

Laboratory Outreach Communication System (LOCS) Call

Monday, June 26, 2023, at 3:00 P.M. EDT

- **Welcome**
 - Sean Courtney, CDC Division of Laboratory Systems
- **SARS-CoV-2 Variants Update**
 - Natalie Thornburg, CDC Coronavirus and Other Respiratory Viruses Division
- **H5 Update**
 - John Barnes, CDC Influenza Division
- **Mpox Outbreak Update**
 - Christina Hutson and A.D. McNaghten, CDC Mpox Response
- **FDA Update**
 - Timothy Stenzel, U.S. Food and Drug Administration
- **Diagnostic Challenges during Outbreak of Fungal Meningitis Associated with Epidural Anesthesia Performed in Matamoros, Mexico — 2023**
 - Anastasia Litvintseva, CDC Division of Foodborne, Waterborne, and Environmental Diseases

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

LOCS Calls

DLS Home > CDC's Laboratory Outreach Communication System (LOCS)

DLS Home

- About Us +
- LIVD Mapping Tool for SARS-CoV-2 Tests
- Strengthening Clinical Laboratories
- CDC's Laboratory Outreach Communication System (LOCS) -**
 - LOCS Messages Archive +
 - LOCS Calls**
 - LOCS Calls Archive +
 - CLCR Call Archive +
 - LOCS Message Level Types
- Laboratory Communicators' Network +
- Free Educational Materials for

CLCR calls are now LOCS calls!

Clinical Laboratory COVID-19 Response (CLCR) Calls are now Laboratory Outreach Communication System (LOCS) Calls. Find an archive of CLCR call audio files, transcripts, and slide presentations, [here](#).

CDC's Division of Laboratory Systems (DLS) 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 calls take place on the third Monday of each month at 3:00 PM Eastern time. DLS posts the audio, slides, and transcripts online after each call.

To submit questions for consideration, email DLSinquiries@cdc.gov in advance or use the question and answer (Q&A) function in Zoom 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.

On this page, you can find:

- LOCS Call information
- Transcripts
- Slides
- Audio Recordings

<https://www.cdc.gov/locs/calls>

We Want to Hear From You!

Training and Workforce Development

Questions about education and training?

Contact LabTrainingNeeds@cdc.gov



NGS Quality Initiative

Tools for a Complete Laboratory Quality Management System (QMS)

- Products for all 12 Clinical Laboratory Standards Institute (CLSI) Quality System Essentials (QSEs) are available for free
- QSEs serve as the building blocks for a complete and foundational QMS for clinical and public health laboratories performing NGS-based tests
- NGS Quality Initiative develops new tools and continuously improves existing products

The screenshot shows the CDC Laboratory Quality website. The header includes the CDC logo and the text "Centers for Disease Control and Prevention" and "CDC 24/7: Saving Lives. Protecting People™". A search bar is located in the top right corner. The main navigation bar is "Laboratory Quality". Below it, the breadcrumb trail reads "Laboratory Quality > Molecular Methods > The Next Generation Sequencing Quality Initiative".

The left sidebar contains a navigation menu with the following items:

- Laboratory Quality
- About Laboratory Quality
- CLIA
- CLIAAC
- Molecular Methods
 - The Next Generation Sequencing Quality Initiative
 - QMS Tools and Resources**
 - Learn about the Initiative
 - New Tools Feature Story
 - Meet NGS Quality Initiative Project Partners
 - Find Additional NGS Quality Materials
- GeT-RM +
- Tools and Resources +

The main content area is titled "QMS Tools and Resources" and includes a "Print" link. The text states: "Public health and clinical laboratories require a foundation of quality to ensure fidelity in the total testing process. Laboratory operations need to be reliable, tests need to be as accurate as possible, and test results must be promptly delivered. Failures at any step within these systems could result in consequences for patient and population health." It further explains that Quality Management Systems (QMS) have been described by the International Organization for Standardization (ISO) and the Clinical Laboratory Standards Institute (CLSI) as "coordinated activities to direct and control an organization with regard to quality." A QMS investigates the entire laboratory system, and many accreditation programs now require clinical laboratories to develop and follow QMS for their NGS-based tests. It also notes that the use of trade names is for identification only and does not imply endorsement by the US Department of Health and Human Services. Finally, it mentions that CDC and APHL adopted the CLSI 12 QSEs as building blocks for developing a QMS for clinical and public health laboratories performing NGS-based tests.

Below the text are two filter sections:

- Manufacturer:**
 - Illumina (33)
 - Oxford Nanopore (6)
 - ThermoFisher (20)
- Sequencing Platform:**
 - iSeq (5)
 - MiniSeq (5)
 - MiSeq (13)
 - NextSeq (5)

On the right side, there is a "Search for Tools" section with a search input field and a search icon. Below the search bar, it says "Found 104 files." and includes buttons for "Download All", "Show 10", and "Order By...". Below this are three tool listings:

- QMS Assessment Tool:** CDC wants users to know that individuals and organizations who download this Excel spreadsheet for use in their quality management system should consider the accessibility needs of their staff, since this product is not currently Section 508 compliant. *QSE Assessments*
- Identifying and Monitoring NGS Key Performance Indicators SOP:** *QSE Continual Improvement*
- iSeq 100 Sequencer Pre-Installation Checklist**

