Laboratory Systems

Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)
Division of Laboratory Systems (DLS)

Overview

Our Mission: To strengthen the nation's clinical and public health laboratory system by continually improving quality and safety, informatics and data science, and workforce competency

Our Work

- **Quality and safety.** Improve the quality and safety of public health and clinical laboratory science and practice.
- **Informatics and data science.** Strengthen interoperability and the application of laboratory data and information systems.
- **Training and workforce development.** Enhance the competency and sustainability of the public health and clinical laboratory workforces.
- **Biorepository science.** Promote excellence in biorepository science to advance population health, patient care, and research.

Our Services

- Execute federal responsibilities for managing the **Clinical Laboratory Improvement Amendments (CLIA) program** in partnership with the Centers for Medicare & Medicaid Services and FDA.
- Develop and evaluate **standards, guidelines, and recommendations** to improve laboratory quality and safety across the nation.
- **Support the advancement of health IT standards—** such as harmonizing laboratory testing codes (e.g., LOINC, SNOMED CT)—to enable meaningful comparison of results worldwide.
- Implement informatics and data science approaches to evaluate laboratory practices and improve **access to and analysis of laboratory information** that supports clinical and public health outcomes.
- Provide reliable **biorepository services** to CDC scientists and collaborators to manage valuable specimen collections and reference materials.

Our Programs

Biorepository Science and Services
- CDC and ATSDR Specimen Packaging, Inventory, and Repository (CASPIR)
- CASPIR Advisory Committee
- CDC Specimen Policy Board
- CDC specimen and collections policies
- Genetic Testing Reference Material Coordination Program (GeT-RM)

Clinical Laboratory Improvement Program
- Clinical Laboratory Improvement Amendments (CLIA) program
- Clinical Laboratory Improvement Advisory Committee (CLIAC)
- Laboratory Medicine Best Practices Initiative (LMBP™)
- Clinical Laboratory Integration into Healthcare Collaborative (CLIHC™)

Informatics and Data Science
- Laboratory Health Information Technology (LabHIT)
- Public Health Laboratory System Database (PHLSD)
- Laboratory Informatics Self-Assessment Tool
- Applied research of laboratory systems and databases

Training and Workforce Development
- Laboratory training resource development and evaluation
- Laboratory competencies and fellowship support

- Develop, deliver, and evaluate laboratory quality, safety, and informatics training and resources to enhance **laboratory workforce competencies**.
- Improve the **effectiveness and sustainability** of state and local public health laboratories by developing shared systems, fostering regional and national coordination of systems, and supporting collective improvement of testing services.

Division Highlights—FY2016

First to publish quality guidelines for **next generation sequencing**

CASPIR manages more than **6.5 million** specimens, nearly half of all specimens at CDC

Provided **302** training activities on **98** laboratory topics totalling **39,224** training hours

Disseminated more than **13,000** quality and safety guidelines and educational products

Implemented more than **100** CLIAC recommendations

Partnering for Success

CDC continues to improve the safety and quality of laboratory practice nationally by partnering with stakeholders such as

- ✓ American Association for Clinical Chemistry
- ✓ American Clinical Laboratory Association
- ✓ American Society for Clinical Laboratory Science
- ✓ American Society for Clinical Pathology
- ✓ American Society for Microbiology
- ✓ Association for Molecular Pathology
- ✓ Association for Pathology Informatics
- ✓ Association of Public Health Laboratories
- ✓ Clinical Laboratory Management Association
- ✓ Clinical and Laboratory Standards Institute
- ✓ College of American Pathologists
- ✓ Institute of Medicine
- ✓ The Joint Commission
- ✓ Federal agencies
- ✓ Hospital, academic, and commercial laboratories
- ✓ Laboratory accrediting bodies
- ✓ State and local health departments
- ✓ Standards organizations
- ✓ Test system manufacturers and software developers

Continuum of Science to Practice

Biorepository Science and Services

We operate the **CDC and Agency for Toxic Substances and Disease Registry (ATSDR) Specimen Packaging, Inventory, and Repository (CASPIR)**—CDC's centralized specimen biorepository—which preserves valuable specimen collections, including those from historical studies, outbreak investigations, and emergency responses. We help develop and support implementation of CDC's specimen-related policies and work in partnership with its Specimen Policy Board and the CASPIR Advisory Committee to ensure compliance with guidelines and policies.

In partnership with the National Institutes of Health (NIH) Coriell Biorepository, we coordinate efforts for the genetic testing community to **contribute, develop, and characterize reference materials** that are needed to ensure accuracy of laboratory test results.

