Laboratory Outreach Communication System (LOCS) Call

Office of Laboratory Systems and Response (OLSR)

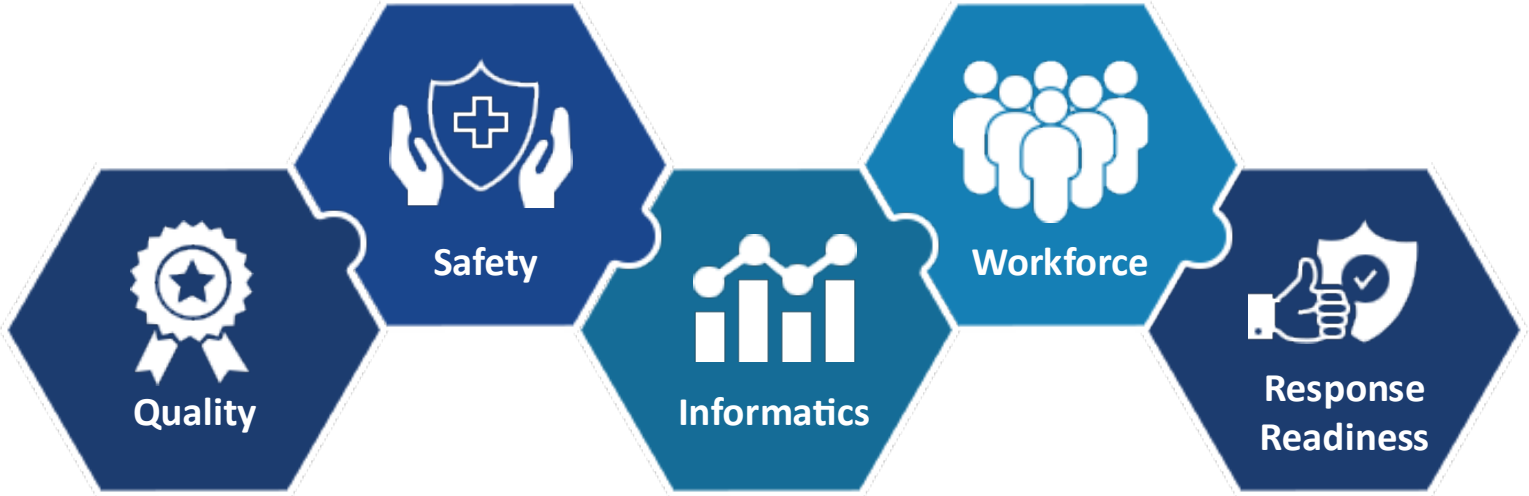
20 July 2026, at 3:00 P.M. ET

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

Agenda

- **Welcome & Announcements**
  - Jasmine Chaitram, Office of Laboratory Systems and Response (OLSR), CDC
- **Cyclospora Outbreak Update**
  - Dianna Blau, Parasitic Disease Branch, CDC
- **Risk Assessment and Mitigation for Routine Diagnostic Testing**
  - Jake Bunn, Division of Laboratory Systems, OLSR
- **Sysmex Hematology Instruments and Sample Processing**
  - Andy Hay, Sysmex America, Inc.
- **Recommended Testing Considerations for Novel Influenza A Viruses**
  - Todd Davis, Influenza Division, CDC
- **Lab Director University**
  - Karen Sutterer, CMS
- **CMS Update**
  - Christina Buie, CMS

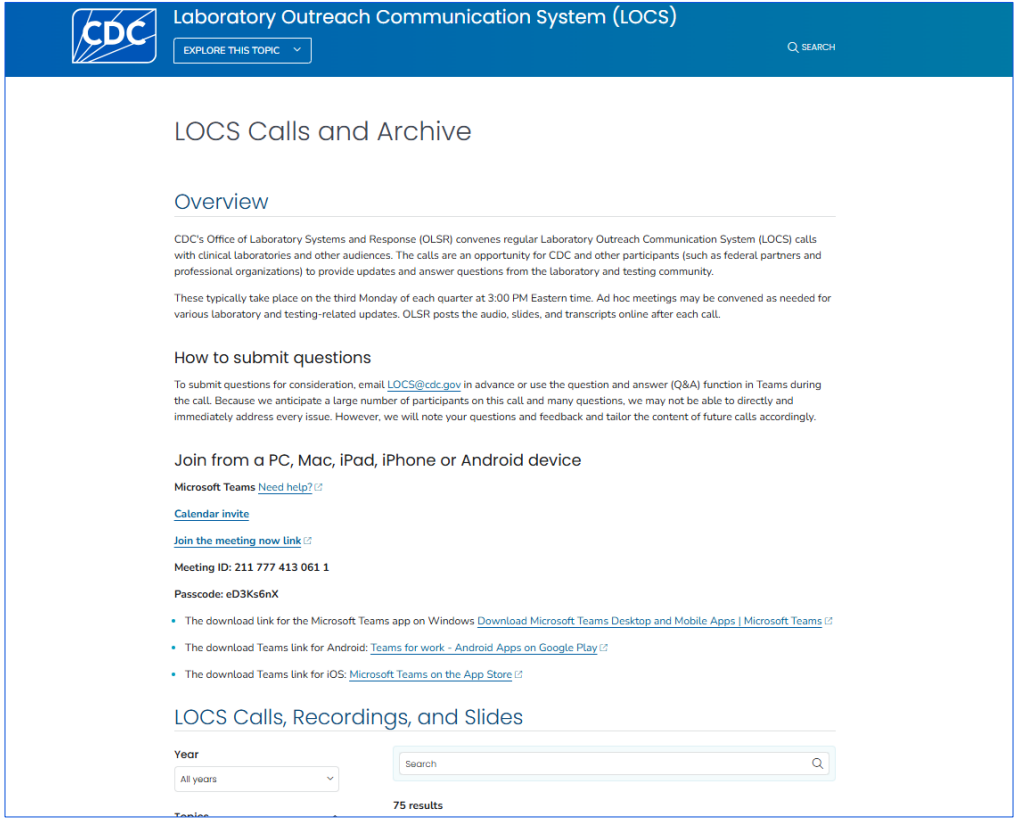
Office of Laboratory Systems and Response (OLSR)



LOCS Calls

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

[LOCS Calls and Archive | LOCS | CDC]



The findings and conclusions in these slide decks are those of the authors and may not necessarily represent CDC’s official position on the topic(s) covered.