<https://www.cdc.gov/labquality/qms-tools-and-resources.html>

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



Division of Laboratory Systems

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, PhD

CDC Coronavirus and Other Respiratory Viruses Division



Division of Laboratory Systems

H5 Update

John Barnes, PhD
CDC Influenza Division



MPOX

Mpox Outbreak Update

June 26, 2023

Christina L. Hutson, PhD, MS

Branch Chief

Poxvirus and Rabies Branch

A.D. McNaghten

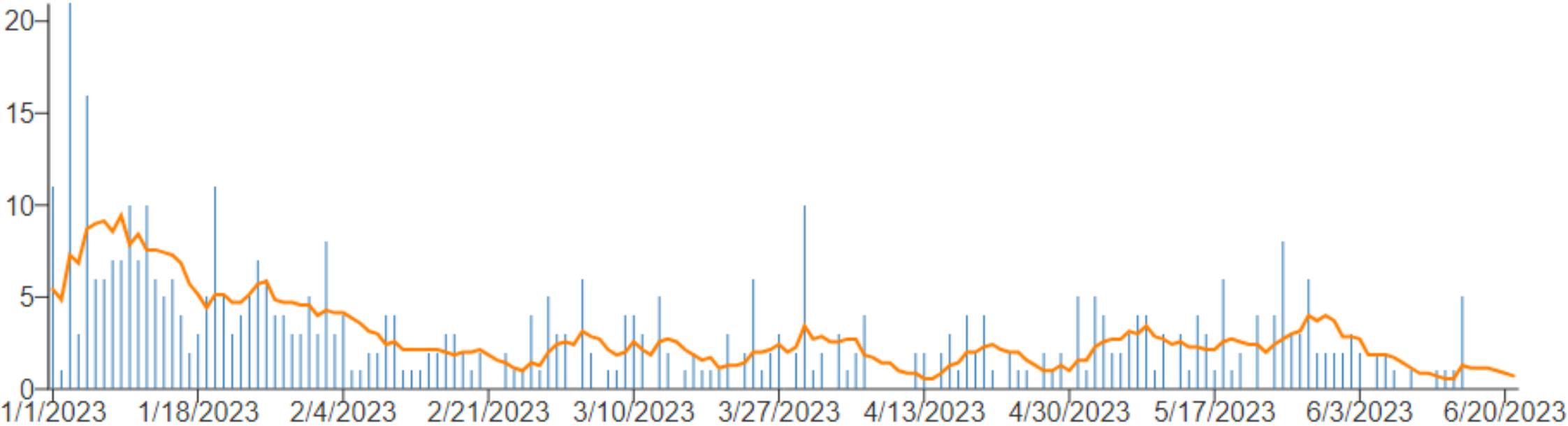
Deputy Incident Manager-Mpox Response

Centers for Disease Control and Prevention



U.S. Mpox Case Trends Reported to CDC

June 20th 2023



7-day average for June 8th onwards has remained at 1 case

Data from the most recent two weeks is provisional.

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

Overview of testing landscape in US as of June 2023

- FDA Cleared Test: 1 held by CDC being run by LRN laboratories and 4 commercial laboratories
- EUA Tests: 6 ([Monkeypox \(mpox\) Emergency Use Authorizations for Medical Devices | FDA](#))
- Laboratories (academic and commercial) that have notified FDA that they are using LDTs for mpox: 87 ([Monkeypox \(mpox\) and Medical Devices | FDA](#))

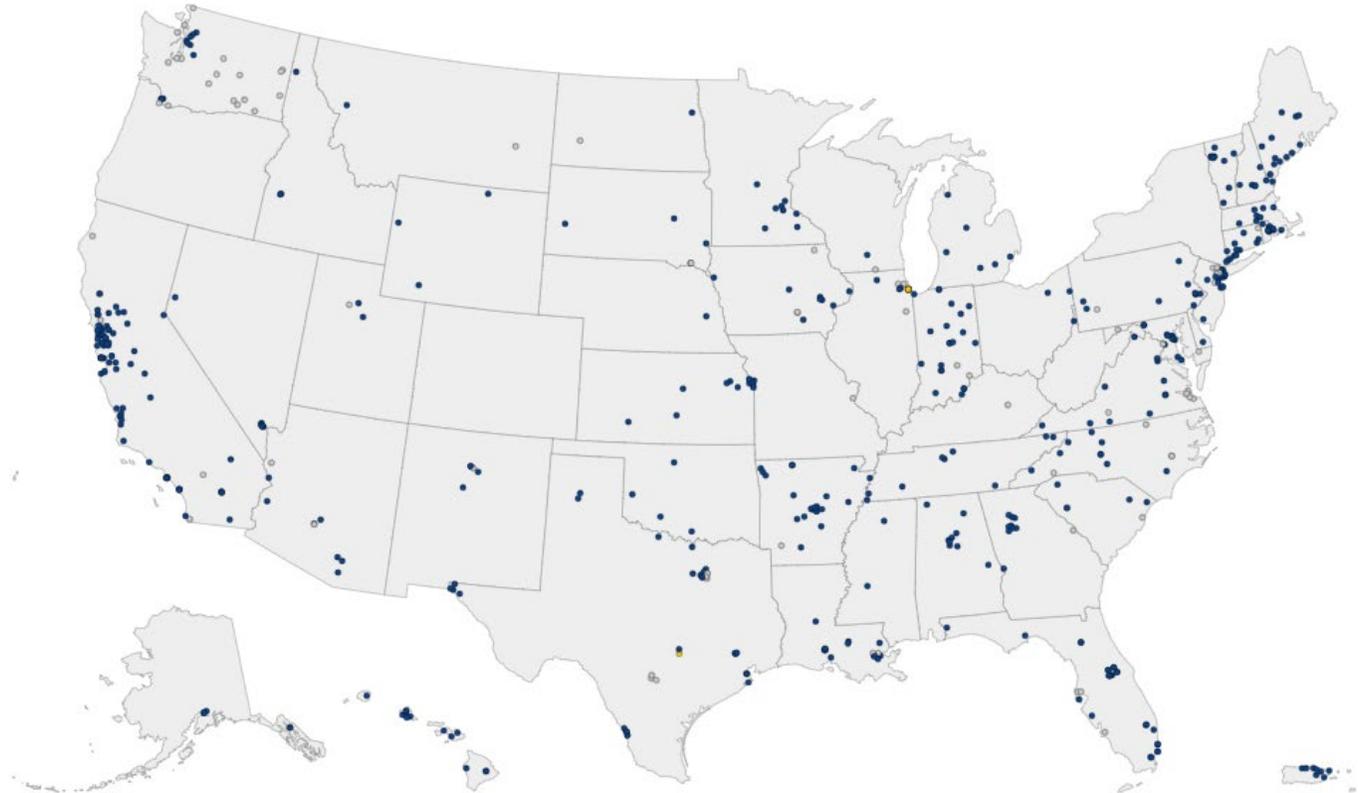
Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes
05/22/2023	Quest Diagnostics Nichols Institute	Quest Diagnostics MpoX Virus Qualitative Real-Time PCR (2-well) 09/07/2022	Real-time PCR, Multiple Targets
03/30/2023	Cepheid	Xpert MpoX 2/10/2023	Real-time PCR, Mult analyte, Multiple Targets
03/17/2023	Cue Health, Inc.	Cue MpoX (Monkeypox) Molecular Test 03/17/2023	Real-time PCR, Sing Target
01/10/2023	DiaCarta, Inc.	QuantiVirus MPXV Test Kit 01/10/2023	Real-time PCR, Multiple Targets
12/14/2022	Roche Molecular Systems, Inc.	cobas MPXV for use on the cobas 6800/8800 Systems (cobas MPXV) 11/15/2022	Real-time PCR, Multiple Targets
10/07/2022	Abbott Molecular, Inc.	Alinity m MPXV 10/07/2022	Real-time PCR, Multiple Targets

