Laboratory Outreach Communication System (LOCS) Call

Monday, July 17, 2023, at 3:00 P.M. EDT

- **Welcome**
  - Sean Courtney, CDC Division of Laboratory Systems
- **Testing for Viral Vaccine-Preventable Diseases**
  - Paul Rota, CDC Division of Viral Diseases
- **Update on Locally Acquired Malaria Cases and Recommendations for Laboratories**
  - Brian Raphael and Molly Freeman, CDC Division of Parasitic Diseases and Malaria

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.

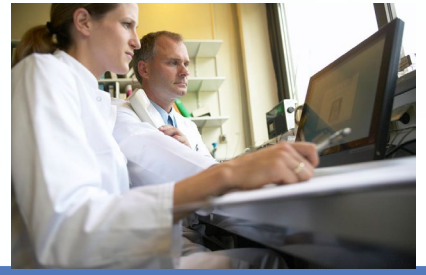
Four Goal Areas

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



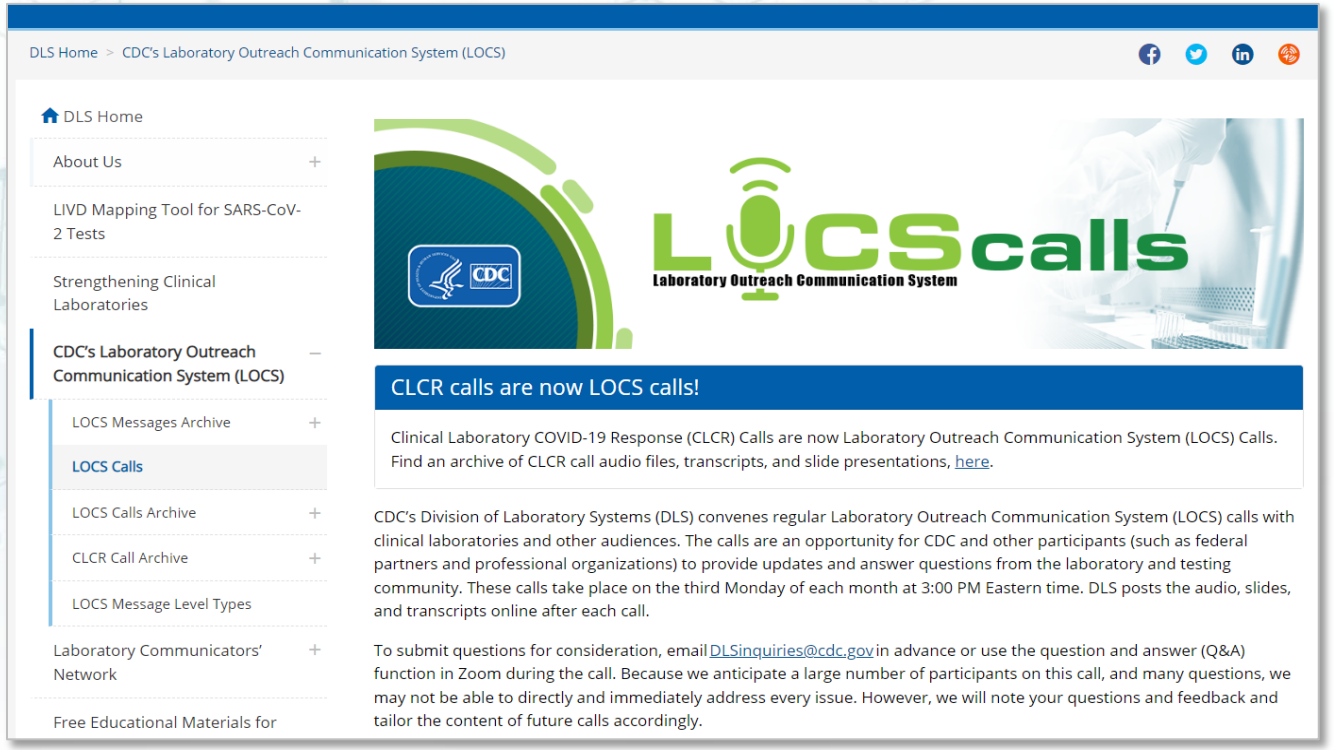
Safe and Prepared Laboratories

- 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



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!

