



# Laboratory Outreach Communication System (LOCS) Call

Office of Laboratory Systems and Response (OLSR)

26 January 2026, at 1:00 P.M. ET

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

# Agenda

- **Welcome & Announcements**
  - Jasmine Chaitram, CDC OLSR
- **Monkeypox Update**
  - Christina Hutson, CDC Division of High-Consequence Pathogens and Pathology
- **CLIA Paperless Certification Process**
  - Penny Keller, HHS, Centers for Medicare and Medicaid Services
- **Newborn Screening Continuity of Operations and Contingency Plans**
  - Beth Bair, S.C. Department of Public Health
- **CDC Specimen Submission and Test Ordering Process**
  - Valerie Albrecht, CDC OLSR

# Office of Laboratory Systems and Response (OLSR)



# LOCS Calls

- **On this page, you find:**
  - LOCS Call Information
  - Transcripts
  - Slides
  - Audio Recordings

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

The screenshot shows the 'Laboratory Outreach Communication System (LOCS)' page. At the top, there is a blue header with the CDC logo, the title 'Laboratory Outreach Communication System (LOCS)', a search bar, and a dropdown menu labeled 'EXPLORE THIS TOPIC'. The main content area is titled 'LOCS Calls and Archive' and includes an 'Overview' section. The overview text states that the CDC's Office of Laboratory Systems and Response (OLSR) convenes regular LOCS calls with clinical laboratories and other audiences. It also provides information on how to submit questions and how to join from various devices. A meeting ID (211 777 413 061 1) and passcode (eD3Ks6nX) are listed. Below this, there are links for downloading the Microsoft Teams app on Windows, Android, and iOS. At the bottom of the screenshot, there is a search filter for 'Year' set to 'All years' and a search bar with '75 results' displayed below it.

# 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 patient, please direct any questions to your healthcare provider



# Announcements

# Join Us at LDU!



Laboratory  
Director  
University

The **CDC Division of Laboratory Systems (DLS)** and the **CMS Division of Clinical Laboratory Improvement and Quality (DCLIQ)** are excited to announce the launch of Laboratory Director University.

## Who is LDU for?

Current and prospective laboratory directors who will oversee CLIA-certified laboratories, CMS surveyors, CLIA-designated personnel, and other laboratory professionals.

## What is LDU?

High-quality training with focused learning pathways and rich supplemental resources that help address CLIA deficiencies and regulatory standards.

## Why should I enroll in LDU?

Benefit from self-paced learning that targets improvements and resolutions to common CLIA deficiencies and earn CE credits!

**Built by Experts. Backed by Compliance. Designed for You.**

For more information, please opt in through OneLab REACH™ or email [OneLab@cdc.gov](mailto:OneLab@cdc.gov).



# **CDC Planning for 2026 FIFA World Cup**

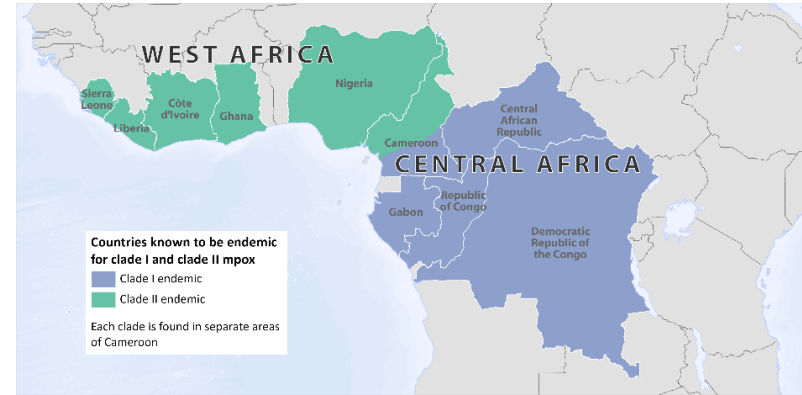
# Monkeypox virus (MPXV) Update, January 2026

