

Division of Laboratory Systems

CDC Update

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Division of Laboratory Systems

Office of Laboratory Systems and Response

CLIAC Fall Meeting 2024

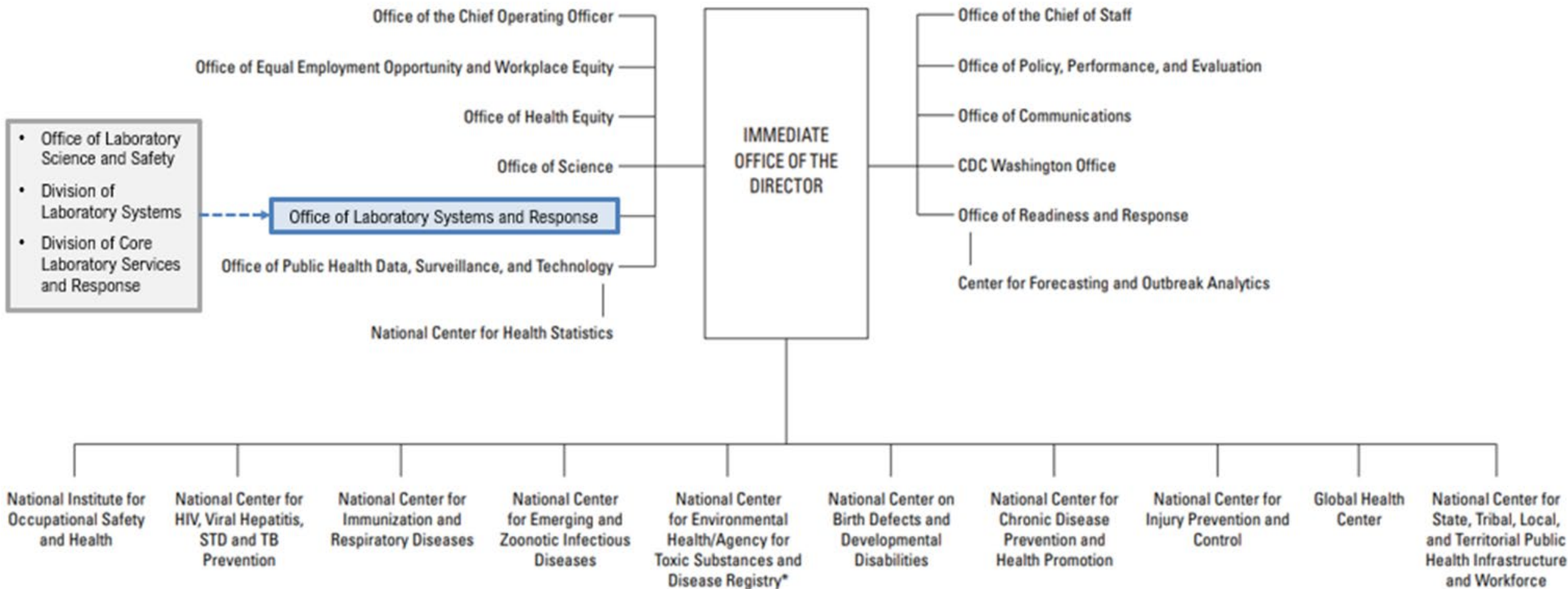




ONE CDC: OLSR REALIGNMENT



Centers for Disease Control and Prevention (CDC)



*ATSDR is an OPDIV within DHHS but is managed by a common director's office.



Office of Laboratory Systems and Response (OLSR)

Mission

Create a core laboratory infrastructure that provides operational and systems support to CDC and the nation's public health and clinical laboratories, ensuring

- High-quality and safe laboratory science
- Reliable diagnostics for outbreaks and harmful exposures
- Improved laboratory readiness and response





