

# Laboratory Outreach Communication System (LOCS) Call

Monday, November 18, 2024, at 3:00 P.M. ET

- **Welcome**
  - Sean Courtney, CDC Division of Laboratory Systems
- **Evaluating and Testing an Ill Patient for a Viral Hemorrhagic Fever**
  - Joel Montgomery, CDC Division of High-Consequence Pathogens and Pathology
- **Clinical Laboratory Biosafety Recommendations, Following Standard Precautions**
  - Nancy Cornish, CDC Division of Laboratory Systems
- **Clade I Mpox Update**
  - Christina Hutson, CDC Division of High-Consequence Pathogens and Pathology

**Thank you for joining, we'll begin the call momentarily.**

# About DLS

## Vision

Exemplary laboratory science and practice advance clinical care, public health, and health equity.

# Four Goal Areas



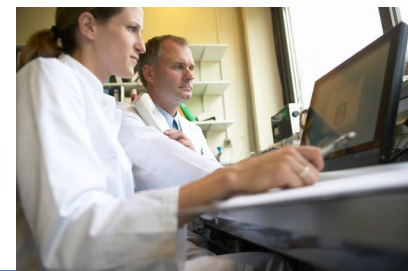
## Quality Laboratory Science

- Improve the quality and value of laboratory medicine 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



# Next Generation Sequencing Quality Initiative

- **Pathway to Quality-Focused Testing**
  - Free, comprehensive tool designed to guide laboratory personnel in method validation of NGS workflows
  - Structured, five-phase approach to address NGS quality requirements, validation, and maintenance of testing
- **Questions?**
  - Contact [NGSQuality@cdc.gov](mailto:NGSQuality@cdc.gov)



Scan QR code to  
access the Pathway



<https://www.cdc.gov/lab-quality/php/pathway/pathway-to-testing.html>

# DLS ECHO Biosafety Program

- **Date:** November 19, 12:00 PM ET
- **Topic:** Biorisk Management Performance Evaluation
- **Speaker:** Michael Pentella, PhD, D(ABMM)
- For questions, contact [DLSbiosafety@cdc.gov](mailto:DLSbiosafety@cdc.gov)



Scan QR code to  
register



[www.cdc.gov/safe-labs/php/echo-biosafety/](http://www.cdc.gov/safe-labs/php/echo-biosafety/)

# We Want to Hear From You!

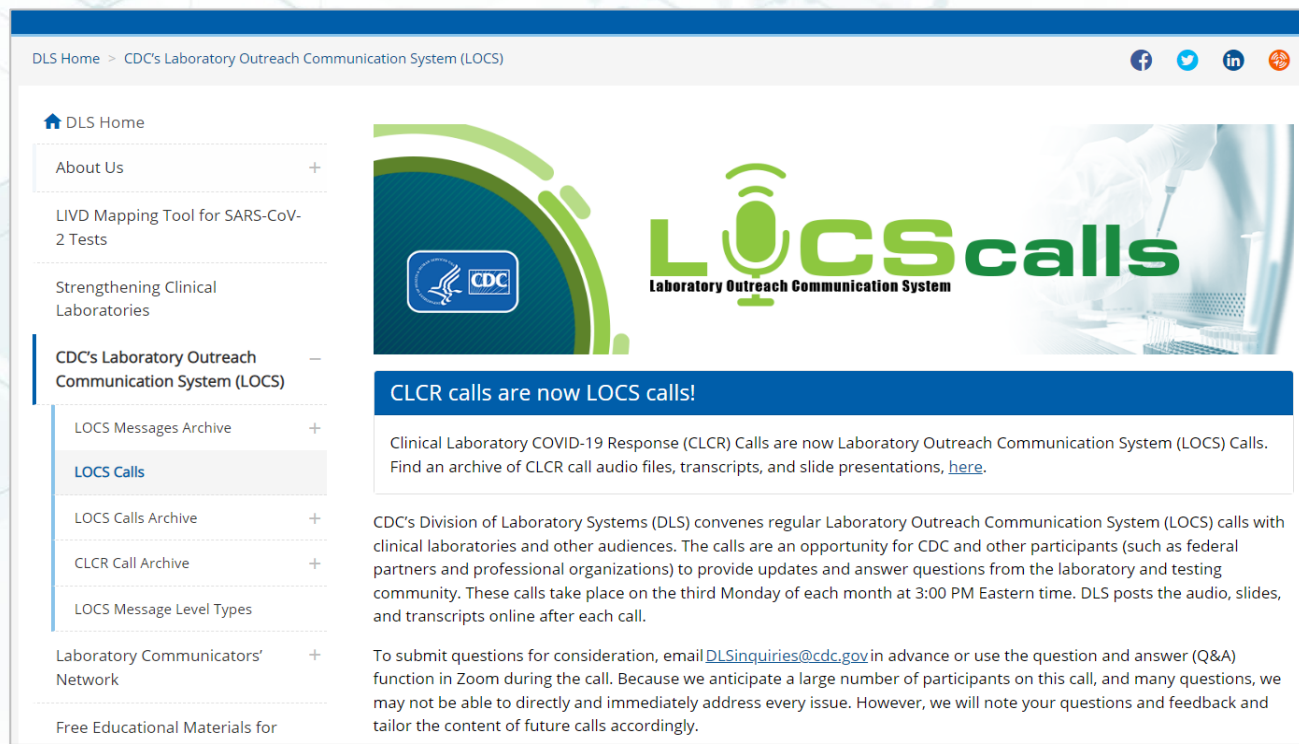
## Training and Workforce Development

Questions about education and training?

