Laboratory Outreach Communication System (LOCS) Call

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

- **Welcome**
  - Sean Courtney, CDC Division of Laboratory Systems
- **SARS-CoV-2 Variants Update**
  - Natalie Thornburg, CDC Coronavirus and Other Respiratory Viruses Division
- **An Update on Dengue Globally and in the U.S.**
  - Joshua Wong, CDC Division of Vector-Borne Diseases
- **Emerging Pathogen Preparedness and Response**
  - Laura Knoll, Texas Health Resources

About DLS

Vision

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

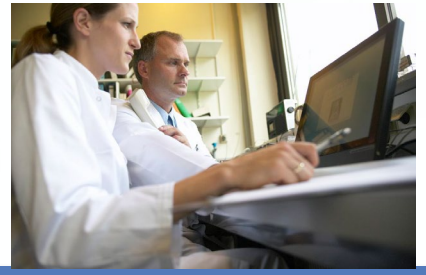
Four Goal Areas

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

CLIAC 2024 Spring Meeting
April 10, Virtual Meeting

- Send oral and written comments to CLIAC@cdc.gov by April 8, 2024
- Topics include:
  - Applicability of CLIA personnel requirements to preanalytic testing
  - Role of artificial intelligence and machine learning in the clinical laboratory
  - Use of clinical standards to improve laboratory quality

Save the date on CDC's CLIAC website:

https://www.cdc.gov/cliac/upcoming-meeting.html

OneLab **Network**

Risk Assessment in Clinical Laboratories

March 27, 2024, 12:00 – 1:00 pm ET

When Ebola entered the United States in 2014, healthcare workers were faced with the very real threat of a deadly exotic disease presenting itself anywhere at any time.

This revealed the importance of needing to be prepared and ready to respond.

Laboratory professionals have since been tasked with performing a risk assessment in an effort to protect themselves and their communities from laboratory-associated infections.

Participants of this webinar will be reminded of how to identify and assess for hazards and mitigate risk and will learn of resources available to assist in what can seem like a daunting process.

OneLab **Summit**

REGISTER **NOW!**

OneLab **Summit**

Thrive: People. Planning. Preparedness.

APRIL 16-18, 2024

A THREE-DAY VIRTUAL LEARNING EVENT

CREATED FOR LABORATORY PROFESSIONALS WHERE ATTENDEES WILL:

- Increase their knowledge of laboratory training development tools and practices
- Gain insights from the clinical and public health laboratory community's success and resilience
- Collaborate and connect with CDC and laboratory education and training peers

REGISTRATION **IS LIVE**! https://reach.cdc.gov/onelabsummit

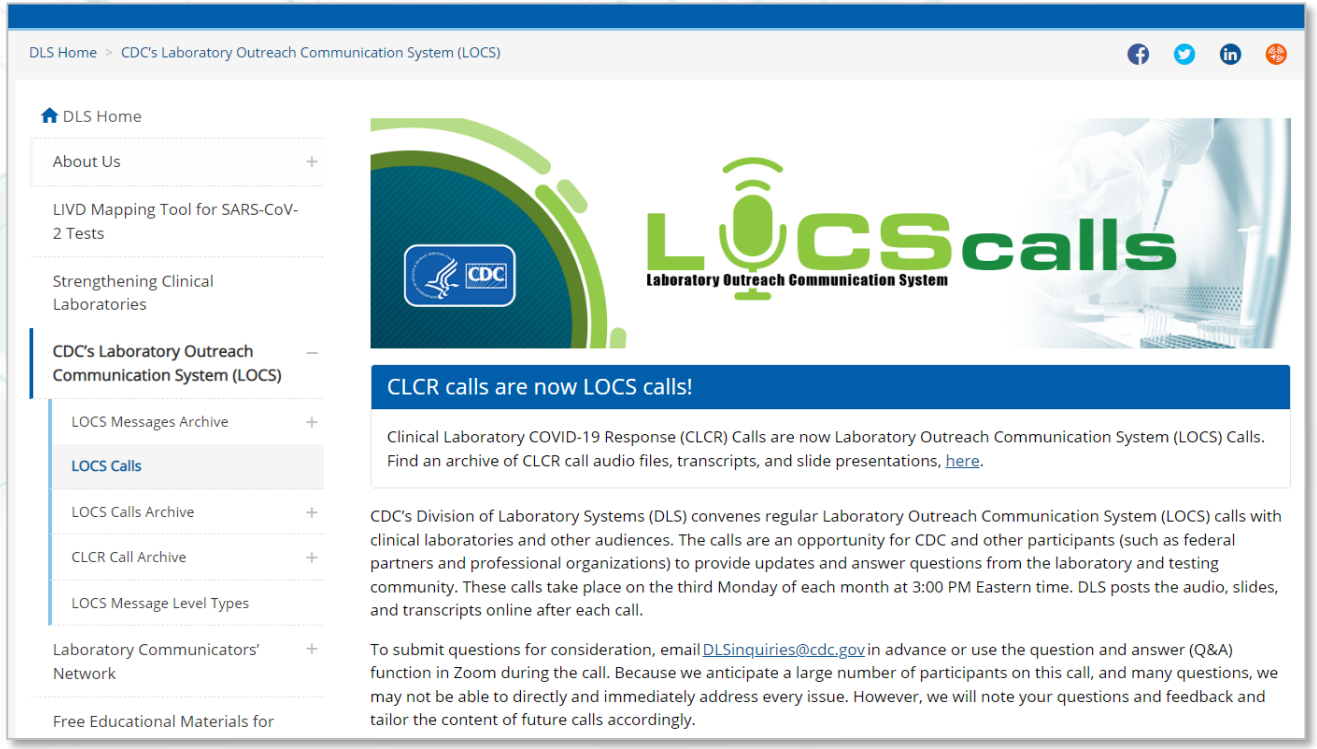
We Want to Hear From You!

Training and Workforce Development

Questions about education and training?

Contact LabTrainingNeeds@cdc.gov

LOCS Calls



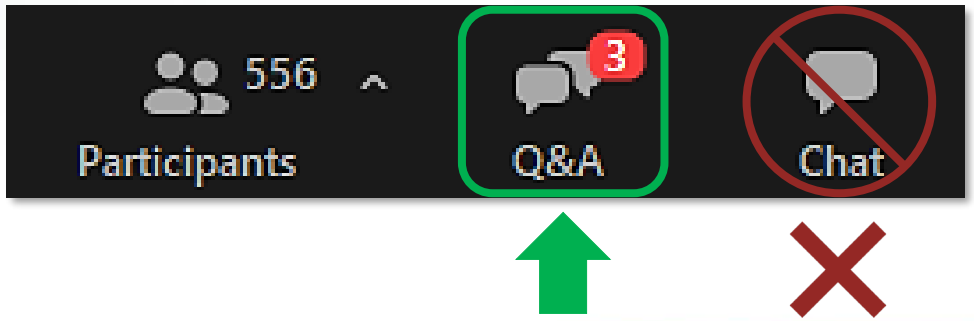
On this page, you can find:

- 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
- If you are a patient, please direct any questions to your healthcare provider

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

An Update on Dengue Globally and in the US:
Laboratory preparedness for dengue testing

Joshua M. Wong, MD

Medical Officer, Dengue Branch, Division of Vector Borne Diseases, NCEZID, CDC

Laboratory Outreach Communication System (LOCS) Call

March 18, 2024

Why should you care about dengue?

The New York Times

Brazil Has a Dengue Emergency, Portending a Health Crisis for the Americas

NPR

Peru is reeling from record case counts of dengue fever. What's driving the outbreak?

What scientists say about the outbreak. Scientists are reluctant to finger climate change as the culprit for this outbreak. But the combination...

Jun 21, 2023

VOA News

WHO: Bangladesh Hit by Worst Dengue Outbreak on Record

Dengue-infected people are hospitalized for treatment...

ReliefWeb

Epidemiological Alert - Increase in dengue cases in Central America and the Caribbean - 15 September 2023 - World

Situation Report in English on World and 20 other countries about Health and Epidemic; published on 15 Sep 2023 by PAHO.

Sep 15, 2023

Africa News

Burkina Faso: more than 350 deaths from dengue fever in a month

An epidemic of dengue fever, a mosquito-borne disease, claimed 356 lives in Burkina Faso between mid-October and mid-November, bringing the...

Nov 24, 2023

Why should you care about dengue?

Chapel converted to hospital ward during dengue outbreak in Honduras

Patients in the corridor of the emergency room in Honduras

Our Discussion Today

- Situation update on global dengue
- Situation update on dengue in the US
- Current state of dengue testing in the US

Dengue Review

Dengue Viruses

- **DENV-1, 2, 3, 4**
  - **Lifelong** DENV type-specific immunity
  - **Short-term** cross-immunity (~1–2 years)
  - Individuals can be **infected up to 4 times** in their life.
- **Clinical Course**
  - ~3 in 4 DENV infections are **asymptomatic**.
  - If symptomatic, onset occurs abruptly after an **incubation period of 5–7 days** (Range 3–10).
  - Early clinical findings are **nonspecific**
    - Can be difficult to distinguish from other pathogens.