LABORATORY QUALITY

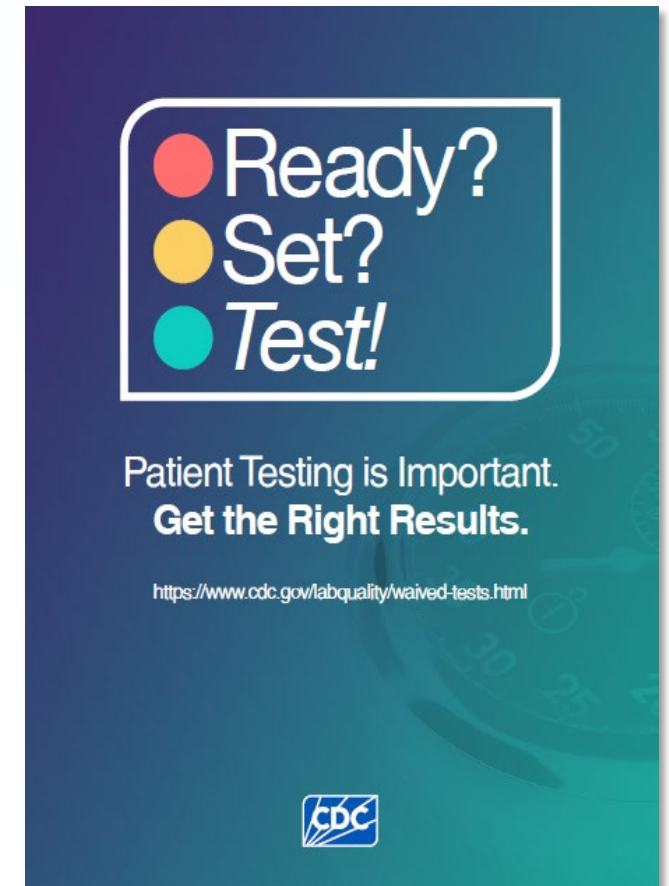


Waived Testing Educational Material Updates

Ready? Set? Test!

- **New! Design and Considerations for Performing Waived Tests**
 - Updated CLIA guidelines – PT Referral for Certificate of Waiver sites
 - Updated safety guidance
 - Quality assessment practices
 - [Self-Assessment Checklist for Good Testing Practices](#)
- **Impact**
 - Over **1,300 physical booklets** were distributed to the laboratory community this year!
 - Over **1,000 booklets** were downloaded in FY 2024!

<https://www.cdc.gov/lab-quality/php/waived-tests/index.html>



Spanish version coming soon!

Waived Testing Educational Material Updates

To Test or Not to Test?



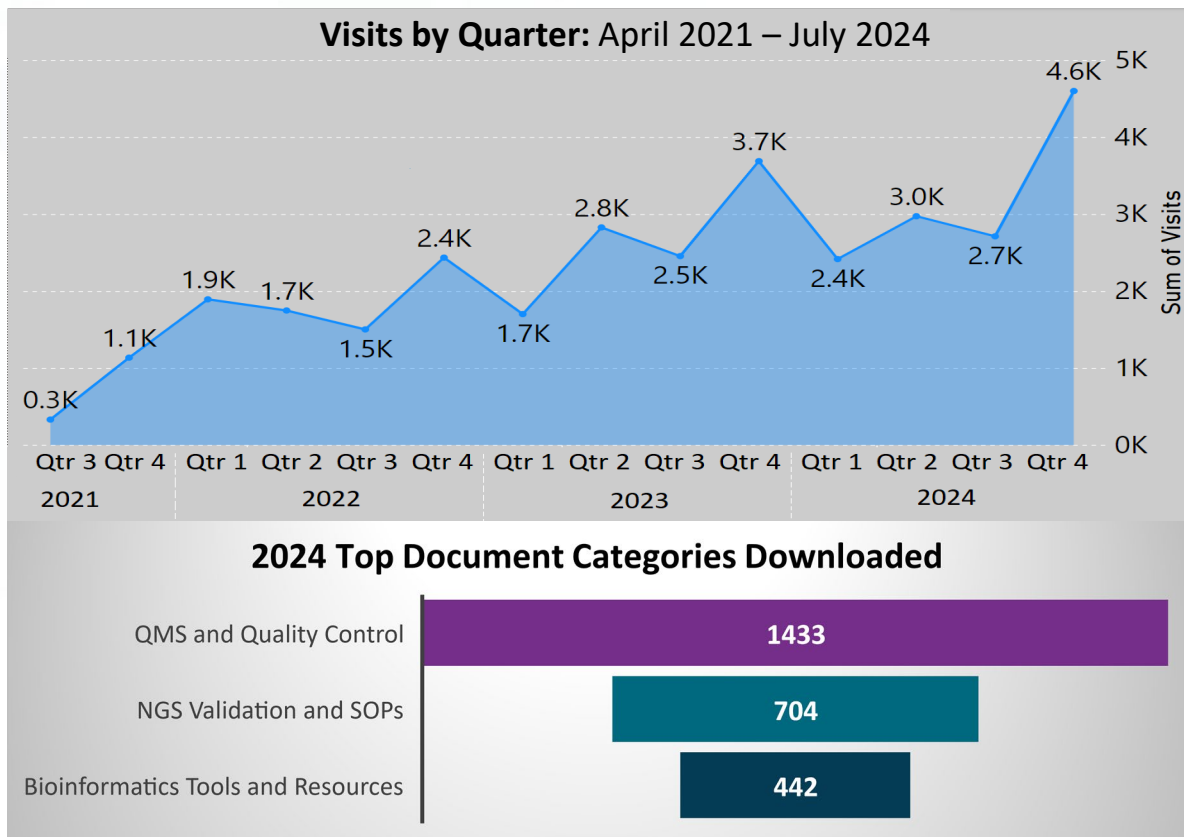
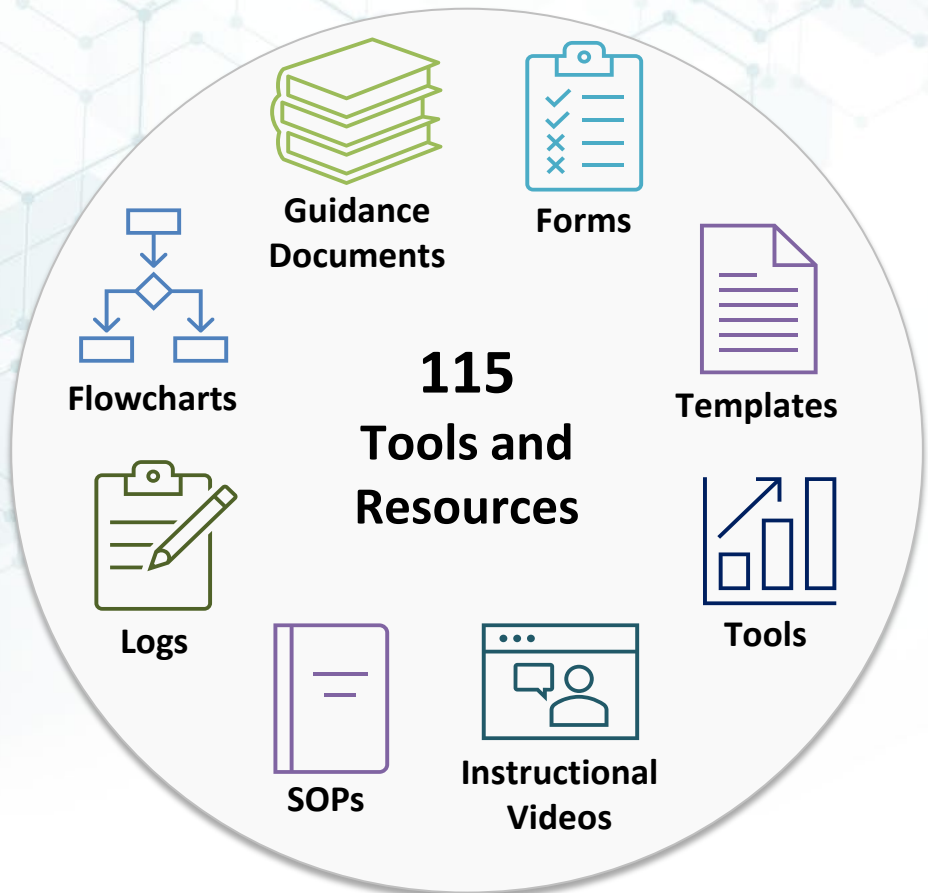
Spanish version coming soon!