Contact [LabTrainingNeeds@cdc.gov](mailto:LabTrainingNeeds@cdc.gov)



# LOCS Calls



On this page, you can find:

- LOCS Call information
- Transcripts
- Slides
- Audio Recordings

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



# 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





## 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.



# Evaluating and testing an ill patient for a Viral hemorrhagic fever

**Joel Montgomery, PhD**

**CAPT US Public Health Service**

**Chief, Viral Special Pathogens Branch**

**Division of High Consequence Pathogens and Pathology**

Laboratory Outreach Communication System (LOCS)

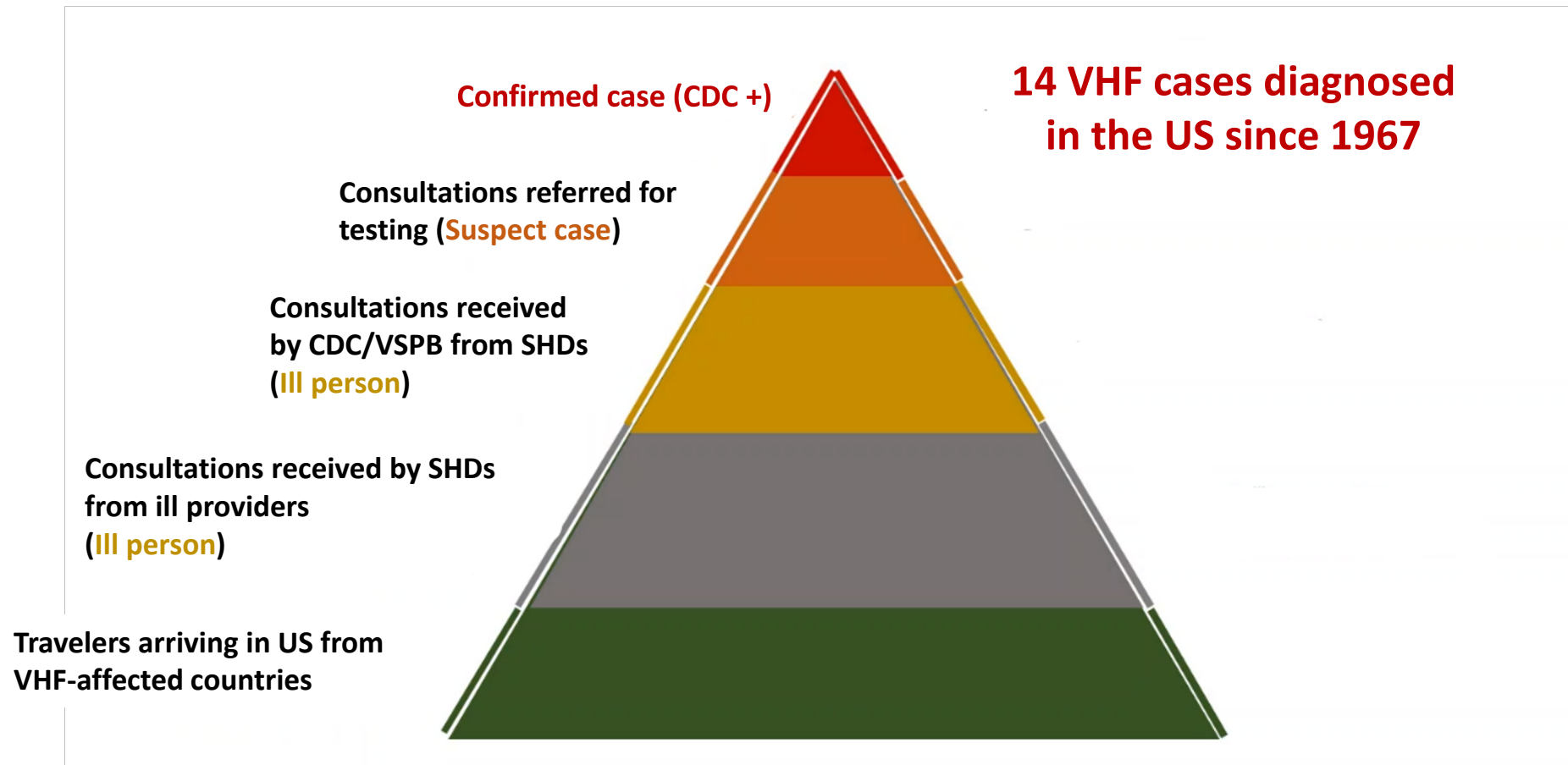
November 2024

# Viral Hemorrhagic Fevers (VHFs)

- **Group of diseases caused by several distinct families of viruses.**
- **VHFs affect organ systems, damage the overall cardiovascular system, and reduce the body's ability to function on its own.**
- **VHFs are endemic in areas of Africa, Asia, the Middle East, and South America**
- **Risk of a VHF being brought into the US by travelers is very low.**
- **Most ill travelers returning from a VHF-affected area do not have a VHF**
  - Typically diagnosed with a more common illness, such as malaria.

