

# Laboratory Outreach Communication System (LOCS) Call

Office of Laboratory Systems and Response (OLSR)

19 October 2026, at 3:00 P.M. ET

**Thank you for joining, we will begin the call momentarily. This call will be recorded.**

# Agenda

- **Welcome & Announcements**
  - Jasmine Chaitram, Office of Laboratory Systems and Response (OLSR), CDC
- **Update on Ebola Outbreak and Response**
  - Amy Schuh, Special Pathogens Branch, NCEZID
- **Updates on Diagnostic Malaria Testing and Diagnostic Stewardship**
  - Nancy Cornish, Division of Laboratory Systems, OLSR
- **Update on Cases of Clade I Monkeypox Virus in the US**
  - Christina Hutson, Poxvirus and Rabies Branch, NCEZID
- **COVID Emergency Declaration Ended and Impact to Emergency Use Authorized (EUA) Tests**
  - Toby Lowe, FDA
- **CMS Update - Clinical Laboratory Improvement Amendment Proposed Rule**
  - Penny Keller, CMS

# Office of Laboratory Systems and Response (OLSR)



# LOCS Calls

- On this page, you find:
  - LOCS Call Information
  - Slides

[LOCS Calls and Archive](#) | [LOCS](#) | [CDC](#)

 Laboratory Outreach Communication System (LOCS)  
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## LOCS Calls and Archive

### Overview

CDC's Office of Laboratory Systems and Response (OLSR) convenes regular Laboratory Outreach Communication System (LOCS) calls with clinical laboratories and other audiences. The calls are an opportunity for CDC and other participants (such as federal partners and professional organizations) to provide updates and answer questions from the laboratory and testing community.

These typically take place on the third Monday of each quarter at 3:00 PM Eastern time. Ad hoc meetings may be convened as needed for various laboratory and testing-related updates. OLSR posts the audio, slides, and transcripts online after each call.

### How to submit questions

To submit questions for consideration, email [LOCS@cdc.gov](mailto:LOCS@cdc.gov) in advance or use the question and answer (Q&A) function in Teams during the call. Because we anticipate a large number of participants on this call and many questions, we may not be able to directly and immediately address every issue. However, we will note your questions and feedback and tailor the content of future calls accordingly.

### Join from a PC, Mac, iPad, iPhone or Android device

Microsoft Teams [Need help?](#)

[Calendar invite](#)

[Join the meeting now link](#)

Meeting ID: 211 777 413 061 1

Passcode: eD3Ks6nX

- The download link for the Microsoft Teams app on Windows [Download Microsoft Teams Desktop and Mobile Apps](#) | [Microsoft Teams](#)
- The download Teams link for Android: [Teams for work - Android Apps on Google Play](#)
- The download Teams link for iOS: [Microsoft Teams on the App Store](#)

### LOCS Calls, Recordings, and Slides

Year

All years

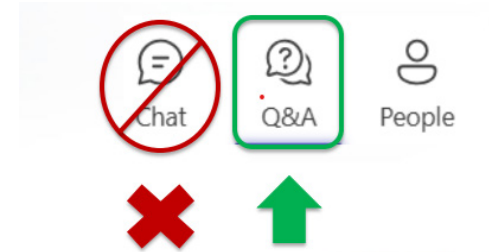
Search

75 results

The findings and conclusions in these slide decks are those of the authors and may not necessarily represent CDC's official position on the topic(s) covered.

# How to Ask a Question

- All participants are muted and chat feature is disabled
- Using the Microsoft Teams System
  - Click the Q&A button in the Microsoft Teams meeting
  - Type your question in the Q&A box and submit it
  - **Please do not submit a question using the chat button**
  - For non-laboratory testing questions, please contact CDC-INFO at [cdc-infostaff@cdc.gov](mailto:cdc-infostaff@cdc.gov)
  - 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



