

Office of Laboratory Science and Safety (CAN)

In carrying out its mission, the Office of Laboratory Science and Safety: (1) Provides scientific, technical, and managerial expertise and leadership in the development and enhancement of laboratory safety programs; (2) oversees and monitors the development, implementation, and evaluation of the laboratory safety and quality management programs across CDC; (3) oversees the development and distribution of guidance and interpretation of Clinical Laboratory Improvement Amendments (CLIA) regulations for infectious disease laboratories and monitors and ensures laboratory compliance; and (4) bridges and strengthens the nation's clinical and public health laboratory system by continually improving quality and safety, informatics and data science, and workforce competency. (Approved 6/28/2023)

Office of the Director (CAN1)

(1) Provides scientific, technical, and managerial expertise and leadership in the development and enhancement of laboratory science and safety programs; (2) oversees and monitors the development, implementation, and evaluation of the laboratory safety and quality management programs across CDC; (3) provides the understanding of CLIA regulations and tools needed by the infectious diseases laboratories to operate in compliance with established requirements; (4) advises on policy, partnerships, and issues management matters; (5) advises on matters related to internal and external public health communications; (6) provides oversight to ensure CDC compliance with regulations for select agents and toxins, and the safe possession, use, and transfer of select agents and toxins; (7) provides oversight to ensure CDC compliance with all applicable laws, regulations, policies, and standards regarding the humane care and use of laboratory animals at CDC; (8) serves as the Institutional Official for purposes of compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals; (9) makes appointments to the CDC Institutional Animal Care and Use Committees; (10) leads responses to laboratory incidents and emergencies; (11) guides the development of laboratory systems standards for quality and safety; and (12) bridges and strengthens the nation's clinical and public health laboratory system by continually improving quality and safety, informatics and data science, and workforce competency. (Approved 6/28/2023)

Office of Infectious Disease Laboratory Quality (CAN12)

(1) Develops and distributes guidance and interpretation of the CLIA regulations for the CDC Infectious Disease (ID) laboratories; (2) serves as liaison with Centers for Medicare & Medicaid Services (CMS) for CDC ID laboratory practices that are subject to CLIA; (3) provides data analysis, summary reports, and technical assistance for laboratory leadership; (4) provides oversight through internal assessments, consultations and routine processes to ensure CDC compliance with all applicable laws, regulations, policies, and standards regarding CLIA regulations and compliance with the Quality Manual for Microbiological Laboratories (QMML) for the CDC Infectious Disease laboratories; (5) serves as the Institutional Official for purposes of CLIA compliance for all ID laboratories; (6) ensures clear communication and coordination with the CDC ID laboratories; (7) develops and implements value added processes related to

laboratory quality management, test method validation, verification and modification, specimen submission and result reporting; (8) provides quality support and guidance to ID laboratories to ensure practical and effective quality management systems are implemented and operational in CLIA, surveillance, and research laboratories; and (9) Engages with internal and external partners as needed related to quality and compliance of ID laboratory testing.

(Approved 1/24/2023; Effective 2/8/2023)

Office of Laboratory Safety (CAN13)

(1) Provides high-level oversight and coordination of laboratory safety at all CDC campuses; (2) develops and assesses the effectiveness of agency-level plans, policies, manuals, and tools for implementation of laboratory safety standards; (3) provides regulatory compliance for biological safety, chemical safety, radiation safety, and the possession, use, and transport of select agents and toxins; (4) provides expertise and consultation for biological safety, chemical safety, and radiation safety; and (5) provides expertise for CDC-wide compliance with all applicable laws, regulations, policies, and standards regarding the humane care and use of laboratory animals at CDC. (Approved 6/28/2023)

Office of Laboratory Science (CAN14)

(1) Provides high-level coordination of policies and guidance for core laboratory training programs in quality management, laboratory safety, and Food and Drug Administration (FDA)-regulated diagnostic devices; (2) manages the catalog of core laboratory quality, safety, and FDA-regulatory compliance training courses; (3) provides expertise and consultation for policy development and implementation of laboratory quality management activities; and (4) provides regulatory expertise and consultation to support policy development and compliance with FDA regulations for in vitro diagnostic devices. (Approved 6/28/2023)

Center for Laboratory Systems and Response (CANB)

The mission of the Center for Laboratory Systems and Response (CLSR) is to collaborate with the nation's clinical and public health laboratory systems as well as CDC's programmatic subject matter experts to ensure scientifically advanced, timely, and efficient laboratory response and diagnostic testing for infectious disease outbreaks, epidemics, and pandemics, and to provide cross-cutting laboratory operation and systems support for CDC's infectious disease laboratories. To carry out this mission, CLSR: (1) Arranges and manages the transfer of CDC diagnostic tests used in national responses to public health and clinical laboratories, including appropriate testing and biosafety guidance; (2) provides cross-cutting laboratory products and services to support laboratory activities of CDC programs; (3) advances the nation's capacity to electronically exchange clinical and public health laboratory testing data through the use of standards and common infrastructure; (4) develops and distributes state-of-the-art laboratory training and development courses and tools to strengthen the clinical and public health laboratory workforce; (5) supports the nation's CLIA laboratory quality program in collaboration with FDA and the Centers for Medicare and Medicaid Services (CMS); (6) functions as the CDC lead for the National Laboratory Response System and oversees CDC's role in the national clinical and public health laboratory system before and during infectious disease outbreaks, epidemics, and