Mpox virus detection in wastewater in the past 4 weeks, United States

- Updated June 21st
- Data from 463 sites total
- Intermittent sites
 - Two sites in Chicago IL
 - Texas
 - Kansas



Note: Click on a state to zoom in.



Chicago Mpox Cases

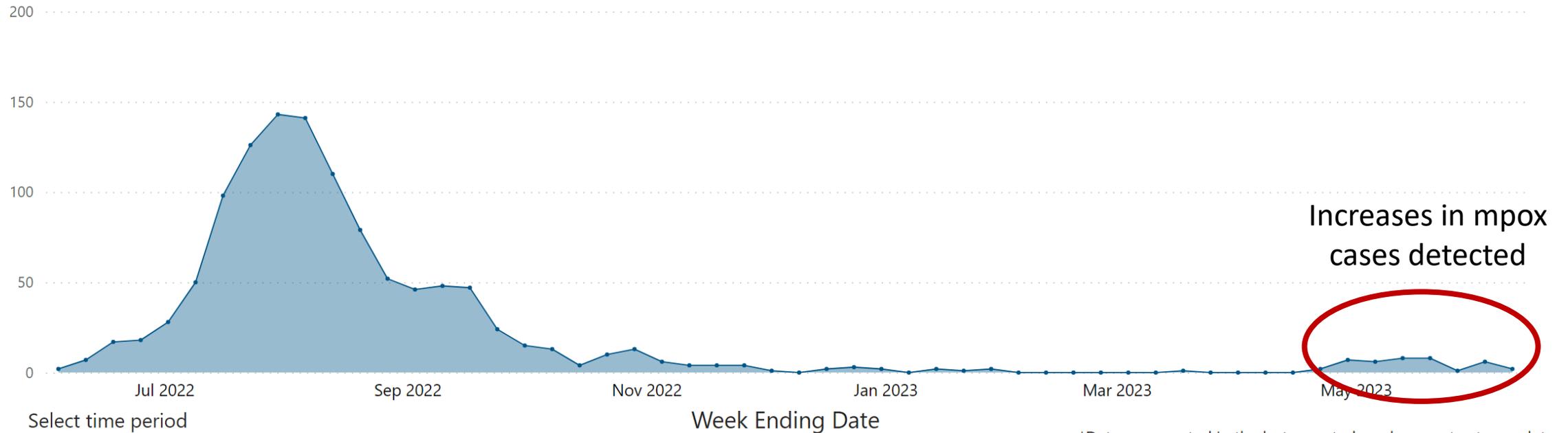
Cases of Mpox Diagnosed in Chicagoans Between 6/4/2022 - 6/10/2023

2 cases were diagnosed last week. This is 66.7% lower than the number of cases diagnosed during the prior week.

Cases
1,163

Hospitalizations
64

Deaths
3



*Data represented in the last reported week are not yet complete.

Cluster of cases in Chicago

- From March 18–June 12, Chicago identified 40 laboratory confirmed mpox cases
 - All males with a median age of 36 years (IQR 23–49)
 - 22 (55%) were vaccinated with 2 doses of JYNNEOS or 1-dose of ACAM2000
 - 5 (13%) were partially vaccinated (i.e., 1 dose JYNNEOS)
 - 13 (33%) were unvaccinated

- 11 were living with HIV
 - 10 were vaccinated with 2 doses of JYNNEOS or 1 dose of ACAM2000 had well controlled HIV

- Median time from 2nd dose of JYNNEOS to mpox diagnosis was 8.4 months (IQR 7.9–8.8 months)

Cluster of cases in Chicago

- Individuals with 2 doses of JYNNEOS or 1 dose of ACAM2000 had self-limiting illness
 - Lower prevalence of mucosal lesions
 - None were hospitalized
- Individuals with 2 doses of JYNNEOS or 1 dose of ACAM2000 had a higher number of sexual partners 3 weeks before symptom onset compared to partially or unvaccinated
- Preliminary sequencing indicates the virus is the same B.1 variant of Clade IIB which is the predominant variant of the 2022–2023 outbreak
 - There were no mutations that would confer increased pathogenicity
- This investigation is ongoing, however no similar clusters are being seen elsewhere in the U.S.