Our Services

- Operate CASPIR and protect the integrity of specimen collections in accordance with **best practice guidelines** for biorepository science.
- Help develop and implement **CDC policies**: CDC Specimen and Sample Management policy, Collections Access policy, and CASPIR policy.
- Offer reliable **biorepository services** to CDC laboratories, such as aliquoting, specimen retrieval, specimen package preparation, and specimen transport.
- Use CASPIR's customized **Specimen Inventory Management System** (SIMS-LV) to manage data and specimen inventories.
- Provide blocks of **specimen identifiers** to CDC centers, institutes, and offices for uniquely identifying all specimens within the agency and for specimen tracking.
- Procure **general commodities** for CDC facilities, such as labels, dry ice, and gases.
- Maintain **liquid nitrogen tank** storage rooms on multiple CDC campuses.
- Assess the **efficiency of operations** through ongoing evaluation and innovation of our services and technical support.
- Characterize **genomic DNA reference materials** for genetic disorders, pharmacogenetics, molecular cancer diagnostic tests, and next generation sequencing, and make them available through public repositories.

Our Impact

- **We provide a controlled, uniform environment to preserve CDC's unique specimens.** Maintaining the integrity of specimens is important for future uses, such as research and development of new tests, vaccines, and treatments.
- **Our specimens play crucial and historical roles in public health research and population health.** CASPIR supports national studies, such as the National Health and Nutrition Examination Survey, the Active Bacterial Core Surveillance Program, and the Child Health and Mortality Prevention Surveillance Network.
- **We publicize the availability of characterized genetic reference materials.** Papers are published in scientific journals, presented at scientific meetings, and posted on CDC and other websites.
- **We provide tools to assess the quality of human genome sequencing.** We collaborated with NIH's National Center for Biotechnology Information and partners in the genetic testing community to create the GeT-RM Browser. This web portal lets laboratories compare their genome sequencing test results with highly characterized reference materials to determine whether they have accurately generated a DNA sequence.
- **We have amassed a large inventory of samples to support genetic testing.** These reference materials—available through Coriell—are used by clinical laboratories, research laboratories, and test developers nationwide to improve the quality and availability of genetic testing and to develop new tests.

CASPIR has more than **200 tanks for liquid nitrogen** storage as well as dozens of mechanical freezers that provide secure long-term preservation.

CASPIR currently manages more than **6.5 million biological and environmental specimens,** representing 620 collections from 33 different CDC divisions.

GeT-RM has characterized more than ***6,000 genetic targets*** in more than ***600 human cell lines***

Find data sets on the GeT-RM Browser
www.ncbi.nlm.nih.gov/variation/tools/get-rm

Find more information on GeT-RM activities
wwwn.cdc.gov/clia/Resources/GetRM

Clinical Laboratory Improvement Program

Through our work with other CDC programs, federal and state agencies, professional societies, and international organizations, we support the development and adoption of standards, guidelines, recommendations, and tools for improved quality and safety in clinical and public health laboratories. In collaboration with the Centers for Medicare & Medicaid Services (CMS) and FDA, we implement the **Clinical Laboratory Improvement Amendments (CLIA)**, which governs all healthcare-related laboratory testing performed on people in the United States.

Our Services

- Through the Clinical Laboratory Integration into Healthcare Collaborative (CLIHC™), study identified gaps and develop solutions to optimize the **effective use of laboratory services** for better patient care.
- Conduct evidence-based systematic reviews using the **Laboratory Medicine Best Practices Initiative (LMBP™) A-6 Method**, and work with experts to develop best practice guidelines for various laboratory testing areas.
- Collaborate with CMS, FDA, and other partners to develop **regulatory standards and guidelines** to implement and support CLIA regulations.
- Manage and support the **Clinical Laboratory Improvement Advisory Committee (CLIAC)**, a federal advisory committee that provides independent scientific guidance on improving laboratory quality and safety practices.
- Evaluate **proficiency testing programs** for CLIA compliance and provide expert recommendations for practical improvement.
- Assess **cytology laboratory practices** to assure quality of testing and practices.
- Enable and support **collaborations with federal partners and other stakeholders** to exchange information about laboratory practices.
- Monitor technological innovations and assess the effectiveness of laboratory practices and **national regulations and voluntary guidelines**.
- Help CDC **CLIA-certified laboratories** interpret CLIA regulations, and facilitate communications with CMS on CLIA-related laboratory testing.