# Announcements



# Laboratory Director University

**Introduction to Laboratory Director Responsibilities**

**CLIA Personnel Qualifications and Responsibilities:  
Moderate Complexity Testing**

**Fundamentals of Quality Practices in CLIA  
Provider-Performed Microscopy Procedures**

**Fundamentals of Laboratory Risk Assessment  
Creating Next-Level Laboratory Training**

**Packing and Shipping Dangerous Goods (PSDG) -  
Sample Training Materials**

**VR Specimen Handling Scenarios**

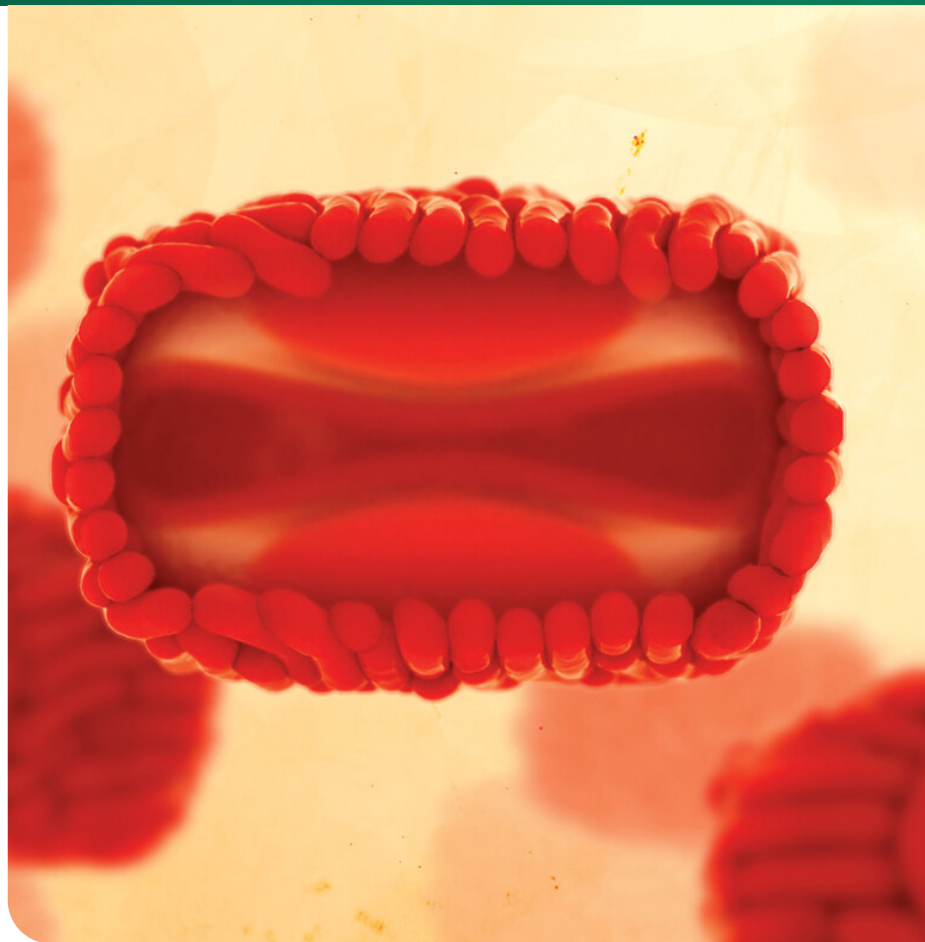
**Visit LDU on OneLab REACH™: [reach.cdc.gov/ldu](https://reach.cdc.gov/ldu)**