DENV Transmission

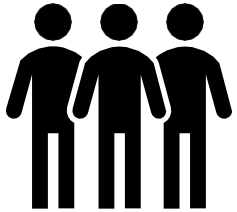
- Vector-borne
  - Saliva of infected Aedes spp. mosquito
- Other modes
  - Vertical from mother to baby
  - Blood transfusion or organ transplantation
  - Needle stick, mucocutaneous, or hospital/laboratory accident
  - Breast milk

Aedes aegypti

Aedes albopictus

Dengue Globally

2023 Global Dengue by the Numbers



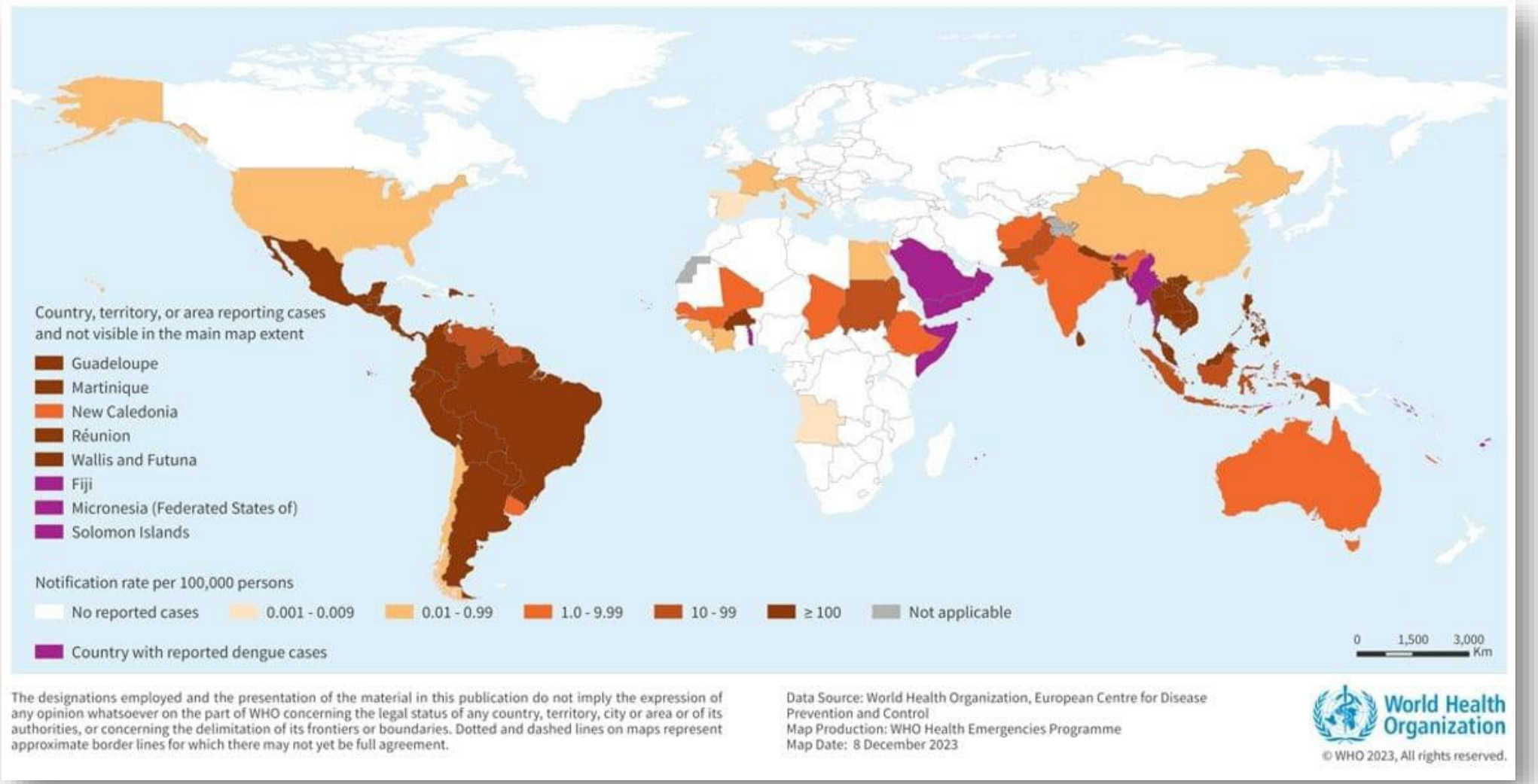
- **>5 million cases** reported worldwide

- **92 countries/territories** reporting cases
  - All 6 WHO regions

- **23 countries** reporting outbreaks

https://www.who.int/emergencies/disease-outbreak-news/item/2023-DON498

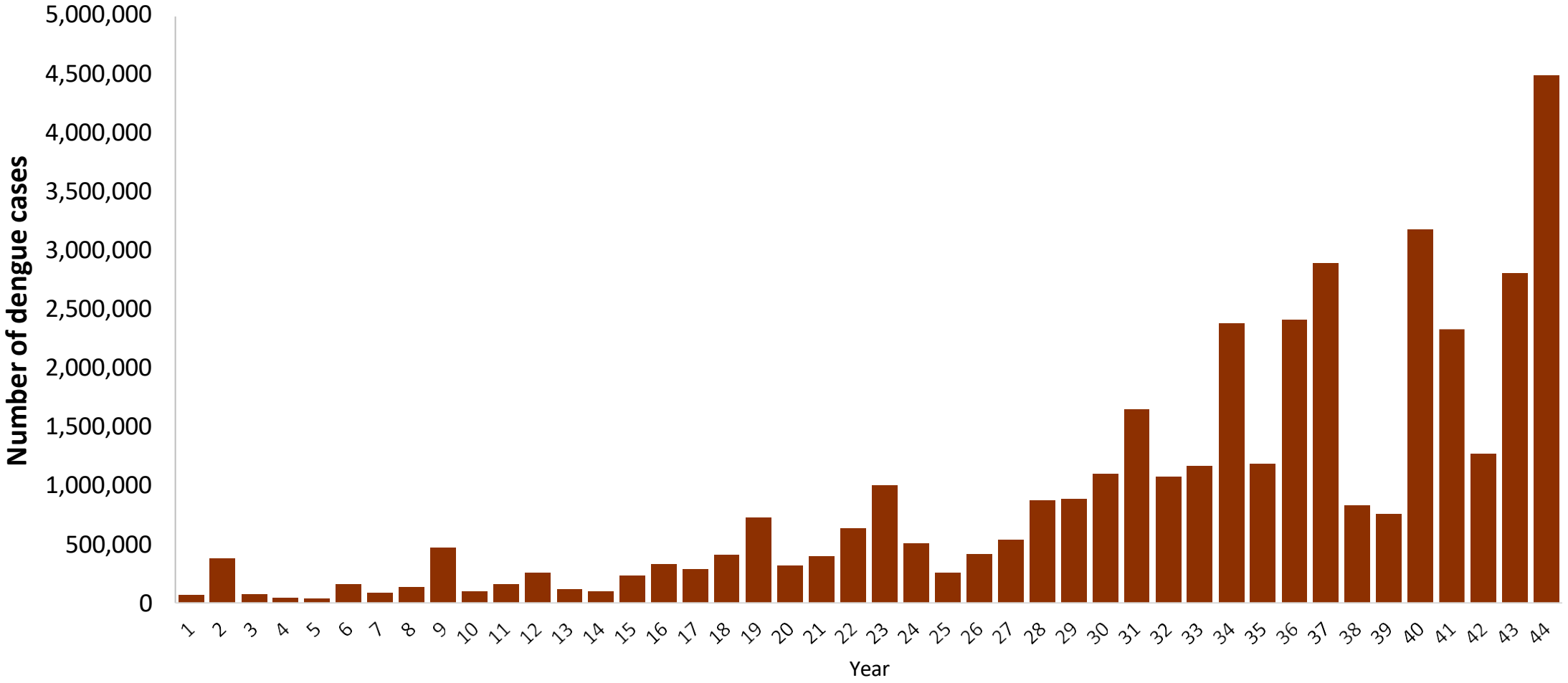
Countries reporting locally acquired dengue cases, Nov 2022–Nov 2023



https://www.who.int/emergencies/disease-outbreak-news/item/2023-DON498

Dengue Cases in the Americas, 1980–2023*

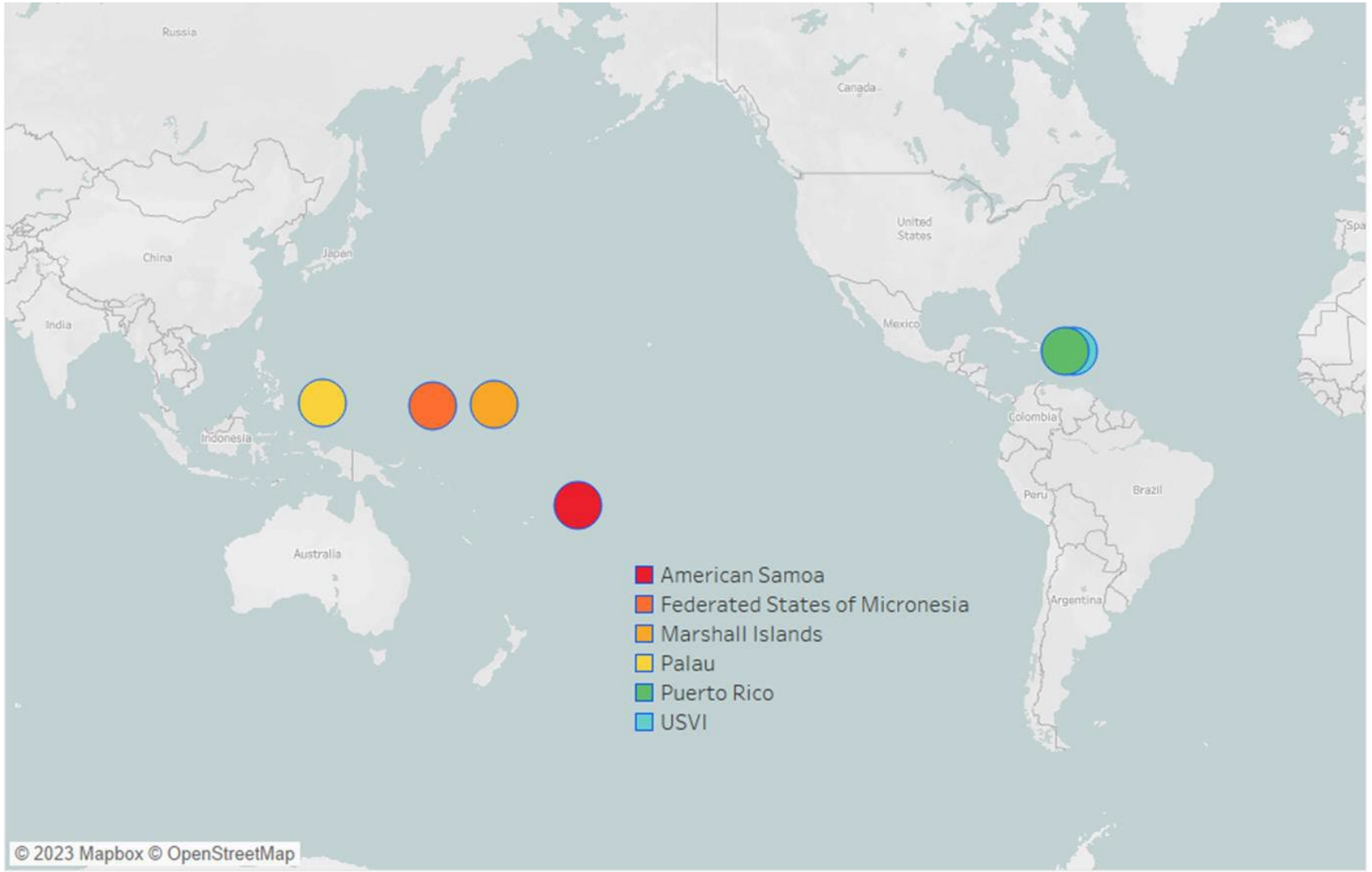
More than 4.4 million cases reported in 2023