- **New! Design and Considerations for Performing Waived Tests**
 - Updated CLIA Certificate of Waiver Requirements for multi-location testing sites
 - Updated CLIA guidelines – PT Referral for Certificate of Waiver sites
 - General safety considerations
- **Impact**
 - Over **600 physical booklets** distributed to the laboratory community this year!
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Next Generation Sequencing Quality Initiative

Tools and Resources

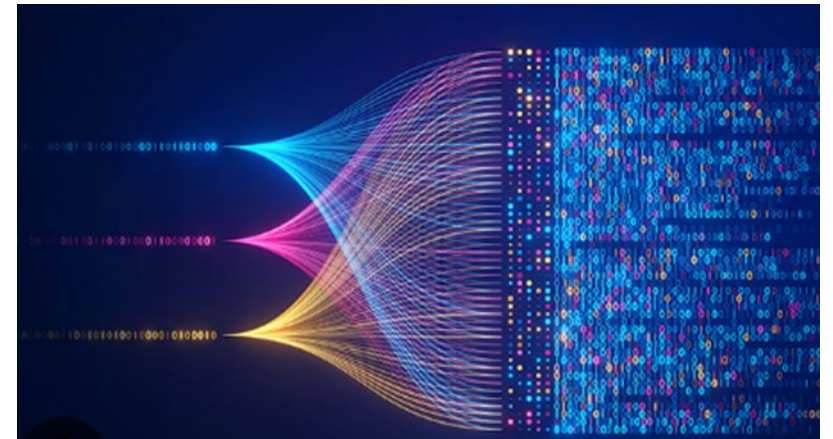


<https://www.cdc.gov/lab-quality/php/ngs-quality-initiative/qms-tools-resources.html>

Next Generation Sequencing Quality Initiative

Meeting the Needs of the Sequencing Community

- QMS Assessment Tool Update
- Pathway to Quality-Focused Testing:
<https://www.cdc.gov/lab-quality/php/pathway/pathway-to-testing.html>
- Reference Materials
- Automated end-to-end sequencing platforms





LABORATORY SAFETY



Biosafety and Biosecurity Month

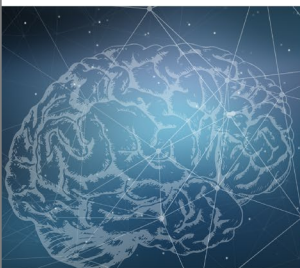
October 2024 Biosafety & Biosecurity Month

