Clinical Laboratory COVID-19 Response Call
Monday, May 16, 2022, at 3:00PM ET

• Welcome
  – Sean Courtney, Division of Laboratory Systems, CDC
• SARS-CoV-2 Variants Update
  – Natalie Thornburg, Laboratory and Testing Task Force, CDC
• CLIA SARS-CoV-2 Test Result Reporting Update
  – Sarah Bennett, Centers for Medicare and Medicaid Services (CMS)
• Scent Discriminating Canines as a Tool for COVID-19 Management
  – Julian Mendel, Florida International University
• Supply Chain Challenges and Solutions
  – Gregory Sossaman, Ochsner Health
About 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
CDC Preparedness Portal


Find CLCR call information, transcripts, and audio recordings on this page.
Next Scheduled Call

The next call will be on

Monday, June 27 @ 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.
SARS-CoV-2 Variants Update

Natalie Thornburg
Laboratory and Testing Task Force, CDC
Disclaimer

This presentation was prepared for informational purposes and is not intended to grant rights or impose obligations. Every reasonable effort has been made to assure the accuracy of the information within these pages.

This publication is a general summary that explains certain aspects of the Clinical Laboratory Improvement Amendments (CLIA) Program, but is not a legal document. The official CLIA Program provisions are contained in the relevant laws, regulations, and rulings. Links to the source documents have been provided within the document for your reference.

The Centers for Medicare & Medicaid Services (CMS) employees, agents, and staff make no representation, warranty, or guarantee that this compilation of CLIA information is error-free and will bear no responsibility or liability for the results or consequences of the use of this guide.
Overview

• Updated CLIA SARS-CoV-2 Test Result Reporting Requirements
• CLIA Reporting Requirements, Additional Information
Updated CLIA SARS-CoV-2 Test Result Reporting Requirements


<table>
<thead>
<tr>
<th>CLIA Certificate Type</th>
<th>Authorized Laboratory Setting/Test complexity</th>
<th>Test platform</th>
<th>Reporting of SARS-CoV-2 positive results</th>
<th>Reporting of SARS-CoV-2 negative and inconclusive results</th>
</tr>
</thead>
<tbody>
<tr>
<td>COW/PPM</td>
<td>Waived (W), Moderate (MC) or High complexity (HC)</td>
<td>Antigen</td>
<td>Required</td>
<td>Optional</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Molecular (NAAT)</td>
<td>Required</td>
<td>Optional</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Serology (Antibody)</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>COC/COA/COR</td>
<td>W, MC or HC</td>
<td>Antigen</td>
<td>Required</td>
<td>Optional</td>
</tr>
<tr>
<td></td>
<td>MC or HC</td>
<td>Molecular (NAAT)</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td></td>
<td></td>
<td>W</td>
<td>Molecular (NAAT)</td>
<td>Required</td>
</tr>
<tr>
<td></td>
<td></td>
<td>W, MC or HC</td>
<td>Serology (Antibody)</td>
<td>Optional</td>
</tr>
</tbody>
</table>
CLIA Reporting Requirements, Additional Information

- CLIA surveying against CLIA requirements for SARS-CoV-2 test result reporting
- CLIA is only assessing if labs have reported, or attempted to report, test results
- Laboratory must have documentation it has reported, or attempted to report results
- The data elements and timelines for reporting in the HHS Secretary’s guidance are outside the scope of CLIA.
Resource Information

- CLIA Website: [Clinical Laboratory Improvement Amendments (CLIA)]
- CMS Emergencies Page
- Policy Memo, SARS-CoV-2 Test Reporting: [QSO-21-10-CLIA REVISED]
Scent discriminating canines as a tool for Covid-19 management

Julian Mendel, Ph.D.
Florida International University
Canine Olfaction in Law Enforcement

- Drugs
- Money
- Explosives & Accelerants
- Trailing & Human Scent
- Guns & Ammunition
- Wildlife Trafficking
- Food

K-9 officer in training Tuco. (Image credit: Massachusetts Vast-a-Dog)
## Outside Law Enforcement

