Clinical Laboratory COVID-19 Response Call
Monday, September 14th, 2020 at 3:00 PM EDT

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

• CMS Update on Interim Final Rule – Laboratory Reporting
  – Regina Van Brakle and Amy Zale, Centers for Medicare & Medicaid Services (CMS)

• Technical Guidance for Implementation of Laboratory Data Reporting
  – Mike Waters, Testing and Diagnostics Task Force, U.S. Health and Human Services (HHS)

• Laboratory Data Reporting for COVID-19 – A Clinical Laboratory Experience
  – Jordan Olson, Geisinger Health System, Department of Laboratory Medicine

• FDA Update
  – Tim Stenzel, U.S. Food and Drug Administration (FDA)
The next call is scheduled for **Monday, Sept. 28 from 3:00 PM to 4:00 PM EDT**
Share Your Feedback!

Help us improve these calls by taking a short 5-minute survey!

https://www.surveymonkey.com/r/CLCRSept14

The survey will close on Thursday, Sept. 17 at 8 AM
We Want to Hear From You!

Training and Workforce Development

Questions about education and training?
Contact LabTrainingNeeds@cdc.gov
COVID-19 Resources for Laboratories

- Interim Guidance for Collecting, Handling, and Testing Clinical Specimens

- Diagnostic Tools and Virus

- Emergency Preparedness for Laboratory Personnel
  https://emergency.cdc.gov/labissues/index.asp

- CDC's Laboratory Outreach Communication System (LOCS)
  https://www.cdc.gov/csels/dls/locs/

- IVD Industry Connectivity Consortium
  https://ivdconnectivity.org/livd/

- LOINC In-Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests
  https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html
COVID-19 Resources for Laboratories (cont.)

- Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes

- Antigen Testing Guidance

- Additions to the Frequently Asked Questions (FAQs) about COVID-19 for Laboratories
  - False Negatives and False Positives from COVID-19 Testing
  - Surveillance, Screening, and Diagnostic Testing for COVID-19
New Preparedness Portal

https://www.cdc.gov/csels/dls/preparedlabs
We’ve Moved!


CLCR call information, transcripts, & audio recordings now live on the new Preparedness Portal
How to Ask a Question

• **Using the 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](mailto:media@cdc.gov)

• If you are a patient, please direct any questions to your healthcare provider
CMS Update on Interim Final Rule – Laboratory Reporting

Regina Van Brakle and Amy Zale
Centers for Medicare and Medicaid Services (CMS)
Centers for Medicare and Medicaid Services (CMS)

- **CLIA Laboratory Guidance During COVID-19 Memo and FAQs**

- **FAQs Only**
Technical Guidance for Implementation of Laboratory Data Reporting: Update

September 14, 2020

Michael Waters, Ph.D.

COVID-19 National Response Operations: HHS Data Strategy and Execution Workgroup (DSEW)

SHIELD\textsubscript{x} Team Lead/OIR RWE Representative

OHT7: Office of In Vitro Diagnostics & Radiological Health (OIR)

Center for Devices & Radiological Health (CDRH)

U.S. Food & Drug Administration (FDA)

FOUO – For Official Use Only
Reportable Data Elements for All COVID-19 Tests

(summary; reportable to federal/state/local authorities, as appropriate)

**Test orders:**
- Test ordered
- Ordering provider name & NPI
- Ordering provider location/contact

**Test results:**
- Test result
- Device Identifier
- Specimen source
- Date specimen collected
- Test Result date
- Accession #/Specimen ID
- Performing facility name/CLIA#
- Performing facility location

**Patient Demographics:**
- Unique patient identifier
- Patient name
- Patient date of birth/age
- Patient race
- Patient ethnicity
- Patient sex
- Patient location/contact
- Patient occupation
- Patient congregate care/living setting
- Patient symptoms
- Patient test & hospitalization history
- Patient pregnancy status

**Harmonization Tools**

**HHS COVID-19 Guide:**

**COVID-19 Test Code Mapping:**
<table>
<thead>
<tr>
<th>#</th>
<th>Data Element</th>
<th>Reporting Requirement*</th>
<th>Technical Specifications</th>
<th>Notes</th>
<th>Example</th>
<th>HL7 Field</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Test result (performed)</td>
<td>Yes</td>
<td>Requested</td>
<td>Test conducted by lab</td>
<td>Example LOINC: 24640-6: SARS coronavirus 2 S gene [Presence] in Respiratory specimen by NAA with probe detection</td>
<td>OBX-5</td>
</tr>
<tr>
<td></td>
<td>Test result (values)</td>
<td></td>
<td></td>
<td>Reporting using codes for pooled specimens</td>
<td>Example SNOMED-CT Qualitative Values:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• 260373001. Detected</td>
<td>• 462371000124108. Detected in pooled specimen</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• 260415000. Not detected</td>
<td>• # of specimens pooled</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• 895231000. Not detected in pooled specimen</td>
<td>• # of specimens pooled</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• 419984006. Inconclusive</td>
<td>• 419984006. Inconclusive</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Device Identifier</td>
<td>Yes</td>
<td>Requested</td>
<td>Manufacturer requests UDI issuance, then provides DI, or pull from GUIDID database</td>
<td>Example DI: 01234567891011</td>
<td>OBX-11,  OBX-18 (barcode)</td>
</tr>
</tbody>
</table>