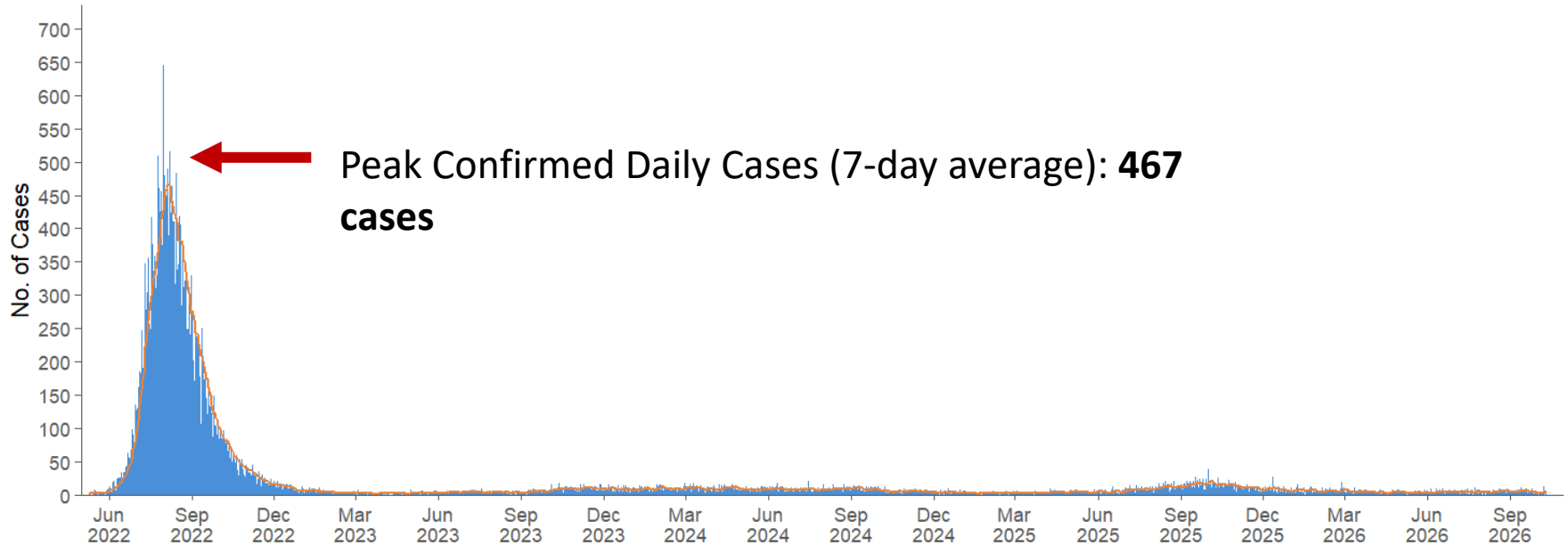


# Monkeypox virus (MPXV) Update, October 2026

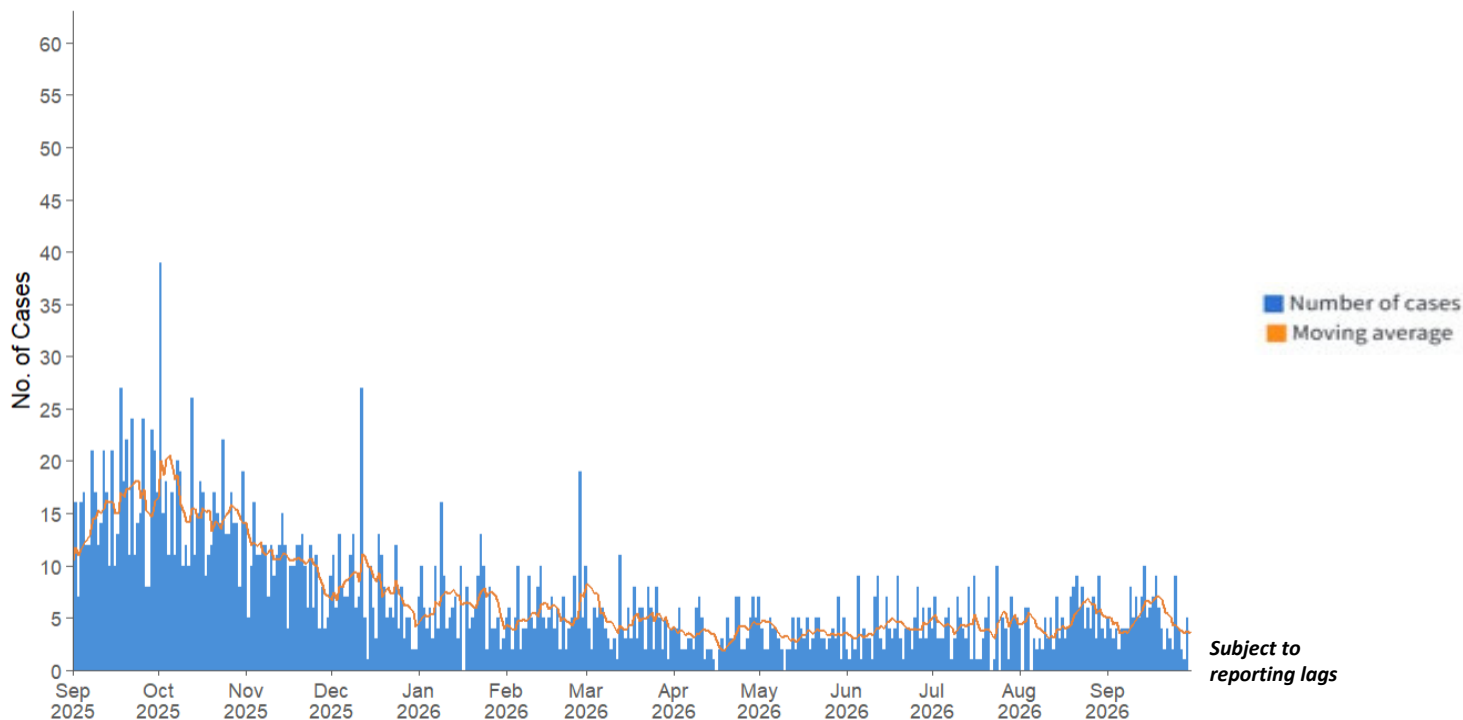
Christy Hutson, PhD, MS  
Chief, Poxvirus and Rabies Branch  
Centers for Disease Control and Prevention (CDC)  
Department of Health and Human Services (HHS)