<table>
<thead>
<tr>
<th>Environmental:</th>
<th>Pests:</th>
<th>Diseases:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fungi, Mold</td>
<td>Bedbugs, Termites</td>
<td>Cancer, Parkinson’s, Diabetes, Malaria, COVID-19</td>
</tr>
</tbody>
</table>
Canine Olfaction

- 10,000 – 100,000 times more sensitive than humans
- >100 times olfactory receptor cells
- Olfactory recess-lined with epithelium and cilia
Laurel Wilt Disease

Xyleborus glabratus  Raffaelea lauricola
Laurel Wilt Disease

- 500 MILLION Laurel trees dead
- ≈25,000 avocado trees dead, 1/3
Detection Dogs have ~98% Average Accuracy

An Evaluation of Scent-discriminating Canines for Rapid Response to Agricultural Diseases
Julian Mendel, Kenneth G. Furton, and DeEtta Mills

Agri-dogs: Using Canines for Earlier Detection of Laurel Wilt Disease Affecting Avocado Trees in South Florida
Julian Mendel, Christina Burns, Beatrice Kallifatidis, Edward Evans, Jonathan Crane, Kenneth G. Furton, and DeEtta Mills
COVID-19

- **Baptist Hospital Collaboration**
  - Provided PPE from patients
  - Positive and Negative

- **Global Forensic and Justice Center**
  - Experimental Design
  - Chemistry
  - Training aids

- **Redland Ahead**
  - Training and Deployment

SARS-CoV-2
Patented or Patent-Pending Training Aids

<table>
<thead>
<tr>
<th>TANK-9</th>
<th>COMPS</th>
<th>UDC</th>
</tr>
</thead>
</table>

[Images of training aids]
Impact of 10-minute UV-C irradiation on a mixture of volatiles. A Student's T-test indicated no significant difference between peak areas of the compounds before and after UV-C treatment (p>0.05).
Training
# Results

217 Training runs prior to double blind trials

<table>
<thead>
<tr>
<th>Canine name</th>
<th>Canine breed</th>
<th>Failure to alert (no.)</th>
<th>False alerts(#)²</th>
<th>ACC/PPV (%)¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hubble</td>
<td>Border Collie Mix</td>
<td>15</td>
<td>6</td>
<td>96.3/87.0</td>
</tr>
<tr>
<td>One Betta</td>
<td>Dutch Shepherd</td>
<td>15</td>
<td>3</td>
<td>98.1/93.0</td>
</tr>
<tr>
<td>Cobra</td>
<td>Belgian Malinois</td>
<td>20</td>
<td>1</td>
<td>99.4/97.6</td>
</tr>
<tr>
<td>Mac</td>
<td>Terrier mix</td>
<td>17</td>
<td>5</td>
<td>96.2/88.6</td>
</tr>
</tbody>
</table>

Double Blind Trials n=40 Using Healthy masks, and blank masks as distractors.
Results

• Headspace SPME-GC-MS
• Clear separation between individuals
• Work ongoing

Figure 4: PLS-DA showing class separation of HS-SPME-GCMS VOCs from COVID-19 positive PPE (masks) vs COVID-19 negative PPE (masks).
Deployments

- Florida State Emergency Operations Center (SEOC)
- South Beach Wine and Food Festival (SOBEWFF)
- Miami International Airport
- BARK Box
- South Motors Jazz Series

Pending

- Port of Miami
- Steven P. Clark Government Center
Thank you

Redland Ahead
  • John Mills
  • Kelley Hall
  • Denise Webb

Baptist Hospital West Kendall

Global Forensic and Justice Center
  • Kenneth G. Furton
  • DeEtta Mills
  • Kevin Lothridge
  • Howard Holness
  • Kelvin Frank
Supply Chain Challenges and Solutions

G. Sossaman, M.D.
E. Occhipinti, M.D.
Department of Pathology and Laboratory Medicine
Ochsner Health System
Worldwide disruption with no end in sight...