# Viral Hemorrhagic Fevers in the US

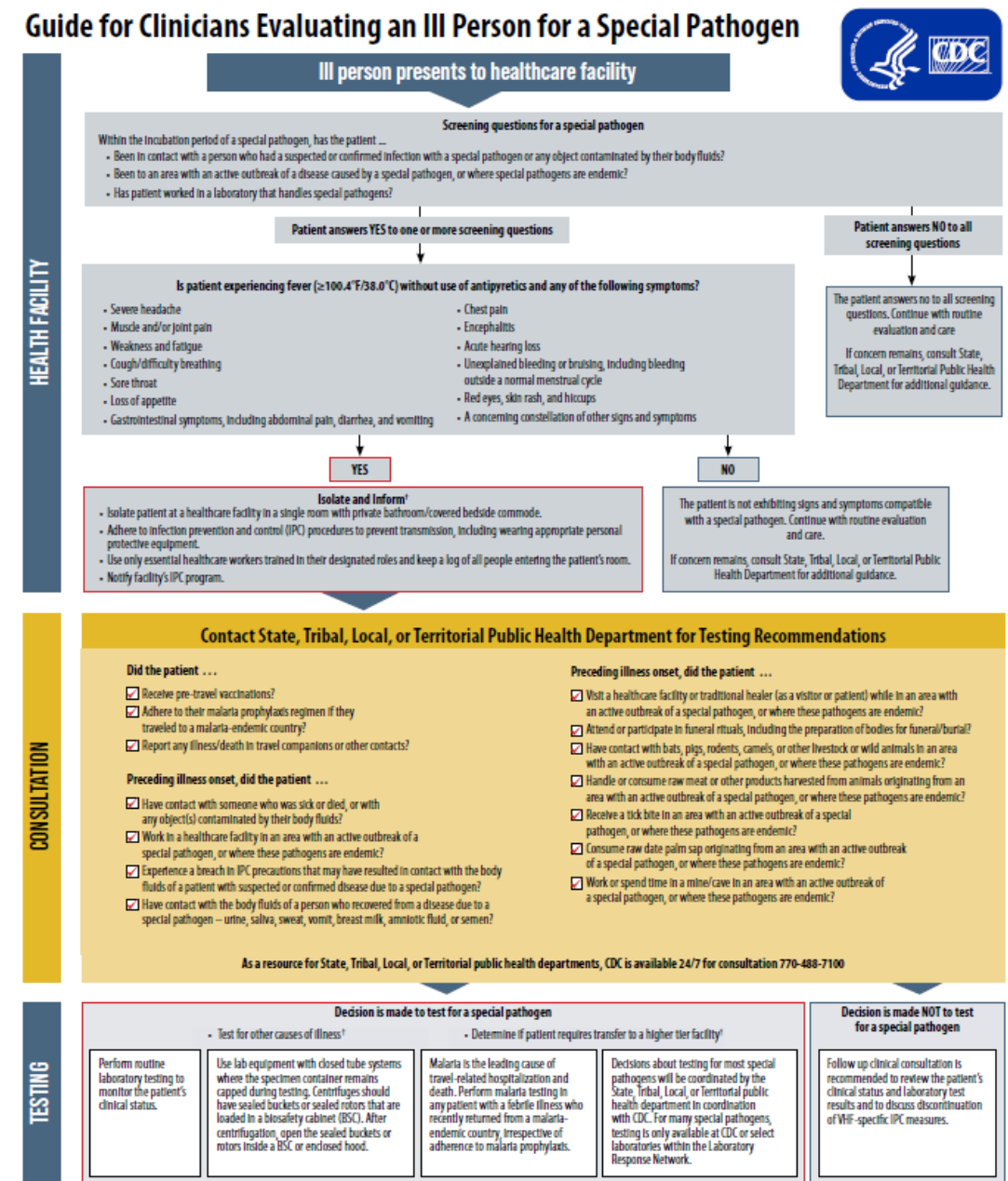
**Ill person** ➡ **Suspect case** ➡ **Confirmed case**





# VHF screening and evaluation process

- Assessing signs and symptoms
- Evaluating epidemiologic risk factors
  - Travel history
  - Location of travel
  - Specific activities
  - Timeline of activities
  - Sick travel partners
- <https://www.cdc.gov/viral-hemorrhagic-fevers/hcp/diagnosis-testing/evaluating-an-ill-person-for-vhf.html>



# Current Outbreak

# 2024 Marburg virus disease (MVD) outbreak

- **October 2024: Outbreak declared in Rwanda**
- **Marburg virus disease (MVD) is a rare VHF, similar to Ebola disease**

# Etiology of Marburg virus disease

- Marburg virus belongs to the virus family *Filoviridae*, species *Orthomarburgvirus marburgense*
- Within the species *Orthomarburgvirus marburgense*, there are two viruses
  - Marburg virus
  - Ravn virus
- Marburg virus disease is caused by infection with one of these two viruses





# Natural Hosts: Egyptian Rousette Bats

- Found in forests and savannahs across sub-Saharan Africa
- Found most often in caves, mines, and abandoned buildings
- Eat at night in fruit trees (figs, mangoes, bananas)
- Can spread the virus through their blood, saliva, urine, and feces