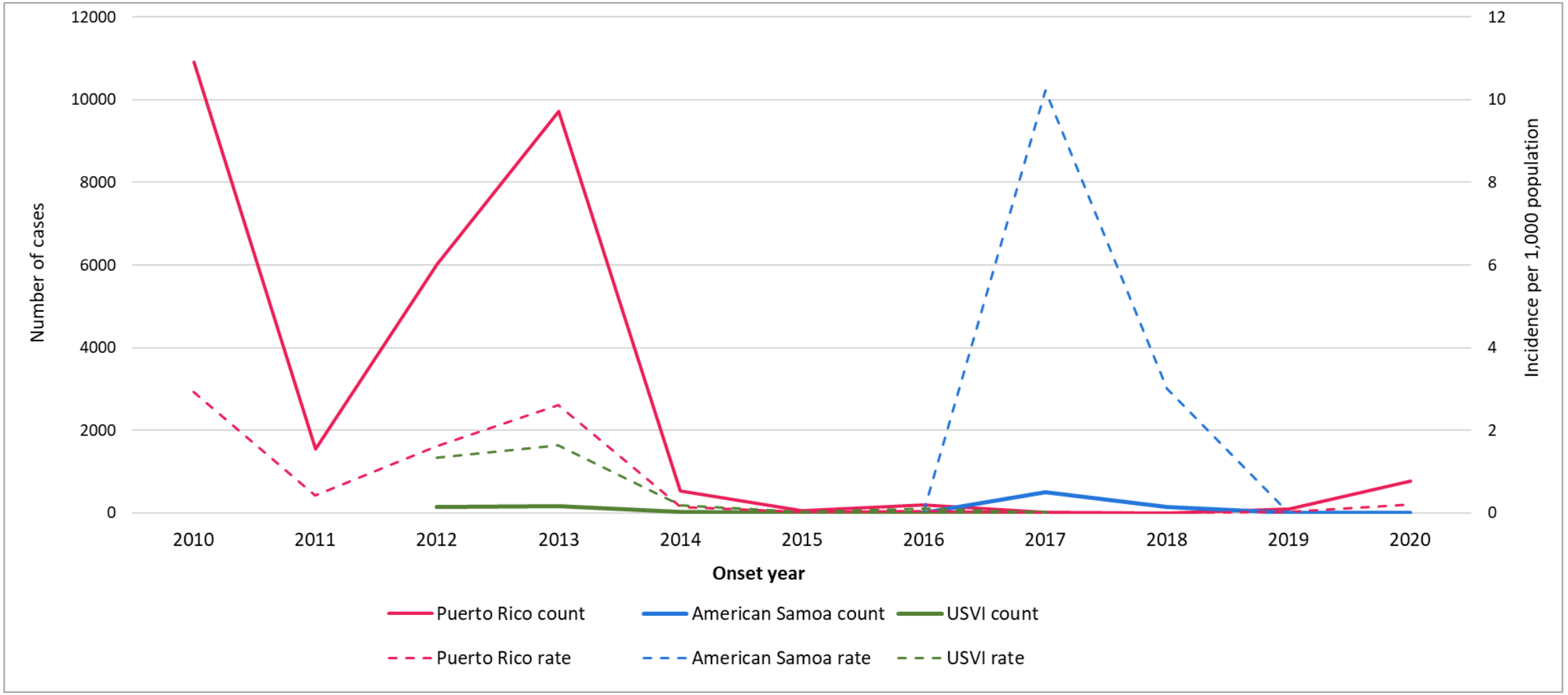
*Data from PAHO PLISA Health Information Platform for the Americas as of January 30, 2024

Dengue in the US

In the United States, dengue is endemic in **6 U.S. territories and freely associated states.**



Dengue cases and rates (per 1,000 population) — Puerto Rico, American Samoa, and USVI, 2010–2020

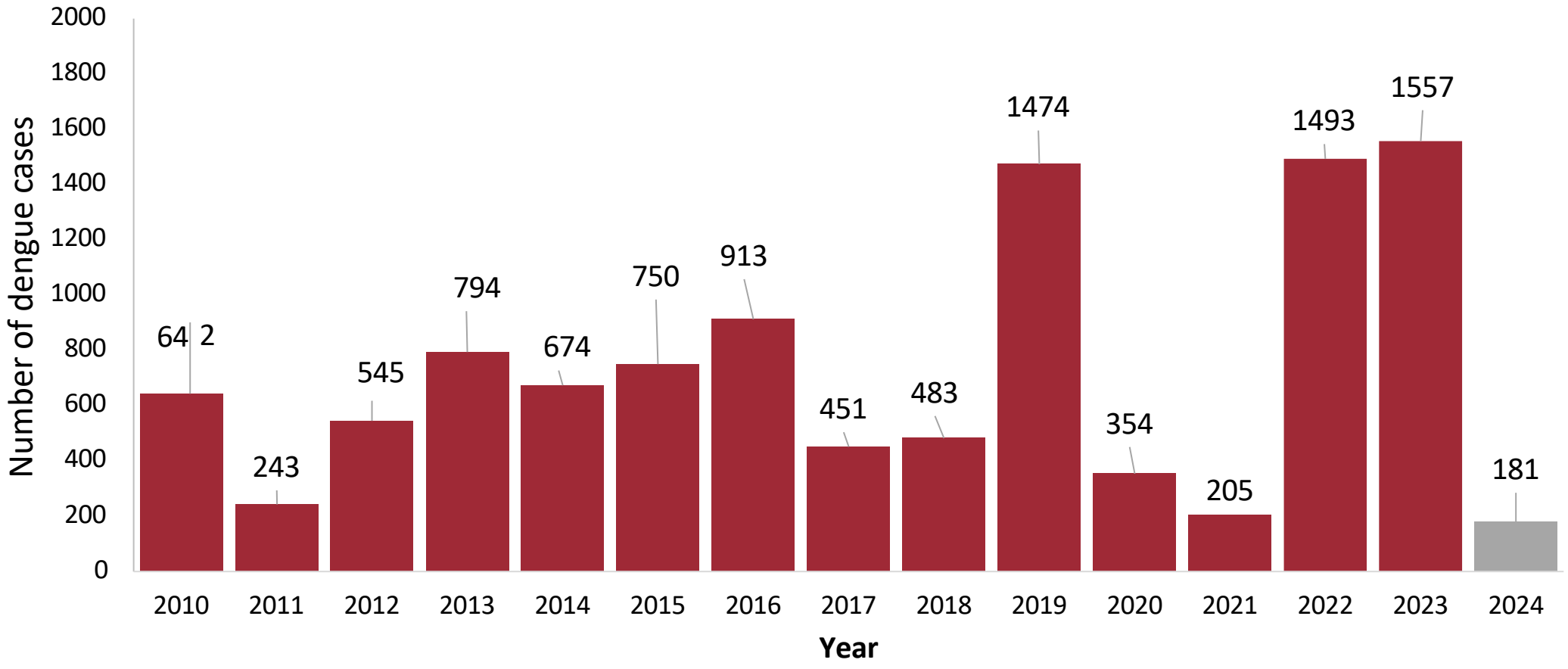


Ryff, K. R., et al. (2023). "Epidemiologic Trends of Dengue in U.S. Territories, 2010-2020." MMWR Surveill Summ 72(4): 1-12.

Among dengue cases reported to ArboNET from 2010–2022,

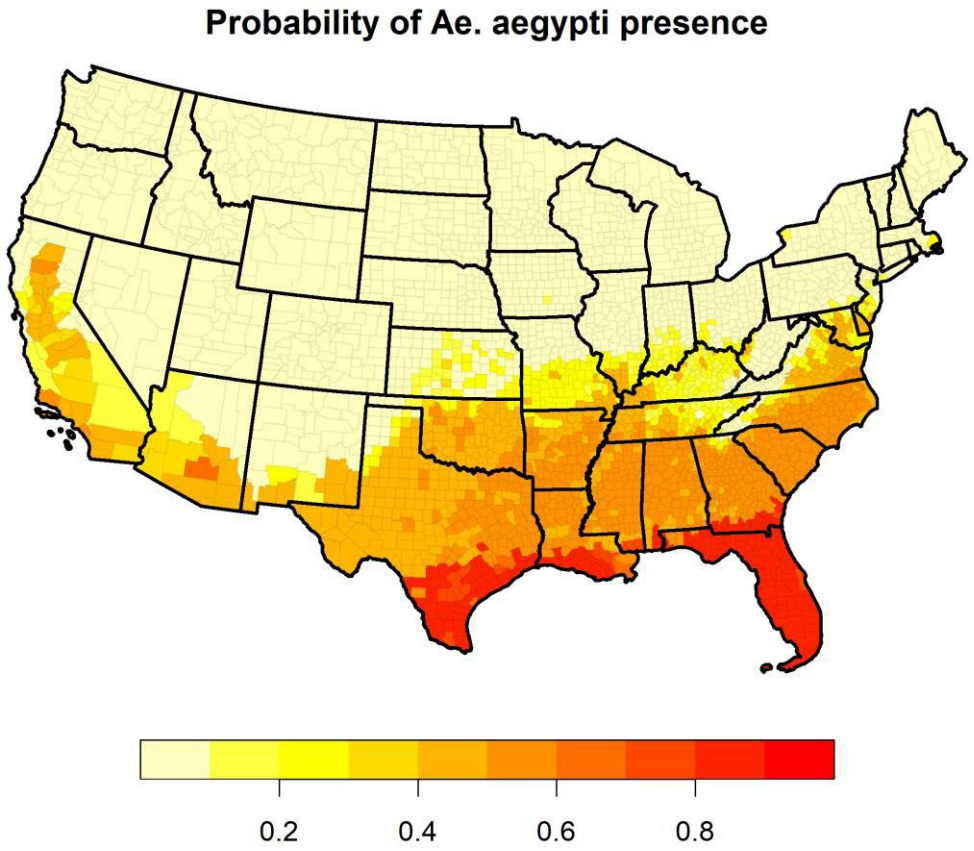
most dengue cases in US states (>94%) were associated with travel to endemic areas.