January 19, 2022 Update: The FDA expanded the medical device shortage list to include all blood specimen collection tubes. For details, see the Blood Specimen Collection Tube Conservation Strategies - Letter to Health Care and Laboratory Personnel.

'This will have a massive impact': Blood tube shortage could limit non-essential tests

CAP Publishes Strategies to Mitigate National Shortage of ‘Blue Top’ Test Tubes

NHS blood test tube shortage: Doctors 'facing difficult choices'
Laboratory Supply Shortages
Turning Crisis to Opportunity

Lee H. Hilborne, MD, MPH, FASCP, DLM(ASCP)CM, 1,6
Greg Sossaman, MD, MACSP, 2
Barbara Caldwell, MS, MASCPL, MLS (ASCP)CM, SHCM, 3
and Steven Kroft, MD, MASCPL 4

From the 1Department of Pathology and Laboratory Medicine, David Geffen School of Medicine at UCLA, Los Angeles, CA, USA, and Medical Affairs, Quest Diagnostics, Secaucus, NJ, USA; 2Department of Pathology and Laboratory Medicine, Ochsner Health, New Orleans, LA; 3Consultant, Mount Airy, MD, USA; and 4Department of Pathology, Medical College of Wisconsin, Milwaukee, WI, USA.
ASCP survey 2022

- Survey of Choosing Wisely Advisory board and ASCP members
- Survey conducted twice- 12/21 and 1/22
- Focus topics:
  - How supply chain issues impacted the laboratory
  - What initiatives were undertaken in response to supply chain issues
  - Suggestions to reduce unnecessary supply consumption
## Survey Results - Impact of Supply Chain Issues

<table>
<thead>
<tr>
<th>Themes</th>
<th>Count</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory supply shortage</td>
<td>88</td>
<td>63.8%</td>
</tr>
<tr>
<td>Taking away critical time from diagnosing cases</td>
<td>53</td>
<td>38.4%</td>
</tr>
<tr>
<td>Utilize alternative methods, vendors or supplies</td>
<td>36</td>
<td>26.1%</td>
</tr>
<tr>
<td>Outsourcing</td>
<td>18</td>
<td>13.0%</td>
</tr>
<tr>
<td>Stress and burnout</td>
<td>12</td>
<td>8.7%</td>
</tr>
</tbody>
</table>

Total number of comments: 138

100.0%
<table>
<thead>
<tr>
<th>Themes</th>
<th>Count</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Using alternative test supplies/vendors/labs</td>
<td>73</td>
<td>55.3%</td>
</tr>
<tr>
<td>Testing conservation strategies</td>
<td>47</td>
<td>35.6%</td>
</tr>
<tr>
<td>Ordering additional supplies</td>
<td>21</td>
<td>15.9%</td>
</tr>
<tr>
<td>Continuing communication with vendor</td>
<td>10</td>
<td>7.6%</td>
</tr>
<tr>
<td>Educate providers</td>
<td>10</td>
<td>7.6%</td>
</tr>
<tr>
<td>Monitor inventory</td>
<td>9</td>
<td>6.8%</td>
</tr>
<tr>
<td>Not in charge</td>
<td>5</td>
<td>3.8%</td>
</tr>
<tr>
<td>Communication with hospital administration</td>
<td>3</td>
<td>2.3%</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>14</td>
<td>10.6%</td>
</tr>
<tr>
<td><strong>Total number of comments:</strong></td>
<td><strong>132</strong></td>
<td><strong>100.0%</strong></td>
</tr>
</tbody>
</table>
Suggestions to Reduce Unnecessary Supply Consumption

<table>
<thead>
<tr>
<th>Themes</th>
<th>Count</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop test utilization strategies</td>
<td>49</td>
<td>39.5%</td>
</tr>
<tr>
<td>Education/Awareness</td>
<td>25</td>
<td>20.2%</td>
</tr>
<tr>
<td>Other</td>
<td>34</td>
<td>27.4%</td>
</tr>
<tr>
<td>Total number of comments:</td>
<td>124</td>
<td>100.0%</td>
</tr>
</tbody>
</table>
What levers to pull?

