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

CMS Reimbursement Update
  – Sarah Harding and Sarah Shirey-Losso, Centers for Medicare and Medicaid Services (CMS)

Individualized Quality Control Plan (IQCP) Q&A
  – Amy Zale, Centers for Medicare and Medicaid Services (CMS)

Antigen Tests - Lessons Learned
  – Reynolds (Ren) Salerno, CDC Division of Laboratory Systems (DLS)

FDA Update
  – Tim Stenzel, U.S. Food and Drug Administration (FDA)
• Find CLCR call information, transcripts, and audio recordings on the Preparedness Portal

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](mailto:media@cdc.gov)
- If you are a patient, please direct any questions to your healthcare provider
The next call will be on **Monday, December 14th** from **3:00 PM to 4:00 PM ET**
# 2021 Proficiency Testing (PT) for SARS-CoV-2

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<tr>
<th>Program</th>
<th>Website</th>
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| Accutest                                          | [www.oneworldaccuracy.com](http://www.oneworldaccuracy.com) | • [support@1wa.org](mailto:support@1wa.org)  
• (800) 665-2575                      |
| ACP Medical Laboratory Evaluation                | [www.acponline.org/mle](http://www.acponline.org/mle)     | • [mle@acponline.org](mailto:mle@acponline.org)  
• (800) 338-2746, ext. 4510               |
| American Academy of Family Physicians            | [www.aafp.org/pt](http://www.aafp.org/pt)                 | • [pt@aafp.org](mailto:pt@aafp.org)   
• (800) 274-7911                          |
| American Association of Bioanalysts Proficiency  | [www.aab-pts.org](http://www.aab-pts.org)            | • [customerservice@aab-pts.org](mailto:customerservice@aab-pts.org)  
• (800) 234-5315                          |
| American Proficiency Institute                   | [www.api-pt.com](http://www.api-pt.com)            | • (800) 333-0958                     |
| College of American Pathologists                 | [www.cap.org](http://www.cap.org)                  | • (800) 323-4040, option 1          |
| Puerto Rico Proficiency Testing Service          | *No website available*                                                | • (787) 274-6827                     |
| Wisconsin State Laboratory of Hygiene            | [www.wslhpt.org](http://www.wslhpt.org)               | • [ptservice@slh.wisc.edu](mailto:ptservice@slh.wisc.edu)  
• (800) 462-5261                          |
COVID-19 Resources for Laboratories

- 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

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

- Antigen Testing Guidance

- Frequently Asked Questions about COVID-19 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 Laboratory Outreach Communication System (LOCS)
  https://www.cdc.gov/csels/dls/locs/
We Want to Hear From You!

Training and Workforce Development

Questions about education and training?
Contact LabTrainingNeeds@cdc.gov
Waste Management Guidance for SARS-CoV-2 Point-of-Care Testing


Audience: Clinical Laboratory Professionals

Level: Laboratory Advisory

When disposing of waste generated from SARS-CoV-2 point-of-care testing, laboratories and testing sites should treat all waste from suspected or confirmed COVID-19 patient specimens and kit components as biohazardous waste. Since waste regulations vary from state to state, disposal must comply with all applicable local, regional, national, and international regulations. Personnel should follow guidance according to federal, state, local, tribal, and territorial regulatory requirements.

Facilities should also perform a site-specific and activity-specific risk assessment to identify and mitigate risks. Risk assessments and mitigation measures depend on several factors:

- The procedures performed
- Identification of the hazards involved in the process and/or procedures
- The competency level of the personnel who perform the procedures
- The laboratory equipment and facility
- The resources available

Follow Standard Precautions when handling clinical specimens, all of which may contain potentially infectious materials. Follow routine laboratory practices and procedures for decontamination of work surfaces and management of laboratory waste.
CMS Reimbursement Update

Sarah Harding and Sarah Shirey-Losso
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
Individualized Quality Control Plan (IQCP) Q&A

Amy Zale
Centers for Medicare and Medicaid Services (CMS)
COVID-19 Antigen Tests – Lessons Learned

Reynolds (Ren) Salerno, PhD
Director, Division of Laboratory Systems

Clinical Laboratory COVID-19 Response Call

November 30, 2020
Antigen Tests - Lessons Learned

How to avoid process errors

- Change gloves between tests to avoid cross-contamination
- Don’t use viral transport media
- Don’t use expired reagents or damaged test cassettes/devices
- Keep track of and follow proper timing for reading the results when testing multiple specimens at the same time
- Use the test cassette/device within specified time after opening
- Keep the test device in a horizontal position when in use
- Results must be interpreted within specified timeframes
Antigen Tests - Lessons Learned

How to avoid process errors

• Change gloves between tests to avoid cross-contamination
• Test specimens within 1 hour of collection
• Use only the correct volume of extraction reagent, no more, no less
• Use the test kit reagents/cards only when they are at room temperature
• Keep the card in a horizontal position when in use
• Read test results promptly at 15 minutes after the swab is inserted. Do not read results before 15 minutes or after 30 minutes
Next Steps

- Quidel Sofia, BD Veritor, and Abbott BinaxNOW lessons learned will be shared with
  - CDC task forces engaged in antigen test studies
  - External partners such as FDA and manufacturers

- Lessons learned are being converted to infographics
  - To be added on the Guidance for SARS-CoV-2 Point-of-Care Testing web page

- Additional communication about the infographics will be provided on partner calls and Laboratory Outreach Communication System (LOCS) messages
For more information, contact CDC
1-800-CDC-INFO (232-4636)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
FDA Update

Tim Stenzel
U.S. Food and Drug Administration (FDA)
Food and Drug Administration (FDA)

- **COVID-19 Emergency Use Authorization (EUA) Information for Medical Devices**

- **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/](https://open.fda.gov/apis/device/covid19serology/)
Food and Drug Administration (FDA)

- 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
CDC Social Media

https://www.facebook.com/CDC

https://twitter.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