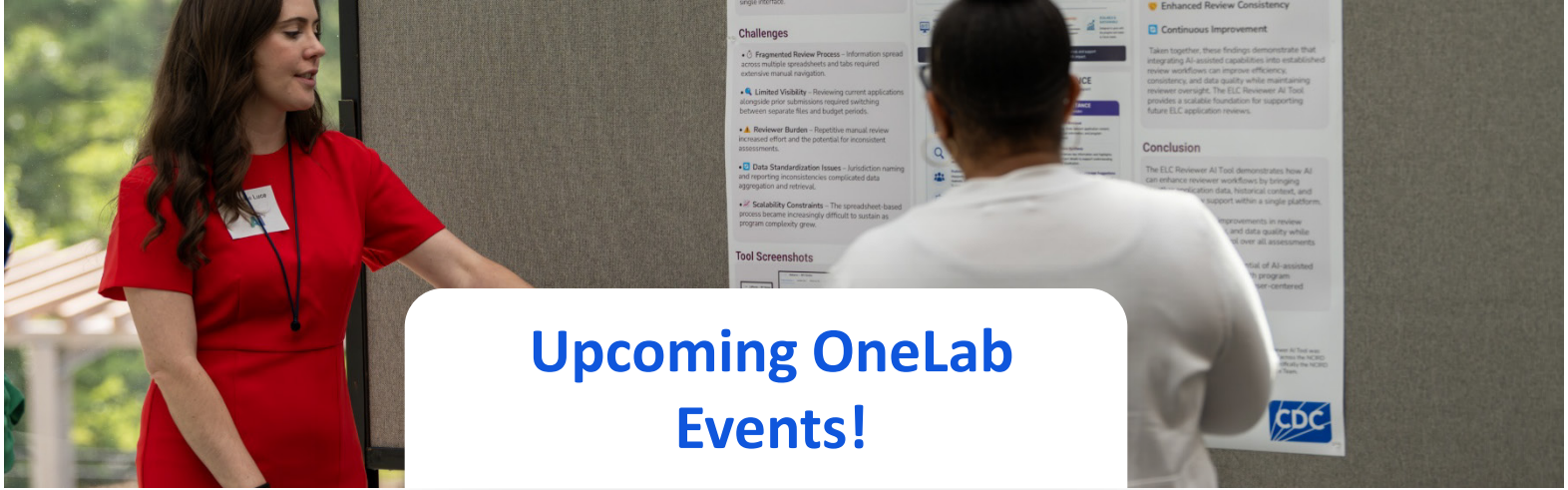
How to Ask a Question

- **All participants are muted and chat feature is disabled**
- **Using the Microsoft Teams System**
  - Click the Q&A button in the Microsoft Teams meeting
  - Type your question in the Q&A box and submit it
  - Please do not submit a question using the chat button
  - For non-laboratory testing questions, please contact CDC-INFO at cdc-infostaff@cdc.gov
  - 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

Announcements

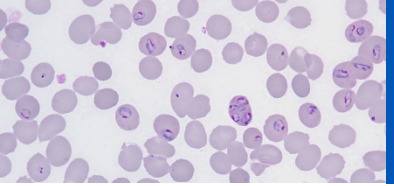
Access to ISO 35001:2019—Biorisk Management for Laboratories

- **If your institution is interested in receiving access to ISO 35001:2019**
  - Designate a point of contact (POC) responsible for biorisk management at your institution (e.g., laboratory director, biosafety officer, etc.)
  - POC will email the DLS Biosafety mailbox (DLSBiosafety@cdc.gov) expressing interest and include your institution's name and address
  - POC will be notified if your institution is approved and coordinate distribution using the names, email addresses, and job titles of individuals who should receive access
  - If you have any questions or require further information, contact DLS at DLSBiosafety@cdc.gov



Upcoming OneLab Events!

Clinical Laboratory Improvement Amendments Request for Information	**July 29th, 2026 12:00 PM ET**
Malaria Laboratory Diagnostic Testing	**September 16th, 2026 12:00 PM ET**
Fundamentals of Laboratory Director University	**September 23rd, 2026 12:00 PM ET**



Background and Resources

Rapid Diagnostics for Malaria

Malaria: an urgent health issue
Malaria is a mosquito-borne disease that can cause severe complications and death if left untreated. In the absence of prompt diagnosis and appropriate treatment, uncomplicated malaria can rapidly progress to severe life-threatening disease.

Malaria in healthcare settings
Travelers returning from areas with malaria transmission can present with symptoms to **any** hospital across the country. **All** U.S. hospitals should be able to perform urgent malaria diagnostic testing.

Malaria burden in the U.S.

Each year, on average:
- **2,000** malaria cases*
- across all **50** states
- **7** malaria related deaths

**Travel-associated malaria cases*

Diagnostic testing
Diagnostic testing for malaria should be done urgently and without delay using point-of-care or laboratory-based testing with turnaround times of **a few hours**. Results are necessary to initiate treatment and guide clinical management. Clinicians should be informed of the turnaround time and urgency for obtaining results when a malaria test is ordered.

Microscopic evaluation of blood specimens must be performed from all individuals with suspected malaria to confirm *Plasmodium* species infection, determine species, calculate parasitemia, and monitor response to treatment. Treatment can be initiated if preliminary review of a blood smear indicates intracellular parasites. In addition, a malaria antigen rapid detection test (RDT) or a nucleic acid amplification test (NAAT) should be performed concurrently if they can provide results more quickly to support prompt treatment.

Smears should be prepared immediately after specimen collection. Blood that is held too long before smear preparation results in poor morphological features that complicate *Plasmodium* species identification. Both thick and thin smears should be prepared.

If positive, parasitemia should be estimated as soon as possible to inform treatment decisions. Patients with a parasitemia of ≥ 5%, regardless of clinical symptoms, require treatment with IV artesunate and possibly a higher level of care.

Laboratory resources for malaria diagnosis

Laboratory bench aids

- Preparation of blood smears
- Staining for malaria parasites
- Identification of *Plasmodium falciparum*
- Identification of *Plasmodium vivax*
- Identification of *Plasmodium ovale*
- Identification of *Plasmodium malariae*
- Calculating percent parasitemia and life cycles of *Plasmodium* species
- Comparison of the *Plasmodium* species which cause human malaria
- Blood stage parasites, thin blood smears

Other resources

- Malaria diagnostics tests
- DPDx- Laboratory identification of parasites of public health concern, diagnostic procedures
- Clinical guidance: Malaria diagnosis & treatment in the U.S.
- Inactivation of Ebola/Marburg for malaria testing
- Request CDC Laboratory diagnostic assistance: dpdx@cdc.gov

CDC Malaria Clinical Hotline

Healthcare providers may call CDC's Malaria Clinical Consult Service for questions related to malaria prevention, diagnosis, or treatment.

- **Monday – Friday**, 9 a.m.-5 p.m. ET
  - 770-488-7788 *or*
  - 855-856-4713 (toll free)
- **Weekends and after hours**
  - 770-488-7100

Situational Update: 2026 Cyclospora Season

Dianna Blau, Acting Branch Chief, Parasitic Diseases Branch

Anna Peterson, Biologist, Laboratory Sciences and Diagnostics Branch

U.S. Cyclosporiasis Surveillance & Outbreak Response

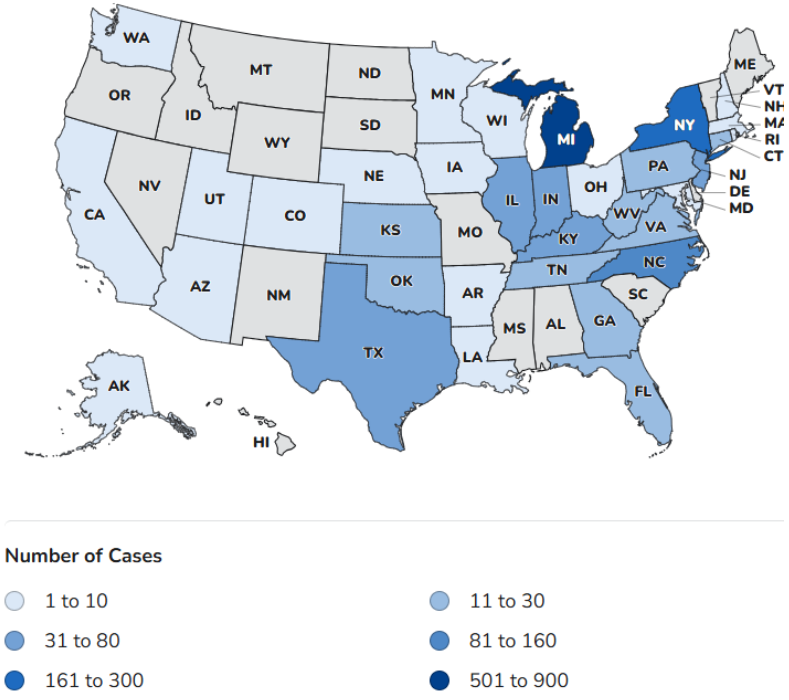
- Nationally notifiable since 1999
- Reportable in 47 states, Washington D. C. and New York City
- CDC outbreak response efforts focus on cases who did not report travel outside of the U.S. during the 14 days prior to illness onset
- Epidemiologic cluster investigations includes collaboration between CDC, jurisdictional partners, and FDA Coordinated Response and Evaluation (CORE) Signals and Response Teams
- An epidemiologic cluster is defined as two or more people who shared a common food exposure within the same (or similar) time frame