Christy Hutson, PhD, MS

Chief, Poxvirus and Rabies Branch, CDC, HHS

# There are two types of MPXV: clade I and clade II

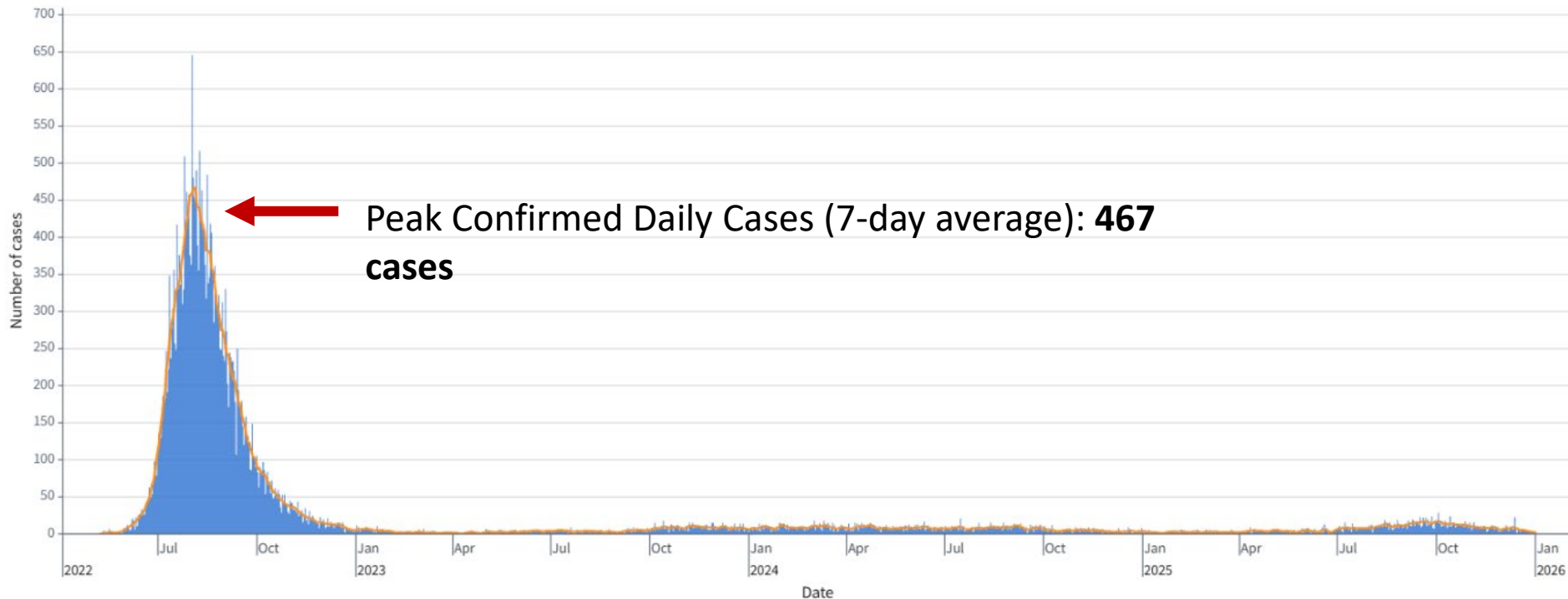
- **Clade I** is responsible for the current rise of cases in [Central and Eastern Africa](#). Historically, clade I caused higher numbers of severe illness than clade II, with *estimated* up to 10% of people dying from it. Recent outbreaks have seen much lower death rates of [<1-3%](#).
  - Sub-clades Ia and Ib
- **Clade II** is the type that caused [the global outbreak that began in 2022](#). Infections from clade II MPXV are less severe for most people. More than 99.9% of people survive. Clade II is endemic to West Africa.
  - Sub-clades IIa and IIb