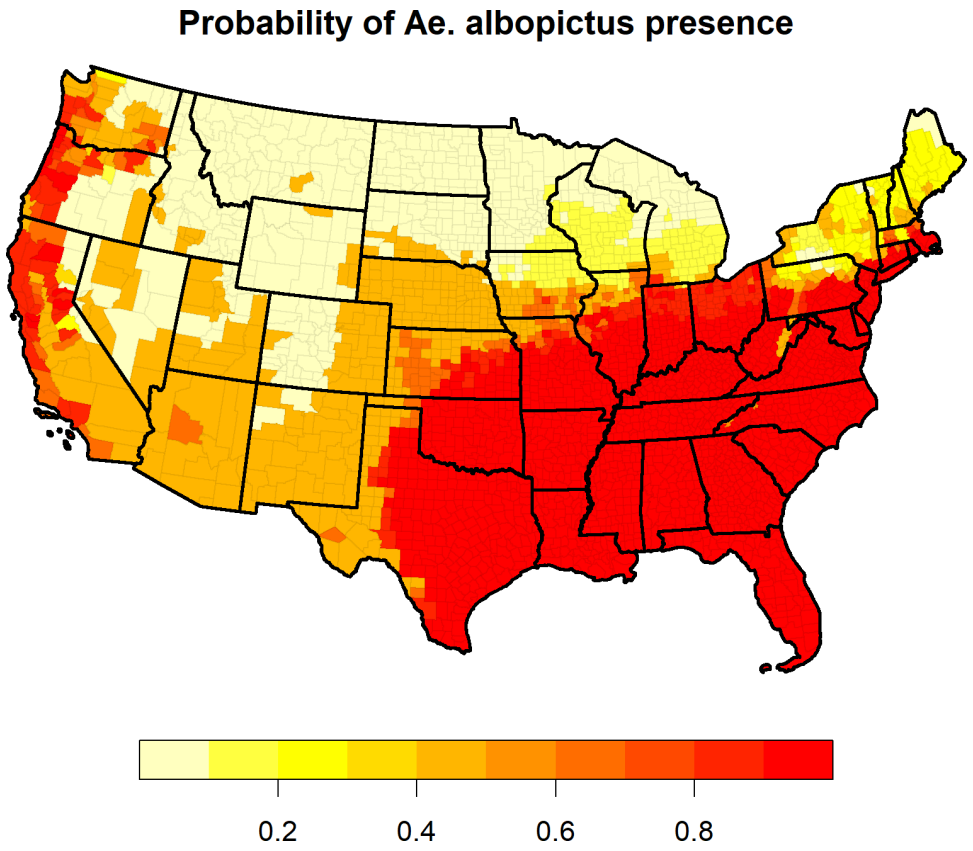
Travel associated dengue cases (N = 10,759) reported in the US by year, 2010–2024



Data from: https://www.cdc.gov/dengue/statistics-maps/data-and-maps.html (accessed 3/16/2024)

Dengue vectors are present across much of the US.

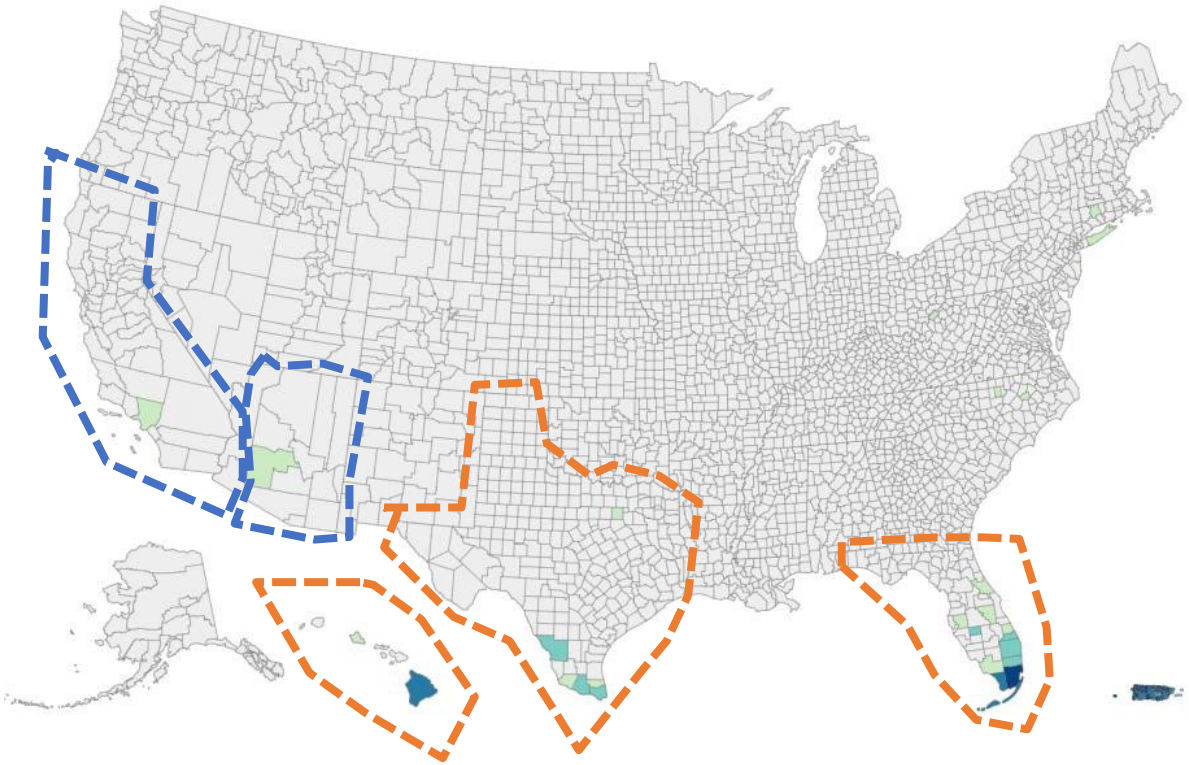




Monaghan AJ, Eisen RJ, Eisen L, McAllister J, Savage HM, et al. (2019) Consensus and uncertainty in the geographic range of Aedes aegypti and Aedes albopictus in the contiguous United States: Multi-model assessment and synthesis. PLOS Computational Biology 15(10): e1007369. https://doi.org/10.1371/journal.pcbi.1007369
https://journals.plos.org/ploscompbiol/article?id=10.1371/journal.pcbi.1007369

Locally Acquired Dengue in US States, 2010–2023

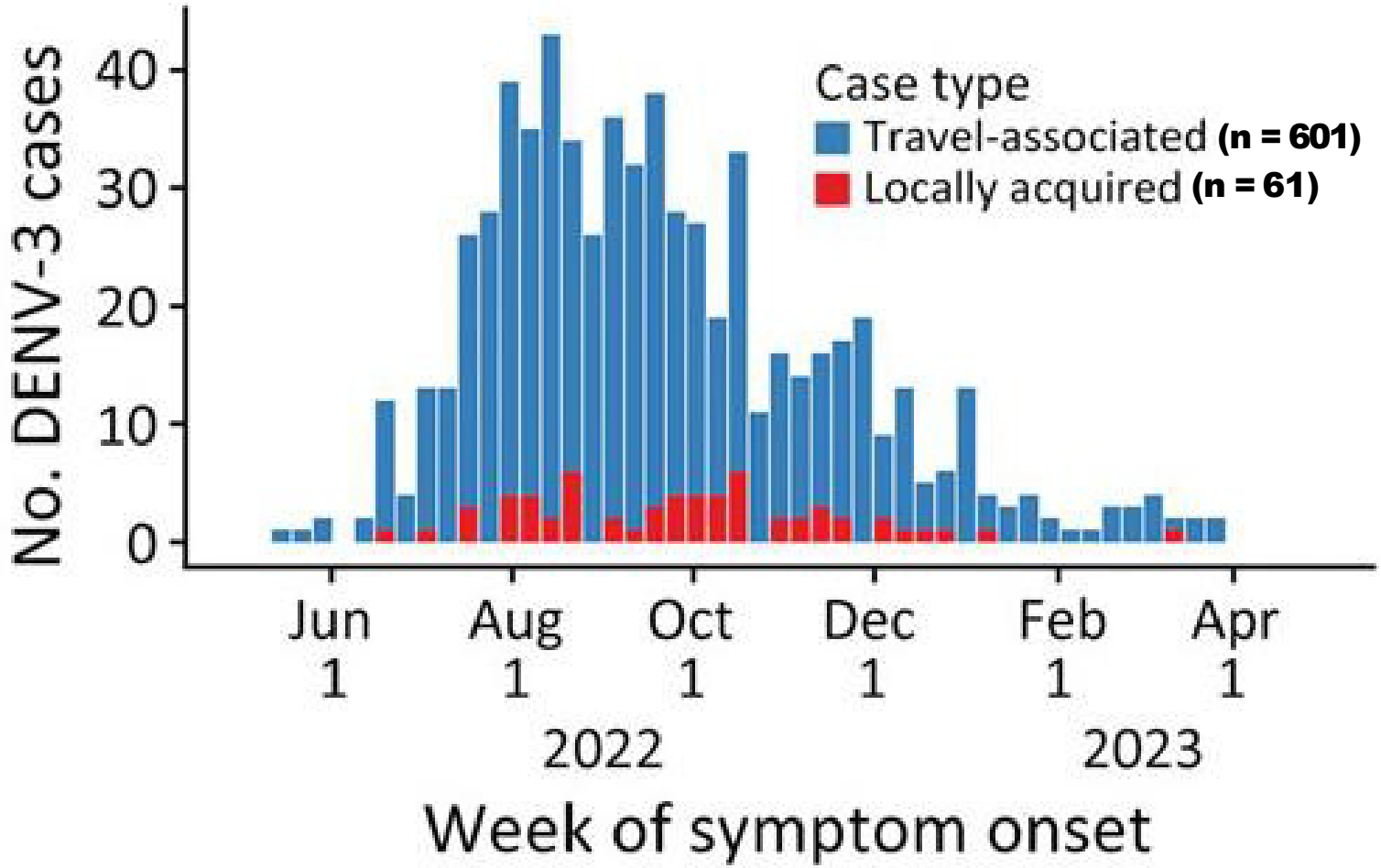
- Sporadic cases to limited outbreaks
  - Florida, Hawaii, Texas
- First evidence of local DENV transmission
  - Arizona, n=2 (2022)
  - California, n=2 (2023)



Map from: https://www.cdc.gov/dengue/statistics-maps/current-data.html

Multiple DENV-3 introductions in Florida from returning travelers resulted in increased local transmission.