Check out our Featured Initiatives:

- ECHO Biosafety Program
- Raising Awareness of ISO 35001:2019
- CLIAC Biosafety Workgroup



OneLab Network REGISTER FOR THE **WEBINAR**



Lab Safety in the Age of AI:
Evaluating Multimedia Options

October 16, 2024 1 PM ET



<https://www.cdc.gov/safe-labs/php/about/>



Viral Hemorrhagic Fever

CDC Guidance Revisions

- Select Viral Hemorrhagic Fevers
- Viral hemorrhagic fevers are in risk group 4
- BSL-4 facilities are recommended for viral propagation and research activities (BMBL)
- Clinical laboratories have different requirements due to smaller contained specimens that could contain unknown pathogens (BMBL Appendix 4)
- Comprehensive updates have been made to VHF pages

CDC Viral Hemorrhagic Fevers (VHFs)

EXPLORE TOPICS

SEARCH

MAY 14, 2024

Laboratory Testing for Patients with a Suspected VHF or High-Consequence Disease

WHAT TO KNOW

- Healthcare providers who suspect a patient is ill with a viral hemorrhagic fever (VHF) or other high-consequence disease must conduct an initial screening, isolate the patient, and notify their health department before testing can take place.
- Routine laboratory testing to monitor the patient's clinical status and diagnostic testing for other potential causes of the patient's illness should be pursued while testing for a VHF or other high-consequence disease is underway.

Scope

Cases of VHFs or other high-consequence diseases in the United States are rare. Most ill travelers returning from an active VHF or other high-consequence disease outbreak or endemic area who undergo testing do not have a VHF or other high-consequence disease. They are typically diagnosed with a more common etiologic agent, like malaria. Timely identification of other more likely pathogens and access to routine laboratory testing, such as blood counts and chemistries, is essential for providing appropriate patient care.

Clinical laboratories can safely perform common diagnostic testing by following [Standard Precautions for All Patient Care](#) which includes the Bloodborne Pathogen Standard (29 CFR 1910.1030).

RELATED PAGES

- [Performing Routine Diagnostic Testing](#)
- [Specimen Collection](#)
- [Specimen Packing and Shipping](#)
- [Guidance for Health Departments](#)
- [Partners](#)

VIEW ALL
Viral Hemorrhagic Fevers (VHFs)