Key Messages

- The number of new mpox cases reported in the United States began trending downward in late August 2022, because of
 - Vaccination
 - Behavior changes
 - Possible infection-acquired immunity
- While the number of new mpox cases reported has been trending downward since August 2022, CDC continues to urge health departments and clinicians to
 - Remain vigilant
 - Institute appropriate infection prevention and control measures
 - Notify public health authorities of suspected cases to reduce disease spread.
- Although vaccine-induced immunity is not complete, vaccination continues to be one of the most important prevention measures.
 - CDC expects new cases among previously vaccinated people to occur, but people who have completed their two-dose JYNNEOS vaccine series may experience less severe symptoms than those who have not.

Division of Laboratory Systems

FDA Update

Timothy Stenzel, MD, PhD
U.S. Food and Drug Administration



Diagnostic Challenges during Outbreak of Fungal Meningitis Associated with Epidural Anesthesia Performed in Matamoros, Mexico — 2023

Anastasia Litvintseva, PhD
Mycotic Diseases Branch,
Centers for Disease Control and Prevention

June 26, LOCS call



HEALTH

Deadly Fungal Meningitis Outbreak Linked to Cosmetic Surgeries in Mexico

Two women dead, two dozen sickened after receiving epidural anesthesia at clinics near the Texas border

By [Dominique Mosbergen](#) [Follow](#)

May 30, 2023 2:54 pm ET

FORBES > INNOVATION

BREAKING

Fungal Meningitis Outbreak In Mexico Kills 2 After Cosmetic Surgeries. Here's What We Know—And Symptoms And Treatment.

Arianna Johnson Forbes Staff

I cover the latest trends in science, tech and

[Follow](#)

2 Are Dead in Suspected Meningitis Outbreak Linked to Surgeries in Mexico

More than 200 others could be at risk from a fungal meningitis outbreak that has been traced to two clinics in Matamoros, Mexico, where people traveled for cosmetic surgeries, health officials said.

Outbreak of Fungal Meningitis Associated with Epidural Anesthesia Performed in Matamoros, Mexico — 2023

May 8: CDC learned of two unusual meningitis cases in Texas with prior epidural anesthesia

May 16: Level-2 Travel Health Notice was published

May 17: HAN Health Advisory was published

May 26: CDC and Mycoses Study Group help a webinar focusing on diagnostic and treatment

May 31: CDC's MDB lab and U Washington identified *F. solani* in CSF by pan-fungal PCR

May 13: Mexico closed two clinics implicated in meningitis outbreak

May 19: Mexican Lab detected *Fusarium solani* DNA in CSF by RT-PCR

May 20: CDC received list of exposed patients at the two clinics and sent state-specific reports.

May 28: UCSF identified *F. solani* in a CSF by metagenomics

As of June 21, 2023:

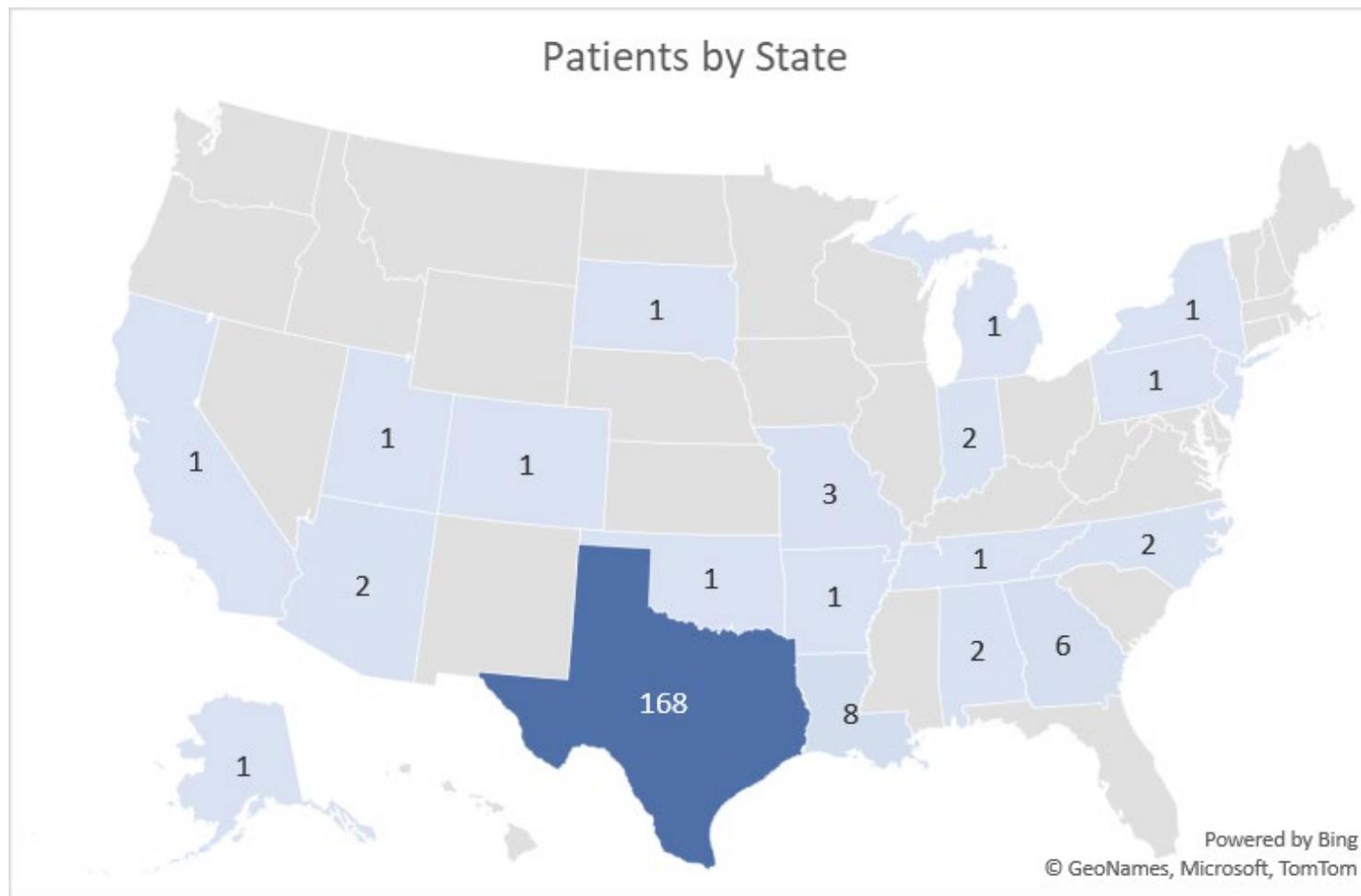
In patients who received a procedure with epidural anesthesia in Matamoros, Mexico, at Clinica K-3 and River Side Surgical Center, since January 1, 2023:

