Clinical Laboratory COVID-19 Response Call
Monday, December 27, 2021, at 3:00 PM EDT

• Welcome
  – Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)

• Potential Increase in Testing Demand
  – Henry Walke, CDC Center for Preparedness and Response (CPR)

• SARS-CoV-2 Variants Update
  – John Barnes, CDC Laboratory and Testing Task Force for the COVID-19 Response

• FDA Update
  – Tim Stenzel, US Food and Drug Administration (FDA)

• LOINC In Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests – Overview
  – MariBeth Gagnon, CDC Division of Laboratory Systems (DLS)
Vision
Exemplary laboratory science and practice advance clinical care, public health, and health equity.

Mission
Improve public health, patient outcomes, and health equity by advancing clinical and public health laboratory quality and safety, data and biorepository science, and workforce competency.
Four Goal Areas

Quality Laboratory Science
- Improve the quality and value of laboratory medicine and biorepository science for better health outcomes and public health surveillance

Highly Competent Laboratory Workforce
- Strengthen the laboratory workforce to support clinical and public health laboratory practice

Safe and Prepared Laboratories
- Enhance the safety and response capabilities of clinical and public health laboratories

Accessible and Usable Laboratory Data
- Increase access and use of laboratory data to support response, surveillance, and patient care
Find CLCR call information, transcripts, and audio recordings on the CDC Preparedness Portal

The **CDC OneLab Network** is a collaborative network of clinical, public health, and CDC laboratory education and training professionals. It is an extension of the OneLab™ Initiative, the goal of which is to meet laboratory learners’ most urgent COVID-19 laboratory education and training needs and collectively support rapid, large-scale responses.

**Join the Network Here**

- **1,978 Members**
- **1,300+ unique organizations**
- **20+ eLearnings and Resources**
  - Courses and job aids aligned to training needs identified in large scale needs assessment
- **8 Educational Events**
  - Topics included validation and verification, crisis leadership, and supply chain lessons learned
- **Laboratory Learning Hub Coming Soon**
  - COVID-19 Laboratory training hub (OneLab REACHTM) for CDC-developed courses
Next Scheduled CLCR Call

The next call will be on Monday, January 10 from 3:00 PM to 4:00 PM ET.
We Want to Hear from You!

Training and Workforce Development

Questions about education and training?
Contact LabTrainingNeeds@cdc.gov
How to Ask a Question

- Using the Zoom Webinar System
  - Click the Q&A button in the Zoom webinar system
  - Type your question in the Q&A box and submit it
  - Please do not submit a question using the chat button

- For media questions, please contact CDC Media Relations at media@cdc.gov
- If you are a patient, please direct any questions to your healthcare provider
Slide decks may contain presentation material from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect CDC’s official position on the topic(s) covered.
Potential Increase in Testing Demand

Henry Walke
CDC Center for Preparedness and Response (CPR)
SARS-CoV-2 Variants Update

John Barnes
CDC Laboratory and Testing Task Force for the COVID-19 Response
FDA Update

Tim Stenzel
US Food and Drug Administration (FDA)
COVID-19 Emergency Use Authorization (EUA) Information for Medical Devices
https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

COVID-19 In Vitro Diagnostic EUAs

COVID-19 Frequently Asked Questions

COVID-19 Updates

FDA Townhall Meetings

Independent Evaluations of COVID-19 Serological Tests
https://open.fda.gov/apis/device/covid19serology/
COVID-19 Diagnostic Development
CDRH-EUA-Templates@fda.hhs.gov

Spot Shortages of Testing Supplies: 24-Hour Support Available
1. Call 1-888-INFO-FDA (1-888-463-6332)
2. Then press star (*)

FDA MedWatch
LOINC In Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests – Overview

MariBeth Gagnon, MS CT(ASCP)HTL
Health Scientist
Informatics and Data Science Branch (IDSB)
Division of Laboratory Systems (DLS)
COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act


- Test order code - LOINC
- Test performed code - LOINC
- Vendor result description - SNOMED-CT
- Vendor specimen description – SNOMED-CT
- Device Identifier
  - Equipment Unique Identification
  - Test kit name ID
The Food and Drug Administration (FDA) Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD) is a public-private partnership that was assembled with a singular focus on improving the interoperability and utility of in-vitro diagnostic (IVD) test data. SHIELD provides the authoritative source of coding for COVID-19 testing and a wide variety of other assays.

