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

CMS Reimbursement Update
– Sarah Harding, Centers for Medicare & Medicaid Services (CMS)

College of American Pathologists (CAP) Letter: Caution Must Be Used in Interpreting the Cycle Threshold (Ct) Value
– Daniel Rhoads, Cleveland Clinic

FDA Update
– Sara Brenner and Toby Lowe, U.S. Food and Drug Administration (FDA)
The next call will be on Monday, November 16th 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
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/
Find CLCR call information, transcripts, & audio recordings on the Preparedness Portal

Guidance for SARS-CoV-2 Point-of-Care Testing


Point-of-care (POC) tests, such as some rapid tests for diagnosing an infectious disease, provide results within minutes of the test being administered, allowing for rapid decisions about patient care. POC tests can also extend testing to communities and populations that cannot readily access care. POC tests are used to diagnose COVID-19 in various settings, such as:

- Physician offices
- Urgent care facilities
- Pharmacies
- School health clinics
- Long-term care facilities and nursing homes
- Temporary locations, such as drive-through sites managed by local organizations

Summary: This CDC Web resource provides guidance on the regulatory requirements for SARS-CoV-2 POC testing, using POC tests safely, and information on reporting POC test results.
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
CMS Reimbursement Update

Sarah Harding
Centers for Medicare & Medicaid Services (CMS)
Centers for Medicare and Medicaid Services (CMS)

- CLIA Laboratory Guidance During COVID-19 Memo and FAQs

- FAQs Only
SARS-CoV-2 Ct-values

CDC’s Clinical Laboratory COVID-19 Response Call
2 November 2020

Daniel D. Rhoads, MD, FCAP, D(ABMM)
Section Head of Microbiology
Cleveland, Ohio

Cleveland Clinic
Fig. 5. A representative diagram showing currently available diagnostic primer sets on SARS-CoV-2 genome. Numbers represent genome positions according to SARS-CoV-2 isolate Wuhan-Hu-1 (GenBank: MN908947.3). Each primer set for the diagnosis was indicated by grey arrows.
Polymerase chain reaction - PCR

1. **Denaturation** at 94-96°C
2. **Annealing** at ~68°C
3. **Elongation** at ca. 72 °C

[https://commons.wikimedia.org/wiki/File:Polymerase_chain_reaction.svg](https://commons.wikimedia.org/wiki/File:Polymerase_chain_reaction.svg)
Ct-value

https://upload.wikimedia.org/wikipedia/commons/4/4e/Qpcr-cycling.png
Specimen type & Ct-value

A. Patient-Collected Tongue Swab

B. Patient-Collected Nasal Swab

C. Patient-Collected Mid-Turbinate Swab

Yuan-Po et al. doi: 10.1056/NEJMc2016321.
Ct-value & prognosis

Low load:  Ct > 30
Medium load:  Ct 25-30
High load:  Ct <25

- NP swab
- UTM
- ORF1ab target
- Roche 6800

Magleby et al. doi: 10.1093/cid/ciaa851
Ct-value & in vitro infectivity

![Graph showing Ct-value and in vitro infectivity](image)

Jaafar et al. doi: 10.1093/cid/ciaa1491
Ct-value limitations

- FDA EUA methods have qualitative interpretations
- No calibrated quantitative test is currently available
- Not all test methods generate a Ct-value
- Specimen collection impacts Ct-value
  - Time from symptom onset to collection
  - Specimen type (NP vs anterior)
  - Transport media (saline vs UTM; 1ml vs 3ml)
- Ct-values vary between test systems, between labs, & between targets

Rhoads et al. doi: 10.1093/cid/ciaa1199
Ct-value limitations

- 3.0 cycle difference between targets (Xpert)
- 12 cycle difference between labs (TaqPath)
- 14 cycle difference between test systems (Luminex & m2000)

Rhoads et al. doi: 10.1093/cid/ciaa1199
SARS-CoV-2 Ct-values

• Ct-values can correlate with prognosis & infectivity.

• Ct-values are not absolutely predictive of prognosis or infectivity.

• Ct-values are influenced by many pre-analytical and analytical variables.
Cleveland Clinic

Every life deserves world class care.
FDA Update

Sara Brenner and Toby Lowe
U.S. Food and Drug Administration (FDA)
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 (*)
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

# love the Lab
# lab professionals rock

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