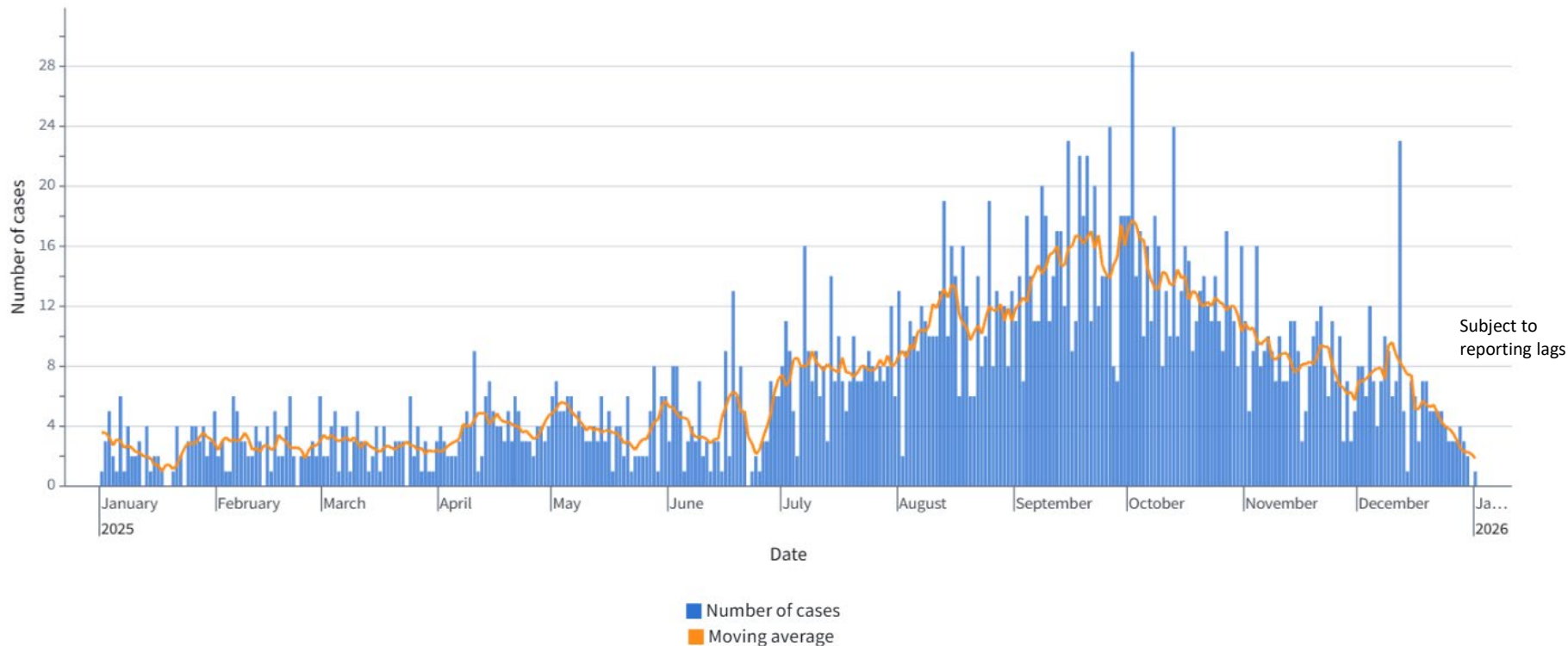
Source: cdc.gov

# Clade II MPXV

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



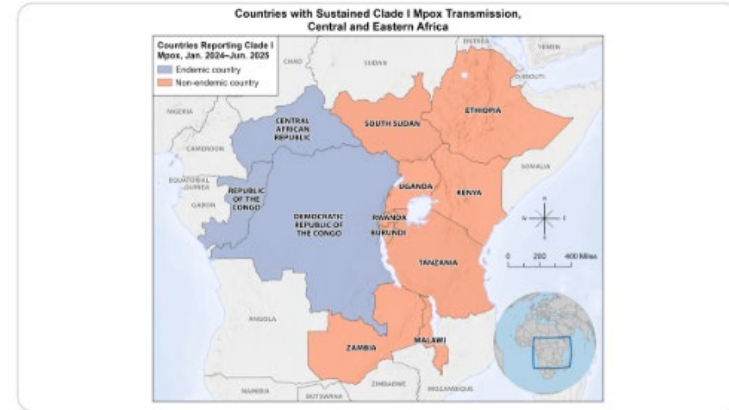
# MPXV Clade II Epi-Curve and 7 Day Moving Average – United States, January 2025 to January 2026



# Clade I MPXV

# Current Clade I MPXV Situation as of January 2026

- To date, there have been more than 150 clade Ib cases in high-income countries.
  - This list is expected to increase as additional travel-related cases occur due to ongoing/expanding outbreaks
- Beginning in Fall 2025, several countries in Western Europe began reporting clade Ib MPXV cases among individuals who had no documented history of international travel. These cases were likely related to intimate or sexual exposure among men who have sex with men. We expect additional cases in Europe and the United States.
- In the U.S, there have been 10 reported cases caused by clade Ib MPXV since November 2024.



[Clade I Monkeypox Outbreaks | Monkeypox | CDC](#)  
[Global Mpox Trends: World Health Organization](#)

# MPXV Testing in the US

- **Rapid Diagnostic Testing for Response to the Monkeypox Outbreak - Laboratory Response Network, United States, May 17-June 30, 2022.**
  - MMWR Morb Mortal Wkly Rep. 2022 Jul. Aden TA, Blevins P, York SW, Rager S, Balachandran D, Hutson CL, Lowe D, Mangal CN, et al.
- **Successful Collaborations that Resulted in Increased U.S. Diagnostic Testing During the 2022 Mpox Outbreak.**
  - J Public Health Manag Pract. 2025 Jan-Feb Hutson CL, Villanueva J, Stenzel T, Olson VA, Gerald N, McNall R, Courtney S, Aden T, Rager S, Egan C, Blevins P, Kuhnert W, Davidson W, Khan T, Baird N, Kling C, Van Meter S, Chaitram J, Salerno RM.
- **U.S. has robust non-variola orthopoxvirus (NVO) testing capacity**
  - CDC 510(k) approved test that targets a conserved area of MPXV genome with little chance for mutation
- **Mpox EUAs: <https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/monkeypox-mpox-emergency-use-authorizations-medical-devices#molecular>**
- ***Clade II testing rules out clade I MPXV***
  - CDC continues to solicit all OPXV/MPXV positive specimens from labs that are not clade testing OPXV/MPXV positives