CDC *Cyclospora* Genotyping Approach

- CDC uses an 8-marker amplicon approach to generate sequence data from *Cyclospora* parasites in stool.
  - Stool samples sent to CDC or partner state public health laboratories.
- Data analyzed through bioinformatic workflow to identify clusters of parasites that are genetically similar and with collection dates within a 2-week sliding window (temporal-genetic clusters/TGCs).
  - TGC data are NOT used to identify outbreaks, but rather as tools to inform cluster and traceback activities. TGCs are reported in SEDRIC.
- Caveats: *Cyclospora* parasites are very biologically different than other foodborne pathogens, making generating sequence data challenging.

Current Situation

- Multiple jurisdictions continue to report an unusually high number of cyclosporiasis cases
  - As of July 13, 1,645 lab-confirmed cases of domestically acquired from 34 states with more than 5,100 additional reports that require further analysis to confirm case definition
- Hospitalization <10%; no deaths reported
- Several clusters of domestically acquired cases being investigated
- Large outbreak in at least 5 midwestern states that have epidemiologic link to iceberg lettuce served at Taco Bell



https://www.cdc.gov/cyclosporiasis/php/surveillance/index.html

Multistate Outbreak

- FDA traceback investigation identified convergence on single supplier, Taylor Farms de Mexico
  - On July 17th Taylor Farms de Mexico voluntarily removed all iceberg lettuce sourced from central Mexico and issued recall alert Taylor Fresh Foods Recall alert

- For up-to-date information on Cyclosporiasis Surveillance, on Iceberg Lettuce Outbreak and FDA Investigation

Division of Laboratory Systems

Conceptual Risk Assessment and Mitigation Measures for Routine Diagnostic Testing for Patients Under Investigation for a Viral Hemorrhagic Fever (VHF)

Jake D. Bunn, MBA, MLS(ASCP)CM, LSSBB

CLIA Core Team Lead (Acting)
Clinical Laboratory Scientist

Risk assessment steps for testing specimens from patients under investigation for a VHF

- What tests need to be run for this patient to manage basic care?
- What clinical laboratory systems and instruments are used to perform these tests?
- What risks are there to laboratory personnel when performing these tests on these instruments?
- What mitigation measures are needed to reduce those risks when performing those tests?
- What are the relative risks of performing these tests after mitigation measures have been applied?

What tests need to be run for this patient? (examples only)

- **Hematology:** Complete Blood Count (CBC), Hematocrit, Hemoglobin
- **Coagulation:** Prothrombin Time (PT)
- **Blood chemistry:** Basic Metabolic Panel (BMP), Liver Function Tests (LFT), Electrolytes, Blood Gas and Lactate levels
- **Urine chemistry:** Urinalysis
- **Microbiology:** Blood culture, Malaria

What systems and instruments does my clinical laboratory use to perform these tests? (examples only and generic)

- **Hematology** – pure closed systems
- **Coagulation** – pure closed systems
- **Blood chemistry** – primarily closed systems
- **Urine chemistry** – pure closed systems
- **Microbiology**
  - Blood cultures pure closed systems during incubation, open system during processing positives
  - Malaria thick/thin smears
- **POC testing – Malaria, blood gas, lactate**

BLOODBORNE TRANSMISSION RISKS AND MITIGATION (EXAMPLES ONLY)

Instrument/Test	Risk	Mitigation
Hematology	Contaminated tubes; faulty tube cap can cause splatter; opening analyzer during operation can result in splash exposure; emptying biohazard waste could result in spillage; cleaning micro-clots or replacing probes could cause sharps injury	Eliminate manual tube inversion; wear gloves, use splash shield, regularly decontaminate surfaces; don't bypass safety door interlocks; place all waste in leak-proof secondary containment bins; wear appropriate PPE when transporting liquid waste; use forceps or manufacturer tool to clear a clot
Coagulation	Tube shatters in centrifuge; cleaning micro-clots or replacing probes could cause sharps injury; high volumes of biohazard waste; contamination of racks, rings, or belts	Practice centrifuge safety if tube breaks or imbalance (face shield, N95, forceps); wear PPE and use forceps when clearing a clot or cleaning a probe or instrument; place all waste in leak-proof secondary containment bins; wear appropriate PPE when transporting liquid waste

BLOODBORNE TRANSMISSION RISKS AND MITIGATION (EXAMPLES ONLY)

Instrument/Test	Risk	Mitigation
Blood Chemistry	Manual manipulation of tube caps could cause splatter; if shields left open, rapid mixing could cause micro-aerosols that settle on surfaces; opening doors while system under pressure can cause a splash; cleaning sampling probe could cause sharps injury; high volumes of biohazard waste	For manual uncapping, use a Biosafety Cabinet (BSC) or splash shield; ensure splash guards, vents, and rubber seals are intact; wear face shield, goggles, mask to investigate instrument fluidics error or mechanical jam; use PPE and forceps to clear a clot or replace a probe; place all waste in leak-proof secondary containment bins, wear appropriate PPE when transporting liquid waste
Urine Chemistry	Removing a lid or cap with gross hematuria could cause splatter; opening analyzer during an active cycle can release airborne droplets; contact with the contaminated plastic strips in the collection bin; shattering of the plastic cuvettes inside sorting mechanisms	For manual uncapping, use face shield, goggles, mask, splash shield; ensure instrument software cuts power when panel opened; use gloves and forceps to clear jammed strips or broken plastic fragments

BLOODBORNE TRANSMISSION RISKS AND MITIGATION (EXAMPLES ONLY)

Instrument/Test	Risk	Mitigation
Blood Cultures	Piercing rubber septum is a sharps risk; back-spray of blood and broth when puncturing septum; forcefully plate streaking or aggressive heat-fixing can cause splatter; sharps in medical waste containers	Wear heavy-duty gloves and use holding block during septum puncture; use BSC for processing; regularly decontaminate surfaces; carefully streak plates; use safe gram staining practices; use shatter-resistant bottles
Malaria Smears	Micro splatters; sharps injury; aerosols during heat fixing; contamination onto microscope	Use BSC for uncapping and initial slide prep; wear gloves, face shield, and mask when handling slides.

BLOODBORNE TRANSMISSION RISKS AND MITIGATION (EXAMPLES ONLY)

Instrument/Test	Risk	Mitigation
POC Tests	Syringe cap removals and splatter; air bubble expulsions; sharps injuries during blood collection and transfer; surface contamination	Use single-use, pressure-activated lancets and puncture-proof sharps box; use gloves, gown, face shield, and mask; safely use needle and syringe to collect and dispense blood; practice surface decontamination

What are the relative risks of these various tests after mitigation measures have been applied? (examples only)

Urine chemistry – very low risk

Hematology – low risk

Coagulation – low risk

POC tests – low risk

Blood chemistry – low-moderate risk

Blood cultures – moderate risk

Malaria smears – moderate risk

Frequently Asked Questions (FAQs)

Frequently Asked Questions (FAQs):

What laboratory testing can we do and not do for suspected Ebolavirus patient?