pandemics; (7) provides scientific guidance, regulatory oversight, clearance review, and coordination across CLSR to support, promote, and ensure scientific quality and integrity of CLSR products and programs; (8) supports CLSR program monitoring, evaluation and reporting efforts to ensure that they advance both health equity and public health outcomes, and reinforces the importance of robust public health evaluation across all of CLSR's programs; (9) supports CLSR programs with strategy development and implementation plans; (10) provides leadership and guidance on policy issues, coordinates with agency and other government organizations about CSLR activities, and helps to define and pursue goals for policy formation and execution; and (11) provides communication services, coordinates with communication professionals about CLSR's activities, and facilitates partnerships across the center. (Approved 6/28/2023)

Division of Laboratory Systems (CANBB)

The mission of the Division of Laboratory Systems (DLS) is to ensure the effectiveness of the National Laboratory Response System and to improve public health, patient outcomes, and health equity by advancing laboratory systems. To carry out this mission, DLS: (1) Functions as the CDC lead for the National Laboratory Response System, and oversees CDC's role in this system before and during infectious disease outbreaks, epidemics, and pandemics; (2) advances the state of the national clinical laboratory system's quality and safety, data exchange, preparedness and response capacity, and workforce competency; (3) strengthens the capacity of the nation's public health and clinical laboratory system, including diagnostic testing facilities, to prepare for and respond to infectious disease outbreaks, epidemics, and pandemics; (4) engages, supports, and bolsters the work of the nation's public health and clinical laboratory community; (5) engages and supports partners and professional organizations in the clinical laboratory and diagnostic manufacturing industries as well as across the U.S. Government; (6) collaborates with CMS and FDA to implement the federal CLIA program; (7) manages and executes CDC's responsibilities for the federal CLIA program; (8) advances the nation's capacity to electronically exchange clinical and public health laboratory testing data through the use of standards and common infrastructure; (9) develops and distributes state-of-the-art laboratory training and development courses and tools to strengthen the clinical and public health laboratory workforce; (10) fosters collaborations and cross-cutting activities with other CDC components and external organizations to support the mission, activities, and operations of DLS; (11) provides stewardship of the agency's cooperative agreement (CoAg) with the Association for Public Health Laboratories (APHL) and other division procurement, grants, CoAgs, materials management, interagency agreements, and extramural resources; (12) addresses policy issues that affect or could affect the National Laboratory Response System or other DLS programs and activities; (13) provides communications, web support, social media presence, responses to media requests, and promotion and outreach efforts to clinical and public health laboratories on emergency response and testing through the CDC's Laboratory Outreach and Communication System; and (14) responds to requests from other CDC programs for technical assistance relating to DLS capabilities. (Approved 6/28/2023)

Office of the Director (CANBB1)

The DLS Office of the Director: (1) Provides leadership and guidance on the development of strategic goals, objectives, and milestones to advance the vision and mission of DLS and CLSR, (2) develops administrative policies, processes, and operations for the division; (3) ensures that health equity principles are applied in all DLS activities; (4) works with the CSLR Office of the Director (OD) to ensure that spending plans and budgets are executed and aligned with the strategic priorities of the division; (5) works with the CSLR OD to establish and maintain a diverse, equitable, inclusive, and accessible workplace; (6) provides DLS communications resources, including web support, writing and editing, social media presence, and promotion and outreach efforts to clinical and public health laboratories; (7) provides scientific guidance and resources, regulatory oversight, clearance review, and coordination with DLS staff to support, promote, and ensure scientific quality and integrity of DLS products and programs; (8) manages the division's CoAgs, including the CDC APHL CoAg (OE20-2001) and Enhancing U.S. Clinical Laboratory Workforce Capacity CoAg (OE22-2202); (9) fosters existing and new partnerships with the clinical and public health laboratory and testing community, other CDC programs, federal and state agencies, and professional organizations to further DLS mission and goals; (10) liaises with CMS and FDA CLIA program partners, CLIA-approved accreditation organizations and proficiency testing programs, and other CDC programs and offices for CLIA-related issues; and (11) analyzes and provides guidance on policy-related issues that affect DLS and the broader public and clinical laboratory community, and ensures that DLS activities, communications, and materials are aligned with agency policy. (Approved 6/28/2023)

National Laboratory Response System Branch (CANBBB)