Reported cases of DENV-3 in Florida, by week— Florida Department of Health, June 2022–April 2023.



Jones, F. K., et al. (2024). "Introduction and Spread of Dengue Virus 3, Florida, USA, May 2022-April 2023." Emerg Infect Dis **30(2): 376-379.**

How do I test for dengue?

Appropriate dengue testing depends on **when the sample is collected.**

- **Within 7 days** of symptom onset*, test with:

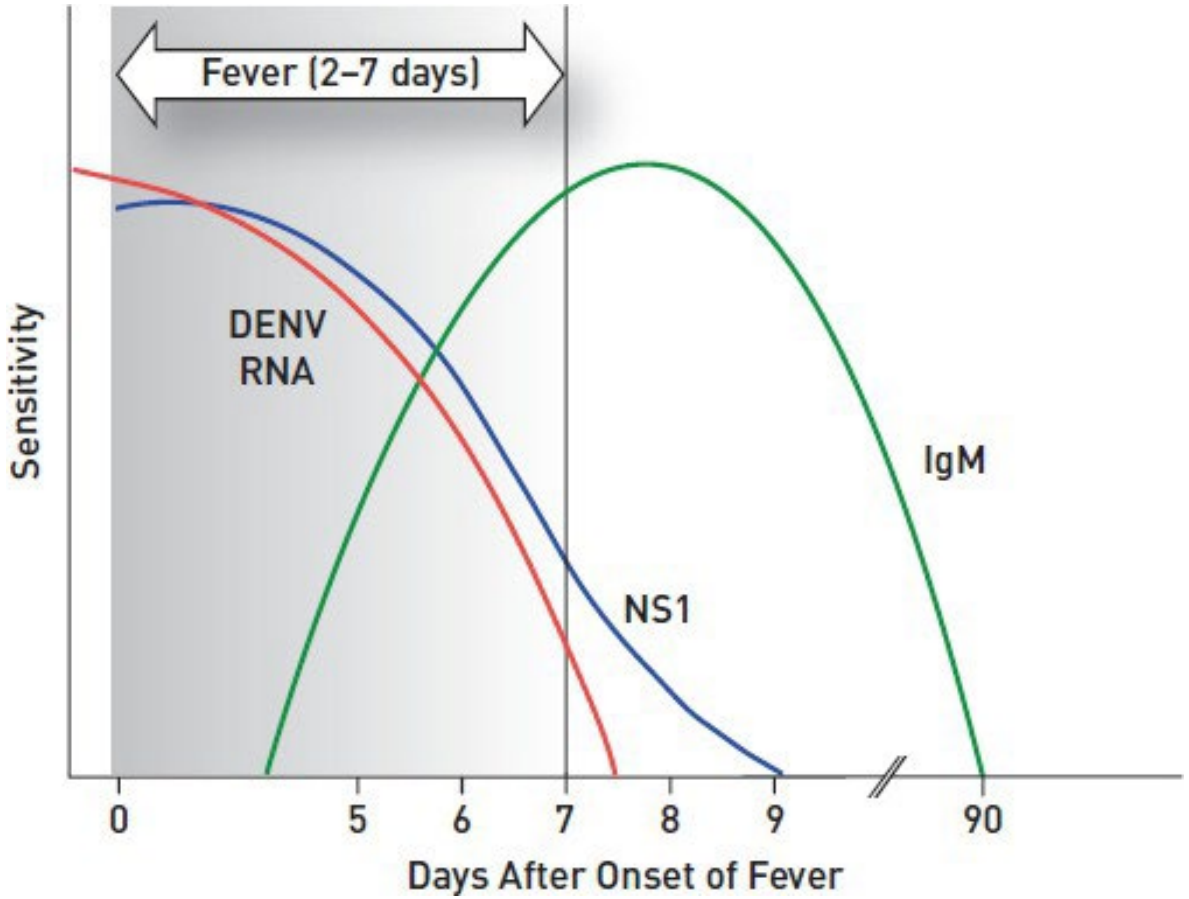
Molecular or NS1 antigen tests

AND

IgM serology

- **After 7 days** of symptom onset*, test only with:

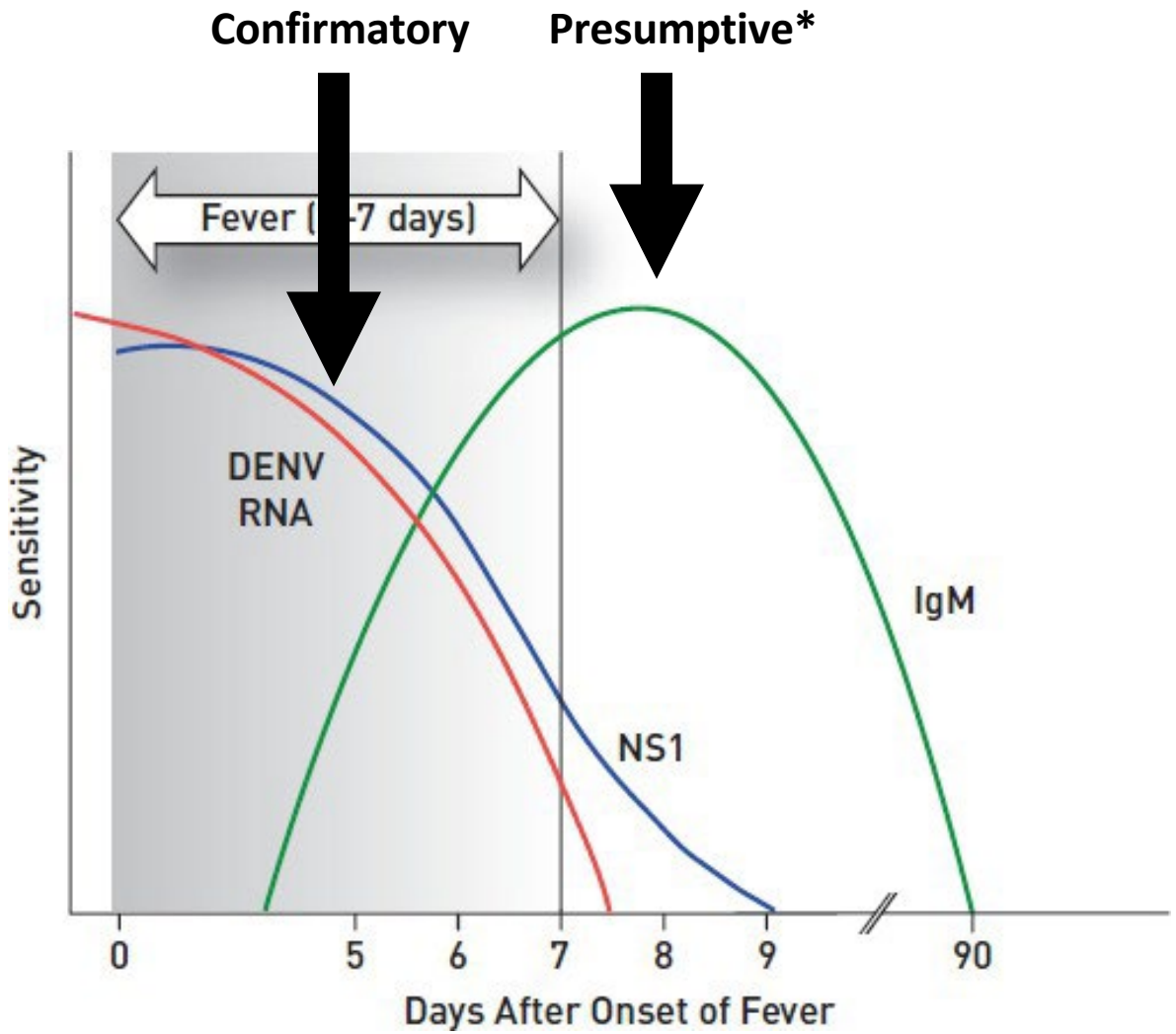
IgM serology



*Testing guidance may vary by jurisdiction, especially in endemic areas.
For more information on testing, visit: www.cdc.gov/dengue/healthcare-providers/testing/

Confirmatory vs. Presumptive Test Results

- Tests that **confirm** dengue virus infection:
  - NS1
  - RT-PCR
- Tests that provide **presumptive** diagnosis:
  - IgM



*Testing guidance may vary by jurisdiction, especially in endemic areas.
For more information on testing, visit: www.cdc.gov/dengue/healthcare-providers/testing/

Where are we currently with dengue testing preparedness?

FDA has approved four tests to diagnose dengue.

Test	FDA approval
CDC DENV-1-4 RT-PCR	IVD (510k)
CDC Trioplex RT-PCR (ZIKV, DENV, CHIKV)	IVD (EUA)
InBios IgM ELISA	IVD (510k)
InBios NS1 ELISA	IVD (510k)

ho offers	
yes	No
Yes	No
ese tests?	
Yes	No (?)
No	No

Who offers FDA approved dengue tests?