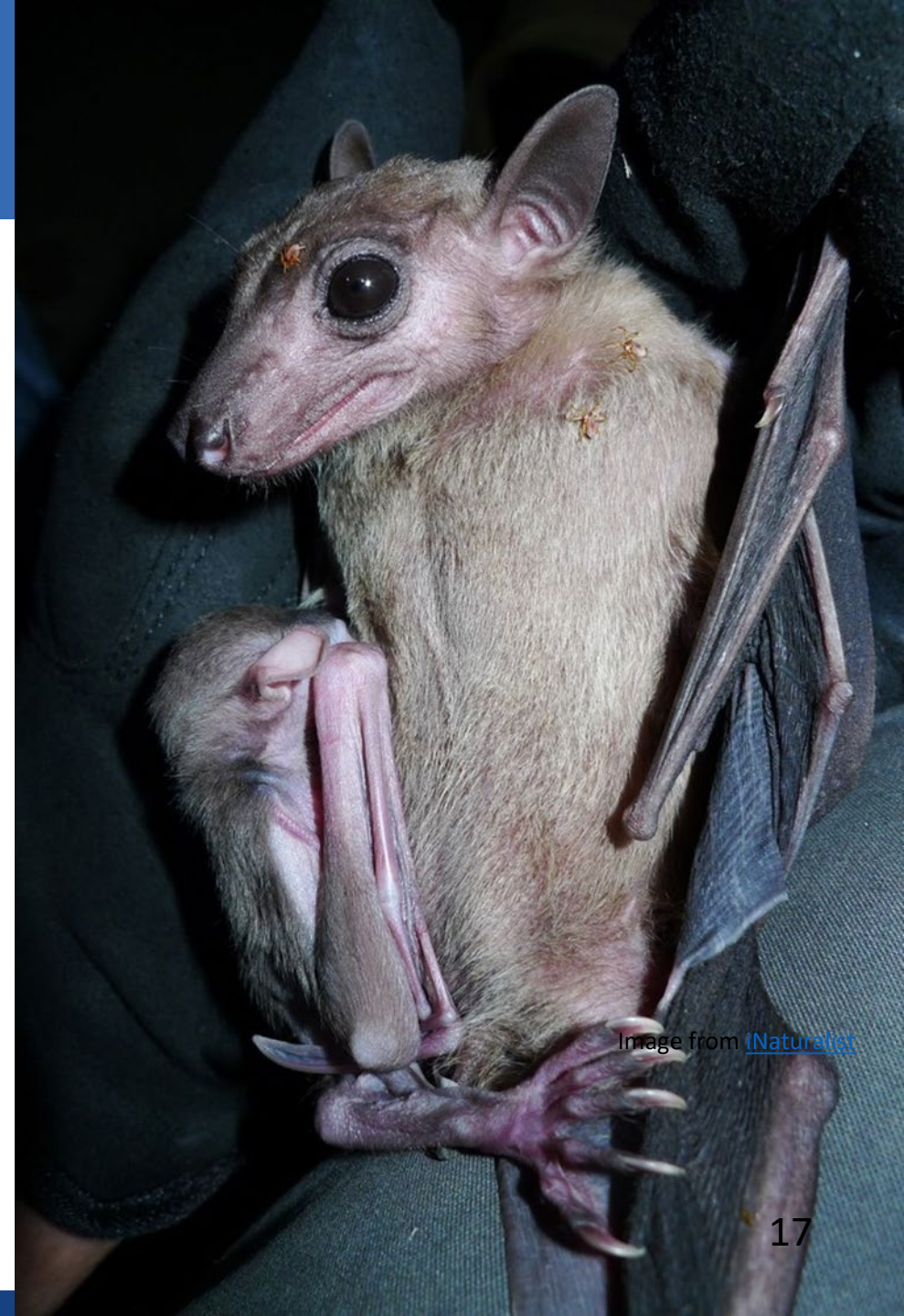


Image from [iNaturalist](#)

# Geographic Distribution

- Most Marburg illnesses have been reported in sub-Saharan Africa
- Cases mostly occur where a type of fruit bats lives
- Historically, a few exported cases elsewhere
  - Travelers returning home ill with Marburg
  - Scientists working with infected animals from Africa
  - This includes first known cases of the disease in Marburg, Germany (1967)



OUTBREAKS OF MARBURG VIRUS DISEASE

● Outbreak Location and Year

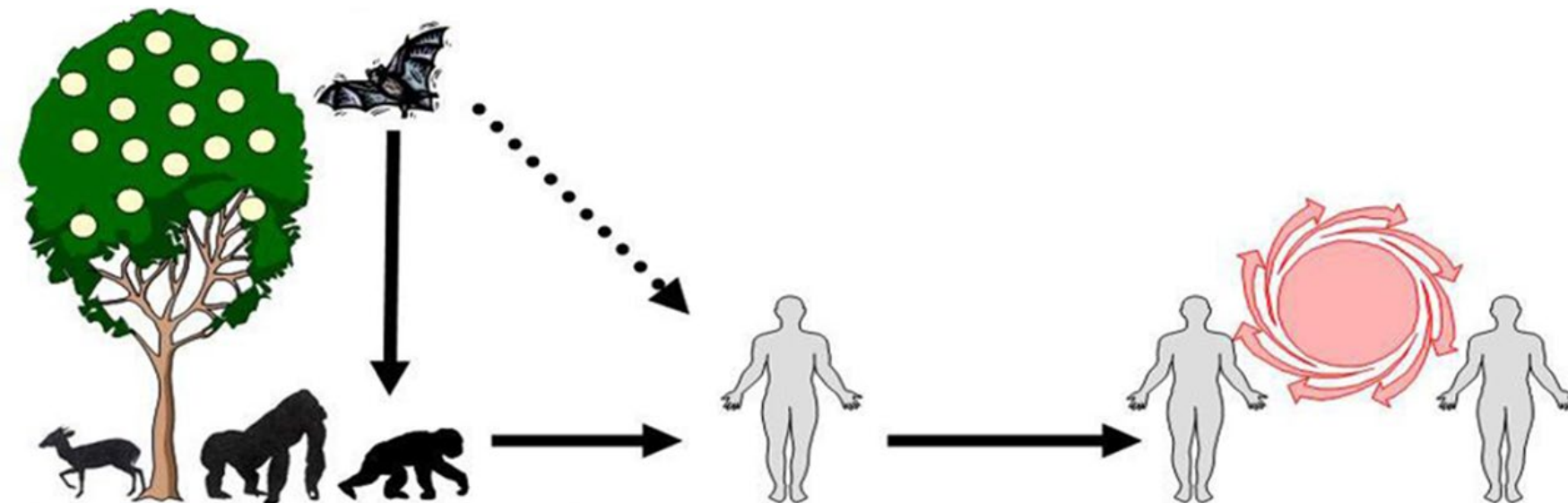
0 250 500 750 mi



Image from CDC

# Marburg Virus Transmission Between Animals and People

1. The virus is maintained in the fruit bat population
2. Spread to primates
3. Spread to individual people
4. Spread between people



# Person-to-Person Spread

- Infection occurs with contact with body fluids of someone with Marburg disease or who has died from Marburg.