Location of data element in LIVD SARS-CoV-2 mapping file

Reporting using codes for pooled specimens
### COVID-19 Lab Data Reporting Implementation Specifications

<table>
<thead>
<tr>
<th>#</th>
<th>Data Element</th>
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<th>Notes</th>
<th>Example</th>
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</tr>
</thead>
<tbody>
<tr>
<td>33</td>
<td>AOE: Pregnant</td>
<td>Requested</td>
<td>Requested</td>
<td>Pregnant</td>
<td>LOINC: 82810-3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Not Pregnant</td>
<td>SNOMED-CT Pregnancy Status:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>UNK - Unknown</td>
<td>- 77385005 Pregnant</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- 60001007 Not Pregnant</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- 261655004 Unknown</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- 27672000 Null</td>
<td></td>
</tr>
</tbody>
</table>

**Reporting Requirements:**

- This table represents a visual, side-by-side comparison of which entities ultimately receive each of the reported data elements. For example, not all data elements reported to the State/Local PHD are reported to the Federal authorities.
- This table is not meant to indicate how data elements are reported in terms of their flow between entities. Current information on reporting requirements for laboratories and associated FAQs are available on CDC's website: "How to Report COVID-19 Laboratory Data"

**Requirement/Request Level:**

- Yes = Required to be reported by August 1st, 2020
- Requested = Every reasonable effort should be made to achieve reporting by August 1st, 2020
- Optional = Strongly encouraged to begin reporting by August 1st, 2020, if possible
- No = Not required to be reported

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**New - National ELR Flat File and HL7 Generator Tool Package**

[https://preparedness.cste.org/?page_id=136](https://preparedness.cste.org/?page_id=136)
Completeness and Harmonization of One Data Element

~ 77 million reported PCR test results *as of 9/11

>99% of transmitted results report data element “Test Result”

12.4% of test results don’t use harmonized LOINC codes

Top three codes
1. NOVELCORONAPCR
2. COVID19
3. Null (empty field)

Data harmonization is improving!
HHS Answer-On-Entry (AOE) Question Implementation:

Geisinger Health System’s Experience

Jordan Olson M.D., FCAP FASCP
September 14th 2020
D.M. Wolk, Ph.D., D(ABMM)
Geisinger Health System

- 9 hospital system in North Central PA
- 87 Office Sites
- 23 Urgent Care sites
- Started in-house COVID testing March 6, 2020
- August 2020 performed approx. 32,000 SARS-CoV-2 RT-PCR tests and 1,500 antibody tests
Timeline

March
• Began in-house testing and manual reporting to PADOH

April
• Began reporting results to PA DOH

June
• Expanded interface messages to PA DOH

Aug 3rd
• PA DOH announces ability to accept AOE content

Sept 9th
• Went live with AOE Questions
• Geisinger Medical Laboratory sits in a complex informatics environment

• Geisinger’s EMR is only one source of orders

• IT changes to accommodate AOE questions must happen and be coordinated in all systems

Simplified Informatics Topology: Answer-on-entry question data flow

Outside Laboratory Clients  Health Information Exchange  Client Interface Systems  Outside Laboratory Clients

Geisinger Electronic Medical Record Users  Electronic Medical Record  LIS  State Department of Health

Outside Clients sending Paper Requisitions
• Geisinger Physician Informaticians have strict guidelines on AOE

- Info available at time of order to clinician
- Info required to act on order
- Not transcription of information available elsewhere

• EMR vendor provided ‘turbocharger packages’ which greatly assisted with build in EMR

Answer-on-entry questions

- Symptomatic for COVID-19 as defined by CDC?
- Hospitalized for COVID-19?
- Admitted to ICU for COVID-19?
- Employed in healthcare setting?
- Resident in a congregate care/living setting?
- Pregnant?
- First COVID-19 test?

- Symptoms
- Date of Symptom Onset
- Hospitalized for COVID-19?
- Admitted to ICU for COVID-19?
- Employed in healthcare setting?
- Resident in a congregate care/living setting?
- Residence type
- Pregnant?
- First COVID-19 test?
• Both internal providers and outside clients unwilling to provide answers

• EMR build does assist with answering and helps capture more accurate data

• Answers often unavailable to laboratory

• LIS requires an answer

• Unknown is an acceptable answer in implementation guidelines - for most questions it is the most common answer reported
Reporting to State

- COVID-19 results reported to State Department of Health
Summary

• “Required” data elements straightforward to report

• Answer on order questions pose significant difficulty
  • Considered a burden by clinicians with no tangible benefit to patient
  • Significant build effort, although EMR vendor provided tangible support
  • Significant effort for lab staff to transcribe information when available

• “Unknown” reported often for AOE questions
Thank you

Jordan Olson MD FCAP FASCP
jeolson@Geisinger.edu
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 (*)
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https://www.facebook.com/CDC

https://twitter.com/cdcgov

https://www.linkedin.com/company/cdc
Thank You For Your Time!

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