

Office of Laboratory Systems and Response (CAN)

To carry out its mission, the Office of Laboratory Systems and Response (OLSR): (1) Provides cross-cutting laboratory products, services, and systems (quality, safety, informatics, workforce, response readiness) support for CDC laboratories that conduct research, surveillance, and routine and emergency diagnostic testing, and develop diagnostic tests; (2) collaborates with the nation's laboratories (public health, clinical, industry, academic, and other government) to ensure scientifically advanced, timely, and efficient laboratory response and diagnostic testing; (3) provides scientific, technical, and managerial expertise and national leadership in the development and enhancement of laboratory quality, safety, informatics, and training and workforce development programs; (4) ensures regulatory compliance and monitors implementation and evaluation of the laboratory safety and quality management programs across CDC; (5) oversees the development and distribution of agency guidance on diagnostic testing and clinical laboratory operations and interpretation of laboratory regulations; and (6) bridges and strengthens the nation's clinical and public health laboratory system by continually improving quality and safety, response readiness, informatics and data science capability, and workforce competency.

(Approved 9/13/2024)

Office of the Director (CAN1)

(1) Serves as the home office of the Associate Director for Laboratory Science and Safety (ADLSS) who serves as the single point of laboratory accountability for all laboratory systems at the agency; (2) provides scientific, technical, and managerial expertise and leadership in the development and enhancement of laboratory systems (quality, safety, informatics, training and workforce development, and response readiness); (3) oversees and monitors the development, implementation, and evaluation of the laboratory safety and quality management programs across CDC; (4) provides expertise and consultation in interpreting and complying with regulations (e.g., Clinical Laboratory Improvement Amendments (CLIA), Food and Drug Administration (FDA)-regulated devices) and develops tools and systems needed by CDC laboratories to operate in compliance with established requirements; (5) 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; (6) 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; (7) ensures compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals; (8) makes appointments to the CDC Institutional Animal Care and Use Committees; (9) provides strategic direction and leadership in management of OLSR fiscal, workforce, information technology, and facilities resources and leads coordination and stewardship of procurement, grants, cooperative agreements, materials management, interagency agreements, and extramural resources; (10) ensures that spending plans (Office and Divisions) and budgets are executed and aligned with the strategic priorities of OLSR; (11) ensures that health equity principles are applied in all OLSR activities; (12) establishes and maintains a diverse, equitable, inclusive, and accessible workplace within all of OLSR; (13) provides scientific guidance, regulatory oversight, clearance review, and coordination across OLSR to support, promote, and ensure scientific quality and integrity of OLSR products and programs; (14) supports OLSR program monitoring, evaluation and reporting efforts to ensure that OLSR programs advance both health equity and public health outcomes, and reinforces the importance of robust public health evaluation across all of OLSR's programs; (15) supports OLSR programs with strategy development and implementation plans; (16) provides leadership and guidance on policy issues, coordinates with agency and other government organizations about OSLR activities, and helps to define and pursue goals for policy formation and execution; (17) provides communication services, coordinates with communication professionals about OLSR's activities, and facilitates partnerships across

Centers/Institute/Offices (CIOs); (18) leads responses to laboratory incidents and emergencies; (19) bridges and strengthens the nation's clinical and public health laboratory system by continually improving quality and safety, response readiness, informatics and data science capability, and workforce competency; (20) serves as the lead for the laboratory and testing task force for all agency-wide public health responses; and (21) maintains CDC's laboratory and diagnostic testing relationships with interagency and public health partners. (Approved 9/13/2024)

Office of Laboratory Quality and Safety (CAN12)