Saliva

Vomit

Semen

Sweat

Feces

Fetal fluids

Blood

Urine

Breast milk

- People with Marburg are infectious only when they have symptoms.
- Fomite transmission possible



# Symptoms

- Symptom progression may include:
  - Fever, headache
  - Muscle and joint pain
  - Rash with flat and raised bumps, often on torso
  - Nausea, vomiting, diarrhea
  - Bleeding from nose, mouth, skin, as well as bloody diarrhea and vomit
- Incubation period 4-17 days (2-21 range)
- Possible persistence in immune privileged sites
  - Brain, eyes, testicles, placenta



Image from CDC [Public Health Image Library](#)

# Treatment

- No licensed treatments for Marburg
  - Some potential treatments are in development
  - Clinical trials of investigational treatments underway in response to Rwanda outbreak.
- Intensive supportive care is important to survival



Image from [cdc.gov](https://www.cdc.gov)

# 2024 Rwanda MVD outbreak

- First recorded MVD outbreak in Rwanda
  - 66 confirmed cases
  - 15 deaths
- There have been 18 MVD outbreaks since 1967
- One imported case of MVD to the U.S. (2008)
  - Traveler developed illness four days after visiting a cave in Uganda that was implicated in prior MVD cases

# CDC Support for Rwanda

CDC is working with Rwanda to stop the outbreak by:

- Collaborating on
  - Laboratory testing, surveillance, case investigation, contact tracing, data analytics and visualization
  - Training response staff
- Providing supplies for laboratory testing
- Providing scientific expertise to advise on
  - Evaluating Rwanda's national response plan
  - Strengthening laboratory practices and networks
  - Enhancing infection prevention and control
  - Investigating vaccines and treatments



Image from [Rwanda Health Magazine on X](#)



# Public Health Screening

- There are no Marburg cases in the US and the risk to the US remains low.
  - There are no direct commercial flights from Rwanda to the United States.
  - The United States receives a low volume of travelers from Rwanda.
- Since October 16, 2024, DHS has redirected flights with travelers from Rwanda to three U.S. airports:
  - John F. Kennedy International Airport (JFK), New York
  - Chicago O'Hare International Airport (ORD), Illinois
  - Washington-Dulles International Airport (IAD), Virginia
- CDC staff is providing public health screening to detect travelers from Rwanda who could be sick or exposed to Marburg.
- All screened travelers from Rwanda receive text message reminders to monitor their health.

# Recommendations for Travelers

CDC has developed and published:

- Recommendations to reconsider non-essential travel to Rwanda for U.S. travelers ([Level 3 Travel Health Notice](#))
- [Recommendations and information](#) for people traveling to the United States from Rwanda
- [Interim recommendations](#) for post-arrival management of U.S.-based healthcare staff returning from Rwanda
- [Recommendations](#) for organizations sending U.S.-based personnel to areas with viral hemorrhagic fever (like Marburg) outbreaks
- [Interim recommendations](#) for post-arrival management of travelers from Rwanda
- Health messages posted at all 18 airports with CDC Port Health Stations

# Guidance for U.S. Healthcare Providers

CDC has developed and published:

- [Health Alert Network](#) health advisory to raise awareness about the outbreak among clinicians and health departments in the United States
- Guidance for healthcare facilities on what to do if a patient might have Marburg
  - CDC is available 24/7 to support healthcare providers who suspect someone may have Marburg.
  - Contact CDC's Viral Special Pathogens Branch (VSPB) 24/7 for consultations about Marburg virus disease or other viral hemorrhagic fevers. Call CDC Emergency Operations Center at 770-488-7100 and request VSPB's on-call epidemiologist.

# Routine Clinical Laboratory Testing

# What to do if a suspect VHF case is detected in the US?

- **Patient meets criteria for VHF testing**
- **Managed under isolation precautions in a healthcare facility during evaluation and testing**
  - Virus detected after symptoms begin
  - Can take up to 72 hours to reach detectable levels
- **Evaluate patients for other causes of illness**



# Routine diagnostic testing

- Routine testing should be pursued while VHF testing is underway.
- Risk of VHF transmission in a clinical lab is like other bloodborne pathogens (e.g., HIV, Hep B & C)
- Diagnostic testing can be safely performed by following Standard Precautions when handling ALL patient specimens
  - <https://www.cdc.gov/infection-control/hcp/basics/standard-precautions.html>

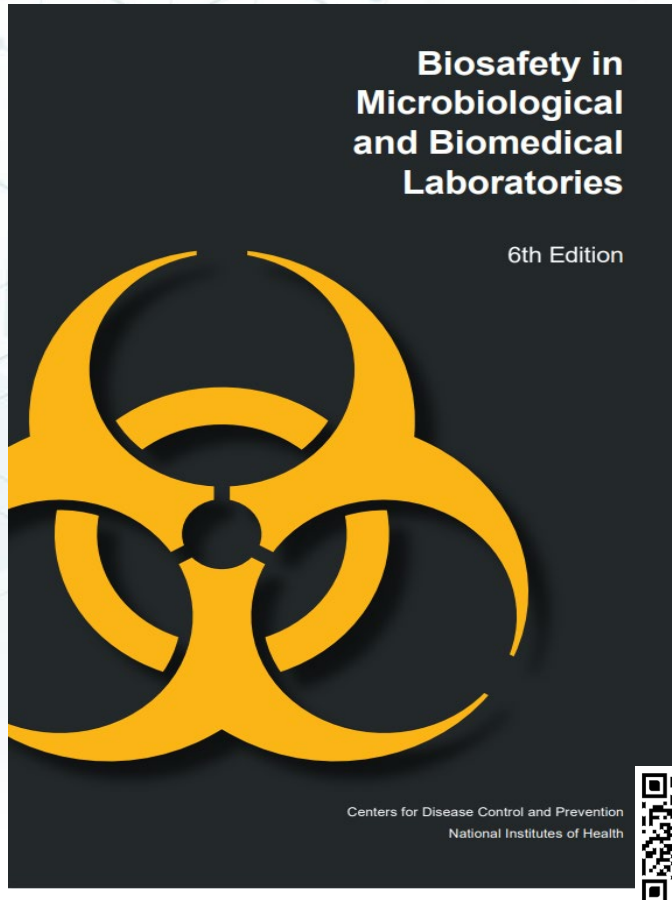
# Clinical Laboratory Biosafety Recommendations Following Standard Precautions