# Recombinant MPXV detection

## Inter-Clade Recombinant Mpxv Virus Detected in England in a Traveller Recently Returned from Asia

■ MPXV



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11 Dec 2025

Dec

1

### Inter-Clade Recombinant Mpxv Virus Detected in England in a Traveller Recently Returned from Asia



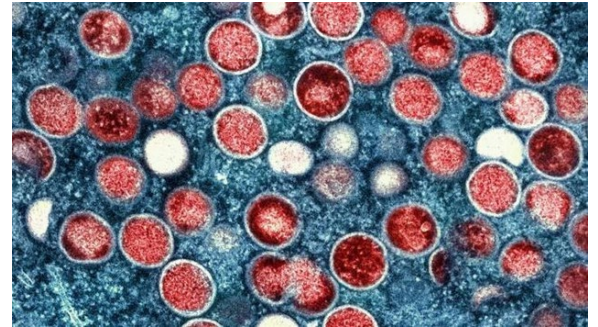
Laboratory Outreach Communication System (LOCS)

EXPLORE THIS TOPIC

SEARCH

12/22/2025 Recent Recombinant Monkeypox Virus Case and Potential Impacts on Laboratory Tests

Public Health  
DEC. 22, 2025



[12/22/2025 Recent Recombinant Monkeypox Virus Case and Potential Impacts on Laboratory Tests | LOCS | CDC](#)

# Clinical Laboratory Improvement Amendments (CLIA) Paperless Certification Process

Penny H. Keller, HHS, CMS

# CLIA Paperless Certification Process

## **i** What's New & Important

### **Last Chance. Act Now!**

This is your **last chance** to go paperless before we eliminate paper fee coupons and CLIA certificates. **After March 1, 2026, paper fee coupons and CLIA certificates will no longer be available. In addition, laboratories must pay their CLIA certification and survey fees online (checks will no longer be accepted).**

**This transition is not optional. Laboratories must sign up** for CMS email notifications to receive electronic CLIA fee coupons and certificates. Failure to go paperless may result in billing and certification issues.

## • **Need help?**

- Contact your [State Agency](#) (SA) or Accreditation (AO) to make the switch to paperless
- Download this [toolkit](#), which provides ready-to-use messaging for your outreach to laboratories and providers, plus these materials you can share: [Fact Sheet](#) | [Poster](#) | [FAQ](#)

# Importance of Continuity of Operations Planning

Beth Bair, MS, PhD

S.C. Department of Public Health



# **Newborn Screening Continuity of Operations and Contingency Plans**

**Beth Bair, MS, PhD**

# Acknowledgements

**South Carolina Newborn Screening Team**

**Tennessee Newborn Screening Team**

**Florida Newborn Screening Team**

**North Carolina Newborn Screening Team**

**APHL**

**Revvity**

Contact: Beth Bair  
bairea@dph.sc.gov

# Continuity of Operations (COOP)



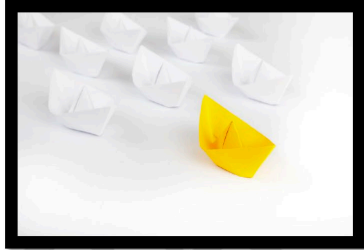
- What it is and how to Plan – COOP Resource Guide
- Working with Partner States
- Lived Experiences – Identifying Risks, Triggers
- Lessons Learned
- Maintaining COOP

# COOP Resource Guide

- Shared document between multiple states (SC, TN, FL, NC, GA)
- 30 pages
- Contacts
- Operating hours (days/times)
- Specimen categories, unsat types
- Disorders tested and cutoffs
- 2<sup>nd</sup> tier testing
- Courier, results reporting
- Communicating abnormal results
- Images of state cards with demographics

State Newborn Screening COOP Resource Guide Last Revision: 1/9/2025 by: Christine Harrelson, harrelcl@dph.sc.gov

## State Newborn Screening COOP Resource Guide



**Table of Contents:**

State Operating Hours	2
State NBS Contacts	2
Pre-Analytical Processes	6
Analytical Processes – Methods & Cutoffs	9
Post Analytical Processes	19
Additional Information	23

# Identifying Risks

- 2021 Network Outage
- 2023 Instrumentation (MS-MS)
- 2025 Cut Fiber Optic Cable, Server Migration