Our Impact

- **Scientific input drives effective regulation.** CLIAC has addressed issues that have faced the national laboratory and healthcare communities for more than 20 years. The committee's insights have resulted in more than 100 formal recommendations as well as many changes to regulations, revisions in policy, development of educational materials, and studies to assess the impact of the CLIA program.
- **We forge new collaborative efforts to unite diverse fields and develop quality standards for emerging technologies.** In 2012 and 2015, we led two national workgroups to develop consensus guidance for next generation sequencing. Prior to our involvement, there were no standards for how to use this new technology in clinical settings.
- **We pioneer effective processes for developing systematic reviews and evidence-based recommendations.** For example, the LMBP defined the A-6 Method—the only evidence-based process to systematically identify laboratory quality improvement practices.
- **We help set national laboratory standards.** Between 2012 and 2016, we contributed to more than 30 published national or international standards and guidelines that address laboratory quality and safety needs. These include specific laboratory testing areas, such as cancer diagnostics, genetic testing, and microbiology testing, among others.

As of 2016

CLIA covers nearly **255,000** U.S. laboratories

More than **11 billion** clinical laboratory tests are performed in the United States each year

About **328,000** diagnostic laboratory professionals use CLIA-related guidance and resources

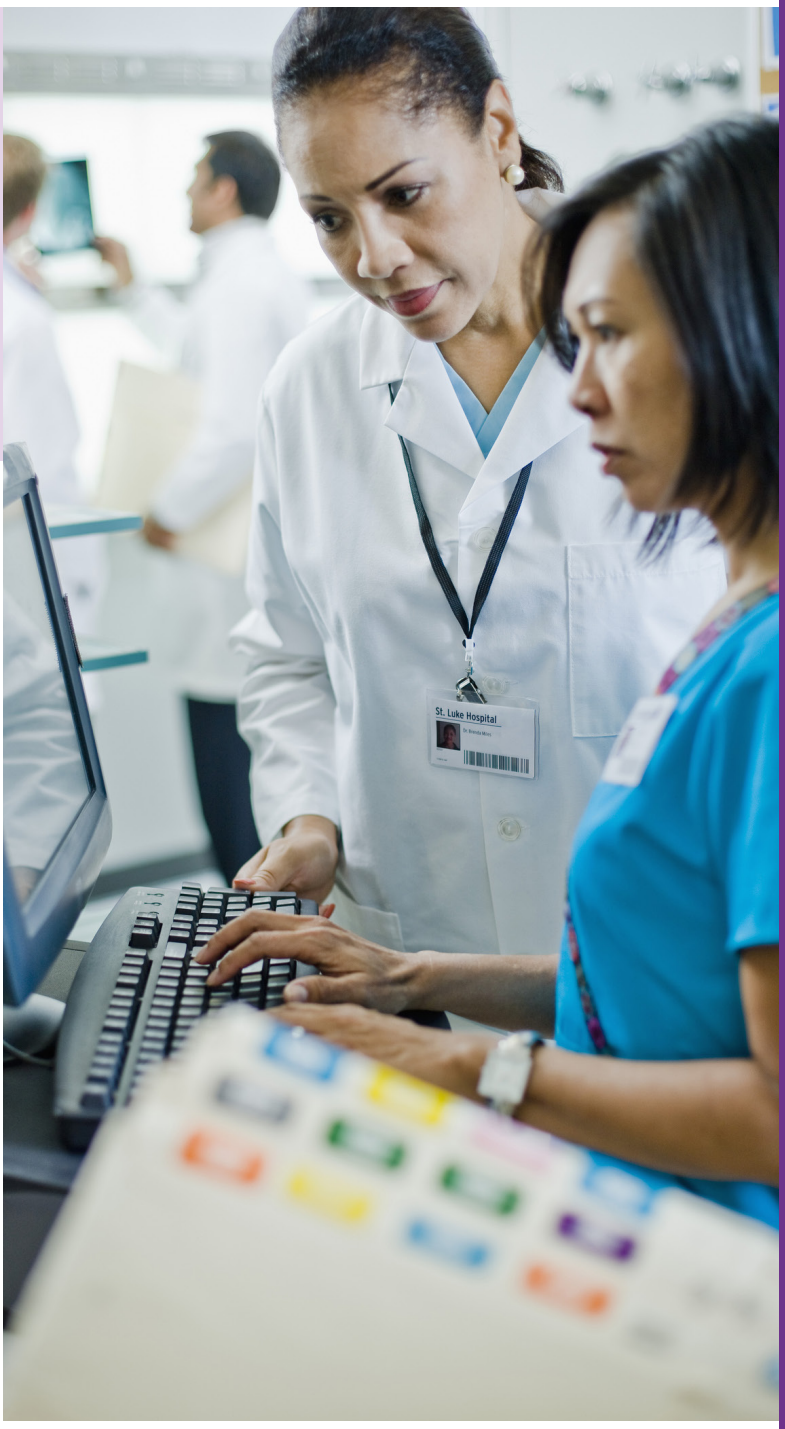
Find out more about CLIA and CLIAC
wwwn.cdc.gov/CLIA
wwwn.cdc.gov/cliac