Nancy E. Cornish

Medical Officer and Senior Advisor for Quality and Safety  
Office of Laboratory Systems and Response, Division of Laboratory Systems



# Clinical Laboratories and Biosafety

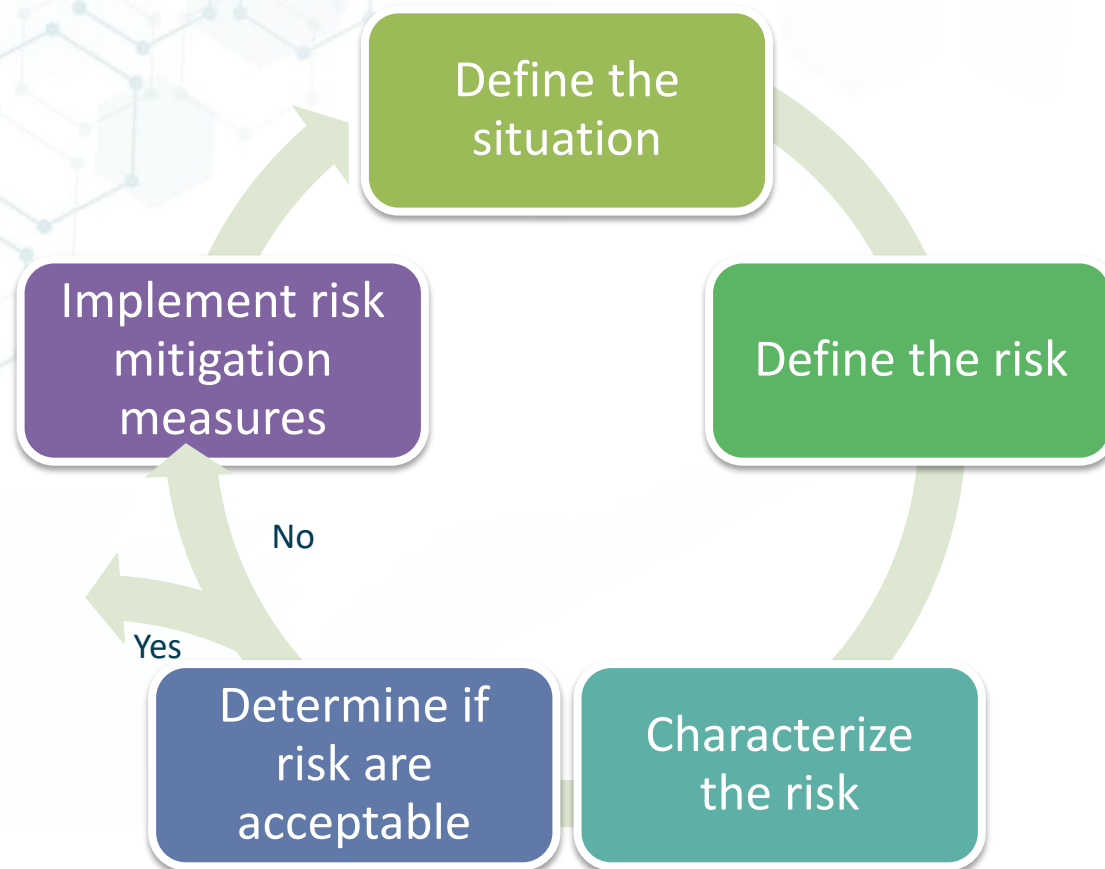


## Appendix N—Clinical Laboratories

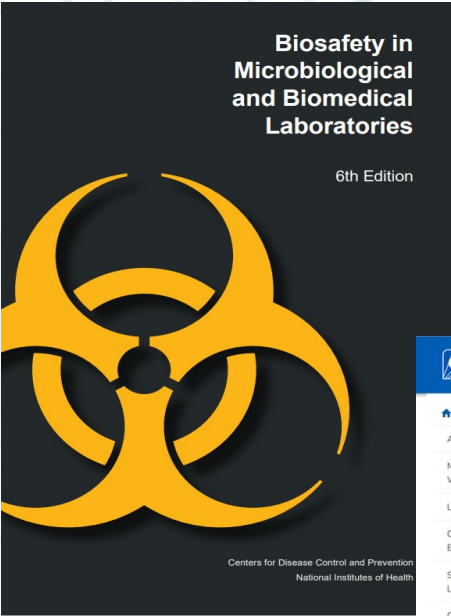
- Developed to address the clinical laboratories needs as critical responders and one of the first lines of public health defense
- Safe and effective operation of clinical laboratories is critical for patients, laboratory professionals, community and environment

[Biosafety in Microbiological and Biomedical Laboratories—6th Edition](#)

# How to Conduct a Risk Assessment



# Risk Assessments Resources



Division of Laboratory Systems (DLS)

Search

DLS Home

About Us

Medical Laboratory Professionals + Week 2023

LVD Test Code Mapping

CDC's Public Health Laboratory ETOR Initiative

Strengthening Clinical Laboratories

CDC's Laboratory Outreach Communication System (LOCS)

Laboratory Communicators' Network

Free Educational Materials for Public Health and Clinical Laboratories

Competency Guidelines for Laboratory Professionals

CDC Biorepository

Biological Risk Assessment: General Considerations for Laboratories

Biological Risk Management for Point of Care Testing Sites

QF22-2202

Biological Risk Assessment: General Considerations for Laboratories

Print

Introduction

What Is It?