- **Person under investigation: 171**
- **Suspected case: 18**
- **Probable case: 9**
- **Confirmed case: 8**

- **Deaths: 4 (Two probable cases and two confirmed cases)**

- **Not a case: 27**

Patients are from 20 U.S. States, D.C., and Puerto Rico



Laboratory summary

LP Results	Average	Min	Max
Glucose (mg/dL)	32	19	57
WBC (K/ μ L)	757	24	1761
Protein (mg/dL)	109	34	254

- All CSF and blood cultures have been negative, to date
- Six CSF beta-d-glucan (BDG) (>500, >500, >500, >500, 488, 364) and two blood BDG (156, 50) have been positive
- Three pan-fungal PCR tests have identified *Fusarium solani* species complex (CDC MDB and University of Washington)
- UCSF identified *Fusarium solani* species complex through metagenomics
- Mexico had six patients test positive for *F. solani* from CSF by RT-PCR

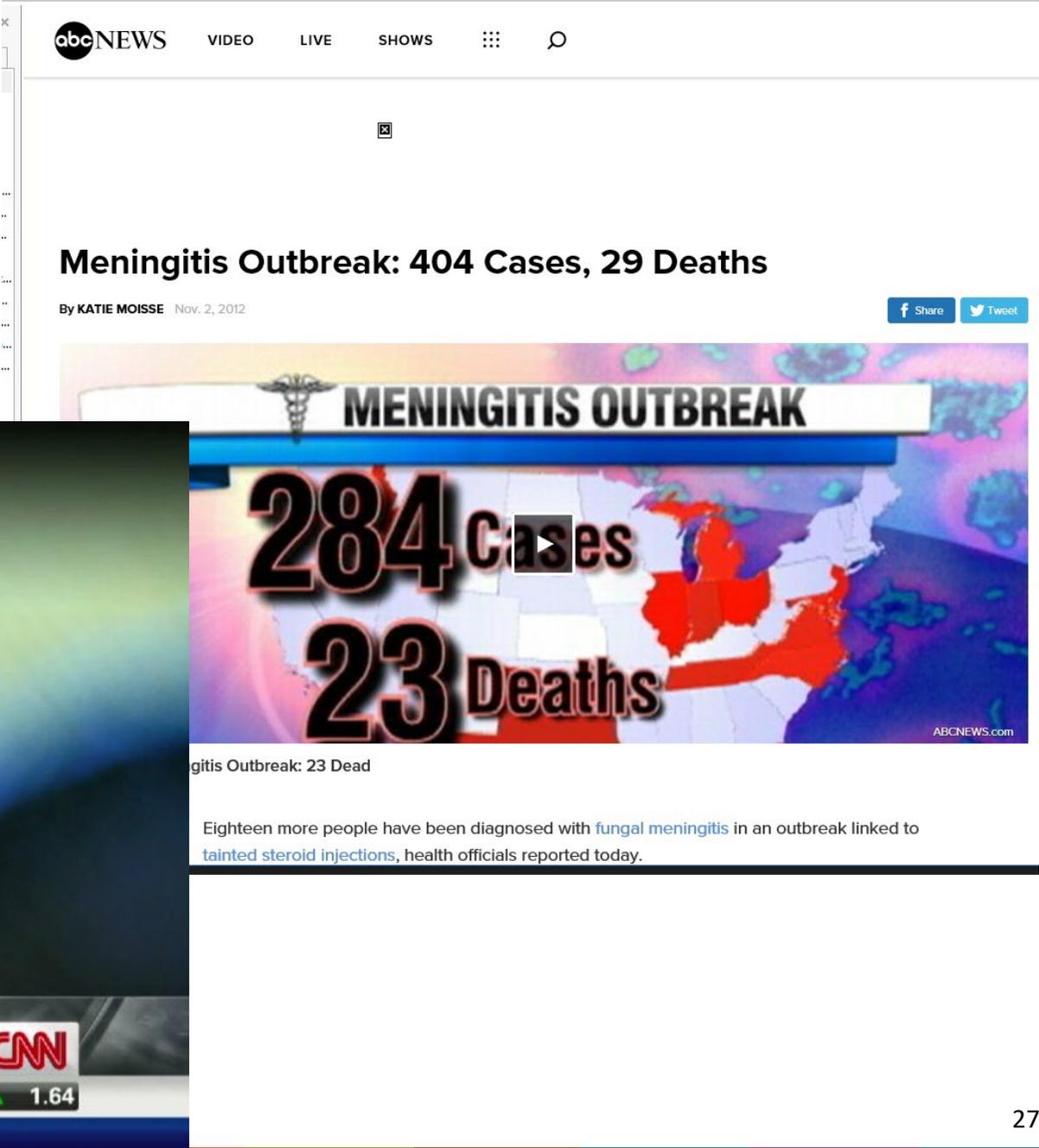
Previous Outbreak: Fungal Meningitis, Durango Mexico, November 2022