All routine laboratory testing can be done in a BSL 2 following Standard Precautions for All Patient Care and the *Bloodborne Pathogen Standard (29 CFR 1910.1030)*.

Why perform malaria testing?

Malaria may be more likely than Ebola – rule in rule out.

Frequently Asked Questions (FAQs):

Would instrument manufacturers service instrument if a confirmed positive was tested?

If there are concerns, please obtain written notification from your manufacturer that they will not service the instrument; let us know and we can try to talk to the manufacturer. Send to DLSinquiries@cdc.gov

Can resources be developed to guide laboratories on how to disinfect equipment if a confirmed positive was tested?

Your laboratory would need to consult each manufacturer and follow their instructions for use.

Frequently Asked Questions (FAQs):

How should liquid waste generated by laboratory instrumentation be handled?

For handling waste within your laboratory/facility can refer to PPE Selection Matrix for Occupational Exposure to Ebola Virus OSHA3761.pdf which has a section about PPE for Handling, transporting, treating, and disposing of waste.

For waste disposal generated by your facility please consult your local and state partners on how this is handled at your specific location.

Frequently Asked Questions (FAQs):

What if we do not have point of care testing for liver function tests, coagulation testing (manufacturer's instructions for use states for coumadin patients only), urinalysis, and complete blood count differential?

CDC is not requiring point of care testing for routine diagnostics for suspect patients. These tests can be done in a BSL 2 facility following Standard Precautions for All Patient Care and the Bloodborne Pathogen Standard (29 CFR 1910.1030).

Frequently Asked Questions (FAQs):

Are there training resources available for donning and doffing PPE?

CDC offers calitraining courses for donning and doffing PPE through the OneLab REACH™ program. Additionally, OSHA provides guidance for appropriate PPE.

Donning and Doffing PPE in Clinical Laboratories: Basic PPE for Routine Laboratory Procedures | OneLab REACH

OSHA3761.pdf

Who certifies a laboratory's biosafety level (BSL)?

There is no "certification" for biosafety levels. Please refer to BSL guidance in the Biosafety in Microbiological and Biomedical Laboratories—6th Edition commonly referred to as the BMBL.

Frequently Asked Questions (FAQs):

How would contact tracing be done if a confirmed positive was tested?

A State Epidemiologist/Health Department would handle in collaboration with CDC.

What if the laboratory is not informed by the clinical care team that submitted specimens were from a patient under investigation for VHF?

It is important to always follow the Standard Precautions for All Patient Care and the Bloodborne Pathogen Standard (29 CFR 1910.1030) since it's not known what is in the specimens received in the laboratory.

Frequently Asked Questions (FAQs):

What would happen if there was an outbreak of a VHF? Would there be support from local, state and federal partners?

The Laboratory Response Network (LRN) offers testing for VHFs and other high consequence pathogens. Contact your state public health laboratory for instructions on packaging and shipping.

Sysmex Hematology Portfolio

High Risk Sample Processing

Andy Hay, Chairman of the Board of Directors
Jill Crist, Senior Manager, Hematology Solutions

Comprehensive Portfolio of Hematology Testing Solutions

Consistent operation, reagents, controls and workflow… Providing comparable results across your health network

from satellite lab …

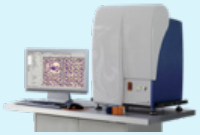
pocH-100*i*

XW-100

XQ-320

XN-L 350, 450, 550

DM1200



DM9600

DC-1

to core lab …

XN-1000 (-R, -BR, -PR)

XN-1000

XN-2000

XN-3100 with DI-60

Integrated Slide Processing

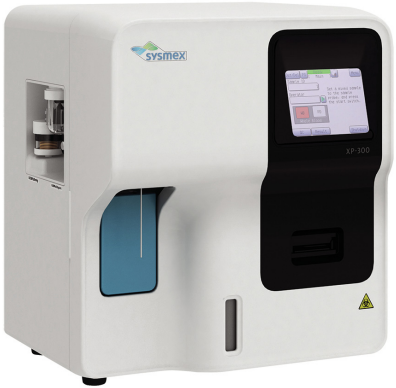
XN-9100 LTM (TS+A1c)

Not recommended for high-risk samples

- Open tube sampling only and should not be used

XW-100

XP-300



XQ-320

XN-330/350

Use of Sysmex PocH-100i

- The Sysmex PocH-100i may be used to analyze samples from known high risk patients in closed tube sampling mode, but **Sysmex does not recommend its use inside a BSL level 3 environment for reasons more associated with the service support of the device than the design and use of the device itself.**
- Sysmex service engineers may not enter BSL level 3 environments to service the system and typical service on this instrument is performed by return to base servicing. Carriers may not accept the instrument for transportation. Sysmex recommends other instruments as more suitable and in main lab settings.

pocH-100*i*

XW-100

- The Sysmex XW-100 is a CLIA Waived hematology instrument with an intended use in clinically uncomplicated patient testing situations.
- FDA Intended Use statement:
  It (The XW-100) is not for use in diagnosing or monitoring patients with primary or secondary chronic hematologic diseases/disorders, oncology patients, critically ill patients, or children under the age of 2.

Acceptable Sysmex closed-tube solutions

- Sysmex closed-tube analyzers are acceptable for all sample types
  - We believe all samples should be handled as potentially high-risk

XN-430/450

XN-550

XN-1000

XN-2000

XN-3100

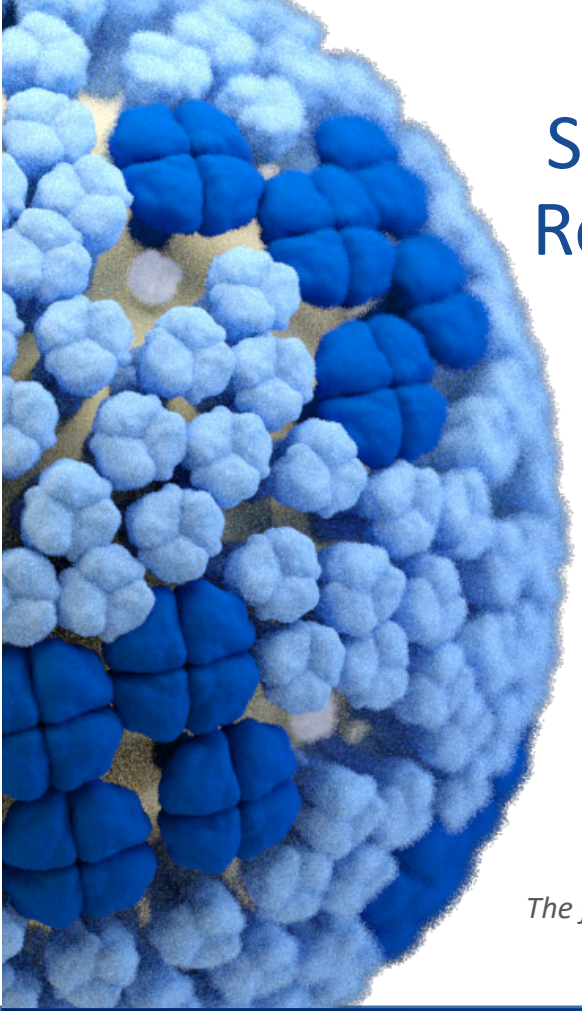
XN-9100

External blood smear preparation

- The standalone Cellavision Digital Morphology Systems from Sysmex require a blood smear to be prepared outside of the instrument.