Find out more about CLIHC and LMBP
www.cdc.gov/ophss/csels/dls/eblm/index.html#CLIHC
wwwn.cdc.gov/futurelabmedicine

We surveyed **1,700 primary care physicians** nationwide and characterized their challenges when ordering and interpreting laboratory tests. The survey results informed the CLIHC agenda and development of tools such as the **PTT Advisor app**.

Informatics and Data Science

We develop, implement, and evaluate informatics and data science approaches to strengthen laboratory information systems for improved clinical and public health outcomes. Our work includes regional and national systems coordination, reporting of laboratory diagnostic information to electronic health records (EHRs), decision-making tools for healthcare providers, research and application of laboratory-related data, and informatics solutions for improved laboratory management, practice, and emergency preparedness.



Our Services

- Improve the collection, maintenance, research, and application of data from **national laboratory systems** and other large health databases such as **medical data warehouses.**
- Provide leadership and coordination for improving the management of **laboratory information systems**.
- Advance **laboratory health information technology (LabHIT)** by working with laboratory and health informatics professionals and other stakeholders to develop national **standards, policies, and certification requirements** for EHRs and the evolving health IT structure.
- Support **interoperable health IT standards**, such as harmonizing laboratory testing codes (e.g., LOINC, SNOMED CT) to enable meaningful comparison of results worldwide.
- Enhance access, analysis, and sharing of information about laboratory services and capacity nationwide through the **Public Health Laboratory System Database (PHLSD)** and the **Informatics Self-Assessment Tool**.

Our Impact

- **Laboratory services are a critical component of health IT.** Accurate, expedient, and user-friendly integration of laboratory diagnostic results into EHRs helps ensure quality patient care and treatment.
- **Our work bridges gaps and encourages collaboration.** We work with teams across CDC, FDA, the Centers for Medicare & Medicaid Services, the Office of the National Coordinator for Health Information Technology, and HL7 to provide subject matter expertise and build consensus. Topics include the development of standardized vocabulary, semantic operability of laboratory test coding, certification of EHR modules, inclusion of CLIA requirements, and laboratory accreditation standards.
- **We communicate the value of laboratory health IT.** Our website provides information and professional guidance on the exchange of test results between EHRs and laboratory information systems to support patient safety. Through research and case studies, we show the significance of laboratory data-related interoperability and propose focus areas for action.
- **We develop groundbreaking tools.** The PHLSD will form the basis of a first-ever online national directory of public health laboratory services. Health departments will be able to immediately direct samples to laboratories that can run the tests needed. Our web-based Informatics Self-Assessment Tool provides the first available data on the informatics capacity of public health laboratories nationwide. It also offers a suite of tools for comparison and analysis from the national to organizational level.
- **Our products provide real solutions using current technologies.** We designed the partial thromboplastin time (PTT) Advisor app, an innovative mobile application that helps clinicians select the right follow-up tests for patients with blood clotting disorders.
- **We stimulate more nimble regional and national systems coordination.** Through partnership with the Association of Public Health Laboratories, we bring attention to systemic efficiencies and sustainability around cross-jurisidictional sharing of laboratory services, informatics capability, innovative practices, and collective workforce development.

Unconventional Results Display: Delayed Diagnosis and Treatment

A young woman's **abnormal Pap smear results** went undetected for four years because of a usability issue with her physician's EHR system. Because of a default setting, the system showed the physician the patient's previously normal laboratory result, and the more recent abnormal result went unnoticed.

The young woman's advanced cervical cancer was only detected when she sought treatment for other symptoms that had developed. As a result of the delay in diagnosis and treatment, the young woman had a hysterectomy. The LabHIT team is working with other federal agencies and its partners in the laboratory and health IT communities to ensure **preventable errors** like this do not occur.