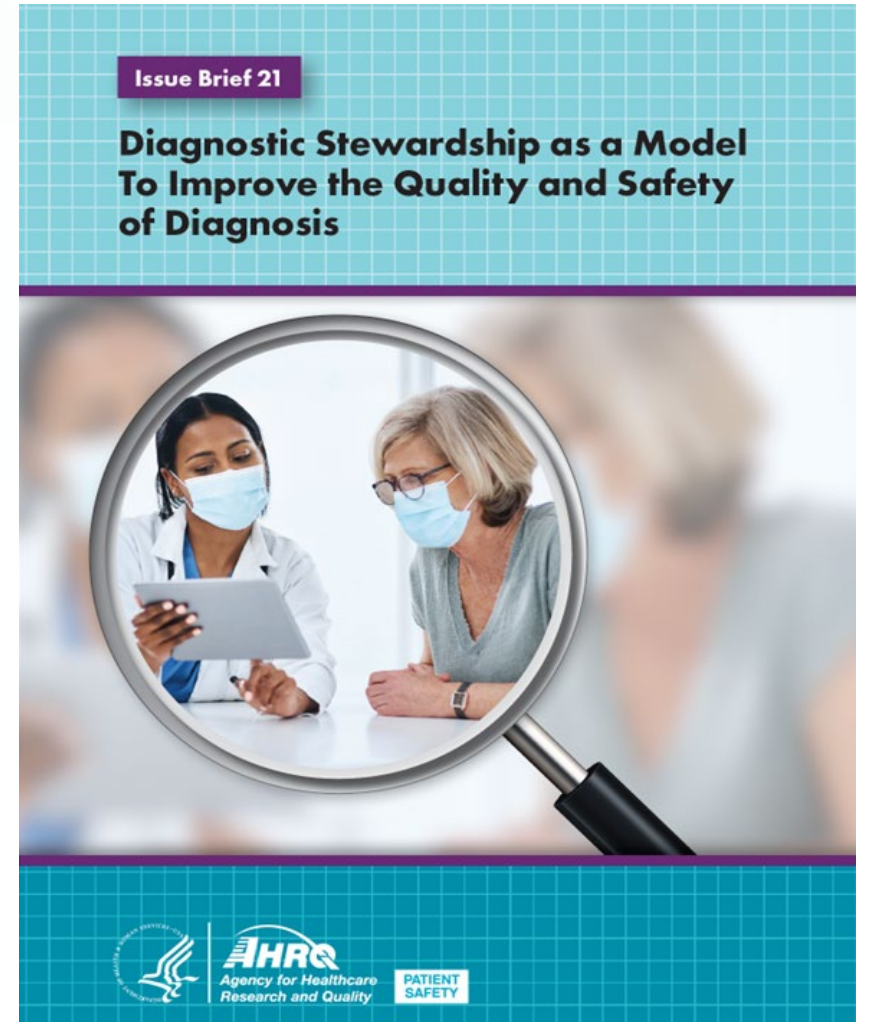


DIAGNOSTIC EXCELLENCE



Diagnostic Excellence

- Issue Brief - Diagnostic Stewardship as a Model to Improve the Quality and Safety of Diagnosis, August 2024; in collaboration with the Agency for Healthcare Research and Quality
- Core Elements of Hospital Diagnostic Excellence, September 2024; in collaboration with the CDC Division of Healthcare Quality Promotion
- Why Clinical Laboratory Testing Matters
 - Patient-directed educational resource about the total testing process, using early diagnosis for chronic kidney disease as a model
 - Release date – 4th quarter 2024



BD Blood Culture Bottle Shortage

Collaboration between CDC, FDA, CMS, and IDSA
July-October

- **Communication and strategies developed to assist clinical laboratories**
 - Outreach through LOCS, CDC/IDSA webinars, HANs messaging, and BD website
- **Provided Diagnostic Stewardship guidance on:**
 - Reducing blood culture (BC) contamination (lowers the need for additional BC)
 - On monitoring correct volume drawn on initial request (lowers the need for additional BC)
 - Evidence-based strategies to improve inpatient blood culture utilization: 25 to 60% of BC may be unnecessary
 - Fabre V, et al . A Diagnostic Stewardship Intervention To Improve Blood Culture Use among Adult Nonneutropenic Inpatients: the DISTRIBUTE Study. J Clin Microbiol. 2020.



LABORATORY READINESS AND RESPONSE



Laboratory Response Network for Biological Threats

- The LRN-B is celebrating its 25th anniversary in 2024
- In 2024, the LRN-B supported CDC's success in obtaining updated EUAs for mpox and MERS
- Collaborating to ensure LRN testing data is widely available for CDC use



<https://emergency.cdc.gov/lrn/biological.asp>

Clinical Laboratory Engagement Team Activities

- **National Response Testing Framework**
 - Roadmap for surge testing support
 - Building testing capacity with commercial laboratories
- **MOU for Surge Testing**
 - Membership expansion
- **Emergency Responses**
 - Mpox
 - Influenza H5
 - VHF's
- **Laboratory Outreach Communication System (LOCS)**
 - 39 messages and 9 calls



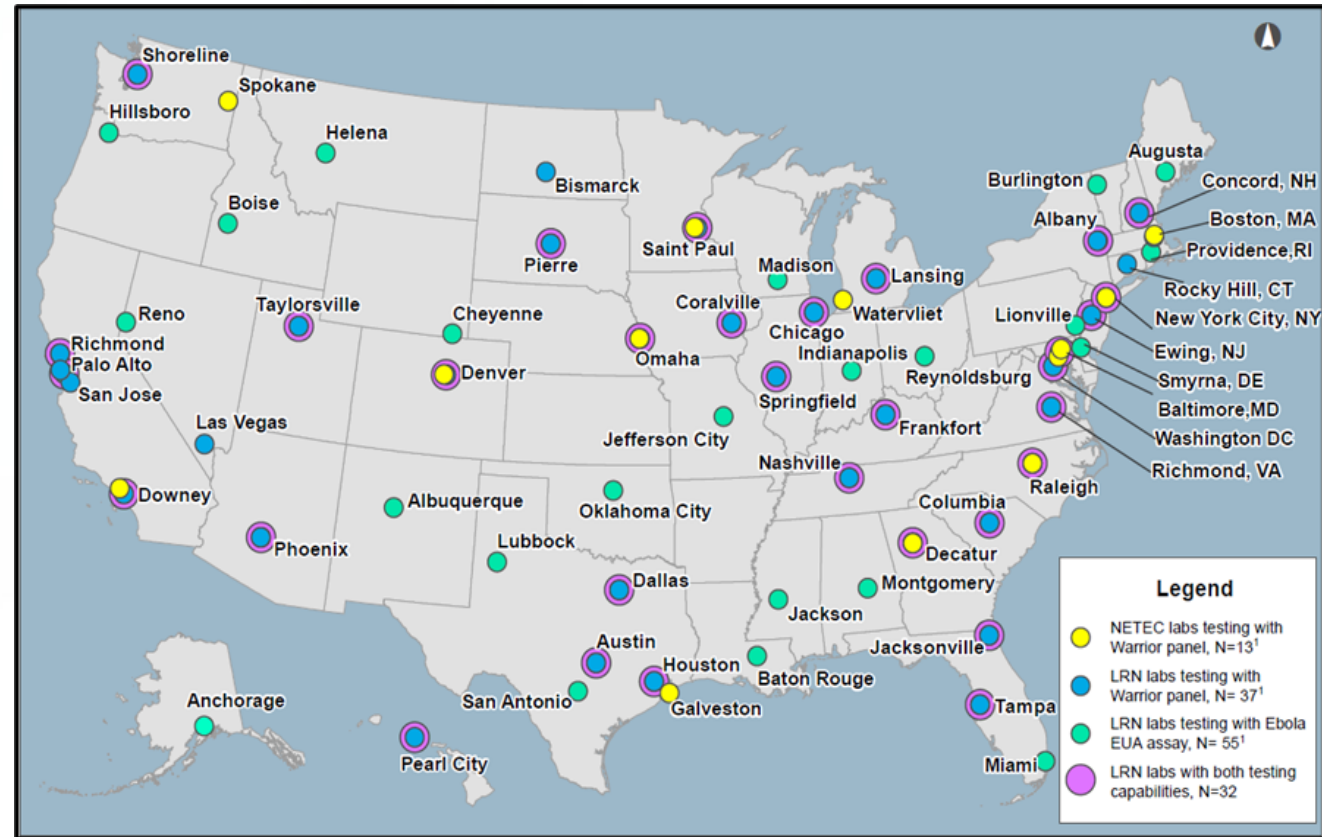
Surge Testing, Test Development, and Data Sharing Indefinite Delivery Indefinite Quantity (IDIQ) Contract