- Labs should follow guidance in the preparation of manual blood smears or use fully automated closed tube sampling systems which are available as part of XN-3100 or XN-9100 configurations.

Together for a better
healthcare journey



Summer 2026 Influenza Surveillance and Recommended Testing Considerations for Novel Influenza A Viruses

Todd Davis

Virology Surveillance and Diagnosis Branch

Influenza Division, National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

Atlanta, GA 30333

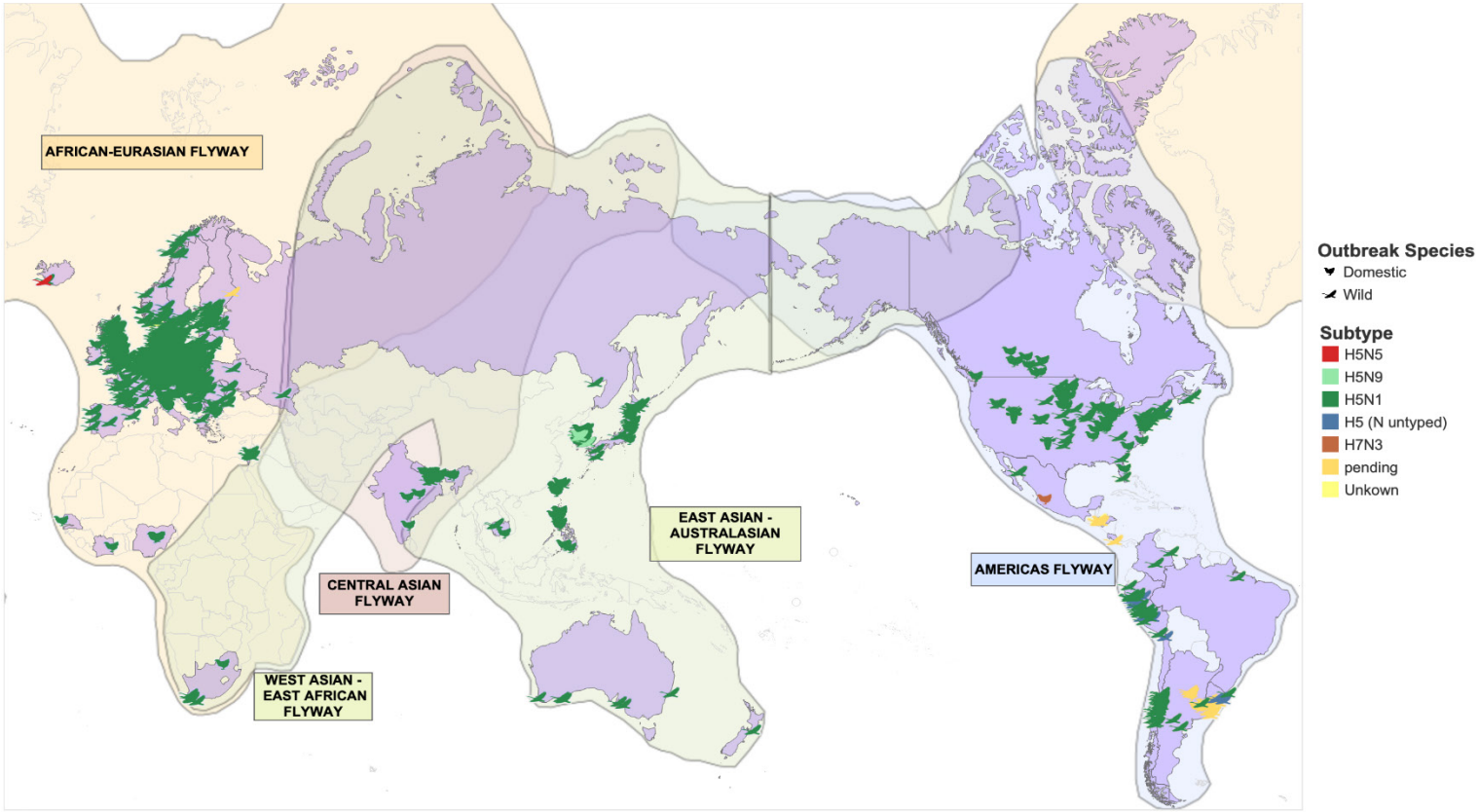
The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

STRATEGY FOR SUMMER 2026 INFLUENZA SURVEILLANCE

- Identify novel influenza A viral infections via symptom monitoring among workers and others with recent exposures to influenza virus infected animals on farms or other locations
- Conduct outreach and education to people who work with, exhibit, and/or are exposed to animals and related animal by-products
- Encourage ongoing influenza testing for both seasonal and novel viruses of individuals with compatible illness
  - Recent history of relevant exposures (e.g., dairy cattle, raw milk, wild birds, poultry, swine, agricultural event attendance)
  - Participation in communal activities or living in congregate settings, such as summer camps
- Conduct surveillance for novel influenza A virus infection among severely ill patients
  - Collection of lower respiratory tract specimens from patients with severe respiratory disease
  - Subtyping influenza A positive specimens
- Conduct surveillance for novel influenza A virus infections in the community
  - Unexplained clusters of respiratory illness, including collection of specimens for testing
- Monitor influenza surveillance data for any unexpected patterns
  - Outpatient, ED visits, Hospitalizations, Mortality
  - Detections of A(H5) and influenza A in wastewater

Summer 2026 Influenza Surveillance Guidance

Laboratory – Reported Animal/Avian Influenza Collected Since Feb. 1, 2026

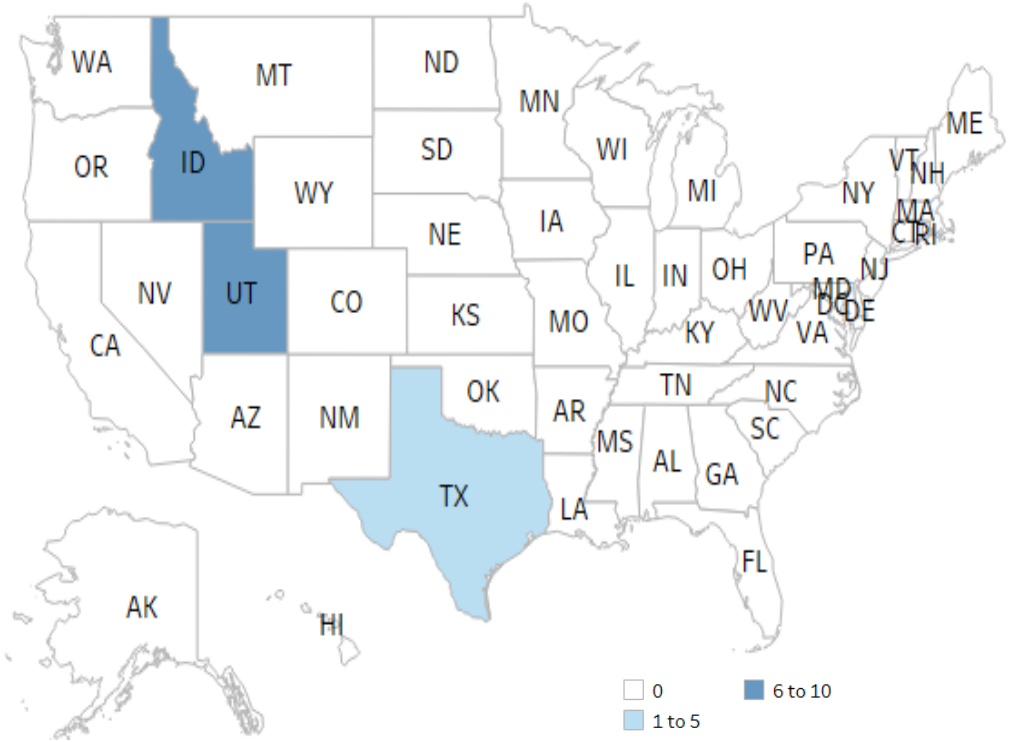


Reported to WOAH and/or FAO; data is from WOAH and FAO open sources that are available online
Flyway regions map is from Arctic Biodiversity Data Service geoserver WMS map (https://geo.abds.is/geoserver/ows?)