# MPXV Epi-Curve and 7-Day Moving Average – United States, May 2022 to September 2026

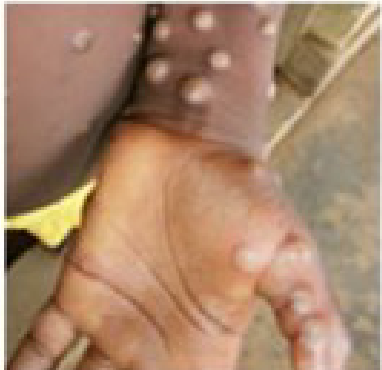


# MPXV Epi-Curve and 7-Day Moving Average – United States, September 2025 to September 2026

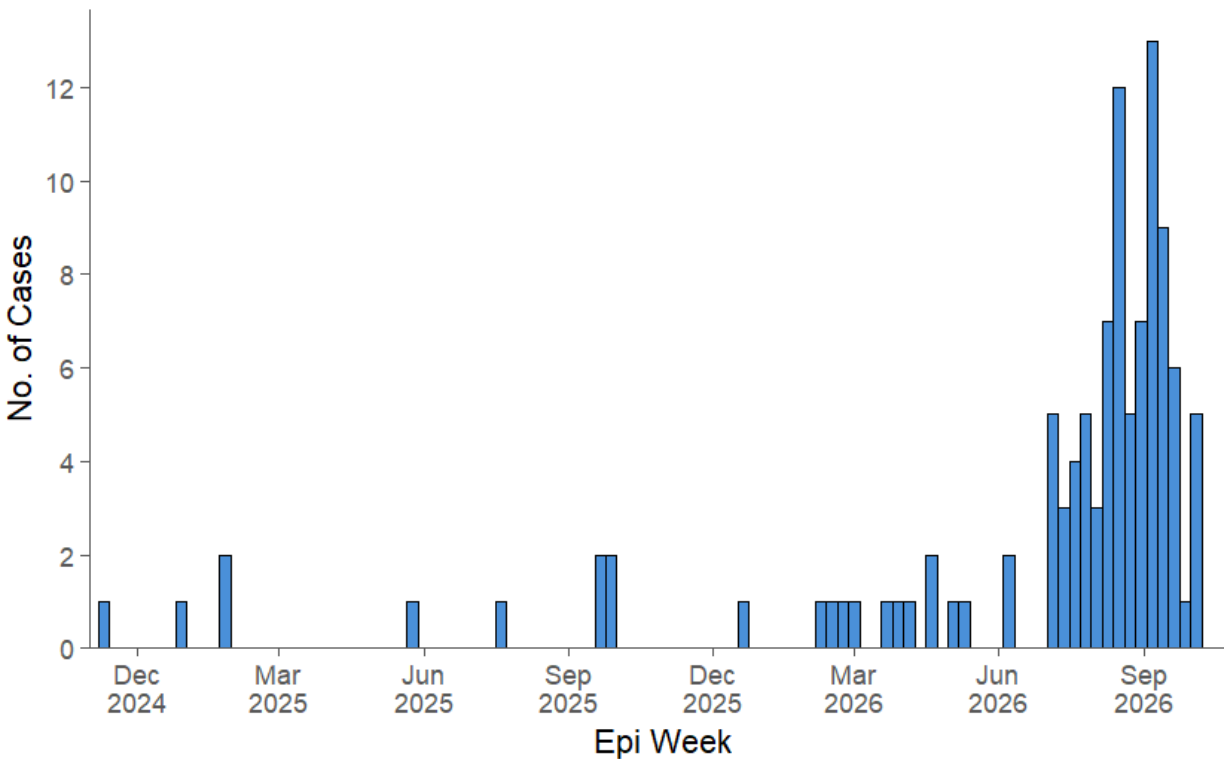
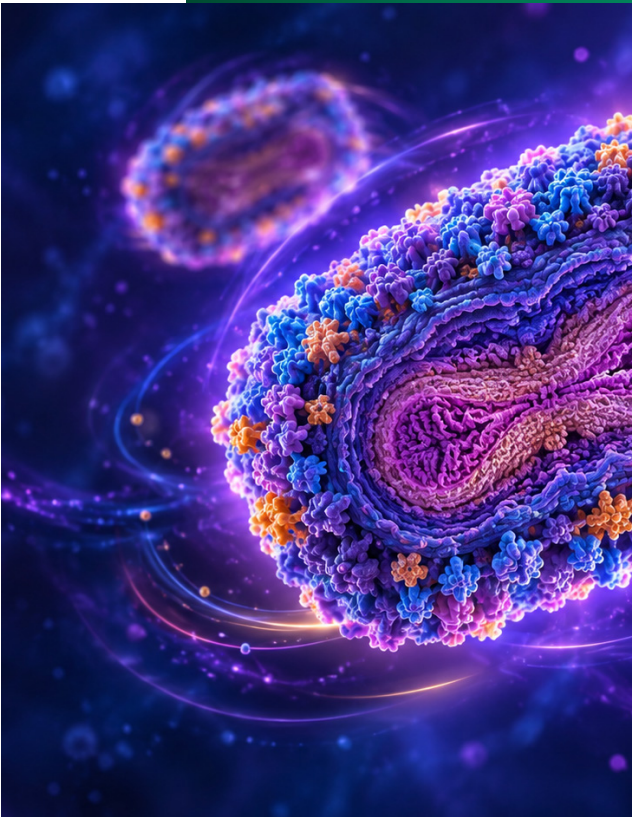