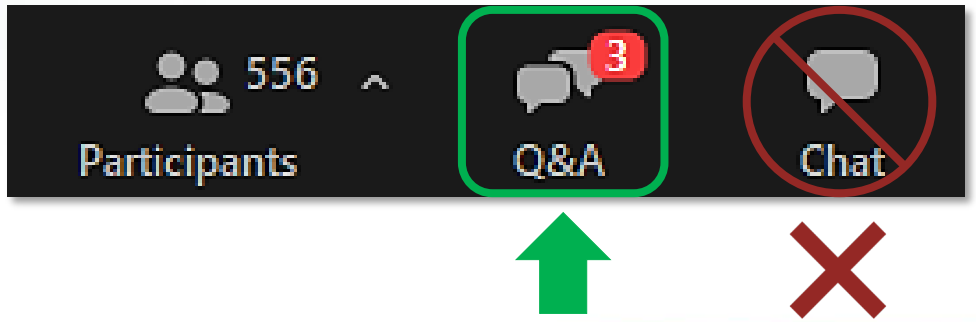
Training and Workforce Development

Questions about education and training?

Contact LabTrainingNeeds@cdc.gov

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.

Testing for Viral Vaccine Preventable Diseases in Commercial/Clinical Laboratories

Paul Rota, Chief, Viral Vaccine Preventable Diseases Branch,
DVD, NCIRD, CDC

The Laboratory Outreach Communication System (LOCS), July 17, 2023

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

What is a Viral Vaccine Preventable Disease

- Measles
- Mumps
- Rubella
- Varicella zoster

Advantages of viral VPD Testing in commercial/clinical laboratories (RT-PCR, PCR, IgM)

- Expanded availability of testing
- Potentially faster turn-around times
- Providers are familiar with commercial labs, “normal” specimen flow
- Link to provider Electronic Medical Record Systems

Challenges for viral VPDs testing in private sector commercial/clinical laboratories (RT-PCR, PCR, and IgM)

- Challenges:
  - Unknown sensitivity and specificity of RT-PCR
  - Lack of detail about performance of IgM assays formats
  - Ability to detect all circulating viral genotypes is unknown
  - Integration with state/county DPH, state PHL for interpretation of results
  - Acceptable specimen types (UTM, Amies, versus VTM)
  - Positive specimens not routinely genotyped
  - Specimens unavailable for additional testing
  - Vaccine-specific assays (for measles) not available; loss in response time and risk for vaccine reactions to be considered as measles cases
  - Specimen storage, unknown specimen stability

Considerations for Commercial/Clinical laboratories

- Turnaround time
- Availability of serum samples for follow up testing including IgM capture assays and IgG avidity
- Reflex testing
- Routine genotyping for positive specimens (measles, mumps, rubella)
    - Not urgent but data are needed to maintain an accurate sequence database
    - Sequence data needed to track transmission and verify continued elimination of measles and rubella
- Distinguish between vaccine and wild-type virus for varicella
- Collect, ship, and store samples in manner that is consistent with CDC Test Directory

CDC Goals

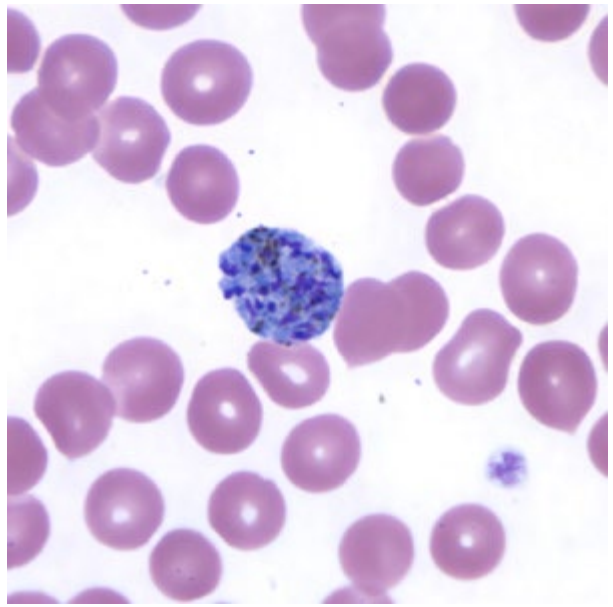
- Continue to engage in dialog with commercial laboratories
  - Develop guidance for commercial laboratories for submission of specimens to CDC including CDC POCs (with APHL)
- Assist commercial laboratories with validation

- Genotyping and vaccine reactions
  - Develop provider awareness on measles vaccine reactions and when laboratory testing is required
    - Develop provider awareness on availability of vaccine specific tests in public health laboratories
  - Awareness for state/county PHLs
  - Develop workflows for routine reflexing of positive samples to CDC or VPD-RCs for genotyping or VZV strain specific PCR.