• **Increase Inventory**
  - Local supply chain coordination
  - Daily vendor meetings/escalations
  - Validation of alternate tube types
  - Explore alternate vendors

• **Decrease Utilization**
  - Eliminate rainbow
  - Eliminate extra tubes
  - Decrease daily labs
  - Decrease repeat orders
  - Cease non essential orders (routine wellness, etc)
Stewardship Framework - Care Variation Committee

- **Multidisciplinary committee** - Over 25 members, all hospital locations
  - Strong IT/EMR representation
  - Finance/rev cycle
  - Population health
  - Primary care, ED and specialty involvement
  - C-Suite
  - Lab operations

- **Monthly meetings** since 2017

- Focus points
  - Reducing variation in laboratory testing
  - Appropriate utilization (over and under)
  - Vetting new test requests, vendors (formulary creation and cultivation)
  - Choosing wisely discussions, sharing best practices
  - EMR rules, modifications

- **Decisions are not made or owned solely by lab!**
Utilization Interventions - Combination Approach

Physician/Nursing Education

- Publications
- Town hall meetings
- Grand rounds
- Huddle helpers/job aids

- Slow
- Resource intensive
- Minimally effective
- Well received

Audits/Personal Feedback

- Published peer comparisons
- Targeted audit reports

- Slow
- Resource intensive
- Marginally effective
- Variably received

EMR Restrictions

- Based on best practices
- Far reaching
- Standardized, controlled

- Fast
- Resource intensive
- Highly effective
- Poorly received - necessary evil
Best Practices
1. Choosing Wisely
2. Society Guidelines
3. Expert Consensus
4. NHS retesting Interval Guidance

Communication and Education
1. Governance/Infrastructure
2. Transparency
3. Frequency
4. Visibility
5. Diversity (c-suite, nursing, providers, laboratory team)

Data
1. Tubes used per day
2. Tube wastage per day (extra, rainbow, rejected)
3. Daily orders by hospitalist- weekly report
4. Outpatient test volume
5. Repeat orders

EMR
1. Hard stops
2. Order set review and curation
3. Specialty Restrictions
First Step - Data Collection

• **Total tubes (avg 50,000 per day) – daily report**
  • Top 3 utilizers: ED, internal med, family med
  • Analysis of site, physician and identifier of outliers

• **Extra tubes, rejected tubes, and rainbow draws- daily report**
  • 1-2% of tube usage but approaching 20,000 per month- pure waste
  • Analysis of site and nurse/phlebotomist
  • Easiest intervention point because it was predominantly under lab control

• **Daily lab orders per hospitalist- weekly report**
  • Challenge- unable to calibrate for patient volume and complexity
  • Most difficult intervention- no organizational consensus

• **In patient order set monitoring- one time report**
  • Most frequently used order sets in institution- can any be altered for removal of daily labs?
Reduction of daily orders

Society of Hospital Medicine – Adult Hospital Medicine
View all recommendations from this society

Released February 21, 2013

Don’t perform repetitive CBC and chemistry testing in the face of clinical and lab stability.

Hospitalized patients frequently have considerable volumes of blood drawn (phlebotomy) for diagnostic testing during short periods of time. Phlebotomy is highly associated with changes in hemoglobin and hematocrit levels for patients and can contribute to anemia. This anemia, in turn, may have significant consequences, especially for patients with cardiorespiratory diseases. Additionally, reducing the frequency of daily unnecessary phlebotomy can result in significant cost savings for hospitals.
Huddle Helper
Blood Collection Guidelines to prevent Recollection/Wasted tubes

Your help is needed to conserve blood collection tubes during this national shortage. To avoid recollections and tube wastage, read below to guide your blood collection technique.