(1) Provides consultation, high-level oversight, and expertise for policy development and implementation of laboratory safety and quality management activities; (2) develops, selects, deploys, and implements agency-level plans, policies, manuals, and tools for laboratory quality and safety standards; (3) assesses effectiveness of agency-level laboratory quality and safety standards; (4) develops and distributes guidance and interpretation of the CLIA regulations for the CDC Infectious Disease (ID) laboratories; (5) provides data analysis, summary reports, and technical assistance for laboratory leadership; (6) ensures CDC laboratory compliance with all applicable laws, regulations, policies, and standards (e.g., possession, uses, and transport of select agents and toxins; CLIA regulations; Quality Management System Regulation (QMSR); laboratory waste and disposal policies; Quality Manual for Microbiological Laboratories (QMML); biological safety; chemical safety; radiation safety) through internal assessments, consultations and routine processes; (7) provides customer-driven services to support CDC laboratory operations (e.g., laboratory equipment certification, space decontamination, incident investigation, laboratory waste and disposal, facility design and renovation consultation, laboratory certification and decertification, and inventory management support); (8) 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; (9) serves as the home office for the CLIA Laboratory Director CDC Roybal campus ID laboratories; (10) provides regulatory expertise and consultation to support policy development and to support centers, institutes, and offices as they fulfill their responsibility to comply with FDA regulations for in vitro diagnostic devices; and (11) serves as the primary coordinating body for engagement with internal and external partners related to quality management systems, safety and regulatory compliance of domestic CDC laboratory research, surveillance and clinical testing. (Approved 9/13/2024)

Division of Laboratory Systems (CANC)

The mission of the Division of Laboratory Systems (DLS) is to ensure the effectiveness of the Laboratory Response Network 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 nation's Laboratory Response Network (LRN), and oversees CDC's role in this network 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 Centers for Medicare and Medicaid Services (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 CDC's as well as the nation's clinical and public health laboratory workforce; (10) manages the catalog of intramural core laboratory quality, safety, and regulatory compliance training courses; (11) fosters collaborations and cross-cutting activities with other CDC CIOs and external organizations to support the mission, activities, and operations of DLS; (12) provides stewardship of division procurement, materials management, interagency agreements, cooperative agreements, and extramural resources; (13) addresses policy issues that affect or could affect the National Laboratory Response System, other DLS programs and activities, and clinical and public health laboratory operations; (14) 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 (15) responds to requests from other CDC programs for technical assistance relating to DLS capabilities. (Approved 9/13/2024)

Office of the Director (CANC1)

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 OLSR, (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 OLSR 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 OLSR OD to establish and maintain a diverse, equitable, inclusive, and accessible workplace; (6) provides DLS communications resources, including web support, writing and editing services, 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) 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; (9) 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 (10) 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 9/13/2024)

Laboratory Readiness and Informatics Branch (CANC B)

The mission of the Laboratory Readiness and Informatics Branch (LRIB) is to serve as CDC's lead for implementing testing strategies in the LRN and commercial laboratories as well as to provide guidance and support to enhance laboratory data exchange before and during infectious disease outbreaks, epidemics, and pandemics. To carry out its mission, LRIB: (1) Strengthens the nation's clinical testing and results reporting capabilities and capacity, especially before and during public health emergencies, through programs, partnerships, and by implementing strategies to improve electronic laboratory data exchange; (2) coordinates and supports preparedness and response activities of public health laboratories (PHLs) that are members of the 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 matters of public health significance through the Laboratory Outreach Communication System and the LRN; (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 Public Health Laboratories (PHLs) to receive electronic test orders from and submit test results to healthcare providers; and (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.
(Approved 9/13/2024)

Quality and Safety Systems Branch (CANCC)

The mission of the Quality and Safety Systems Branch (QSSB) 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 Clinical Laboratory Improvement Amendments of 1988 program to ensure the quality and safety of clinical and public health laboratory testing; (5) hosts and manages the Clinical Laboratory Improvement Advisory Committee (CLIAC) 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 9/13/2024)

Training and Workforce Development Branch (CANCD)

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 CDC's and 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 CDC and the 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 testers in non-laboratory settings 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 CDC, 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 OneLab Rapid Education And Capacity-building Hub (REACH), a free, publicly accessible learning management system tailored to the needs of CDC and U.S. clinical laboratory professionals; (7) facilitates site-specific training and increases CDC and U.S. clinical laboratories' capacity to sustain their own workforce development programs; (8) develops, delivers, and maintains a catalog of 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 9/13/2024)

Division of Core Laboratory Services and Response (CAND)