Test	FDA approval	Commercially available	Public health labs	Private labs
CDC DENV-1-4 RT-PCR	IVD (510k)	No	Yes	No
CDC Trioplex RT-PCR (ZIKV, DENV, CHIKV)	IVD (EUA)	No	Yes	No
InBios IgM ELISA	IVD (510k)	Yes	Yes	Unknown, but tests can be purchased
InBios NS1 ELISA	IVD (510k)	Yes	No	Unknown, but tests can be purchased

Current Dengue Diagnostic Gaps and Needs

- In Puerto Rico:
  - Private labs in Puerto Rico **do not offer comprehensive dengue testing**.
  - The public health lab has **strong testing practices** but can be **overwhelmed** during epidemics.
- In US states:
  - Private labs **rarely offer** confirmatory molecular and NS1 antigen dengue testing.
  - As a result, their dengue testing algorithms are often **incomplete** and likely **imprecise**.
- **No FDA-approved, commercially available RDTs are available** in the US to assist clinicians with dengue diagnosis.

Early recognition and appropriate treatment of dengue saves lives.

- Up to **13% mortality** if left untreated, but can be **reduced to <0.05%** mortality with early recognition and appropriate management.*
- Clinicians are counseled to initiate treatment based on clinical suspicion (e.g., **don't wait for test results!**).
- Rapid diagnostic tests could assist clinicians in **identifying dengue early**.

For further dengue training resources, visit: https://www.cdc.gov/dengue/healthcare-providers/education-training.html

*Kabra, S. K., et al. (1992). "Dengue haemorrhagic fever in children in Delhi." Bull World Health Organ 70(1): 105-108.
Kalayanarooj, S. (1999). "Standardized Clinical Management: Evidence of Reduction of Dengue Haemorrhagic Fever Case-Fatality Rate in Thailand."
Lam, P. K., et al. (2013). "Clinical characteristics of Dengue shock syndrome in Vietnamese children: a 10-year prospective study in a single hospital." Clin Infect Dis 57(11): 1577-1586.

What is CDC Dengue Branch doing to improve dengue testing capacity?

- **Increasing** production of CDC's RT-PCR test kits to meet demand from public health labs in the U.S and the Americas
- **Supporting** and **collaborating** with the Puerto Rico Department of Health to improve laboratory capacity and timely detection of cases
- **Adapting** the CDC RT-PCR tests to work with current equipment (re: sunset of Thermo Fisher devices)
- **Conducting** a landscape analysis of RUO tests, including RDTs
  - **Facilitating** further clinical evaluations required for regulatory filing
- **Assessing** private laboratory practices and **providing** recommendations on best laboratory practices for dengue diagnosis

In Summary

- Dengue cases globally are increasing.

- Dengue cases in the US are increasing.
  - Competent vectors and frequent travel-associated introductions **might lead to local transmission events**.

- Dengue Diagnostics:
  - FDA has approved **4 tests** for diagnosing dengue.
  - Appropriate dengue testing depends on **when the sample is collected**.
    - RT-PCR testing is the preferred test to confirm dengue, but it **is not commercially available**.
    - NS1 and IgM testing are recommended and **are commercially available**.
  - Dengue testing is available in public health and private labs, **with some limitations**.
  - CDC Dengue Branch is working **to improve dengue testing capacity**.

Thank you! Questions?

Test	FDA approval	Commercially available	Public health labs	Private labs*
CDC DENV-1-4 RT-PCR	IVD (510k)	No	Yes	No
CDC Trioplex RT-PCR (ZIKV, DENV, CHIKV)	IVD (EUA)	No	Yes	No
InBios IgM ELISA	IVD (510k)	Yes	Yes	Unknown, but tests can be purchased
InBios NS1 ELISA	IVD (510k)	Yes	No	Unknown, but tests can be purchased

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

Joshua M Wong, MD
nof9@cdc.gov

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

Emerging Pathogen Preparedness and Response

Laura Knoll M.S., M.A., MT (ASCP) MB (ASCP)^{CM} | Manager; Special Procedures Lab
lauraknoll@texashealth.org

Texas Health Resources™

Disclaimer

- The material described in this presentation covers what one institution has implemented for handling of emerging infectious diseases (specifically Viral Hemorrhagic Fever).
- The procedures and suggestions described may not be applicable to all institutions but are intended to be an example that could be modified for use.
- Please consult with leadership at your facility prior to implementing any new process to ensure safety.

Annual Training

System Training (Train the Trainer = 1x/year)

- HLPPE Don/Doff
- Review of Specimen Handling in Entity Laboratories
- Transport of Samples to HUB laboratory
- Chain of Custody

On Site Training

- HLPPE Don/Doff (2x/year)
- Response Team (minimum 2x/year and when adding a new team member)
  - Practice entire rapid testing process (both tester and buddy roles for each team member)
  - Review scripting for changes
  - Engage outside observers to review motions of process to identify safety concerns

Scripting

- Initial Calls
- HLPPE Don/Doff
- Testing Process

EMERGING PATHOGEN PHONE SCRIPT AND TO DO LIST

Use this as a guide and check-sheet for questions to ask and things to do when taking a phone call regarding potential specimen collection and testing for emerging pathogens. This includes but is not limited to the following: Ebola (or other Viral Hemorrhagic Fever - **VHF**), MERS, Avian Influenza.

Place caller on brief hold and obtain the Emerging Infectious Disease Lab Test Menu spreadsheet and the Emerging Infectious Disease Sendout Chart

Date/Time of Call: _____

Phone Call Scripting:

- ☐ Has infection prevention been informed? (*If the answer is no, instruct the caller to page IP via Ext 8480 once this call is complete and remind the caller that BEFORE any collections are made, IP is required to be contacted first.*)
- ☐ Has the physician contacted the Dallas County Epidemiologist? *(If the answer is no, provide DCH contact info located at the bottom of the chart.) CONSULT EMERGING INFECTIOUS DISEASE CHART TO DETERMINE IF EPI CALL IS REQUIRED FOR SUSPECTED AGENT*
- ☐ Let me assist you with specimen collection. There is an Emerging Disease order set in Care Connect that can help guide you with specimens and orders; Select the appropriate panel from the group (if Ebola/Lassa/Marburg – use the VHF panel).
  - Can also *consult the THR Emerging Disease Laboratory Test Menu for specimen collection details for each emerging pathogen. (Available on the Intranet Emerging Infectious Diseases webpage →EID Contacts and Resources → Laboratory Resources.) https://mytexashealth.texashealth.org/EmployeeResources/Health/EIDsite/Pages/EID-Contacts-and-Resources.aspx*
  - If you do not have the required collection materials, I can send you collection supplies after this call.
- ☐ May I please have some patient information
  - Patient Name_____ MRN_____
  - Tube Station _____ (*if sending collection materials*)
  - Physician Name and Number_____
  - RN Contact Name and Number _____
- ☐ **Please do NOT tube the samples to the lab.** What time and where should the lab arrive to pick up the specimen? _____
- ☐ For you to have one point of contact for lab, let me give you my name and phone number. Please ask for me if you need to call back with any questions. We limit the points of contact to eliminate confusion throughout the event.

To Do List:

- ☐ Collection material has been sent (if necessary) and specimen pick-up time noted above.
- ☐ SPL Manager/Supervisor/Medical Director notified.
- ☐ Core Lab Supervisor notified to arrange specimen pickup. Copy of this form provided to the Core Lab supervisor.
- ☐ Dallas County Laboratory Contacted – **PHD Lab must call in addition to the physician call to DCH Epi *IF REQUIRED FOR AGENT***
- ☐ THD Infection Prevention Contacted – **PHD Lab must call in addition to the physician/RN *IF REQUIRED FOR AGENT***
- ☐ **View MQC 4.000 Guidelines for Highly Infectious Agent Response SPL for dept specific information (policies, test scripts, room inventory, kits)**
- ☐ **For VHF**: HLPPE go-kit obtained and stocked, containment room stocked, individual testing go-kits prepared, shipping materials ready and labeled
- ☐ **For VHF**: Tester, Buddy, Coach identified.

TESTING SCRIPTS

The following directions are to be used by the buddy to direct the tester's motions inside the BSC. The tester is not to begin an action until the buddy has read the step out loud. The buddy is to observe the tester's actions throughout the process. Laminated copies of the scripts are available in the HLPPE Go-Kit and may be used by the buddy to "check-off" each step in the process.

Opening of Specimen Containers

If the specimen is inside a transport box

- ☐ Place the box inside the hood (if not already within the hood)
- ☐ Bleach/alcohol all surfaces on the outside of the box. Dispose of bleach/alcohol wipe in BSC trash.
- ☐ Lay down a clean bleach/alcohol wipe in the BSC and place to the left hand side.

Laboratory Services Doffing Script

Note: if the employee is likely to need assistance, the buddy can assist as needed. The doffing coach may not assist.

When testing is complete and after testing area has been decontaminated, notify the Doffing Coach th are ready to begin the doffing process

1. Coach: **Enter designated doffing area**
2. Coach: **During this process, avoid reflexive actions that may put you at risk, such as touching your face c rubbing your eyes. I will read each step of the doffing process out loud. Do not begin each step until I ha finished reading the instructions and have made eye contact with you.**
3. Coach: **Turn completely around. I will inspect the PPE to assess for visible contamination, cuts, or tears l you start the doffing process.** (If any PPE is visibly contaminated, then clean and disinfect using an EPA-registered disinfectant alcohol wipe. Allow to stay wet for 2 minutes and then let air dry).
4. **Sanitize each arm of the surgical gown (top to bottom), the front of the apron, and gloves with disinfectant alcohol wipe. Use a separate wipe for each area (gown, each arm, gloves). Do not wipe u down. Allow to stay wet for 2 minutes then air dry.**
5. Coach: **Remove the blue plastic apron. Pull down the top of the apron, at s tie. Roll top of apron away from your body. Pull forward to break the waist ti side of the gown inward until it is in a tight ball. Avoid contact of yourself an the gown during removal. Dispose of it in a red bag**
6. Coach: **Sanitize outer gloves with disinfectant alcohol wipe. Allow to stay w**

Laboratory Services Donning Script

Preparing for Entry: Prepare to be in PPE for 1-2 hours. Please consider eye drops to prevent dry eyes, clean glasses and secure with strap, any routine medication is taken.