- 1,480 patients possibly exposed to contaminated epidural anesthesia
- 80 patients identified with meningitis
- 39 died

- *Fusarium solani* isolated from several patients
- *Alternaria* from one patient

- Mexico determined that poor IPC practices may have been the cause

2012 Multistate outbreak of Fungal meningitis and other infections



abc NEWS VIDEO LIVE SHOWS

Meningitis Outbreak: 404 Cases, 29 Deaths

By KATIE MOISSE Nov. 2, 2012

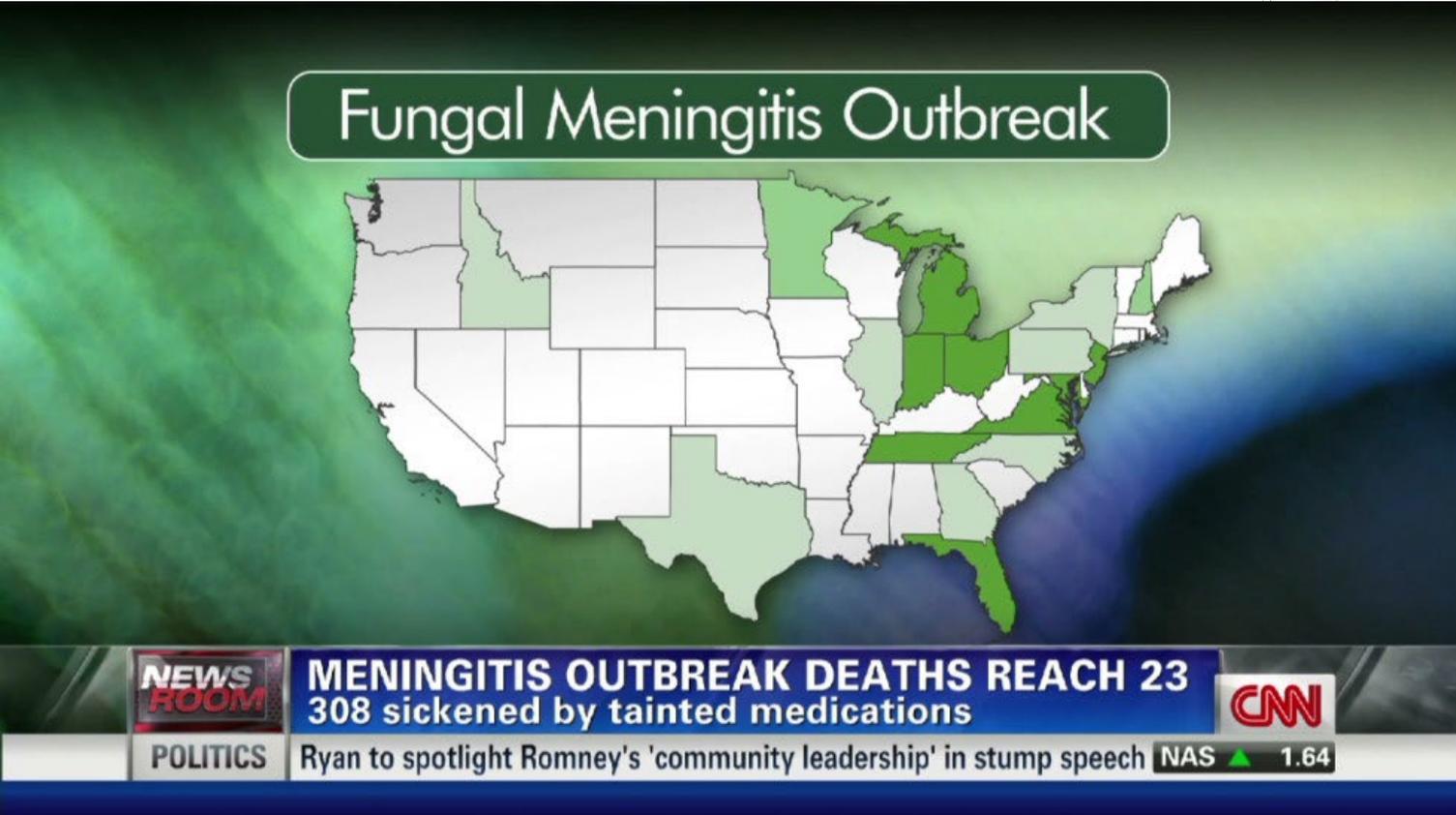
Share Tweet

MENINGITIS OUTBREAK

284 Cases
23 Deaths

Meningitis Outbreak: 23 Dead

Eighteen more people have been diagnosed with [fungal meningitis](#) in an outbreak linked to [tainted steroid injections](#), health officials reported today.