Highly Pathogenic Avian Influenza A(H5) in U.S. Dairy Cattle

- In the last 30 days, there have been **20** new detections of HPAI A(H5) in **Idaho (9), Texas (3) and Utah (8).**
- Since March 2024, USDA APHIS has confirmed HPAI A(H5) in **1,160** dairy herds across 20 states.

U.S. cases of A(H5) in dairy cattle in last 30 days



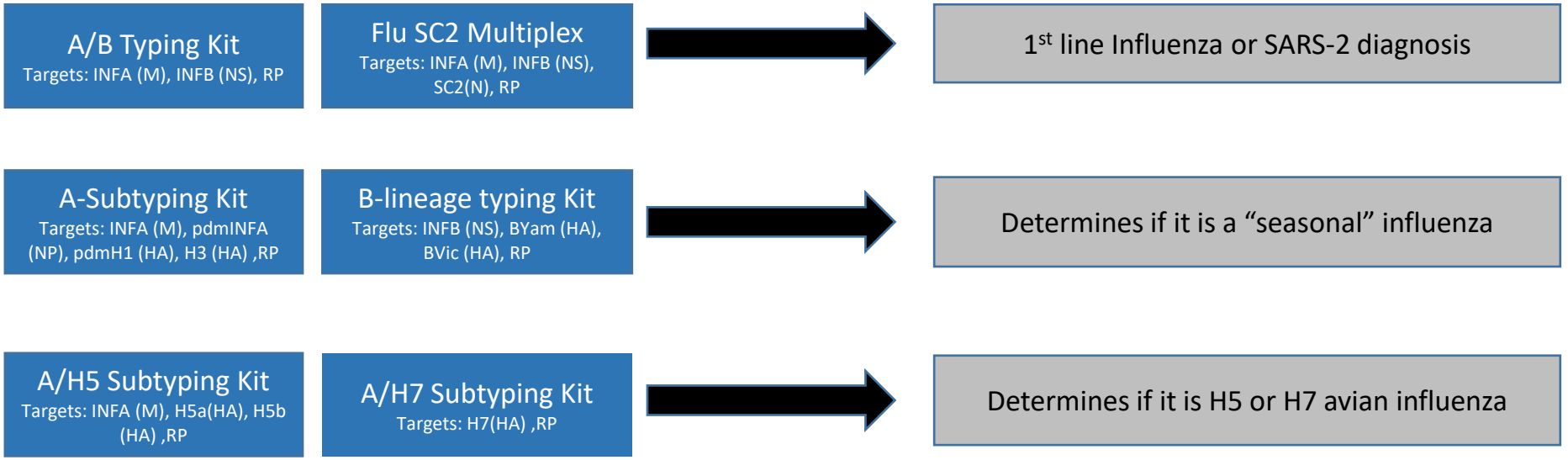
HPAI Confirmed Cases in Livestock | APHIS

SUMMER 2026 INFLUENZA SURVEILLANCE – A(H5)

- **Surveillance for seasonal influenza viruses and monitoring for novel influenza A virus infections, including HPAI A(H5), remain critical during the summer months**
- **Influenza testing (NAAT-based preferred) for persons with compatible illness**
  - Persons with animal or raw animal product exposures (including collection of conjunctival swabs if symptoms present)
  - Severely ill hospitalized patients (including collection of lower respiratory samples when feasible)
- **A(H5) testing should only be performed when clinical, epidemiologic, or public health response criteria are met**
  - Follow recommended diagnostic testing algorithm and avoid unnecessary or out-of-sequence subtyping
  - Deviations from recommended workflows may increase the likelihood of false-positive results and unnecessary public health investigations and response activities
- **Immediately notify State Public Health Departments**
  - Specimens may be requested by the State PHL or CDC for additional testing and virologic characterization
  - Any positive or inconclusive influenza A(H5) result or a result indicating a novel influenza virus, please
- **Maintaining adherence to recommended influenza testing practices** remains critical to supporting routine influenza surveillance, early detection of novel influenza cases and public health response activities

Summer 2026 Influenza Surveillance Guidance

CDC Influenza Testing Algorithm



Should not be performed unless the patient meets clinical, epidemiologic and public health response criteria for testing suspect specimens

Additional considerations

- **CDC requests commercial laboratories continue to send specimens to PHLs for further testing/characterization**
  - Influenza A positive specimens that are unable to be subtyped by tests designed to provide an influenza A subtyping result and confirmed upon retest.
  - Influenza A positive specimens that are subtype influenza A(H1) and not influenza A(H1)pdm09 on tests designed to provide an influenza A(H1) subtyping result and confirmed upon retest.

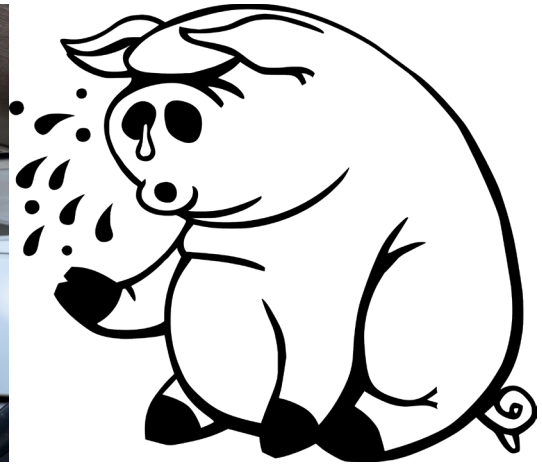
- **If a laboratory is performing A(H5) subtyping with an internally developed Laboratory Developed Test (LDT)**
  - Algorithm should include testing influenza A positive samples for seasonal A(H1) and A(H3) viruses before (or in parallel with) A(H5) testing

- **If using the CDC A(H5) assay… first three influenza A(H5) identified patient cases by a PHL should be treated as presumptive positives and the PHL must send specimens from those three cases to CDC for confirmation.**
  - After three presumptive positive patients have been confirmed A(H5) positive by CDC, subsequent A(H5) testing can be treated as confirmed at the PHL

It's Showtime!