- CDC recently awarded a contract to Labcorp, Aegis, ARUP, Quest, and Ginkgo Bioworks
- Warm base capacity, surge diagnostic testing, test development, and specimen collection
- Data sharing for over 200 reportable conditions

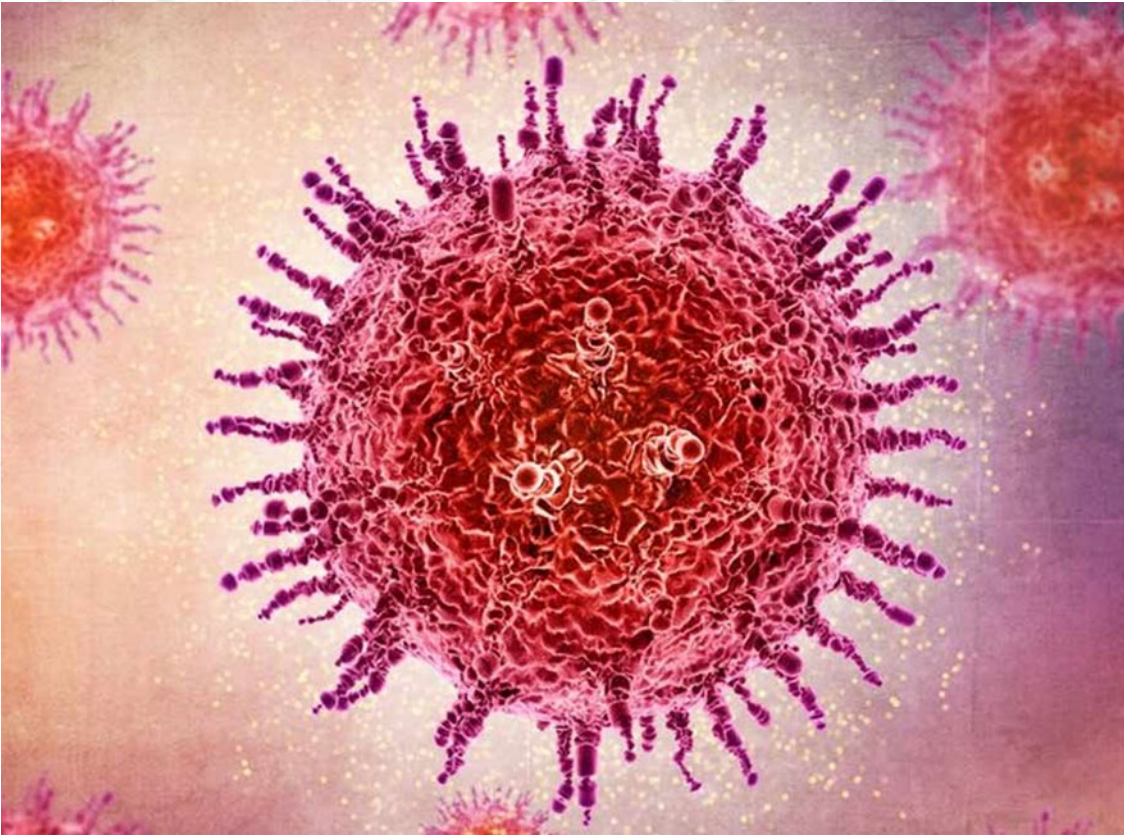


Marburg 2024 Response

- Rwanda is experiencing its first Marburg outbreak
- 6 cases, most are healthcare workers and their contacts link to two hospitals
- CDC and 40 Laboratory Response Network (LRN) laboratories have testing capability