Fungal Meningitis Outbreak

NEWS ROOM

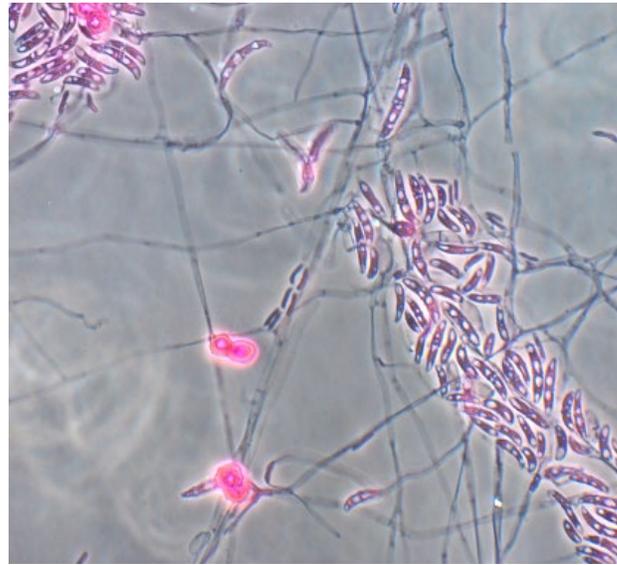
MENINGITIS OUTBREAK DEATHS REACH 23

308 sickened by tainted medications

POLITICS Ryan to spotlight Romney's 'community leadership' in stump speech NAS ▲ 1.64

Laboratory diagnostics for mold meningitis

Culture



Advantages

- Diagnostic gold standard
- Can be used for WGS to inform epidemiological investigation
- Isolates can be tested for susceptibility to antifungals (although no breakpoints are available)

Drawbacks

- Low sensitivity: During 2012 *Exerohilum* Outbreak, only 14% of patients were positive by culture
- So far, not a single positive culture from this outbreak

Beta-D-Glucan Detection



Basic Principle

- Detects Beta-D-Glucan polysaccharide in the fungal cells wall
- Colorimetric assay based on modified Limulus Amebocyte Lysate Pathway

Advantages

- FDA approved for serum
- Offered by several commercial labs for CSF
- Showed 100% sensitivity in the 2012 Outbreak of *Exserohilum* Meningitis

Drawbacks

- Cannot identify species, only provides presumptive diagnosis
- Does not detect Mucoromycetes and a few other fungi
- Can have false-positive results in patients on hemodialysis, those exposed to glucan-containing gauze or sponges, and others

Pan-fungal PCR



University of
Washington

Basic Principle

- PCR amplification of fragments of fungal DNA followed by Sanger sequencing

Advantages

- Provides identification down to genus/species complex level
- Pathogen agnostic
- Multiple genes can be targeted to increase sensitivity
- During 2012 *Exserohilum* Meningitis Outbreak, sensitivity of conventional PCR was 29% and RT-PCR was 47%

Drawbacks

- Highly dependent upon DNA extraction: fungal hyphae do not circulate, free circulating DNA should be targeted to improve sensitivity (larger volume of CSF is needed)
- Presence of DNA does not always indicate infection
- PCR is highly sensitive to contamination: some results are hard to interpret
- Very few commercial laboratories offer clinical testing

Metagenomic Next-Gen Sequencing

Basic Principle

- Direct sequencing and analysis of DNA from body fluids

Advantages

- Provides identification down to species level
- Pathogen agnostic
- Interrogates entire genome: primer/target agnostic
- No PCR: lower chance of contamination, higher confidence in results

Drawbacks

- Highly dependent upon DNA extraction: free circulating DNA should be targeted (larger volume of CSF is needed)
- Presence of DNA does not always indicate infection
- Technically and analytically complex, methodology is not freely available

Fusarium-specific RT-PCR (only available in Mexico)

Basic Principle

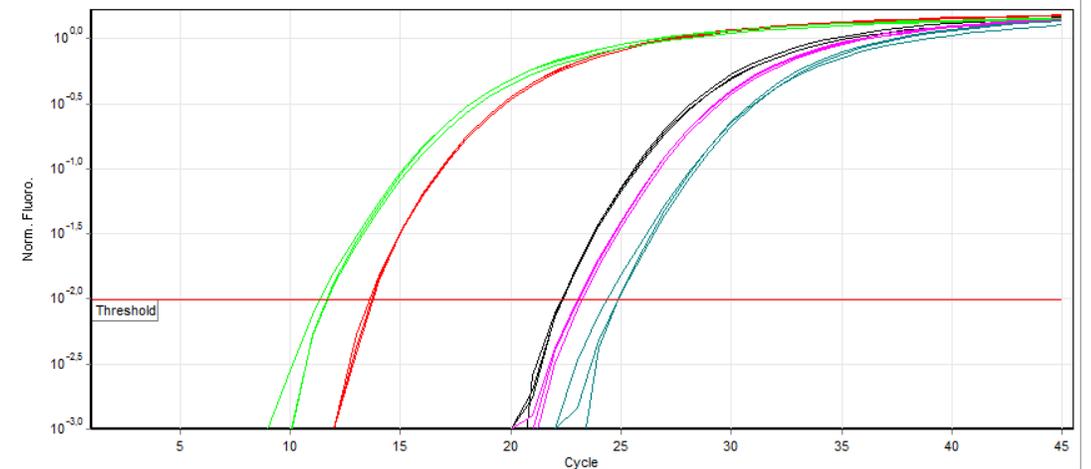
- Real-time-PCR amplification of several fungal DNA targets coupled with hybridization with *Fusarium*-specific probe

Advantages

- Specific to *Fusarium*
- Commercially available kit
- First test to identify *Fusarium solani* in this outbreak
- Sensitive

Drawbacks

- Only available in Mexico
- Performance characteristics are unknown, PCR primer and probe sequences are proprietary
- All other PCR test drawbacks