Update on Locally Acquired Malaria and Recommendations for Laboratories

Brian Raphael, PhD, PHLD(ABB)
Chief (Acting), Laboratory Science and Diagnostics Branch
Division of Parasitic Diseases and Malaria

Molly Freeman, PhD
Lead, Malaria Laboratory Research & Development Team
Laboratory Science and Diagnostics Branch
Division of Parasitic Diseases and Malaria



Schizont of P. vivax in a thin blood smear
Image from: https://www.cdc.gov/dpdx/malaria/index.html

Current status of locally-acquired malaria cases

- **6 cases of locally-acquired malaria since May 2023 in Florida**
- **1 case reported in Texas in June 2023**
- **Cases determined to be caused by *Plasmodium vivax***
- **Ongoing state public health response**
  - **Active surveillance for additional cases**
  - **Mosquito surveillance and control measures**
  - **Outreach and prevention education**

- **What is CDC doing?**
  - Providing recommendations to U.S. residents and clinicians for malaria prevention and treatment
  - Responding to requests for information
  - Supporting investigations through
    - Laboratory testing (including remote telediagnosis, confirmatory testing)
    - Epidemiology technical assistance
    - Entomology (mosquito testing, technical assistance)

Malaria Diagnostics

- **Microscopic examination of thick and thin blood smears is the "gold standard"**
  - Should be available 24 hours/day
  - Not always possible to differentiate species
- **PCR**
  - Laboratory developed tests
  - Note that some assays can only differentiate *P. falciparum* from other *Plasmodium* spp.
  - Assays should be selected that can definitively differentiate human-infecting species including *P. vivax*
- **Rapid Diagnostic Assays (RDTs)**
  - Detects malaria antigens in blood specimen (may differentiate *P. falciparum* from other *Plasmodium* spp.)
  - Single FDA cleared assay available in the US; not CLIA-waived

Malaria RDTs

- **BinaxNOW™ Malaria RDT is the only FDA-approved RDT for use in the U.S.**
  - *In vitro* immunochromatographic assay for the qualitative detection of *Plasmodium* antigens in blood
- **When to use:**
  - Aid in the rapid diagnosis of human malaria infections and in the differential diagnosis of Pf from Pv, Po, and Pm
  - Test individuals with clinical suspicion of malaria, **not** for use in screening asymptomatic populations
- **Specimen collection and laboratory confirmation**
  - Venous (within 3 days) or capillary EDTA anticoagulated whole blood (immediately)
  - Additional testing needed to differentiate Pv from Po and Pm
  - Microscopy still needed for clinical management; clinicians should request an RDT and microscopy concurrently
    - Negative RDT results must be confirmed by thin / thick smear microscopy x 3
    - Positive RDT results require species identification for non-Pf infections and % parasitemia

https://www.globalpointofcare.abbott/us/en/product-details/binaxnow-malaria

Importance of molecular assays

- **Differentiating *Plasmodium* spp. is critical**
  - Important to ensure additional treatment for *P. vivax* or *P. ovale* species, to prevent relapsing illness(es)
- **Genotyping**
  - Sequence analysis may help elucidate the genetic relationships between strains
  - Understanding multiplicity of infection (i.e., are individuals infected with one or more strains)
  - Most published reports of molecular genotyping have been conducted in endemic areas for population-based studies. CDC is assessing multiple genotyping methods including high-resolution genomic approaches for analysis of specimens from individuals in a **non-endemic area**

What can laboratories do?

- **Ensure availability of thick and thin blood smear analysis and RDTs in hospital clinical laboratories**
  - Rapid telediagnosis of blood smear images is available from CDC (M–F, 9 am – 5 pm)
  - Image and sample requisition form are uploaded to secure server
  - DPDx@cdc.gov
- **Submit specimens to public health laboratory for confirmatory analysis including PCR**
- **Retain positive specimens for genotyping analysis**

Resources and Contact Information

Points of Contact
Brian Raphael (elx9@cdc.gov)
Molly Freeman (evy7@cdc.gov)

Malaria Hotline
malaria@cdc.gov

Preapproval for submission of diagnostic specimens
parasiteslab@cdc.gov

More information on malaria
CDC - Parasites - Malaria
CDC – DPDx – Diagnostic Procedures
CDC - DPDx - Malaria

Surveillance specimens
MalariaLab@cdc.gov

Telediagnosis at CDC
DPDx@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.