Oropouche



- More than 8,000 cases reported from South America and Cuba
- Approximately 20 cases in travelers returning to US
- CDC currently has CLIA PRNT and RT-PCR tests (Fort Collins)
- RFP for Oropouche test development in process (IDIQ)



LABORATORY TRAINING: ONELAB™ INITIATIVE



OneLab Initiative

OneLab™ membership has **doubled** since April 2024, now totaling over **41,000 unique members!**

OneLab **Resources**

- OneLab training materials (eLearning and VR courses, job aids, webinars, videos, etc.) attracted **439,000+ registrations** in FY24 – 2.6 times the FY23 total
- Launched new eLearning courses in Fall 2024:
 - [*Fundamentals of Quality Management Systems*](#)
 - [*Fundamentals of Bloodborne Pathogens*](#)
- Just launched: [OneLab VR Autoclave Safety](#)

 OneLab **REACH™** **38,900+ learners** with **18,900 new learners** in the past six months

 OneLab **Network** **18,000+ members** with **8,300 new members** in the past six months

 OneLab **TEST** **8,000+ members** with **4,300 new members** in the past six months

<https://www.cdc.gov/lab-training/php/onelab>

CLIA Laboratory Director University (LDU)

- CMS and CDC are partnering to develop a free, online training program to meet CLIA's continuing medical education (CME) requirement for doctors of medicine, osteopathy, or podiatric medicine seeking to qualify to direct a laboratory that performs moderate complexity testing
 - 20+ hours of CME credits
 - Combination of webinars, eLearning courses, job aids, case studies, and other training formats with pre/post tests and a capstone to assess knowledge gain
 - Online CLIA surveyor tool will map training materials to common deficiencies so that they can serve as initial remediation as appropriate
 - Will include an evaluation of LDU's short-term and long-term impact

LDU Trainings in Development

- CMS approved the overall training plan in March 2024
- Three eLearning courses launching between late 2024 and mid 2025:
 - CLIA Proficiency Testing
 - CLIA Personnel Qualifications and Responsibilities: High Complexity Testing
 - CLIA Personnel Qualifications and Responsibilities: Moderate Complexity Testing
- Based on CMS feedback, CDC/DLS is developing the outlines for the remaining trainings and will send them in batches for CMS review
- Goal: To launch all trainings and the online tool for surveyors by 2027



DATA SCIENCE



Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD) Workgroups

Data Exchange Standards



- **Define Standards** that enable reliable semantic interoperability and data exchange
- Ensure **consistent data flow** throughout the healthcare system

Create Knowledge Management Tools



- **Laboratory Interoperability Device Reference (LIDR)** and infrastructure to harmonize test information
- **In Vitro Diagnostic (IVD) Data Hub** and associated tooling to access de-identified data

Communications

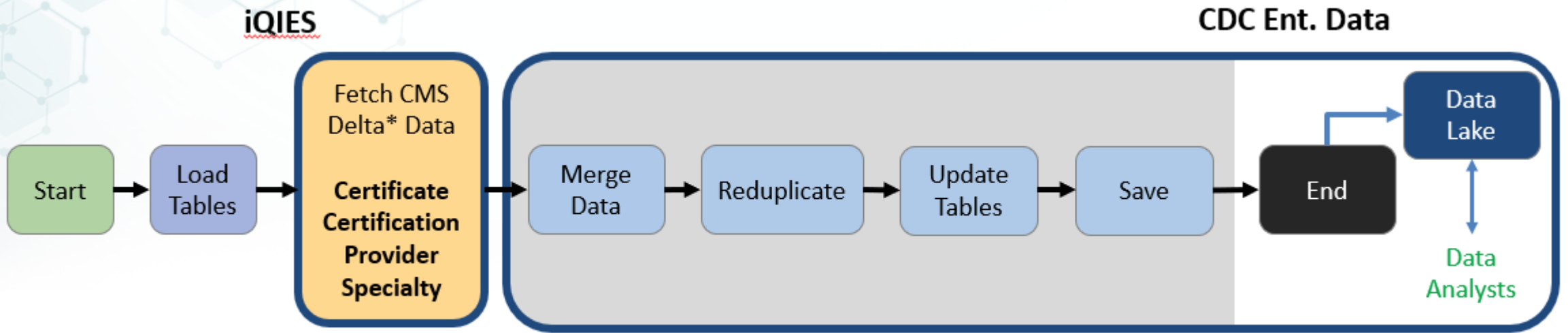


- **Communication and Branding** to align public and private partners on a single way forward

CMS to CDC Data Stream (C2CDS)

Modernizing Data Transmission

- Automated data transmission from the CMS Internet Quality Improvement & Evaluation System (iQIES) to CDC's enterprise data environment
- Consolidate multiple data sources into the CDC data lake
 - Accelerate access to & analysis of data



*Delta: All observations that have been modified since the data were last processed.