# Working with Partner States



- Phase 1: standardize our newborn screening cards

APPLY BLOOD TO ONE SIDE OF CARD  
ONE LARGE DROPPER CIRCLE

[LOT] 7307924 WZ21		NEWBORN SCREENING PUBLIC HEALTH LABORATORY SC DEPT. OF PUBLIC HEALTH 8231 PARLANE ROAD, COLUMBIA, SC 29223 803-896-0874
		Use By 2029-04-30
		DPH LAB USE ONLY
	BABY'S LAST NAME MOTHER'S LAST NAME MOTHER'S ADDRESS CITY STATE COUNTY ZIP CODE	BABY'S FIRST NAME MOTHER'S FIRST NAME PARENT(S) / GUARDIAN'S PHONE NO. HOSPITAL / SPECIMEN SUBMITTER NO. HOSPITAL NAME / SUBMITTER NAME STREET ADDRESS CITY, STATE, ZIP
	MEDICAL RECORD NO. PRIMARY MD LICENSE NO. [SNI] SC00000000001 [SNI] SC00000000001 [SNI] CO	DATE OF BIRTH TIME OF BIRTH DATE OF COLLECTION TIME OF COLLECTION COLLECTOR ID / INITIALS SEX <input type="checkbox"/> M Male <input type="checkbox"/> F Female RACE <input type="checkbox"/> 1. White <input type="checkbox"/> 4. Asian <input type="checkbox"/> 2. AF-Amer. <input type="checkbox"/> 5. Amer. Ind. <input type="checkbox"/> 3. Hispanic <input type="checkbox"/> 6. Other BIRTH WEIGHT IN GRAMS PRESENT WEIGHT IN GRAMS MULTIPLE BIRTHS <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> Use By 2029-04-30 IF MULTIPLE: A,B,C, etc. LAST TRANSFUSION DATE FEEDING <input type="checkbox"/> 01 BREAST <input type="checkbox"/> 02 LACTOSE <input type="checkbox"/> 03 NONLACTOSE <input type="checkbox"/> 04 TPN <input type="checkbox"/> 05 NPO GESTATIONAL AGE _____ WKS.
		DPH LAB USE ONLY
		D-1327 (7/2024)
		[REV] 10534690 Rev. AF [LOT] 7307924 WZ21
		D-1327 (7/2024)

# Working with Partner States



- Phase 2: Identify demographics that we each must have to report results.

Demographics Needed for Reporting
Kit Number
Accession Number
Laboratory ID Number (the other state's accession number)
Infant's Last Name
Date of Birth/Time
Date of Collection/Time
Birth Weight (g)
Feed Status
Transfusion Date/Time
Submit to State Lab
Gestational Age at Birth (must allow for 2 – 3 digit entries and decimal points)
Sex
Birth Order (if multiples)

# Working with Partner States



- Phase 3: Establish a COOP demographic entry screen.
  - Requires working with vendor for configuration.
    - Planning – including this in the overall NBS timeline of things that we need to do, in collaboration with partners
    - Configuration = \$\$
    - January 2026
- Phase 4:
  - HL7 Connectivity (pie in the sky)
  - Someday.....



# Activating COOP



Time	Incident	Action
8:30 AM	Cut fiber optic cable coming into the PHL – loss of network.	LIMS administrator notifies OIT and lab director that network is down.
10:00 AM	Lab managers and supervisors convene a meeting to discuss what they can do/cannot do without network. Plan next steps.	Specimen accessioning group moves to offsite location with laptops to key specimens. Some newborn screening staff also go to result patient specimens from the previous day.
11:30 AM	Updates from OIT with ETA on someone from AT&T coming to repair the damaged fiber optic cable.	Staff continue to do what they can without network availability at the PHL. Other staff move to offsite location to continue working on laptops.
1:00 PM	No news regarding repair timeline. Lab managers and supervisors start planning for day 2.	NBS reaches out to Tennessee and puts them on COOP alert for the following day.
2:30 PM	Email communication received that fiber optic cable has been repaired.	Normal operations.

# Lessons learned



- Communication!
- Need to know the other states' hours of operation (days & times), disorders tested, cutoffs, unsat types, testing, and reporting.
- Experience makes a huge difference!
- Commercial couriers have variable schedules.
- Time zones matter.
- Need support from multiple groups: IT, Procurement, LIMS, etc.
- Vendor support!



# Things you can do now...



- Start talking about COOP!
- Read APHL's CONPLAN, V.3
- Establish MOU's with partner states and/or vendors
- Hold roundtable exercises with internal (IT, procurement, LIMS, QA, logistics, etc.) and external partners.
- Establish a COOP SOP
- Remember: every situation is different!