1. Coach: **My role is to ensure you have no exposed clothing, skin or hair through visual inspection at the conclusion of the donning process. I will read each step of the donning process out loud. Do not begin each step until I have finished reading the instructions and have made eye contact with you.**

Enter Donning Area

a. Coach: **Remove jewelry and place personal items in storage area.**
b. Coach: **If hair is long enough, tie back into a low bun. Secure any loose hair from face.**
c. Coach: **If you wear contacts/glasses, bring and wear your glasses.**
d. Coach: **If you are wearing glasses, makes sure they are secured with ties.**
e. Coach: **Are your shoes made of fluid resistant material with a back or heal strap?**
f. Coach and Staff: **Let's inspect the PPE for holes or tears. Let's make sure that the appropriate equipment and sizes are available for use** (such as gloves and lab coat).

2. Coach: **Put on knee-high booties with arrows pointing towards toes.** (Knee-high impervious booties)

3. Coach: **Put on knee length disposable lab coat** and snap close. **I will cut thumb holes to allow sleeves to be anchored inside gloves.**

4. Coach: **Put on extended cuff inner gloves**

Test Menu Initial Rule Out

Emergency Department Laboratory Testing Menu and Guidelines for Suspected Viral Hemorrhagic Fever

Call the microbiology laboratory at x6350 to notify the lab of the PUI prior to specimen collection.

Guidelines for Test Orders, Specimen Collection, Handling and Transport

1. **Collect the following specimens**
   a. **Two - Lavender top 3 mL**
   b. **One – Dark Green 3 mL**
   c. **One – Light Green 5 mL**
   d. **One – Yellow top (non-additive) urine**
   e. **One – Throat swab**
   f. **One – Nasopharyngeal swab in UTM**
2. **Refer to the *SAF 9.025 Preparation and Delivery of Lab Specimens Protocol for VHF* for cleaning, labeling, and packaging instructions:** ***located on the THD Laboratory Test Directory site (type "thdlab" into your browser from the home page, emerging disease links on the right side of the page) OR the THR Emerging Disease Site (ED Contacts and Resources Section).***
3. **Reminder: Call the laboratory for specimen pickup. Do not send specimens through the tube station. Do not give specimens to the ED liaison.**

Based on collection of the above, the Laboratory will provide the following tests for ED patients with suspected VHF:

- Blood Parasite (includes Thin Smear and Malaria Antigen)
- Urinalysis without microscopic
- CBC without differential
  - WBC
  - RBC
  - HGB
  - HCT
  - MCV
  - MCH
  - TDW
  - MPV
  - Platelet
- CMP (Comprehensive Metabolic Panel)
  - Sodium
  - Potassium
  - Chloride
  - CO2
  - Glucose
  - BUN
  - Creatinine
  - Total Protein
  - Albumin
  - Bilirubin (total)
  - AST
  - ALT
  - Calcium
  - Alkaline Phosphatase
  - eGFR

Specimen Packaging

Preparation and Delivery of VHF Laboratory Specimens

Note: please request samples be placed into two separate bags as indicated below:

Bag 1:	Bag 2:
- 1 lavender - 1 dark green - 1 yellow top urine	- 1 lavender - 1 light green - 1 NP swab in UTM - 1 throat swab (if suspect Lassa)

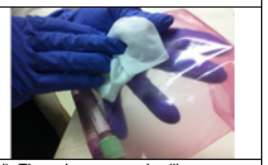
Collection process:

Once collected, at the patient's bedside – wipe outside of each container with appropriate disinfectant.

Once dried, label with **patient identification labels**.

Packaging Process:

1. Package one purple tube, gray top urine and NP swabs into one bag.
2. Package all other samples into a separate bag.
3. Wipe the outside of the bag(s) with alcohol wipe after specimen are in each bag.



4. Show the bag to the anteroom coach (or laboratory personnel). The anteroom coach will ensure that all specimens are appropriately labeled (correct patient identification) and will inform the lab personnel of the collected specimens inside the bag.
5. Roll the specimens up in the bag and seal the bag.
6. Place each specimen bag into another bag. Wipe the outside of the bag(s) with alcohol wipe. Roll the specimens up and seal the bag.
7. The anteroom coach will receive the specimen from the primary nurse via retrieval with a third bag (inside out on the coach's hand) to triple bag the specimen.



8. Wipe the triple-bagged specimen with an alcohol wipe. Anteroom coach will walk to the lab personnel with the decontaminated specimen bags.
9. Lab personnel will hand two pressure bags to the anteroom coach.
10. The anteroom coach will place each prepared specimen bag into a single pressure bag. The coach will seal the bag and wipe with an alcohol wipe.



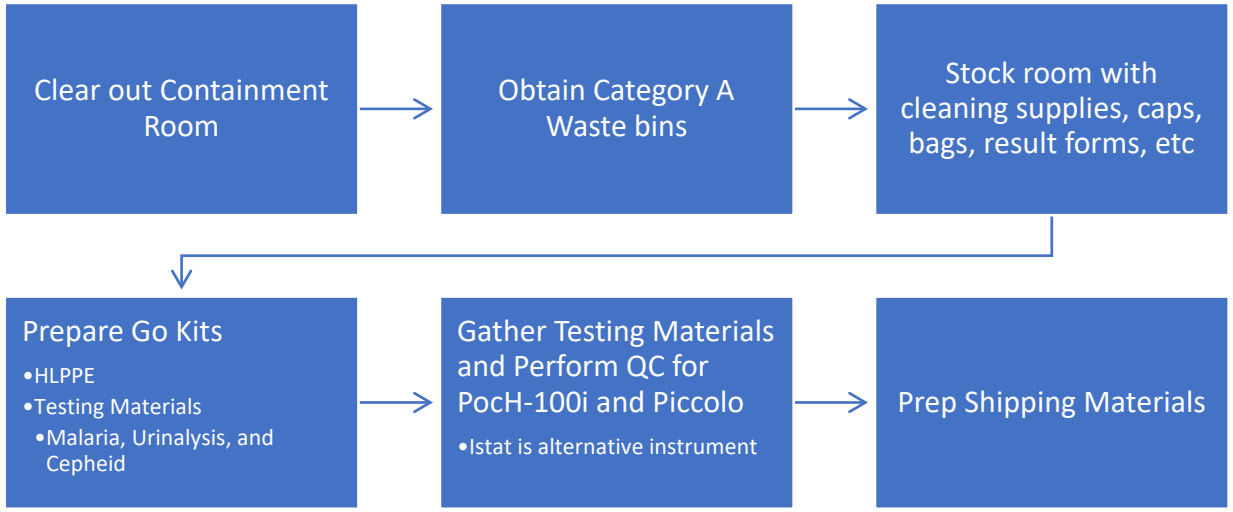
11. The anteroom coach will provide the names and employee ID numbers of the two RNs that have verified the accuracy of the specimens.
12. Laboratory staff (buddy) will:
    - Obtain a patient chart label for the Chain of Custody form (this label should not come from the hot zone).
    - Record the RN name(s) on the Chain of Custody form.
    - Complete the packing list and place into the transport container.
13. Laboratory staff will hold open the designated laboratory transport container. The anteroom coach will place the pressure bags inside. The laboratory staff should not touch the pressure bag and the anteroom coach should not touch the container.

Note: transport container may be:
- Hard sided sealed laboratory transport box (HUB)
- Category A shipping box (Entity)


Alternate transport box

14. Laboratory staff will seal the transport container and deliver to the designated area for courier pick-up or laboratory testing.

Containment Room Readiness



Supplies Needed for the Containment Room and Testing

- ➢ Inside Biosafety Cabinet
  - 1 container of bleach and/or alcohol wipes, lid removed for easy access to remove wipes
  - Sharps container without lid with red biohazard trash bag inserted
  - Suction container (**without lid**) filled 1/3 with bleach; for pipettes, slides, tubes, contaminated disposables, etc.
  - Plastic backed absorbent pad soaked with disinfecting agent (10% bleach or Oxivir)
  - Mini-vortex
  - 5 extra vacutainer tube caps
  - 1 extra yellow top urine cap
- ➢ Inside Room
- ✓ Place near Buddy Area
  - Test tube rack (white)
  - 1 container of alcohol wipes
  - 1 suction container lid with blue cap only on 3 small vents (leaving largest vent open)
  - 6 Small and 2 large (dry ice) plastic bags
  - Sealable shipping bags and pressure vessel
  - Autoclave bags (3 large, 2 small), autoclave tape, and Prospore ampules
  - 2-3 Moisture absorbing bench pads with plastic backing
  - Bottle of Oxivir or fresh 10% bleach
  - 1-2 disposable pipettes
  - 4x4 orange biohazard wipes (several)
  - Scotch tape
  - Paper towels
  - Small, medium, large extended cuff gloves
  - Precut strips of ParaFilm
  - Folder on the counter for keeping any paperwork (Chain of Custody forms etc)
  - Marker, pencil, pen
  - Pre-printed patient accession labels; additionally patient FIN/CSN needed for iSTAT testing
  - EID result form (for Piccolo, PocH-100i, urinalysis, etc. results)
  - iSTAT instrument (**IF** Piccolo unavailable for use)
    - 2 Chem8+ iSTAT cartridges (room temp, unopened)
    - 2 1ml slip tip syringes or 3ml luer lock syringes
    - 1 Vacutainer blood transfer device (REF 364880)

Malaria Go-Kit

Contents:

- **30 ml each in a 50 mL conical tube**
  - **Hemacolor stains 1,2, &3**
  - **Milli-Q water**
  - **Methanol**
- **Plastic slide box containing 4 slides**
- **2-3 plastic pipettes**
- **Pencil**
- **Capped polystyrene tube containing 4-5 drops Rapid Malaria reagent**
- **Rapid Malaria Card**
- **Timer (in separate plastic bag for buddy)**

The Buddy System

Two techs in high-level PPE

- One tech to perform testing
- One tech to record results, prevent others from entering testing area, observe technique and prompt performing tech for adjustments or to slow pace, provide supplies, communicate results
- An additional tech used as a “runner” in anteroom for extra supplies and a go-between for placing secondary shipping containers into the final shipping box