Source: Sawchuk M, Linville M, Cornish N, Pollock A, Lubin I, Gagnon M, et al. The essential role of laboratory professionals: ensuring the safety and effectiveness of laboratory data in electronic health record systems. Atlanta, GA: Center for Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention; 2014.

Find more information on LabHIT
www.cdc.gov/labhit

Learn more about the PTT Advisor app
itunes.apple.com/us/app/ptt-advisor/id537989131?mt=8

www.cdc.gov/ophss/csels/dls/eblm/index.html#CLIHC

Download the PDF version of the Informatics Self-Assessment Tool
www.aphl.org/MRC/Documents/LEI_2013Jun_Informatics-Self-Assessment-Tool-for-PHLs.pdf

Training and Workforce Development

We provide leadership and support to enhance the clinical and public health laboratory workforce through initiatives that strengthen recruitment, retention, management, and training. Our trainings help scientists combat emerging threats, learn evolving practices, and stay current with the newest standards and technologies. We also develop frameworks, models, and resources that support laboratory-related competencies for fellowships and health science education.

Our Services

- Apply instructional design support and knowledge of adult learning best practices to help more than 60 CDC laboratories and external partners develop **effective training products**—to maintain a competent, prepared, and sustainable national and global laboratory workforce.
- Provide competency-building content across **nearly 100 laboratory topics** to keep CDC, public health, and laboratory scientists proficient in areas such as essential laboratory methodologies, new test procedures, informatics, and quality and safety.
- Design **innovative, comprehensive, and convenient training programs** featuring state-of-the-art video and graphics production in a variety of formats, including workbooks, hands-on workshops, e-learning, webinars, virtual classrooms, and smartphone apps.
- Help develop and promote **laboratory workforce competencies** through a national workforce strategic plan and the implementation of public health laboratory competency guidelines.
- Evaluate the efficiency and effectiveness of public health laboratory education and training, including measuring outcomes on the **transfer of knowledge and skills to improved laboratory practice**.

Our Impact

- **Our products and programs address competency gaps for laboratory professionals and healthcare providers.** These resources help improve on laboratory and point-of-care testing practices. Our *Ready? Set? Test!* booklets, posters, postcards, and online training course help laboratories and other testing facilities meet Clinical Laboratory Improvement Amendments (CLIA) regulations and follow recommended guidelines.
- **Our training programs help laboratories improve their safety and quality of practice.** Over half of our training participants have reported implementing new or improved laboratory procedures as a result of the training. More than 75% of our biosafety and biosecurity training attendees implemented changes in their facilities' programs.
- **We inform national laboratory capacity for emergency preparedness and response.** In 2015, we successfully conducted the first Virtual Knowledge Assessment for Sentinel Laboratories—a group of several thousand local clinical laboratories that serve as the frontline response to biological threats in support of the Laboratory Response Network. Our assessments—offered at no cost to the local laboratories—cover rule-out-or-refer procedures to identify potential bioterrorism agents.
- **We publish work to impact the broad laboratory community.** In May 2015, together with the Association of Public Health Laboratories (APHL), we published Competency Guidelines for Public Health Laboratory Professionals as a *Morbidity and Mortality Weekly Report Supplement* issue. The guidelines inform training and curriculum development, fellowship programs, and management processes across public health and clinical laboratory systems.

Educational Tools Help Laboratories Continually Improve

We develop and disseminate a growing inventory of educational resources, including online courses, e-learning tools, web-based resources, and print materials. Here are some examples

More than 4,400 people have completed our *Ready? Set? Test!* online training course on preparing and performing waived testing. Our **booklets, posters, and postcards** have reached laboratories in 50 states and the District of Columbia.

Our workbook to help laboratories implement individualized **quality control plans** received more than 3,000 web page views in the first 3 months after launch.

People in the United States and 11 other countries have registered for our online **continuing education course** on good laboratory practices for molecular genetic testing.

Download the CDC/APHL Competency Guidelines for Public Health Laboratory Professionals
www.cdc.gov/mmwr/preview/ind2015_su.html

Find more information on laboratory training
www.cdc.gov/labtraining

CDC scientist Dr. J.V. Lange wears a maximum containment suit to handle dangerous specimens in one of CDC's early containment laboratories, also known as biosafety level 4 environments. Scientists who work in these laboratories must use highly specialized protective equipment such as these airtight suits. CSELS helps develop the standards and guidelines that address laboratory quality and safety nationally and internationally.