[U.S. Mpox Case Trends Reported to CDC | Mpox | Poxvirus | CDC](#)

# Clade I MPXV



# U.S. CLADE IB MONKEYPOX CASES AS OF SEPT. 30, 2026



Clade I Monkeypox Outbreaks  
| Monkeypox | CDC

# CDC also recommends clade-specific testing

- Helps track changes in incidence of clade II and I in the US, case demographics, morbidity and mortality trends in clade I confirmed cases, identify recombinant MPXVs, helps prioritize sequencing efforts
  - In Europe, total case counts remain far below the 2022 peak, but clade I has overtaken clade II
- CDC can do MPXV non-CLIA testing and genetic sequencing
- CDC will alert both the relevant laboratory and the state about clade I positives
- Email [poxvirus@cdc.gov](mailto:poxvirus@cdc.gov) with any questions



### For More Information

For more information on the Federal Select Agent Program, please visit [www.selectagents.gov](http://www.selectagents.gov)  
or contact the agencies directly using the information below:

Centers for Disease Control and Prevention  
Division of Regulatory Science & Compliance

Telephone: 404-718-2000

770-488-7100 (after hours)

Fax: 404-718-2096

Email: [LRSAT@cdc.gov](mailto:LRSAT@cdc.gov)



## FEDERAL SELECT AGENT PROGRAM

Overview ▾

Select Agents & Toxins ▾

Compliance ▾

Regulations & Policies ▾

Forms ▾

Select Agents > Resources > Select Agent (SA) Grams

🏠 Select Agent (SA) Grams

2025

2024

2023

## 2022 SA Grams

10/4/22 - Monkeypox Reporting Requirements

9/14/22 - 2022 U.S. Monkeypox Outbreak & FSAP Regulations



## FEDERAL SELECT AGENT PROGRAM

Overview ▾

Select Agents & Toxins ▾

Compliance ▾

Regulations & Policies ▾

Forms ▾

Select Agents > Compliance > FAQs

🏠 FAQs

Biosafety

## FAQ: Outbreaks

[Print](#)

# Thank you.

For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 <https://www.cdc.gov/>  
Follow us on social @CDCgov

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



## **Update on Ebola Outbreak and Response**

Amy Schuh PhD, Research Scientist, Viral Special Pathogens Branch, CDC

# Updates on Diagnostic Malaria Testing and Diagnostic Stewardship

Nancy E. Cornish MD Medical Officer, Division of Laboratory Systems

19 October 2026

# Why Malaria Testing in the United States?

- **National Malaria Eradication Program cooperative by states and CDC (then called the Communicable Disease Center) in 1947 resulted in public health initiative that decreased number of cases**
  - 15,000 cases in 1947
  - 2,000 cases in 1950
- **Blood donations are screened**
  - Travelers to area with malaria cannot donate for 3 months after return
  - Former residents of areas with malaria cannot donate for 3 years
- **U.S. international travelers, military personnel, citizens living abroad are at risk**

