February 12, 2020

Dear State and Local Public Health Laboratory Directors,

This communication will provide further information and a set of Frequently Asked Questions (FAQs) to support the PHL-to-CDC 2019 Novel Coronavirus (2019-nCoV) data messaging work. Please note that we are aware of the name change to:

- Disease Name: Corona Virus Disease (COVID-19)
- Virus: the International Committee on Taxonomy of Viruses has decided on SARS-CoV-2, which “formally recognizes this virus as a sister to severe acute respiratory syndrome coronaviruses.”

However, the messaging structure aligns with the current CDC Emergency Use Authorization (EUA) Assay. If CDC amends the EUA, APHL will work with its partners to update messaging structure/naming convention.

As a reminder, on February 4, 2020, APHL sent Lab Alert #6, which described the collaborative efforts of APHL, the CDC, and the Regenstrief Institute to define the standard terminology and codes associated with the 2019-nCoV RNA panel. Additionally, Lab Alert #6 included specific instructions for 2019-nCoV electronic message validation processes and engaging with APHL informatics technical assistance resources.

The goal to validate and move as many PHL 2019-nCoV data feeds into production by Friday February 14 remains unchanged.

We thank all the PHLs who have completed the informatics readiness assessment and ask that those laboratories who have not completed this short 2-question survey do so as soon as possible. APHL will be following up with all PHLs who have not completed the assessment later this week.

For informatics related technical assistance requests, 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 J. Becker, MS
Executive Director
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scott.becker@aphl.org
@scottjbecker
## Technical Assistance (TA) Requests and Help Desk

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
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| 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 2019-nCoV 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 2019-nCoV TA to date, please open a new APHL's Help Desk ticket outlining your TA needs and include 2019-nCoV 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 2019-nCoV Messages

<table>
<thead>
<tr>
<th>Question</th>
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| How do I send my HL7 test messages? | PHLs will send 2019-nCoV HL7 test 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 MUST be successfully validated by the CDC 2019-nCoV messaging leads in order to receive approval to migrate to production.  
  
  As such, all test messages must be sent from a Staging Environment, not Production.  
  
  If you cannot meet these requirements, please open an Informatics Help Desk ticket or respond to an existing 2019-nCoV TA request with additional questions or issues. |
| May I send a single message to see if my transport is set up correctly? | 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. |
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 2019-nCoV Help Desk ticket or opening a new ticket entitled **2019-nCoV 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.

Are there sample 2019-nCoV messages we can use to build our test messages?

APHL has developed 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:
- **2.5.1 Inconclusive**
- **2.5.1 Not Detected**
- **2.5.1 SpmUnsat**
- **2.5.1 Detected**
- **2.3.1 Detected**
- **2.3.1 Not Detected**
- **2.3.1 SpmUnsat**
- **2.3.1 Inconclusive**

How will I know I am ready to send 2019-nCoV 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.

Mapping 2019-nCoV message mapping

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<tr>
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</table>
| Which descriptions should we use, as there seems to be minor differences in the target descriptions between the EUA and the APHL 2019-nCoV Encoding Guidelines? | PHLs should use the descriptions indicated in the 2019-nCoV Encoding Guidelines to report nCoV targets in conjunction with the associated LOINC codes in OBX-3.1 to OBX-3.3. For example:
  - ‘SARS-like CoV N’ should be used instead of ‘N3’. 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.** |
There seems to be differences in the interpretation descriptions between the EUA and the APHL 2019-nCoV Encoding Guidelines. Which should be used for PHLIP reporting of 2019-nCoV?

PHLs should use the interpretation descriptions indicated in the 2019-nCoV Encoding Guidelines for 2019-nCoV 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.

### Data Element Questions

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
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<tbody>
<tr>
<td>Are we required to report nCoV targets? Or can we report a conclusion?</td>
<td>Your PHL can choose to report either nCoV targets or conclusions, or both. Refer to the 2019-nCoV Encoding Guidelines for valid order/observation combinations.</td>
</tr>
<tr>
<td>Are nCoV PUI numbers required to be included in the nCoV HL7 message?</td>
<td>No, at this time, PUI numbers are not required in the PHLIP message.</td>
</tr>
<tr>
<td>Does the RP have to be reported?</td>
<td>If your PHL plans to report the nCoV targets, then the RP must be reported as well. The RP is important for determining the result interpretation.</td>
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</table>

### Epidemiological data elements

<table>
<thead>
<tr>
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<th>Response</th>
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<tbody>
<tr>
<td>Are there any additional epidemiological data elements required for nCoV data reporting?</td>
<td>At this time, there are no requirements related to the inclusion of additional epidemiological-related data.</td>
</tr>
</tbody>
</table>

### nCoV Response Unique Identifier

What is this nCoV Response Unique Identifier I am hearing about?

See details below

#### 2019-nCoV Response Unique Identifier

CDC has instructed state health departments to assign a 2019-nCoV Unique Identifier, based on the CDC defined format, to track and link data for suspect 2019-nCoV cases. This unique identifier will accompany all documents/messages and forms associated with the suspect case - including laboratory test requests. PHLs are encouraged to assess the ability to include this new ID in their LIMS and include this data element in their nCoV data stream. Detailed implementation information follows:

- PHLIP reporting of the nCoV ID is currently optional.
• Epidemiological-related OBXs will be used to populate the nCoV 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 nCoV testing order codes OBR-4 = 94306-8 or 94309-2 that is being utilized to report nCoV 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 nCoV 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 nCoV.

• **If you use an alternate method of transport to submit 2019-nCoV data, contact Krista Kniss (krk9@cdc.gov)** for further instructions.

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

[2.5.1 Inconclusive]
[2.5.1 Not Detected]
[2.5.1 SpmUnsat]
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[2.3.1 Inconclusive]

Helpful Informatics Links:

• [2019-nCoV Encoding Guidelines](#)
• [Informatics Help Desk](#)
• [Informatics 2-question Assessment](#)
• [Test Message Scenarios](#)