CDC's Division of Laboratory Systems knows that incidents involving biological, chemical, physical, and radiological hazards can have a significant impact on the safety and health of those who work in laboratory settings. Risk management is a continuous process to identify, assess (evaluate), control, and monitor risks. The risk assessment components of the overall risk management process are:

Risk Management Process

Review Effectiveness of Controls

Identify Hazards and Risks

Evaluate Risks

Determine Controls

Implement Controls

See [ISO 35001](#) for the complete risk management process.

Process Steps

Step 1:  
Identify the hazards and risks.

Step 2:  
Evaluate the risks.

Steps 3-4:  
Implement a risk mitigation plan, as needed.

Step 5:  
Evaluate effectiveness of controls.



May 05, 2016

## Risk Assessment Best Practices

Dear Biosafety Officials:

The Association of Public Health Laboratories (APHL) has established a Biosafety and Biosecurity Committee (BBC) to assist public health laboratories with strengthening biosafety and biosecurity programs across the United States. A key activity of the BBC is to develop and promote biosafety and biosecurity tools (for example-risk assessments).

Risk assessments are an essential component of maintaining safety within a laboratory. The goal of a risk assessment is to identify and mitigate the risks of working in a laboratory environment. While all laboratories (including public health laboratories) should be performing risk assessments, the content and design of the template may be unique to the facility. Risk assessments must be performed regularly based on procedure or agent, and when there are changes in agents, procedures, equipment or staff. Risks identified by the assessment should be prioritized, and a mitigation plan should be established based on that prioritization. In other words, the highest risks should be mitigated relatively more than lower risks. The mitigation plan should be documented and clearly communicated to all relevant personnel. A risk assessment should follow the workflow from pre-analytical processes (sample receipt), through the laboratory (analytical), to post-analytical processes (waste disposal) and be reviewed by leadership (lab directors). It must be noted that risk assessments are dynamic documents that must be updated if any of the working assumptions for that protocol (equipment, personnel, materials) changes.

### Components of a Risk Assessment

Key components of a risk assessment should address:

#### Workforce

- Identify personnel (individuals) who will be affected throughout the work-flow

DLS Safe Labs Portal

EXPLORE TOPICS

Q SEARCH

SEPTEMBER 21, 2024

## Risk Assessment for Clinical Laboratories

ECHO BIOSAFETY SESSIONS | PAGE 18 OF 19 | ALL PAGES ↓

### WHAT TO KNOW

The views expressed in written materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services, nor does the mention of trade names, commercial practices, or organizations imply endorsement by the U.S. government.



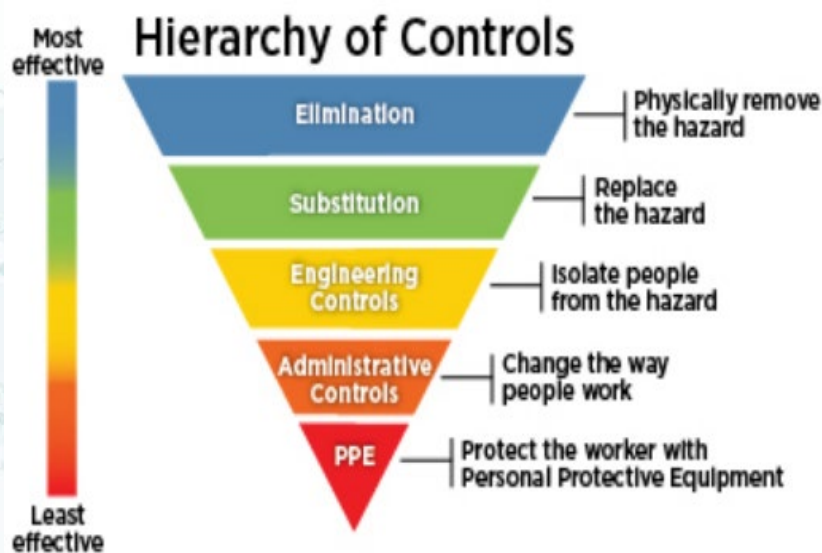
[DLS Safe Labs](#) | [Safe Labs Portal](#) | [CDC](#)



# Conducting Risk Assessments in Clinical Laboratories

- Foundation of Bio-Risk Management (BMR)
  - [Biological Risk Assessment: General Considerations for Laboratories](#)
  - [APHL Risk Assessment Best Practices and Examples.pdf](#)
  - [APHL-Template for Public Health Laboratory Risk Assessment for Ebola Virus Disease \(EVD\) Testing.pdf](#)
  - [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\) 6th Edition | CDC Laboratories](#)
    - Section II -Biological Risk Assessment (page 9)
  - [Risk Assessment for Clinical Laboratories | Safe Labs Portal | CDC](#) ECHO Session

# Biosafety Considerations



## Engineering Controls

- Reduce hazards and provide barriers
- Biosafety cabinets, sharp containers, shields

## Administrative Controls

- Changes to work practices
- Written Standard Operating Procedures

## Personal Protective Equipment

- PPE is equipment worn to minimize exposure to hazards
- Gloves, safety glasses, face shields, masks, respirators

## Waste Management

- All clinical specimens may contain potentially infectious agents or organisms

# Mitigation Resources: BMBL Appendix N

- Engineering Controls:
  - Engineering Controls can reduce hazardous conditions or place a barrier between the laboratory professional and the hazard.
  - Barriers commonly used are Class II BSCs, sharps containers, centrifuge safety cups, removable rotors, *splash shields*, directional inward airflow into the laboratory, closed automation systems, automated decappers or cap-piercing test systems, and handwashing sinks.
  - *When specific engineering controls are not possible, one option may be to include alternative containment devices such as an enclosed workstation in combination with additional work practices and/or enhanced PPE*