- National livestock exhibitions, jackpot shows and agricultural fairs occur in summer and early Fall in many states
- Additional vigilance is important to prevent human infection and spread when in close contact with potentially infected animals

[Considerations and Information for Fair Exhibitors to Help Prevent Influenza | Influenza in Animals | CDC]



Novel influenza A(H1N2)v case investigation

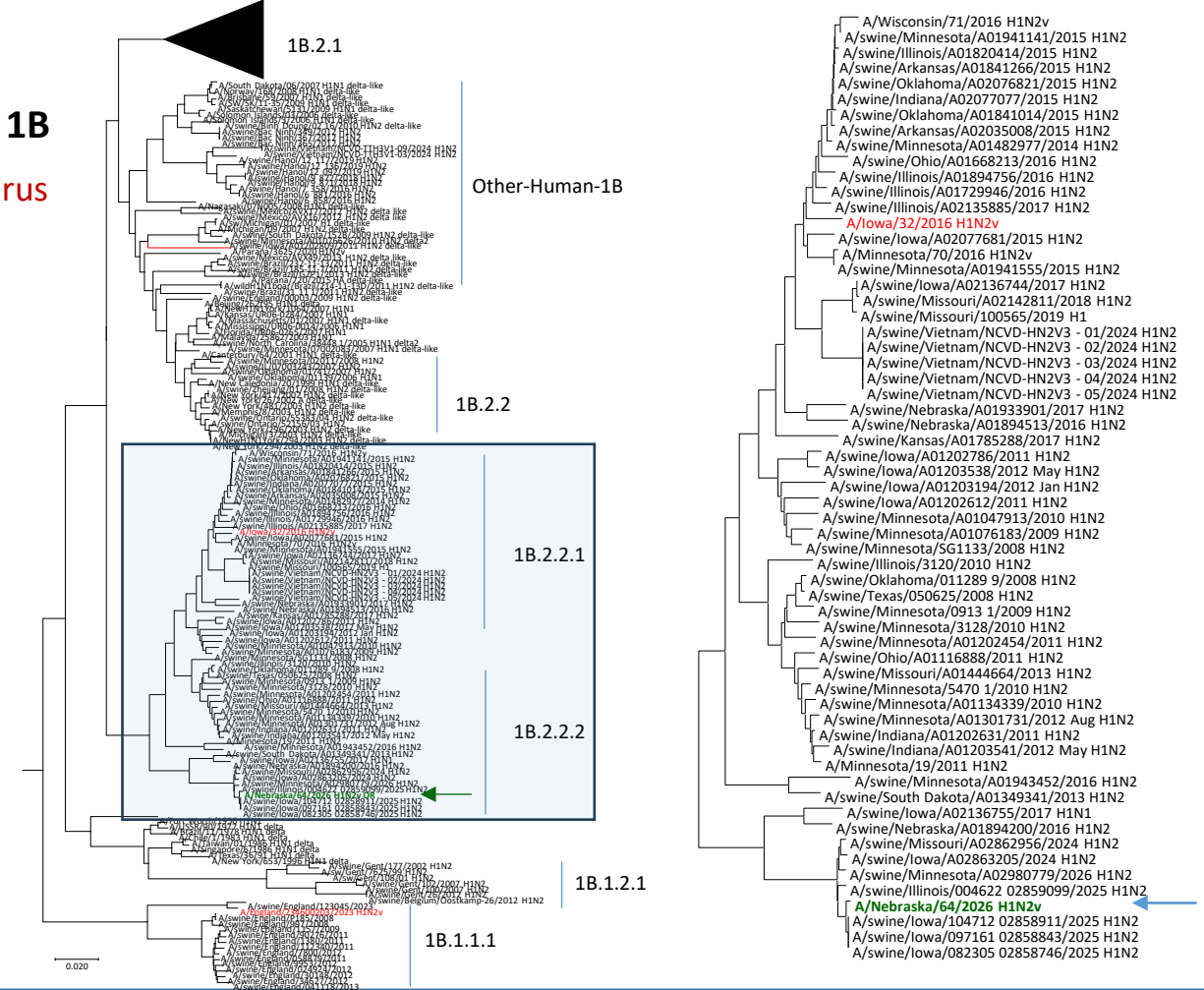
- **Individual aged <18 in Nebraska developed respiratory illness on 2 April 2026**
  - The patient sought outpatient medical care during the week following illness onset
  - On 17 April 2026, the patient again sought outpatient care due to worsening symptoms
  - The patient recovered from their illness.

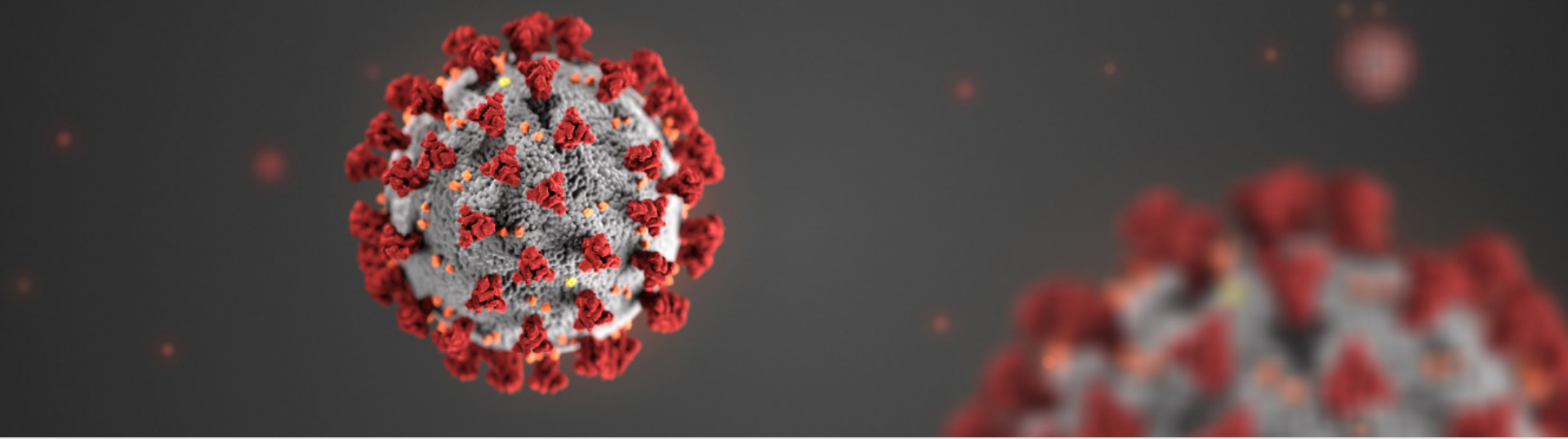
- **Respiratory specimen was collected from the patient and was positive for influenza A(H1) virus by BioFire**
  - Specimen forwarded to NE Public Health Laboratory as part of routine surveillance
    - FluA subtyping with CDC assay:
      - Positive for InfA (MP), pdm InfA (NP), and internal control (RP)
      - Negative for pdmH1 (HA)
  - Specimen forwarded to CDC
    - RT-PCR testing and NGS by CDC determined the sample was positive for an influenza A(H1N2)v

- **First influenza A(H1N2)v virus infection identified in the United States during 2026**
  - Since reporting of novel influenza A became nationally notifiable in 2005, 45 human infections of influenza A(H1N2)v in U.S.
  - Since 2005, a total of 525 variant virus infections (of all subtypes) have been identified in the United States.

Evolutionary Relationships Among Influenza A(H1)v HA, 1B

H1v candidate vaccine virus





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

Laboratory Director University

Centers for Medicare & Medicaid Services

Division of Clinical Laboratory Improvement & Quality

Centers for Disease Control and Prevention

Division of Laboratory Systems

Laboratory Director University (LDU)

- Laboratory Director University offers **free** and **focused eLearning** for **current and aspiring laboratory directors** whose job will include overseeing CLIA-certified laboratories, as well as CLIA-designated personnel, and other laboratory professionals.