# Thank you!

Contact: Beth Bair  
bairea@dph.sc.gov

# CDC Specimen Submission Update

Valerie Albrecht, CDC Office of Laboratory Systems and Response

# CDC Specimen Submission

- [Submitting Specimens to CDC | Infectious Diseases Laboratories | CDC](#)

- CDC Test Order Directory
- CSTOR- CDC Specimen Test Order and Reporting
- CDC Specimen Submission Form (50.34)



Antimicrobial Susceptibility Testing (AST) - Bacteria

CDC-10223

Synonym(s) Antimicrobial Susceptibility Testing (AST), sensitivity, resistance, Minimum Inhibitory Concentration (MIC) testing

CDC Pre-Approval Needed None

Supplemental Information Required The CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) must include the State Public Health Department contact information, specific antibacterial agent(s) of interest, previous results and testing method, as well as the date the submitted culture was inoculated onto transport media.

Supplemental Form None

Performed on Specimens from Human

Acceptable Specimen Type for Testing Pure culture isolates of bacteria demonstrating unusual resistance or unusual isolates on which the submitter cannot perform susceptibility testing.

Minimum Volume Required Not Applicable

Select the Specimen Origin to Begin the Form

HUMAN

**CDC SPECIMEN SUBMISSION FORM: SPECIMENS OF HUMAN ORIGIN** Form Approved | OMB Control No. 0920-1109 | Expiration Date: 10/31/2026

**LABORATORY EXAMINATION REQUESTED**

Test order name: \_\_\_\_\_  
 Test order code: \_\_\_\_\_  
 Suspected Agent: \_\_\_\_\_  
 Date sent to CDC:

At CDC, bring to the attention of: \_\_\_\_\_

**PATIENT INFORMATION**

Patient Name: \_\_\_\_\_  
 Birth date:  Case ID: \_\_\_\_\_  
 Sex:  Age:  Age Units: \_\_\_\_\_  
 Race:  White  Black or African American  Asian  American Indian and Alaska Native  Native Hawaiian and Other Pacific Islander  
 Clinical Diagnosis: \_\_\_\_\_  
 Date of onset:  Pregnancy Status: \_\_\_\_\_  
 Fatal:  Date of Death:

**SPECIMEN INFORMATION**

Specimen collected date:  Time:  \_\_\_\_\_  
 Material Submitted: \_\_\_\_\_  
 Specimen source (type): \_\_\_\_\_  
 Specimen source modifier: \_\_\_\_\_  
 Specimen source site: \_\_\_\_\_  
 Specimen source site modifier: \_\_\_\_\_  
 Collection method: \_\_\_\_\_  
 Treatment of specimen: \_\_\_\_\_  
 Transport medium/Specimen preservative: \_\_\_\_\_  
 Specimen handling: \_\_\_\_\_

**STATE PHIL / NEW YORK CITY DEPARTMENT OF HEALTH & MENTAL HYGIENE / FEDERAL AGENCY / INTERNATIONAL INSTITUTION / PEACE CORPS**

Name (Laboratory Director or designee): \_\_\_\_\_  
 Institution name: \_\_\_\_\_  
 Street Address: \_\_\_\_\_  
 City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP Postal Code: \_\_\_\_\_  
 Country: \_\_\_\_\_  
 Fax: \_\_\_\_\_  
 Point of Contact (Person to be contacted if there is a question regarding this order): \_\_\_\_\_  
 Phone: \_\_\_\_\_  
 Patient ID: \_\_\_\_\_ Alternative Patient ID: \_\_\_\_\_  
 Specimen ID: \_\_\_\_\_ Alternative Specimen ID: \_\_\_\_\_

**ORIGINAL SUBMITTER** (organization that originally submitted specimen for testing)

Name (Laboratory Director or designee): \_\_\_\_\_  
 Institution name: \_\_\_\_\_  
 Street Address: \_\_\_\_\_  
 City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP Postal Code: \_\_\_\_\_  
 Country: \_\_\_\_\_  
 Fax: \_\_\_\_\_

# Test Order Directory – CLIA and non-CLIA Test Orders

Narrow the results with a keyword, test title, test synonym, or point of contact:



[A](#) [B](#) [C](#) [D](#) [E](#) [F](#) [G](#) [H](#) [I](#) [K](#) [L](#) [M](#) [N](#) [O](#) [P](#) [R](#) [S](#) [T](#) [V](#) [W](#) [Y](#)

Showing 265 of 265 tests.