The mission of the Division of Core Laboratory Services and Response (DCLSR) is to provide products, services, and specialized expertise to CDC programs in support of emergency response activities, laboratory research, and laboratory operations. To carry out its mission, DCLSR: (1) Provides laboratory support to outbreak responses through sample accessioning, pre-clinical processing of diagnostic specimens, surge testing capacity, and long-term sample management, including the CDC Biorepository; (2) provides laboratory supplies, glassware, mammalian tissue cultures, microbiological media, special reagents, and other laboratory materials in support of research and service activities to laboratories and CDC investigators; (3) promotes animal welfare and improves the quality and integrity of animal-based research by engaging in independent and collaborative research, providing state-of-the-art training to researchers and partners, and offering a broad range of fully integrated professional veterinary services; (4) works with CDC pathogen specific programs and public health partners in test design and evaluation, including innovative and novel diagnostic tests and assays (molecular, immunological, and sequence based) and new instrument platforms and technologies to detect emerging and known pathogens; (5) develops and implements applied research programs to expand and enhance the use of animal models necessary to support research and diagnostic programs and to improve breeding and husbandry procedures; (6) conducts applied research in cell biology and in the expansion of tissue culture technology as a research and diagnostic tool for infectious disease activities; (7) serves as an important entry point for emerging and advanced laboratory technologies, and a central core facility for high-capacity or high-output instrumentation that can support multiple program activities; (8) provides services for laboratory investigators in DNA and peptide synthesis, genomic sequencing, bioinformatics, mass spectrometry, and proteomics; (9) obtains and distributes experimental and orphaned vaccines, drugs, antisera, antitoxins, and immune globulins; (10) manages and distributes the inventory, maintains the computerized system database, and provides general technical service support for the dispensing, lyophilizing, capping, and labeling of CDC reference reagents; (11) receives, triages, processes, and distributes samples to CDC laboratories for reference diagnostic testing, research studies, and epidemics, and reports diagnostic test results to submitting organizations; (12) manages all CDC exports and ensures compliance with regulations and serves as CDC liaison with the Department of Commerce for export-related issues; (13) produces and distributes specialized reagents and diagnostic products for research and development, surveillance, preparedness activities, outbreak and emergency response; (14) provides services and expertise in implementation of quality systems to support compliance with FDA regulations on production, distribution, and use of laboratory diagnostic reagents; (15) provides liaison activities,

resources, and expertise for inquiries regarding multiple animal species relevant to zoonotic diseases; (16) provides a centralized activity for tracking requests for and distributing select agents to investigators outside of CDC in compliance with federal regulations; and (17) provides staffing and support for emergency responses at the program, division, center, and agency levels. (Approved 9/13/2024)

Office of the Director (CAND1)

(1) Manages, directs, and coordinates the activities of DCLSR; (2) provides leadership and guidance on the development of strategic goals, objectives, and milestones to advance the vision and mission of DCLSR; (3) distributes investigational and licensed drugs and unique biologicals (antitoxins) to approved physicians for the treatment of rare, tropical, or exceptional diseases; (4) develops administrative policies, processes, and operations for the division; (5) ensures that health equity principles are applied in all DCLSR activities; (6) works to ensure that spending plans and budgets are executed and aligned with the strategic priorities of the division; (7) works with OLSR OD to establish and maintain a diverse, equitable, inclusive, and accessible workplace; (8) provides scientific, business, and policy oversight and guidance for all programs and activities housed in the division; and (9) works closely with other CIOs during outbreak investigations and on an ongoing basis, providing support, guidance, collaboration, and expertise. (Approved 9/13/2024)

Biotechnology Core Facility Branch (CANDB)

(1) Serves a vital function at CDC, enabling rapid, high-quality and state-of-the-art sequencing services for infectious and biothreat agents, environmental, human, animal, and vector species in support of the agency's public health mission; (2) provides qualitative and quantitative proteomic analyses (identification of expressed proteins by mass spectrometry) and analysis of functionally relevant post-translational modifications of proteins; (3) provides mass spectrometry-based positive identification of bacteria and fungi; (4) provides synthetic oligonucleotide chemistry in support of development of rapid diagnostic tests and characterization of pathogens and their hosts; (5) provides synthetic peptide chemistry in support of studies of immune response and antigen-antibody interactions; (6) provides biotechnology seminars and methods evaluation; (7) works with CDC pathogen-specific programs in the evaluation of new instrument platforms and technologies to detect emerging and known pathogens and in the evaluation of existing and in the design of innovative and novel diagnostic tests and assays (sequence based); and (8) assesses and supports advanced analytical methodologies for the CDC scientific community. (Approved 9/13/2024)