Compilation of Resources

- **Fungal Meningitis Outbreak Webpage**
 - [Suspected Fungal Meningitis Outbreak Associated with Procedures Performed under Epidural Anesthesia in Matamoros, Mexico | HAI | CDC](#)
 - <https://www.cdc.gov/hai/outbreaks/es/meningitis-epidural-anesthesia.html>
- **Travel Health Notice:**
 - [Fungal Infections Following Surgical Procedures in Mexico - Alert - Level 2, Practice Enhanced Precautions - Travel Health Notices | Travelers' Health | CDC](#)
- **HAN #1:**
 - [Health Alert Network \(HAN\) - 00491 | Outbreak of Suspected Fungal Meningitis in U.S. Patients who Underwent Surgical Procedures under Epidural Anesthesia in Matamoros, Mexico \(cdc.gov\)](#)
- **HAN #2:**
 - [Health Alert Network \(HAN\) - 00492 | Important Updates on Outbreak of Fungal Meningitis in U.S. Patients Who Underwent Surgical Procedures under Epidural Anesthesia in Matamoros, Mexico \(cdc.gov\)](#)
- **MSGERC clinician-focused webinar**
 - <https://www.youtube.com/watch?v=7hzAxASLcbs>
- **Interim Recommendations, One-Pager, & Algorithm**
 - [Interim Recommendations for Diagnosis and Management of Cases of Fungal Meningitis Associated with Epidural Anesthesia Administered in Matamoros, Mexico](#)
- **COCA Call Recording**
 - [Webinar Thursday, June 8, 2023 - Interim Recommendations for Diagnosing and Managing Suspected Fungal Meningitis Associated with Epidural Anesthesia Administered in Matamoros, Mexico \(cdc.gov\)](#)

Next Scheduled Call

Monday, July 17
3 PM - 4 PM EDT



CDC Social Media

<https://www.facebook.com/CDC>



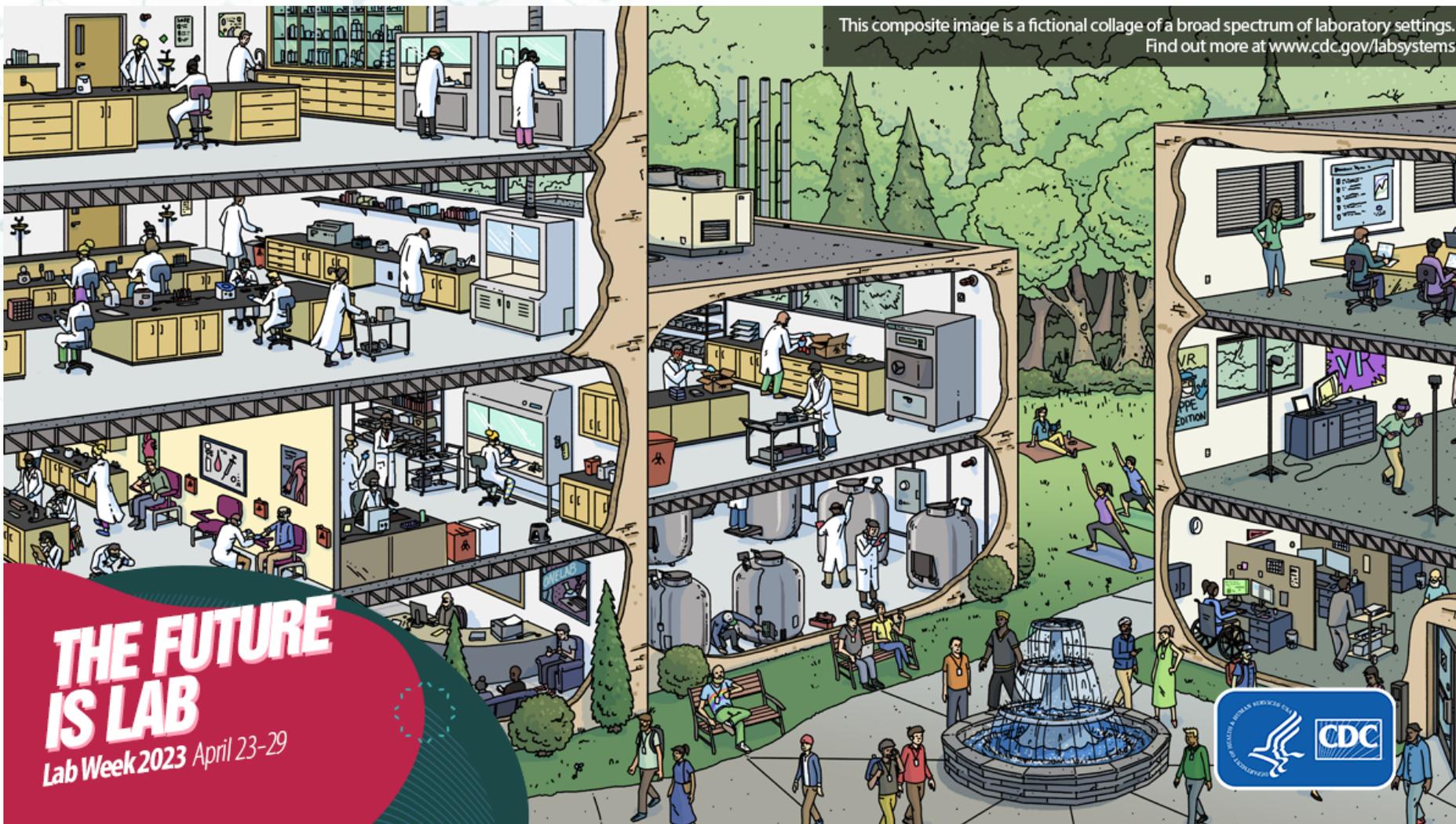
<https://twitter.com/cdcgov>

<https://www.instagram.com/cdcgov>



<https://www.linkedin.com/company/cdc>

Thank You For Your Time!





For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Images used in accordance with fair use terms under the federal copyright law, not for distribution.

Use of trade names is for identification only and does not imply endorsement by U.S. Centers for Disease Control and Prevention.

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