Exploring Laboratory-Led Interventions With Real-World Data

Commercially Available EHR and Claims Databases

- Use of Electronic Health Record (EHR) and medical claims data to explore use of laboratory-related data to improve patient care

Robust, Complex Data

- Medical history
- Diagnostic codes
- Medications
- Laboratory test data
- Costs
- Demographic data
- Laboratory test result*

Representativeness

- >150 million patients
- Billions of patient encounters
- Inpatient and outpatient



*[Zhang et al.](#) and [Ehrenstein et al.](#)

Real-World Data Examples

Guideline Recommended Pharmacogenetic Testing

Study to evaluate adherence to recommended genetic testing

- HLA-B*57:01 screening before abacavir prescription
 - screening supported by literature, guidelines, and an FDA black box warning
 - <50% of patients with HIV screened prior to drug initiation

Adult Blood Culture Contamination Rate

A national measure for clinical laboratories and antibiotic stewardship programs

- Utilizing EHR data in determining
 - sepsis testing accuracy
 - blood culture contamination rates



HEALTH EQUITY



Advancing Electronic Test Orders and Results (ETOR) to Promote Health Equity

What We'll Do

Goal: By December 2025, **30% of newly established ETOR systems** will be between public health laboratories and healthcare organizations that support people who are medically underserved.

Why It Matters

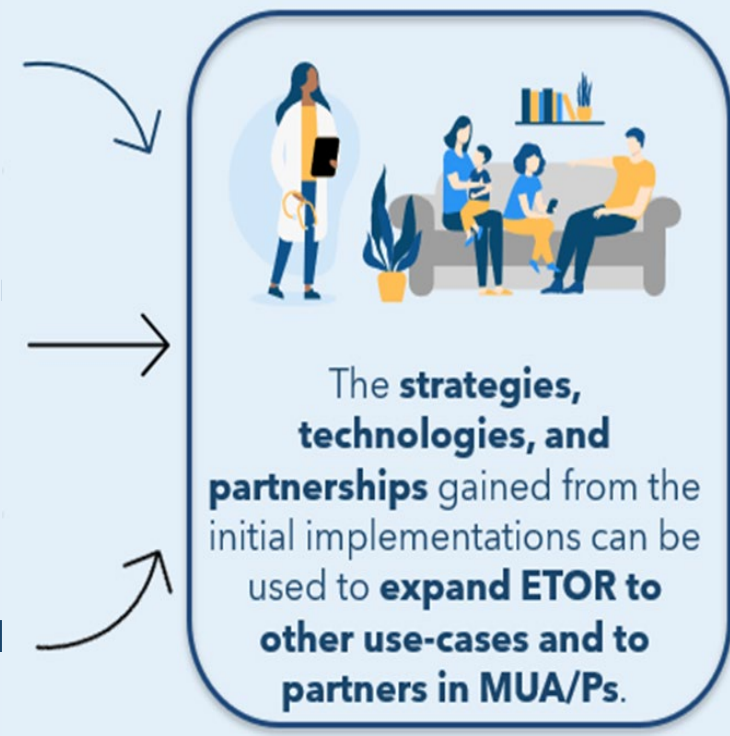
ETOR enables **direct exchange** of patient information, test orders, specimen data, and test results **improving data quality and timeliness**

What we have accomplished

Five jurisdictions are participating in an initial implementation of **ETOR for newborn screening**.

CDC and APHL are providing technical assistance **to the Iowa PHL and its partner healthcare organization in Alaska**, which serves **medically underserved areas and populations (MUA/Ps)**.

Partners in Florida are exchanging ~500 orders and results a week since they **launched ETOR in August** with results in the patient's chart **~2 days sooner**.




Million Hearts Project


LDL Lab Messaging Project

- Designed to achieve timely diagnosis of severe hypercholesterolemia and statin prescribing to reduce risk for heart disease
- Implemented a process at Zufall Health, a federally qualified health center, to identify test results reporting LDL \geq 190 mg/dL that triggers messaging to patients and their clinicians
- Increased statin prescribing found in preliminary analysis of results
- Mapped the workflow at Zufall Health as a basis to scale processes to other federally qualified health centers

Increasing Diversity within the Laboratory Workforce


Why It Matters


The public health laboratory workforce should **better reflect the diversity of the communities** it serves 

COVID-19 highlighted **disparities in the public health laboratory workforce** 

Reducing disparities hinges on expanding the workforce pipeline

What We'll Do


Identify barriers through feedback from organizations that serve under-represented groups (e.g., students of color, who are LGBTQ+, are veterans, have disabilities) 

Reduce and eliminate barriers with continual partner input. **Attract more applicants from under-represented groups and communities** by increasing recruitment/promotion and ensuring selection criteria are clear and objective 

How We'll Do It

Expand laboratory fellowships and internships program

Goal: By September 30, 2026, increase the percentage of graduate fellows and undergraduate interns from under-represented groups and communities by 40% placed in state, local, territorial public health laboratories

Leverages **new ARP investments** 

Thank you!

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

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