# Mitigation Resources: BMBL Appendix N

- Administrative Controls, examples
  - Active medical surveillance program
  - Occupational health program
  - Immunizations (e.g. Hep B and N. meningitis)
  - Written Standard Operating Procedures
- Work Practice Controls, examples
  - Frequent handwashing
  - Safer sharps (e.g., self-sheathing needles and needless systems)
  - Routinely decontaminating work surfaces
  - Using biosafety cabinets appropriately

# Biosafety Cabinets Resources

- [Fundamentals of Working Safely in a Biological Safety Cabinet \(BSC\) | OneLab REACH](#)
  - [BSC-Checklist.pdf](#)
- [OneLab VR | OneLab REACH](#)
  - Safe and Proper Use of a Biosafety Cabinet (coming soon)
- [OneLab VR: Tutorial Scenario | OneLab REACH](#)



# Personal Protective Equipment

- Trainings- Donning and Doffing
  - <https://youtu.be/YFrRe16qgUE>
- Other Trainings
  - [Fundamentals of Personal Protective Equipment \(PPE\) in Clinical Laboratories | OneLab REACH](#)
  - [Fundamentals of Bloodborne Pathogens | OneLab REACH](#)
  - [Fundamentals of Laboratory Safety | OneLab REACH](#)
  - [Biosafety Trainings | Safe Labs Portal | CDC](#)

# Waste Management

- Trainings:
  - [Packing and Shipping Dangerous Goods: What the Laboratory Staff Must Know | OneLab REACH](#)
  - [OneLab VR: Packing and Shipping Dangerous Goods | OneLab REACH](#)
- ECHO session
  - [Medical Waste Management | Safe Labs Portal | CDC](#)

# Questions?

**Contact:**  
**[DLSinquiries@cdc.gov](mailto:DLSinquiries@cdc.gov)**



# Division of Laboratory Systems

## Clade I Mpox Update

Christy Hutson

CDC Division of High-Consequence Pathogens and Pathology



# Next Scheduled Call

Monday, December 16  
3 PM - 4 PM ET



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



# CDC Social Media

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



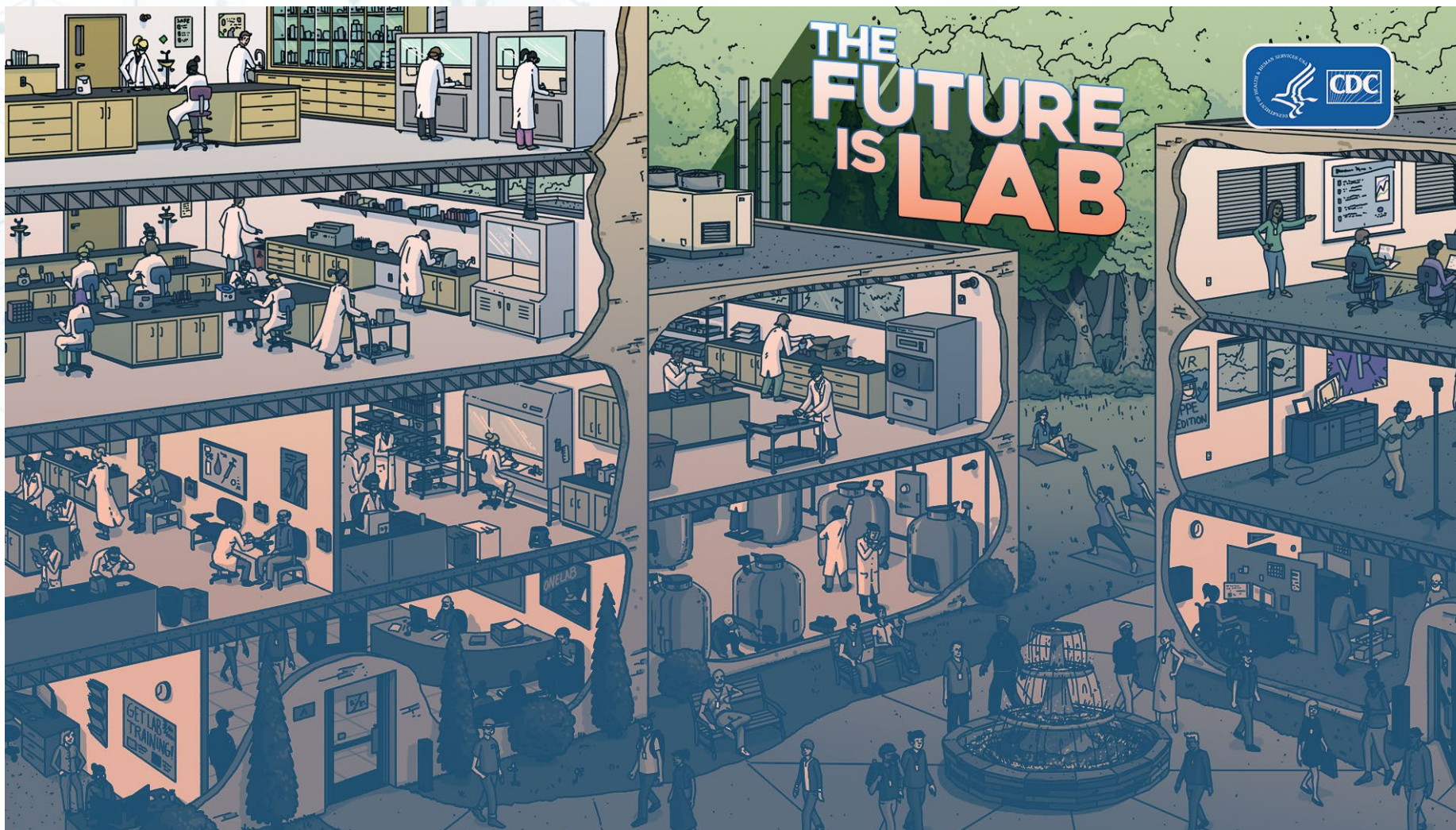
<https://x.com/cdcgov>

<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](http://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.