

CDC Laboratory Update: CLIA regulations, resources for clinical laboratories, and more

Reynolds M Salerno, PhD
Director, Division of Laboratory Systems

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Reynolds M Salerno, PhD

Acting Associate Director for Laboratory Science and Safety

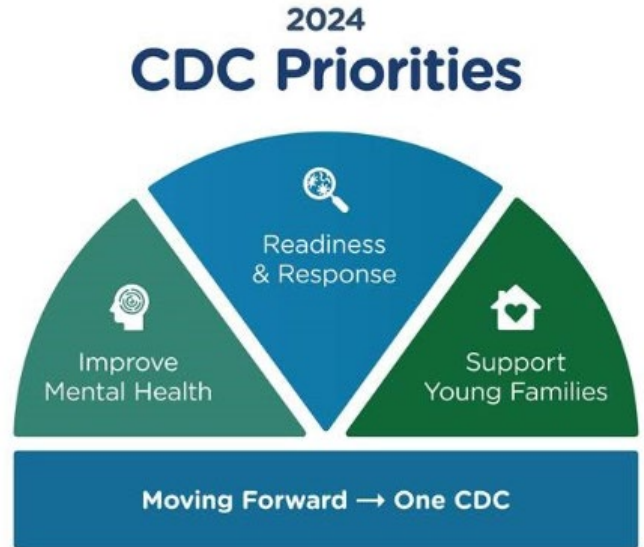
Acting Director, Office of Laboratory Science and Safety

Acting Director, Center for Laboratory Systems and Response

Organizational Updates

2024 CDC Priorities

- Readiness and response to health threats
- Improve mental health
- Support young families
- Moving Forward → One CDC



Laboratory systems are fundamental components of that core public health infrastructure



Top priorities for CDC laboratory programs

- High-quality laboratory science
- Reliable laboratory diagnostics and informatics for outbreaks and harmful exposures
- Extensive engagement with public and private-sector partners

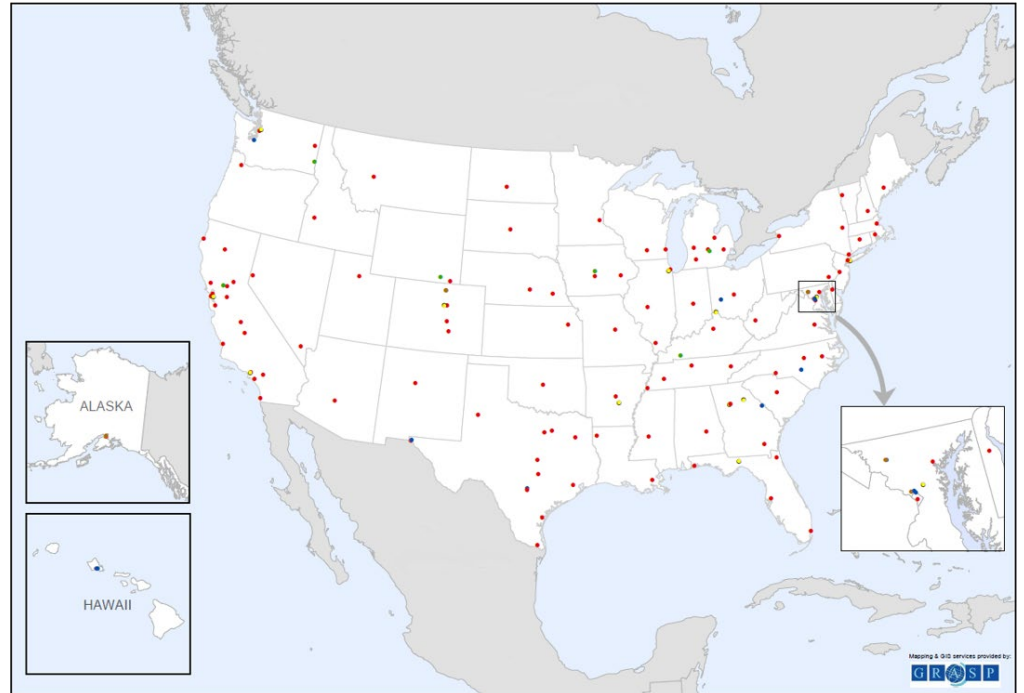
Partnership Updates

Examples of CDC Partnerships for Diagnostics and Laboratory Response

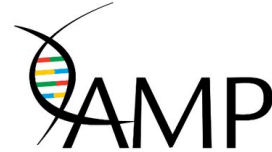
- Laboratory Response Network (LRN)
- Memorandum of Understanding (MOU) for Diagnostic Surge Testing Capacity for Public Health Emergencies
- Clinical Laboratory Improvement Amendments (CLIA) laboratory quality program

Laboratory Response Network (LRN)

- Provides rapid laboratory response to biological and chemical threats to inform critical decisions about public health and safety
- Comprises ~**120** laboratories – state and local public health, DoD, FBI, international, veterinary, food, VA hospital



MOU Partners – Surge Testing Capacity During PHEs



CLIA Updates

CLIAC Updates

- November 2023 CLIAC meeting
- April 2024 CLIAC meeting
- Ongoing CLIAC Workgroups
 - [Biosafety Workgroup](#)
 - [Next Generation Sequencing Workgroup](#)
- The next CLIAC meeting will be held virtually November 6-7, 2024



<https://www.cdc.gov/cliac/index.html>

Digital Pathology and Remote Review

- May 11, 2023, Director, Quality, Safety & Oversight Group (QSOG) Clinical Laboratory Improvement Amendments of 1988 (CLIA) Post-Public Health Emergency (PHE) Guidance [memo](#)
- [CLIA Regulations Assessment Workgroup](#)
- [CLIAC Recommendations](#)

Data as a Specimen

- [CLIA Regulations Assessment Workgroup](#)
- November 2022 CLIAC recommended defining the term “materials derived from the human body” to include data derived from a human specimen.
- April 2023 CLIAC recommended development of a new standard related to data analysis is needed in Subpart K - Quality System for Nonwaived Testing under General Laboratory Systems.

Questions?

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