Next Scheduled Call

Monday, August 21

3 PM - 4 PM EDT

CDC Social Media

https://www.facebook.com/CDC

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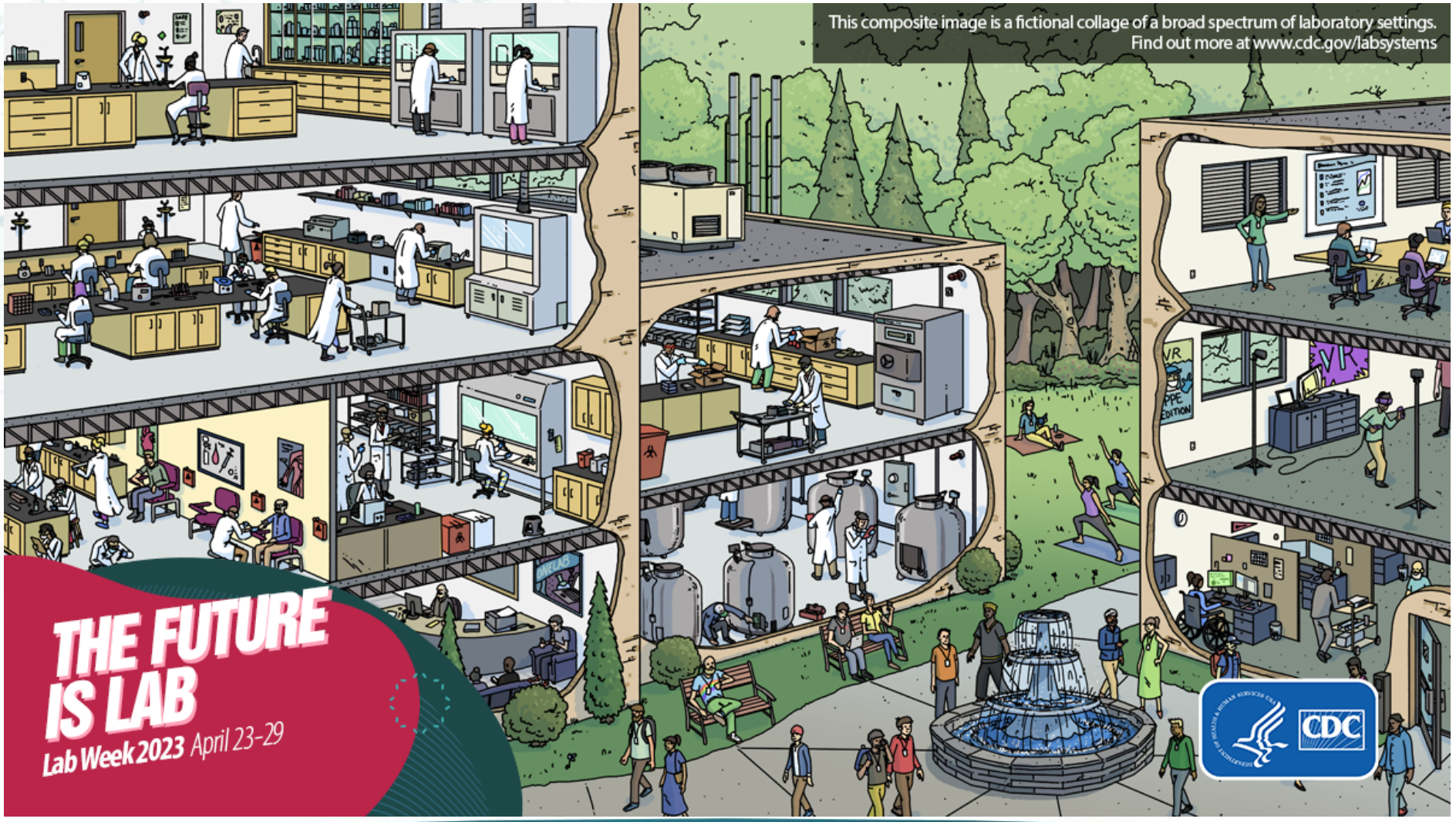
https://www.instagram.com/cdcgov

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