Comparative Medicine Branch (CANDC)

(1) Acquires and distributes laboratory animals for research; (2) provides appropriate housing, husbandry, and psychological enrichment for all research animals; (3) provides veterinary services, including clinical and surgical support, for the laboratory animals; (4) develops standard operating procedures for animal care and use in accordance with the policies established by Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International, the Animal Welfare Act, The Guide for the Care & Use of Laboratory Animals, and the CDC International Animal Care & Use Committee; (5) conducts applied research to improve the care and use of animals in research and collaborates on research projects that use laboratory animals; (6) provides consultation and laboratory animal technology training to investigators, technical staff and animal care personnel; and (7) provides oversight, support and investigator training for the graphical animal information technology protocol development and animal tracking database. (Approved 9/13/2024)

Preparedness, Response, and Outbreak Services Branch (CANDD)

(1) Provides centralized specimen management services for diagnostic, reference, and outbreak investigations; maintains a bank of biological specimens of epidemiological significance to CDC's research and diagnostic activities; manages and tracks systems of specimen collections; (2) receives, triages, processes, stores, and distributes specimens to CDC laboratories for reference diagnostic testing, research studies, and reports diagnostic and surveillance test results to submitting organizations; (3) provides extracted nucleic acids under a CLIA approved workflow that can be used for sequencing and molecular diagnostics; (4) maintains and manages the biological laboratory component of the LRN; (5) provides strategic guidance for LRN test development and reagent inventory operations; (6) provides technical input for assay development for federally managed environmental monitoring systems and guidelines developed through U.S. government collaborations for the validation and use of environmental detection devices; (7) develops LRN protocols for specimen handling and testing for bioterrorism agents; (8) produces and manages inventory of high-quality reagents available to LRN laboratories and expedites shipping of products to support emergency response needs; (9) collaborates with CDC and external partners to assist in administering proficiency testing programs for critical agents for LRN member laboratories; (10) evaluates and validates advanced technology for the identification and characterization of agents of bioterrorism and other emerging infectious diseases; (11) works with CDC pathogen-specific programs in the evaluation of existing and in the design of innovative and novel diagnostic tests and assays (molecular and immunological); (12) provides laboratory triage capability at CDC for unknown biological and chemical agents; (13) produces hybridomas, monoclonal, and polyclonal antibodies, and in vitro diagnostic products for diagnostic research purposes, proficiency testing, pandemic preparedness, outbreak response and surveillance activities; (14) collaborates with subject matter experts in regulatory compliant development, production, packaging, storing and distribution of Biosafety Level 2 (BSL2)/Biosafety Level 3 (BSL3) reagents, select agents, novel immuno- chemical reagents and reference diagnostic reagents; (15) provides dispensing, lyophilizing, label production, and device assembly services; (16) improves the process of bench-top development and in-house pilot scale production, providing immediate availability for distribution, preventing backorders, and streamlining commercialization; (17) operates the CDC Biorepository as a centralized resource to preserve CDC's valuable samples and provide ongoing support to CDC programs; (18) manages sample collections, along with associated information and data obtained from CDC's public health surveillance, research, and outbreak responses; (19) serves as the administrator that issues CDC's required standardized identifiers: the CDC Sample Identifier and CDC Unique Identified; and (20) provides consultation in all of the above technical services. (Approved 9/13/2024)

Laboratory Products and Services Branch (CANDE)

(1) Maintains laboratory water treatment systems to ensure the quality of CDC reagent grade laboratory water; (2) produces, develops, evaluates, and distributes custom microbiological and cell culture media, buffers, chemical reagents, and cell cultures; (3) maintains CDC's Biological Reference Reagent Inventory and a serviceable inventory at the DCLSR Continuity of Operations storage facility; (4) packages infectious substances, clinical specimens, and other materials, ensuring compliance with shipping regulations; (5) manages all CDC exports and deemed exports ensuring compliance with regulations and serves as CDC liaison with the Department of Commerce for export-related issues; (6) coordinates laboratory glassware and consumable stockroom operations; and (7) provides consultation in all of the above technical services. (Approved 9/13/2024)