to move to full production. Please do NOT send any messages through production until instructed to do so.

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### COVID-19 message mapping

**Question**

Which descriptions should we use, as there seems to be minor differences in the target descriptions between the EUA and the APHL COVID-19 Encoding Guidelines?

**Response**

PHLs should use the descriptions indicated in the COVID-19 encoding guidelines to report targets in conjunction with the associated LOINC codes in OBX-3.1 to OBX-3.3. These are the official LOINC descriptions approved by CDC.

The EUA target descriptions may be incorporated as local test codes in OBX-3.4 to OBX-3.6.

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**Question**

There seems to be differences in the interpretation descriptions between the EUA and the APHL COVID-19 Encoding Guidelines. Which should be used for COVID-19PHLIP reporting?

**Response**

PHLs should use the interpretation descriptions indicated in the encoding guidelines for COVID-19 reporting in conjunction with the associated SNOMED codes in OBX-5.1 to OBX-5.3.

For example:

- ‘Detected’ should be used instead of ‘Presumptive positive.’
- ‘Specimen unsatisfactory for evaluation’ should be used instead of ‘Invalid.’

These are the result descriptions agreed upon by APHL and CDC.

The EUA interpretation descriptions may be incorporated as local result codes in OBX-5.4 to OBX-5.6.

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### Data Element Questions

**Question**

Are we required to report COVID-19 targets? Or can we report a conclusion?

**Response**

Your PHL can choose to report either COVID-19 targets or conclusions, or both. Refer to the encoding guidelines for valid order/observation combinations.

**Question**

Does the RP have to be reported?

**Response**

If your PHL plans to report the COVID-19 targets, then the RP must be reported as well. The RP is important for determining the result interpretation.
**COVID-19 Response Unique Identifier**

Are COVID-19 PUI (also referred to as the nCoV unique identifier) numbers required to be included in the HL7 message?

CDC has instructed state health departments to assign a COVID-19 Unique Identifier, based on a CDC defined format, to track and link data for suspect COVID-19 cases. This unique identifier will accompany all documents/messages and forms associated with the suspect case - including laboratory test requests.

Although not currently a required data element, PHLs are encouraged to assess the ability to include this new ID in their LIMS and include this data element in their COVID-19 data stream. Detailed information/implementation information follows:

- PHLIP reporting of the COVID-19 unique ID is currently optional.
- Epidemiological-related OBXs will be used to populate the COVID-19 ID in the PHLIP message.
- OBX-3 = PLT248 and PLT249 must **BOTH be included together** in the message. These OBXs should be placed under a separate Epi order code OBR-4 = 68991-9. **If this is not feasible,** the OBXs may be placed under the COVID-19 testing order codes OBR-4 = 94306-8 or 94309-2 that is being utilized to report COVID-19 tests and results. (See table)
- For PLT249, the OBX-5 must be PLR138^outbreak^PLR to indicate the ID is associated with an outbreak event.
- For PLT248, OBX-5.1 should include the COVID-19 ID in the format designated by the DCIPHER algorithm (i.e. AL000001). The Assigning authority name in OBX-5.4.1 will be the state health department name, followed by its OID, and then ISO. OBX-5.5 should be populated with the code PHC for Public Health Case Identifier. These are required fields.
- Populate the remainder of the OBR and OBX segments with the required data elements. The table below shows select applicable fields for reporting the unique ID.

<table>
<thead>
<tr>
<th>OBR-4</th>
<th>OBX-2 (CWE (2.5.1) CE (2.3.1))</th>
<th>OBX-3 (PLT249^Sample is related to program/study/event^PLT)</th>
<th>OBX-5 (PLR138^outbreak^PLR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>68991-9^Epidemiologically important information for public health reporting panel^LN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OBX-2</td>
<td>OBX-3</td>
<td>OBX-5</td>
<td></td>
</tr>
<tr>
<td>CWE (2.5.1) CE (2.3.1)</td>
<td>PLT249^Sample is related to program/study/event^PLT</td>
<td>PLR138^outbreak^PLR</td>
<td></td>
</tr>
<tr>
<td>CX</td>
<td>PLT248^Identifier with assigning authority^PLT</td>
<td>[nCoV ID]^AAA[Assigning authority name]&amp;[Assigning authority OID]&amp;ISO^PHC</td>
<td></td>
</tr>
</tbody>
</table>