Top Reasons for Rejected Specimens

Venipuncture Technique (Preventable Errors)
- Hemolysis
- Clotting
- Contamination
- Quantity Not Sufficient (QNS): not enough sample to process the test

Causes of Hemolysis
- Prolonged tourniquet time
- Cleaning with alcohol/CKNS and not allowing to dry
- Pricking and/or traumatic venipuncture
- Drawing through IV catheter or small needle
- Excessive force on syringe plunger
- Forcing blood from syringe to evacuated tube
- Vigorous mixing or shaking

Causes of Clotted Specimens
- Leaving blood in syringes too long before putting in tube
- Slow draw using a syringe
- Improper mixing of anticoagulated tubes

Causes of Contaminated Specimens
Presence of IV Fluids
- Venipuncture directly above the site of infusion
- Drawing from an existing IV line or existing EMS line
- Inappropriate discard volume from central line or midline
- Additives from blood tubes
- Incorrect order of draw
- Did not use waste tube
- Transfer syringe makes contact with anticoagulant

Phlebotomists: Please refer to MedLab for a more extensive Order of Draw job aid.
Nursing: Order of Draw for Adults (left) and Neonatal Pediatrics (right) below ↓

- BD Microtainer™ Tubes with Microgard™ Closure

**ORDER OF DRAW BADGE BUDDY**

<table>
<thead>
<tr>
<th>Lab Label</th>
<th>Tube Code</th>
<th>Tube Color</th>
<th>Tube Contents/Tube Type</th>
<th>Inversions</th>
</tr>
</thead>
<tbody>
<tr>
<td>M300C</td>
<td>M100CL</td>
<td>Blood Tubes</td>
<td>8-10 Times</td>
<td></td>
</tr>
<tr>
<td>MILKBLUE</td>
<td>MIPS00</td>
<td>Metal-Free No Additive Tube</td>
<td>8-10 Times</td>
<td></td>
</tr>
<tr>
<td>BLUE</td>
<td>GOLDS</td>
<td>Gel Separating Tube</td>
<td>3-4 Times</td>
<td></td>
</tr>
<tr>
<td>GOLD</td>
<td>REDS</td>
<td>Citrate Tube</td>
<td>8 Times</td>
<td></td>
</tr>
<tr>
<td>RED</td>
<td>GREEN</td>
<td>Car Anticoagulant Secure Tube</td>
<td>3 Times</td>
<td></td>
</tr>
<tr>
<td>DEG能量</td>
<td>DEDHANA</td>
<td>Hepacase/No Gel Tube</td>
<td>8-10 Times</td>
<td></td>
</tr>
<tr>
<td>GREEN</td>
<td>BRONZE</td>
<td>Hepacase/Gel Gel</td>
<td>8-10 Times</td>
<td></td>
</tr>
<tr>
<td>LAVENDER</td>
<td>FLEUR</td>
<td>EDTA Tube</td>
<td>8-10 Times</td>
<td></td>
</tr>
<tr>
<td>LAVENDER</td>
<td>LAVEND</td>
<td>Fluorescent (Uracitube)</td>
<td>8-10 Times</td>
<td></td>
</tr>
<tr>
<td>ORANGE</td>
<td>ACID</td>
<td>ACD Tube</td>
<td>8-10 Times</td>
<td></td>
</tr>
</tbody>
</table>

- **Correct Order of Draw can prevent: hemolysis, clotting and contamination**
  - One Inversion = top, bottom, top →

- **BD Microtainer™ Tubes with Microgard™ Closure**

- **Phlebotomists:** Please refer to MedLab for a more extensive Order of Draw job aid.
- **Nursing:** Order of Draw for Adults (left) and Neonatal Pediatrics (right) below ↓

- **BD Microtainer™ Tubes with Microgard™ Closure**
Summary

• Managing supply chain disruption requires decisive **process change** and strong **infrastructure** that fosters:
  • Data collection
  • Standardization of processes and interventions
  • Communication/transparency/flexibility
  • Interdepartmental collaboration- guidance is not solely lab driven
• Education alone is insufficient
• Change is ongoing
CDC Social Media

https://www.facebook.com/CDC

https://twitter.com/cdcgov

https://www.instagram.com/cdcgov

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

This box being opened by an American Hero
#lovetheLab
#labprofessionalsrock

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