Benefits of FDA SHIELD

- **Eases the burden** for all stakeholder groups through a unified approach
- **Advances greater standards-based** information exchange across laboratories and healthcare institutions
- **Lays the foundation for improved semantic** interoperability by implementing infrastructure that directly harmonizes the process of how laboratory data standards are practically applied to IVD test data
LIVD Core Catalogue

- LIVD Publication
- HHS Mapping to LIVD
- Acronyms
- LOINC Mapping
- Background Information
- LOINC Mapping Columns
- Release Notes
SHIELD LIVD Core Team

- IVD Industry - Ed Heierman (Abbott)
- Regenstrief – David Baorto
- SNOMED-CT – John Snyder
- APHL – Riki Merrick and Jerry Sable
- FDA – Ryan Karsner
- CDC – MariBeth Gagnon and Jasmine Chaitram
- ONC – Andrew Northup
LOINC In Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests

On June 4, 2020, the Department of Health and Human Services (HHS) announced new laboratory data reporting guidance for COVID-19 testing. Using LOINC and SNOMED-CT to identify and report SARS-CoV-2 test results in electronic reporting systems will facilitate timely and quality data reporting to state and federal public health agencies. The following document (developed per the LIVD specification) provides LOINC and SNOMED mappings for SARS-CoV-2 diagnostic tests available in the United States. The LIVD mapping catalogue provides coding for these data elements: LOINC test order, LOINC test result, SNOMED-CT test description, SNOMED-CT specimen source, and Device Identifier.

Mapping tool: LIVD SARS-CoV-2 Test Codes.xlsx
LIVD publication date 2021-12-01.
<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Model</th>
<th>Vendor Analyte Name</th>
<th>Vendor Specimen Description</th>
<th>Vendor Result Description</th>
<th>Test Performed LOINC Code</th>
<th>Test Ordered LOINC Code</th>
<th>Testkit Name ID</th>
<th>Equipment UID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bio-Rad Laboratories, Inc.</td>
<td>Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit</td>
<td>SC2 Result Interpretation</td>
<td>nasopharyngeal swab (235800001<em>Nasopharyngeal swab</em>SCT) anterior nasal swab (697989009<em>Anterior nares swab</em>SCT)</td>
<td>SARS-CoV-2 detected (260373001<em>Detected</em>SCT) SARS-CoV-2 not detected (260415000<em>Not Detected</em>SCT)</td>
<td>94533-7</td>
<td>95422-2</td>
<td>Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit, Bio-Rad Laboratories, Inc.</td>
<td>CFX96 Touch Real-Time PCR System_BioRad</td>
</tr>
<tr>
<td>Bio-Rad Laboratories, Inc.</td>
<td>Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit</td>
<td>FluA Result Interpretation</td>
<td>nasopharyngeal swab (235800001<em>Nasopharyngeal swab</em>SCT) anterior nasal swab (697989009<em>Anterior nares swab</em>SCT)</td>
<td>Influenza A detected (260373001<em>Detected</em>SCT) Influenza A not detected (260415000<em>Not Detected</em>SCT)</td>
<td>92142-9</td>
<td>95422-2</td>
<td>Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit, Bio-Rad Laboratories, Inc.</td>
<td>CFX96 DX Real-Time PCR System_ORM</td>
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<td>95422-2</td>
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For more information, contact CDC
1-800-CDC-INFO (232-4636)

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of Centers for Disease Control and Prevention.
Thank You For Your Time!

This box being opened by an American Hero

#love_the_Lab
#lab_professionals_rock

Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center