Test Name	Test Code
<a href="#">Acanthamoeba Molecular Detection- CLIA</a>	CDC-10471
<a href="#">Acanthamoeba Molecular Detection- Non-CLIA</a>	CDC-10611
<a href="#">Adenovirus Molecular Detection- CLIA</a>	CDC-10401
<a href="#">Adenovirus Molecular Detection- Non-CLIA</a>	CDC-10581
<a href="#">Aerobic Actinomycetes - Identification and Antimicrobial Susceptibility Testing- CLIA</a>	CDC-10149
<a href="#">Aerobic Actinomycetes - Identification- CLIA</a>	CDC-10148
<a href="#">Alkhurma Hemorrhagic Fever Testing- Non-CLIA</a>	CDC-10274
<a href="#">Ameba Identification (Acanthamoeba, Balamuthia, Naegleria)- CLIA</a>	CDC-10286
<a href="#">Ameba Identification (Acanthamoeba, Balamuthia, Naegleria)- Non-CLIA</a>	CDC-10613

<b>CLIA Test Orders</b>	<b>120</b>
<b>Non-CLIA Test Orders</b>	<b>145</b>

	CLIA Test Orders	Non-CLIA Test Orders
<b>SPECIMEN LABELING VALUE</b>	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

# CDC Specimen Test Order and Reporting



Create Test Order Requests

Submit Specimens

Ship Package

Check Status

View Reports

Manage Organization

- A web portal that streamlines the process to request test orders, submit specimen information, and receive reports from the CDC
- Online alternative to using the 50.34 form
- Provides a way to centralize test order approvals, specimen data, shipment status, and CDC reports
- Over 115 external organization connected with almost 1000 users

A screenshot of a web portal interface. At the top, a blue header bar contains the text 'My Needs Attention - 5'. Below this, a white card displays a red error icon and the text 'Patient Birth Date'. Underneath, the 'Date' is listed as '10/31/2019'. The 'Action Required' is 'Field', and the 'Specimen ID' is 'SS-10518', which is highlighted with a yellow box. The 'Patient ID' field is empty. At the bottom of the card, a blue button with a white pencil icon and the text 'Edit' is highlighted with a red border.

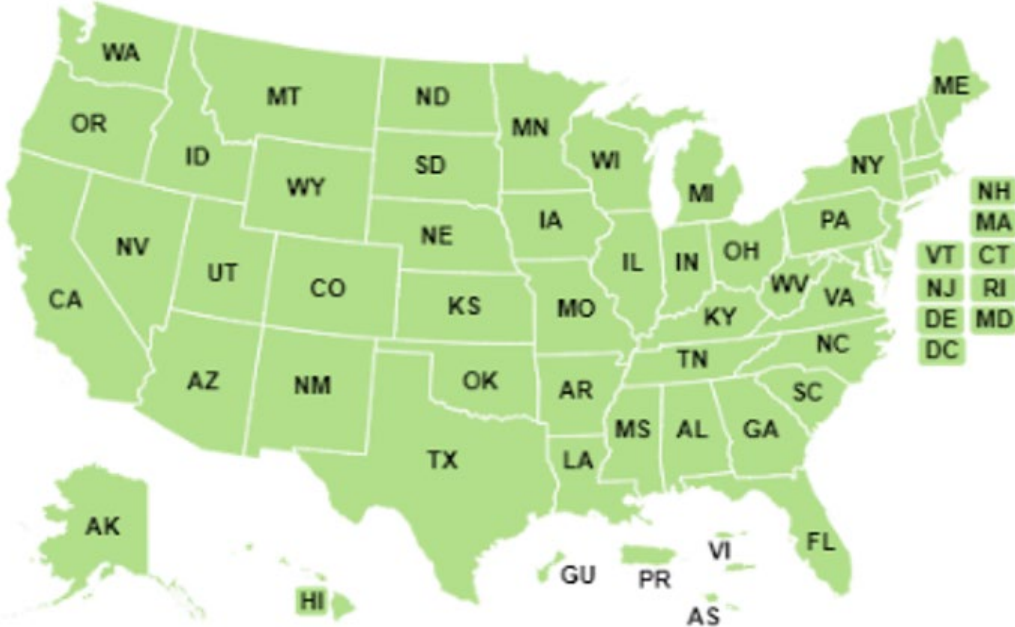
# CDC Specimen Test Order and Reporting

## Key Benefits



- **Faster, more secure specimen submission and report retrieval**
- **Test order requests and approvals/rejections are tracked electronically in one system**
- **Submitters can directly attach supplemental forms at the test order or specimen level**
- **Data can be corrected on the platform before samples get accessioned**
- **Reports in CSTOR are easy to access**
  - Anyone in the organization can access
  - Searchable by test order name, submitter IDs, etc