The mission of the National Laboratory Response System Branch (NLRSB) is to serve as CDC's lead for the National Laboratory Response System and to oversee CDC's role in this system before and during infectious disease outbreaks, epidemics, and pandemics. To carry out its mission, NLRSB: (1) Strengthens the nation's diagnostic testing and reporting capabilities and capacity, especially before and during public health emergencies, through programs, partnerships, test deployment and distribution, and electronic data exchange; (2) coordinates and supports preparedness and response activities of public health laboratories (PHLs) that are members of the Laboratory Response Network (LRN) for biological threats; (3) develops and maintains partnerships for expanded emergency diagnostic testing capacity to national commercial and other clinical laboratories; (4) provides communication to clinical and PHLs and laboratory partners on laboratory matters of public health significance through the Laboratory Outreach Communication System; (5) provides informatics solutions and technical assistance to LRN member laboratories that share laboratory testing data with CDC for surveillance and response; (6) promotes the development and use of standards to advance the quality and semantic interoperability of laboratory data; (7) oversees the development of existing systems, new infrastructure, and tools and services for PHLs to receive electronic test orders from and submit test results to healthcare providers; (8) participates in and chairs interagency workgroups or task forces for the rapid development and deployment of emergency diagnostics, including the Tri-Agency Task Force for Emergency Diagnostics; and (9) supports clinical, research, outbreak, and other event response work by managing multiple aspects of the Enterprise Laboratory Information Management system, providing a centralized location for data storage, specimen

management, testing, and reporting and allowing for harmonized data transfer and enhanced collaboration across CDC's laboratories. (Approved 6/28/2023)

Quality and Safety Systems Branch (CANBBC)

The mission of the Quality and Safety Systems Branch is to improve the quality and safety of laboratory testing in clinical and public health settings across the nation. To carry out its mission, QSSB: (1) Collaborates across CDC and engages broadly with external partners, including other federal agencies, state agencies and programs, and professional organizations; (2) develops laboratory quality and safety standards, guidelines, and recommendations in collaboration with partners; (3) promotes the adoption of these products by clinical and public health laboratories; (4) provides scientific and technical support for the national CLIA program to ensure the quality and safety of clinical and public health laboratory testing; (5) hosts and manages the Clinical Laboratory Improvement Advisory Committee and its workgroups on behalf of a tri-agency partnership among CDC, CMS, and FDA; (6) provides expertise in the development and revision of CLIA technical standards and voluntary guidelines for laboratory quality and safety; (7) provides quality and safety subject matter expertise to the DLS Training and Workforce Development Branch for the development of training courses for external clinical and PHLs; (8) leads the Next Generation Sequencing Quality Initiative to develop adaptive quality management systems that support next generation sequencing workflows; (9) leads the implementation of biorisk management system standards for the safety of laboratory and testing professionals and their communities; (10) advances the integration of laboratory expertise in healthcare systems to improve the accuracy of diagnoses and to reduce diagnostic errors; (11) develops, promotes, and implements data science approaches for improved use of large and complex data sets in support of adherence to CLIA standards; and (12) leverages data acquired from large health databases to evaluate laboratory testing practices, capabilities, capacity, and public health outcomes. (Approved 6/28/2023)

Training and Workforce Development Branch (CANBBD)

The mission of the Training and Development Branch (TWDB) is to strengthen laboratory practice and systems through strategic, innovative training, and leadership of initiatives to recruit, develop, and retain a diverse, well-prepared laboratory workforce. To carry out its mission, TWDB: (1) Develops, promotes, and disseminates laboratory capacity-building resources that enhance the clinical laboratory community's ability to combat emerging threats, learn evolving practices, and stay current with the newest standards and technologies; (2) designs and disseminates innovative training on laboratory core science, quality, safety, informatics, and emergency preparedness for U.S. clinical and public health laboratories and the testing community – including eLearning, printable and video job aids, live webinars, Training of Trainers programs, and virtual reality courses that build learners' skills in a safe, simulated laboratory environment; (3) engages clinical and public health laboratory professionals and point-of-care testers and connects them to CDC and to each other to rapidly identify and respond to urgent training needs and sustain a capacity-building community; (4) develops just-in-time training for an integrated network of domestic and international laboratories on how to respond to biological and chemical threats and other high-priority public health emergencies;

(5) leverages expertise in instructional design, multimedia production, evaluation, and project management to rapidly identify and prioritize training needs, select the optimal format for a given training goal, audience, and timeline, and efficiently develop laboratory training that meets CDC Quality Training Standards and Section 508 standards for learners with disabilities; (6) maintains a free, publicly accessible learning management system tailored to the needs of U.S. clinical laboratory professionals; (7) facilitates site-specific training and increases U.S. clinical laboratories' capacity sustain to their own workforce development programs; (8) develops quality, safety, and regulatory affairs training informed by agency-specific policies and guidelines and tailored to the needs of CDC laboratory staff; (9) designs and delivers hands-on training at CDC's laboratory training facilities; (10) provides leadership and support of the laboratory workforce through sustainable initiatives that strengthen recruitment, retention, management, and training; (11) increases awareness of and access to laboratory education and training opportunities among under-represented groups and communities to increase diversity within the laboratory workforce and ultimately advance health equity; (12) develops frameworks, models, and resources that support competency-based laboratory training; and (13) evaluates the efficiency and effectiveness of laboratory education, training and workforce development programs to ensure the effective knowledge transfer and skills attainment to improve laboratory practice. (Approved 6/28/2023)