Instrumentation

- Rule Out (Rapid)
  - Istat
  - Piccolo
  - PocH-100i
  - Cepheid (Ebola cartridge)

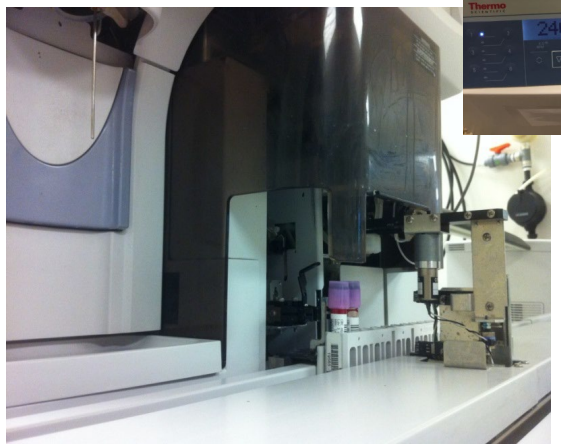
Piccolo (Chemistry) Testing

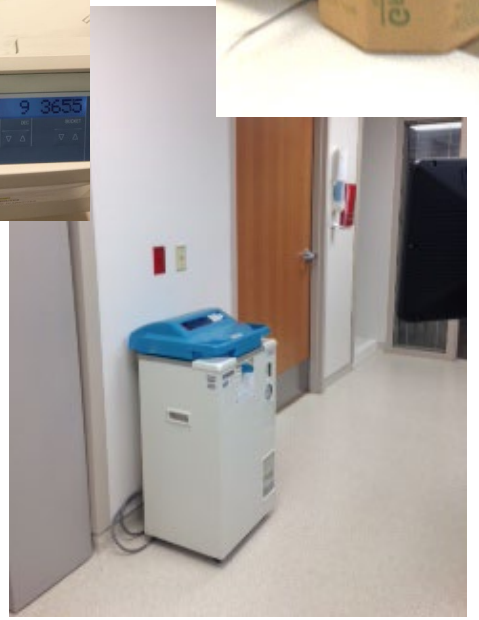
- ☐ Receive test tube rack from buddy.
- ☐ Receive orange biohazard wipe from buddy and place on the disinfectant soaked pad.
- ☐ Retrieve the dark green top tube, mix/invert, then place the tube into the rack.
- ☐ Open the blood tube with a bleach/alcohol wipe covering the cap to prevent aerosol. Set the tube of blood into the test tube rack for stability. Discard the cap and wipe into the BSC trash.
- ☐ Buddy will pass open Piccolo disc to tester. Tester will set the disc on the orange biohazard wipe.
- ☐ Buddy will prepare Piccolo pipettor and tip and hand to the tester.
- ☐ Remove pre-calibrated 100ul of whole blood and deliver slowly to the sample hole at the center of the Piccolo disc.
- ☐ Buddy will hand a bleach/alcohol wipe to the tester.
- ☐ Using the bleach/alcohol wipe, wrap it around the pipette tip and slowly remove it from the pipettor. Dispose of the tip still wrapped in the bleach/alcohol wipe into the bleach container.
- ☐ Wrap the pipettor in a new bleach/alcohol wipe and set to the right hand side, out of the testing area.
- ☐ Securely re-cap the tube of blood with a new cap and place to the back LEFT of the testing rack.
- ☐ Bleach/alcohol your outer most gloves, remove gloves into BSC trash bag. Don a clean pair of outer gloves.
- ☐ ***Important!*** *At this point in the testing procedure, only the buddy will touch the analyzers (Piccolo and PocH-100i) and only the tester will touch the immediate testing materials.*
- ☐ Buddy selects "Analyze". The door will open.

Engineering Controls etc.

- Transport Container to Pick-Up Specimens from Unit (Hard, Lockable with Absorbent Material)
- Limited Access Areas
- Biosafety Cabinet
- Locked Freezer
- Category A Waste Container
- Capped Centrifuge Buckets
- Autoclave
- Negative Air Pressure


2400 0.05
9 9 3655





Debrief

Laboratory Staff, Medical Director, Lab Director, Infection Prevention, Infectious Disease, ED

Walk through from patient arrival to final determination of status

Additional Planning

- ED Liaison – specimen receipt scenarios
  - ED liaison receives ED staff notification that there is a PUI patient. **Samples have not been collected**
  - Samples arrived in the ED Liaison area, **no testing has been performed**, ED staff notifies Liaison that patient is a PUI and nursing will be in HLPPE (no samples sent through tube system)
  - Samples in ED Liaison area, **testing has been performed by the liaison**, ED staff notifies Liaison that patient is a PUI and nursing will be in HLPPE
  - Samples sent to ED Liaison area, **no testing performed AND samples have been sent through the tube system**, ED staff notifies Liaison that patient is a PUI and nursing will be in HLPPE

Decontamination of ED Liaison area

Printed name and signature of person completing this form: _____

Date: _____

Identify areas of specimen contact and testing

Initial all applicable areas		Specimen, Waste or Instrument Retrieval Completed Yes/No/na	Decontamination Completed Yes/No/na
	Specimen Drop-off Bucket		
	Front desk and computer, keyboard, chairs, phones, label printer		
	Back desk and computer, keyboard, chair, phones, label printer		
	I-STAT (4 possible) and reader S/N: S/N:		
	I-STAT specimen rack		
	Centrifuges: STAT-Spin or large centrifuge		

Supervisor Checklist: Highly Infectious Specimen (VRF) Exception Handling

1. Tubes delivered to ED Liaison area (check all that apply)
   - ☐ All tubes still in original transport bag – no testing performed
   - ☐ Pregnancy test (urine / serum) and/or Strep screen performed in ED – samples still in ED
   - ☐ I-STAT performed in ED – sample(s) still in ED
   - ☐ Samples sent to Core Lab – no testing performed
   - ☐ Samples sent to Core Lab – testing performed
   - ☐ Samples sent to Special Procedures Lab

2. If specimen(s) are located in ED Liaison area, shut down ED Liaison area for specimen processing. Evacuate personnel. Place notification sign in window and on door. Assemble transport team to pick up samples and decontaminate area (follow policy).

3. Notification:

THANK YOU!

Next Scheduled Call

Monday, April 15
3 PM - 4 PM EDT

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

CDC Social Media

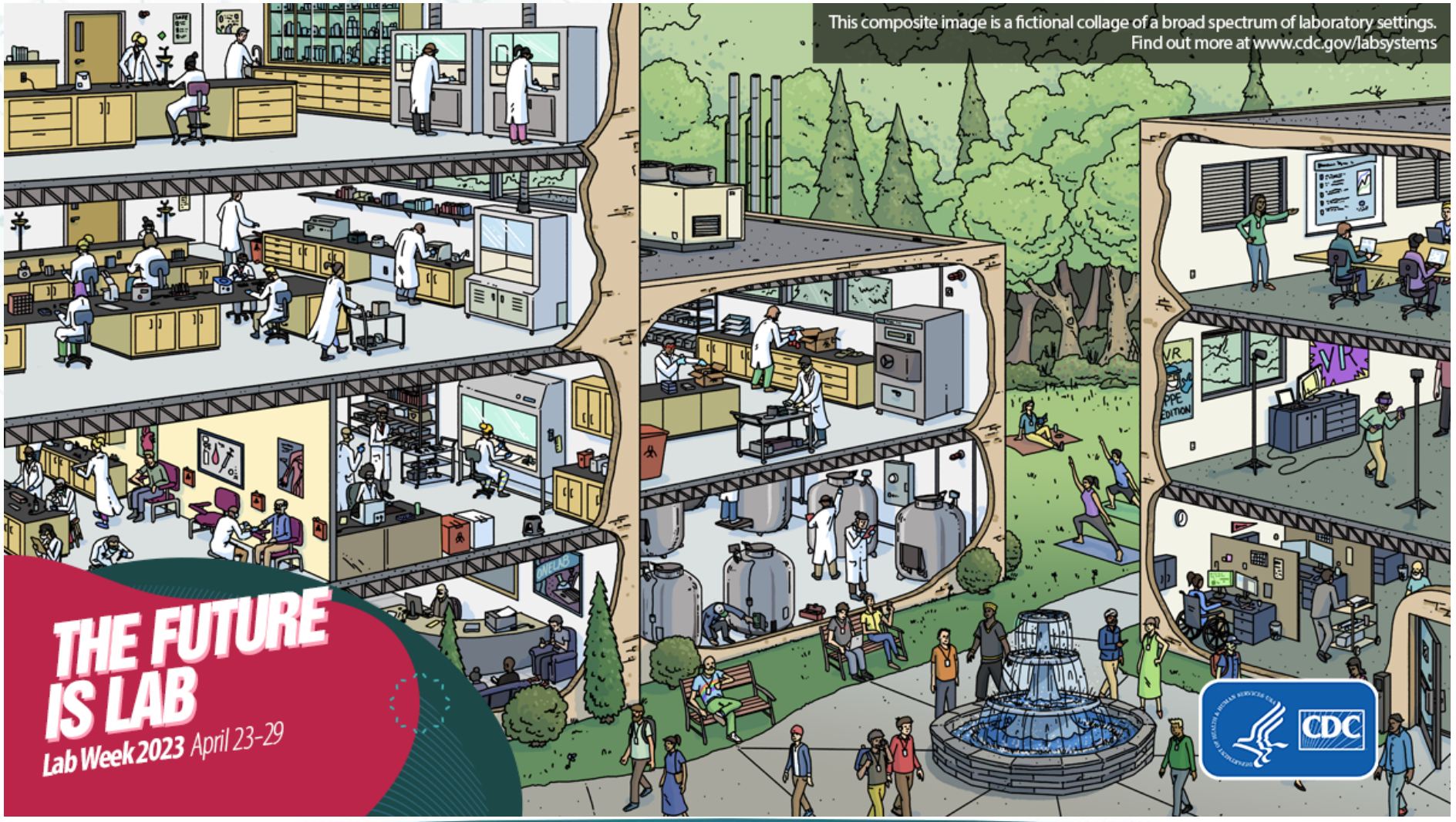
https://www.facebook.com/CDC

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