# CSTOR Onboarded SPHLs

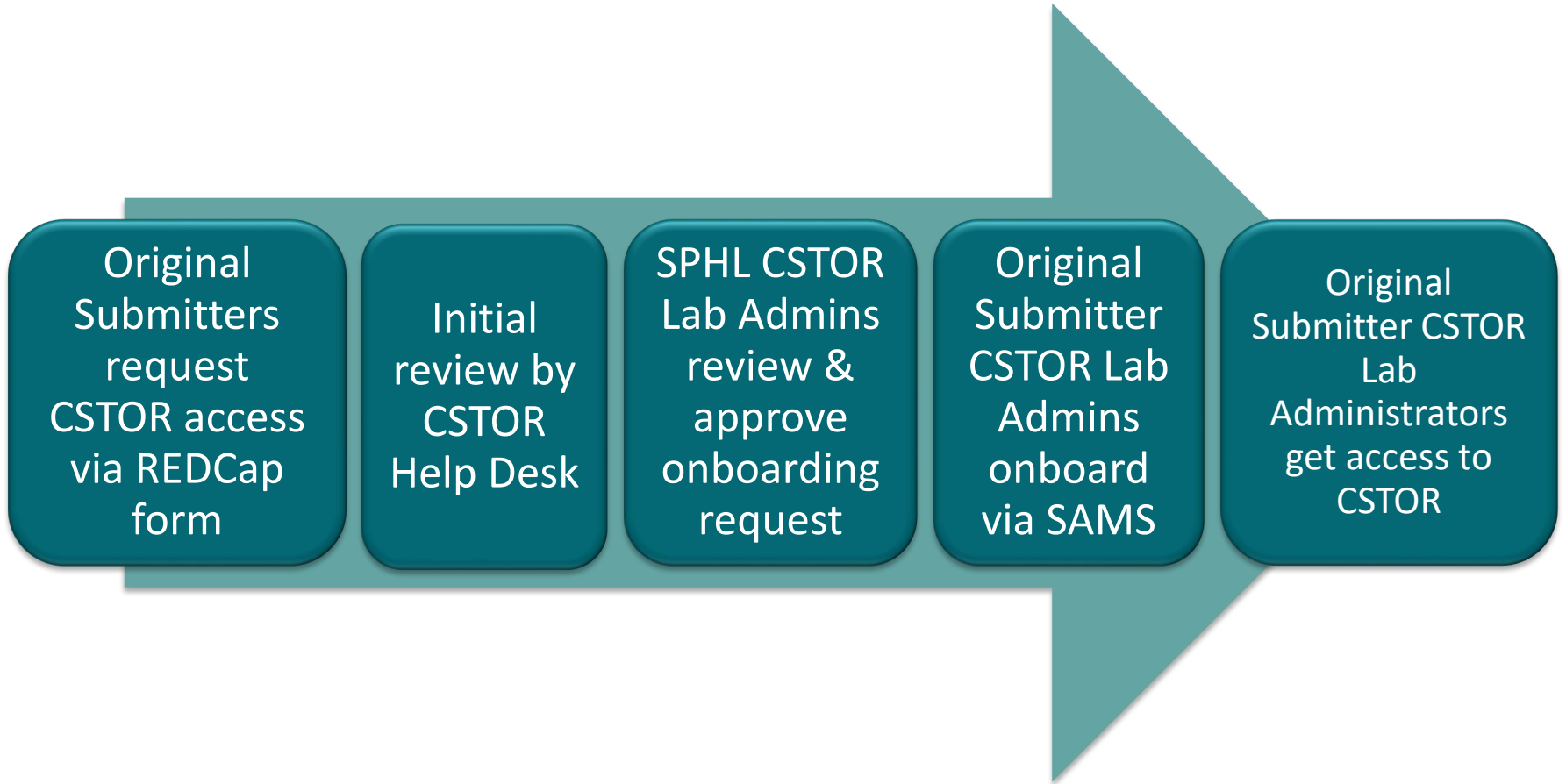


# Original Submitter CSTOR Onboarding Goals

- **For CDC**
  - Higher quality, more secure data submissions coming to CDC
  - Streamlined submissions and report delivery through centralized hub
- **For SPHLs**
  - More visibility into submissions from original submitters in your jurisdiction, leading to easier distribution of CDC reports to original submitters
- **For Original Submitters**
  - Faster, smoother workflow to receive SPHL approval and submit specimens to CDC (for specimens the SPHL approves to go directly to CDC) and access reports



# COSO - Workflow



# COSO Submissions-Workflow

SPHLs set up which TOs require SPHL review/ approval

Original Submitters create TOR & specimen submission form(s)

If TO requires SPHL pre-approval, SPHL reviews and approves

If TO requires CDC pre-approval, CDC reviews and approves

Original Submitters finalize specimen form(s) & electronically ship package

**Next Scheduled Call: April 20 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)

Follow us on X (Twitter) @CDCgov & @CDCEnvironment

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.