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

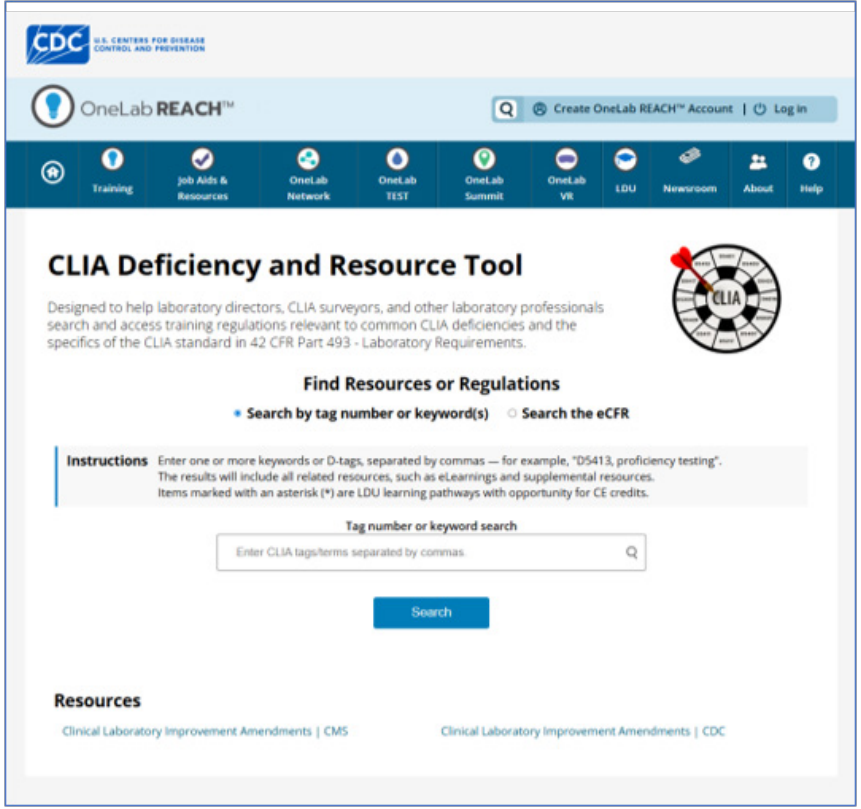
For more information, please opt in through OneLab REACH™ or email OneLab@cdc.gov.

LDU Learning Pathways & Topics

1. **Introduction to Laboratory Director University**
   Summarizes fundamental concepts of CLIA regulations and the basics of waived and nonwaived testing.
2. **Laboratory Director Responsibilities**
   Summarizes laboratory director responsibilities, distinguish delegated and nondelegated.
3. **Personnel Responsibilities**
   Covers responsibilities for the laboratory director and delegation of responsibilities to personnel.
4. **The Survey Process**
   Summarizes laboratory director requirements before, during, and after the survey process
5. **Quality Systems for Nonwaived Testing**
   Covers application of quality practices for accurate, reliable testing
6. **Participation in CLIA PT for Nonwaived Testing**
   Covers successful proficiency testing from start to finish.
7. **LDU Capstone**
   Learners apply LDU concepts in real-world scenarios

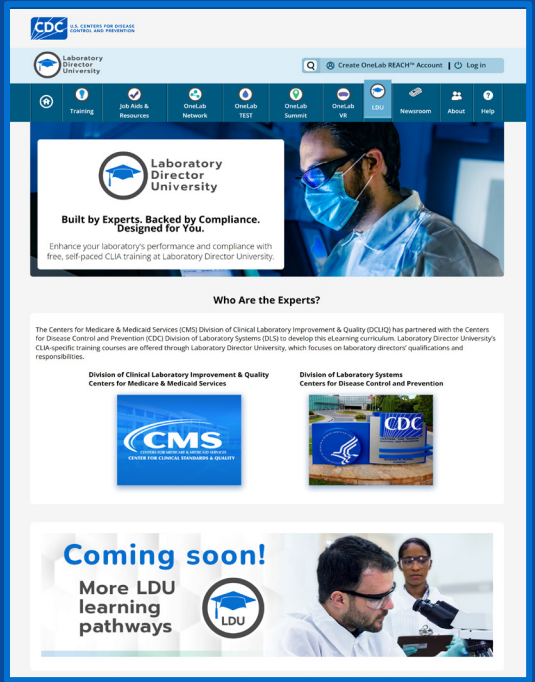
Hit the Bull's-Eye with CDART

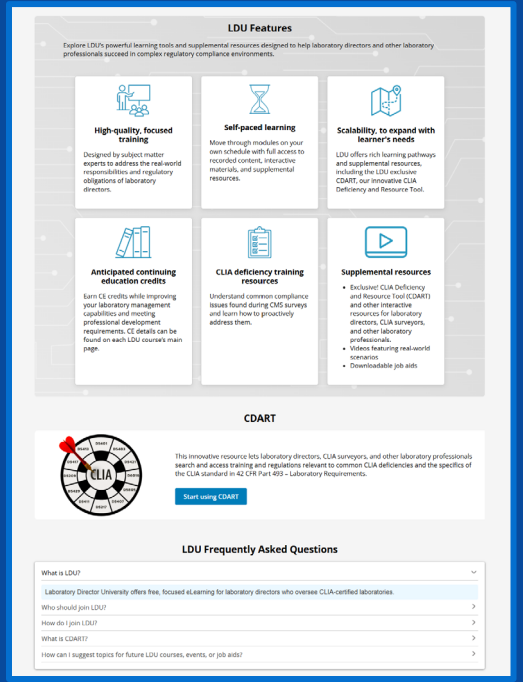
LDU's innovative and exclusive CLIA Deficiency and Resource Tool – known as CDART – connects laboratory professionals and CMS surveyors with CLIA resources relevant to common CLIA deficiencies.



LDU Landing Page

The LDU landing page includes details of the program, its components, and easy user registration.





LINKS

- Laboratory Director University | OneLab REACH

Clinical Laboratory Improvement Amendment(CLIA) Request for Information (RFI)

Disclaimer

- This presentation was prepared for informational purposes and is not intended to grant rights or impose obligations. Every reasonable effort has been made to assure the accuracy of the information within these pages.
- This publication is a general summary that explains certain aspects of the Clinical Laboratory Improvement Amendments (CLIA) Program, but it is not a legal document. The official CLIA Program provisions are contained in the relevant laws, regulations, and rulings. Links to the source documents have been provided within the document for your reference.
- The Centers for Medicare & Medicaid Services (CMS) employees, agents, and staff make no representation, warranty, or guarantee that this compilation of CLIA information is error-free and will bear no responsibility or liability for the results or consequences of the use of this guide.

Review and Comment Submission

- Comment period is from 07/16/2026– 09/14/2026
- To read the RFI and submit your comment(s):

  Visit:
  https://www.federalregister.gov/documents/2026/07/16/2026-14358/request-for-information-clinical-laboratory-improvement-amendments-of-1988-clia-regulations

Purpose

The RFI seeks information on areas where:

- Laboratory practices have evolved
- New technologies are being used
- New operational models have emerged

Four Topics for Review in the RFI

Breath Testing

- Clinical applications of breath testing
- Testing technologies and methodologies
- Laboratory settings performing breath testing
- Specimen collection, transport, and storage

Laboratory Processes and Procedures

- Pathology specimen block retention
- Specimen preparation activities and personnel qualifications
- Management of suboptimal specimens
- Establishing and verifying performance specifications
- Calibration verification practices
- Postanalytic interpretation and use of AI
- Data-only facilities
- Remote direct observation for competency assessment

Topics for Review

Emergency Preparedness, Biosafety and Biosecurity, and Cybersecurity

- Emergency preparedness planning and response
- Biosafety and biosecurity protocols
- Cybersecurity policies and practices
- Operational challenges and best practices

Specialty Testing Areas

- General specialty and subspecialty considerations
- Clinical cytogenetics
- Immunohematology
- Microbiology, specifically blood culture contamination practices

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Questions

Next Scheduled Call: Oct 19 at 3pm

Thank you!

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 cdc.gov
Follow us on X (Twitter) @CDCgov & @CDCEnvironment