# Malaria Cases In The United States

- Each year on average:
  - Approximately 2000 cases a year (166 cases a month)
  - 7 deaths a year
  - Across all 50 states
- Travel associated (imported) for approximately 20 years
- Locally acquired malaria cases reported in 2023
  - 10 cases
  - 4 states (FL, TX, MD, AR)
  - *Anopheles* mosquitoes, the vector for malarial parasites remain common in the U.S. therefore continued vigilance is necessary

# Malaria Facts

- Travelers returning from endemic areas can present to any hospital across the country
- All hospitals should be able to perform urgent malaria diagnostic testing (within a few hours)
- Thick and thin smears should be prepared immediately\* after specimen collection and microscopic evaluation must be performed to:
  - Confirm *Plasmodium* species present
  - Calculate parasitemia
  - Monitor response to treatment

\* Blood that is held too long before smear prep results in poor morphological features that may prevent species identification

# CDC Resources Now Available to Assist Clinical and Public Health Laboratories

- [Rapid Diagnostics Toolkit | Malaria | CDC](#)
  - Laboratory Bench Aids PDFs
- [CDC - DPDx - Diagnostic Procedures - Blood Specimens](#)
- [Guidance for Malaria Diagnosis in Patients with Suspected Orthoebolavirus or Orthomarburgvirus Infection in the United States](#)
- [Algorithm for Malaria Diagnosis and Treatment in the United States | Malaria | CDC](#)
  - Please share with clinicians who utilize your laboratory and pharmacists

# Malaria Testing Training Now Available

- [OneLab REACH | OneLab REACH](#)
- Resources include free trainings, video and printable job aids and toolkits
- [Malaria Laboratory Diagnostic Testing | OneLab REACH](#)
- Rapid diagnosis of malaria is crucial to initiate appropriate treatment since uncomplicated malaria can rapidly progress to a life-threatening disease.
  - Biology of malaria parasites
  - Instructions for preparing and examining blood smears
  - The role of rapid diagnostic tests.
  - 1.0 contact hour P.A.C.E. provided

# Malaria Screening

- [Clinical Testing and Diagnosis for Malaria | Malaria | CDC](#)
  - For patients suspected of having a viral hemorrhagic fever, consider malaria infection
  - [Malaria Diagnostic Tests | Malaria | CDC](#)
  - If unable to test for malaria in your facility develop a plan for timely testing (2 to 4 hours turn around saves lives)
  - Consider consulting with your public health laboratory and/or neighboring institutions who may offer reference testing
  - Contact the Malaria Hotline/Clinical Consult Service\* for Healthcare Providers (Monday–Friday, 9:00 AM–5:00 PM EST) at 770-488-7788, 855-856-4713 (toll-free), or via email at [malaria@cdc.gov](mailto:malaria@cdc.gov).
  - For 24/7 after-hours support, contact CDC's Emergency Operations Center at 770-488-7100 and request to speak to a CDC Malaria Branch clinician or email [malaria@cdc.gov](mailto:malaria@cdc.gov)

\* The Malaria Hotline receives 250 calls a month!

- The CDC Yellow Book is a comprehensive resource for healthcare professionals providing care to international travelers before and after travel. It provides health information for international travel
- [CDC Yellow Book™](#) | [CDC](#)



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## **COVID Emergency Declaration Ended and Impact to Emergency Use Authorized (EUA) Tests**

Toby A. Lowe, Deputy Office Director, U.S. Food and Drug Administration

# **Clinical Laboratory Improvement Amendments (CLIA) Proposed Rule: CMS-3478-P**

*Penny Keller, BS, MB(ASCP)  
Centers for Medicare and Medicaid Services  
Division of Clinical Laboratory Improvement and Quality*

*October 19, 2026*

# 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 it 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.

# Purpose

- Proposed rule updates CLIA regulations at 42 CFR Part 493
- Four main topic areas:
  - Virtual access for remote review of lab data and images
  - Gynecologic cytology proficiency testing (PT)
  - Personnel qualification requirements
  - Other changes: SARS-CoV-2 reporting, certificates, test reports, enforcement, public consultation, and editorial and technical changes

# Review and Comment Submission

Comment period is from October 08, 2026 to December 07, 2026.

A large, light gray downward-pointing arrow indicating the flow from the comment period to the rule information.

To read the CLIA Proposed Rule, visit Federal Register, [www.federalregister.com](http://www.federalregister.com), [CMS-3478-P](#).

A large, light gray downward-pointing arrow indicating the flow from the rule information to the submission methods.

Comments may be submitted in one of the following three ways: electronically, regular mail, or overnight/express mail.

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# 1. Virtual Access

# Virtual Access: Proposed Changes

- Codifies existing post-COVID enforcement discretion into regulation
- New definition for "virtual access"
- Personnel may remotely review digital laboratory data, digital results, live imaging, and digital images
- Secure connection to the primary laboratory systems (LIS, EHR, instruments)
- Applies to CoR, CoC, and CoA certificates — not PPM
- Cytology is excluded — testing must be performed on-premises (obtain a separate CLIA certificate)

# Virtual Access: Proposed Changes, continued

- Citations and enforcement actions attach to the primary laboratory certificate
- Primary laboratory director remains responsible for all remote testing
- Primary laboratory is responsible for retaining all documentation, including remote work
- Remote staff should be added to Form CMS-209 (Laboratory Personnel Report)
- Lab must provide a list of remote staff upon request
- Test reports should indicate the remote site location where the testing is performed (a coding system is allowed)
- Primary laboratory must be certified for the specialty/subspecialty being reviewed remotely

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## 2. Gynecologic Cytology PT

# Cytology PT: Proposed Changes

- PT programs may use digital images of glass slides
- PT programs must have a system in place to monitor the integrity of testing, including digital images
- Same PT scoring rules apply to digital images as glass slides

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## 3. Personnel Qualifications

# Personnel: Proposed Changes

- Laboratory director qualification pathways updated: lab supervisory experience requirements changed from "and" to "or"
- Board certification requirement removed for doctoral-level pathways
- Removes "human-only" limitation — animal/veterinary lab experience can now qualify
- New qualification pathway for Mohs dermatology laboratory directors
- New qualifications for histopathology gross tissue examination personnel, and extends the technical supervisor review timeframe
- PPM laboratory directors are no longer required to evaluate personnel competency
- Removes the on-site requirement for laboratory directors
- Moderate complexity Technical Consultant and testing personnel for blood gas analysis

# Personnel: Proposed Changes, continued

- Adds grandfather clause to moderate complexity Clinical Consultant
- Uses the U.S. Department of Education's National Center for Education Statistics (NCES) Classification of Instructional Programs (CIP) categories
- Revises definitions of Biological degree, Chemical degree, Clinical or Medical Laboratory Science or Medical Technology Degree, Doctoral degree, experience directing or supervising, and Laboratory training or experience
- Codifies interpretive guidance for high complexity testing personnel by possessing an associate degree in chemical, biological, clinical, or laboratory science, or medical technology from an accredited institution

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## 4. Other Changes

# Proposed Other Changes

- SARS-Cov-2 reporting requirements will be removed.
- Proposed Certificate Requirements: Defines “campus” and revises the multiple-site exception for clarity. Requires laboratories to provide email address updates for all certificate types.
- Proposed Test Report Requirements: Add the laboratory’s CLIA number and the name of the laboratory as it appears on the CLIA certificate to the test report.
- Proposed Enforcement Requirements: Removes the mandatory 6-month wait after PT failure and allows laboratories to resume testing after 2 successful PT events. Alternative sanctions (for example, DPOC) can continue until the certificate is revoked. Allows CoW laboratories to have CMP imposed if found to have condition-level deficiencies.
- Public consultation requirement will be changed to “may” establish CLIAC.
- Editorial and technical changes

# Timeline & Next Steps

- Comments due 60 days after Federal Register publication (December 07, 2026).
- Submit comments via [regulations.gov](https://www.regulations.gov), docket CMS-3478-P.

# Questions



**THANK YOU!**

*Penny Keller*

Penny.Keller@cms.hhs.gov



**Next Scheduled Call: Jan 25 at 3pm**

# Thank you!

For more information, contact CDC

1-800-CDC-INFO (232-4636)

TTY: 1-888-232-6348 [cdc.gov](https://www.cdc.gov)

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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 the U. S. Centers for Disease Control and Prevention.