Division of Laboratory Sciences
FY 2024 Annual Report

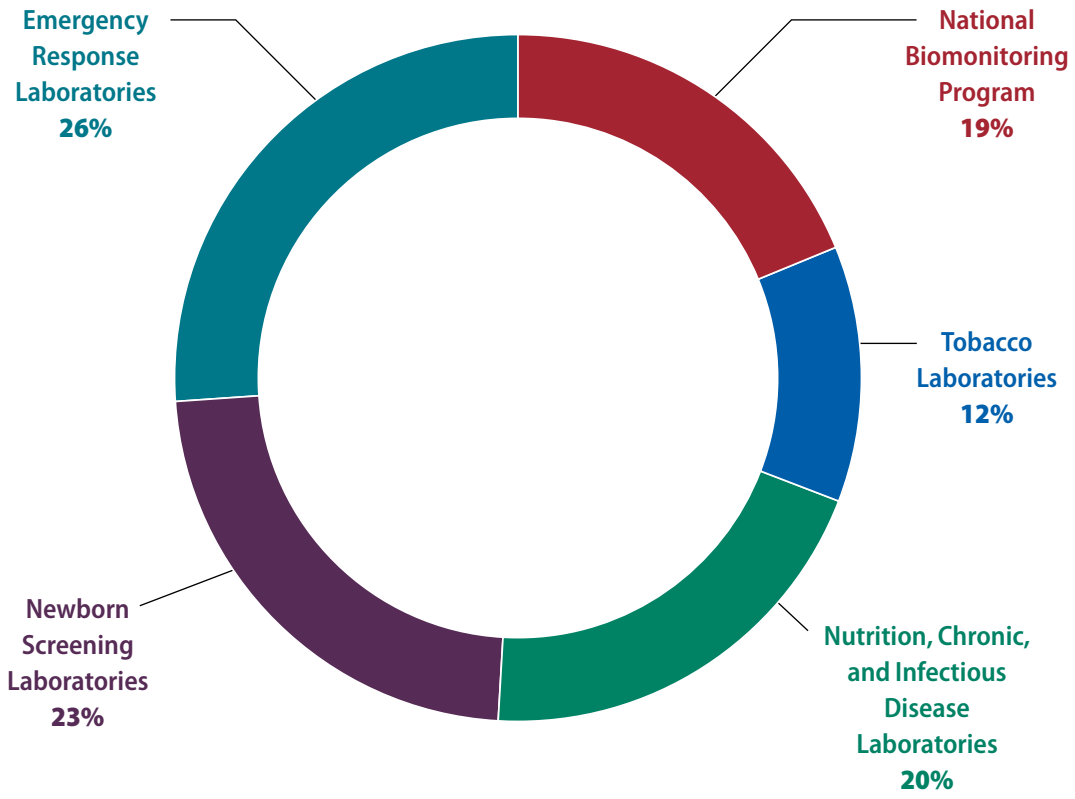
CS 362173-A

Contents

Funding Overview—FY 2024

Funding Source	Amount
Direct Appropriated Funding—Environmental Health Laboratory	$49,518,952
Financial support from other CDC programs	$27,749,883
Financial support from other U.S. government agencies	$18,077,424
Financial support from other sources (including user fees and gifts)	$3,359,490
Total Dollars IN	**$98,646,679**

Spending Overview—FY 2024



The Division of Laboratory Sciences (DLS) improves Americans' health by developing laboratory methods to diagnose or assess risk of disease, testing for exposure to harmful chemicals, helping other labs improve the quality of their tests, and responding to public health emergencies.

DLS strategically partners with U.S. government agencies, state and local health departments, academic institutions, community groups, philanthropy foundations, and international organizations to achieve its mission. In FY 2024,

Quality Improvement

DLS quality assurance and standardization programs worked with **nearly 1,700 laboratories worldwide** to improve the quality of their laboratory measurements.

Formal Agreements

DLS maintained formal research agreements with **54 partner organizations**, including **11 international organizations**.

Funding Support

DLS provided funding support to **seven public health laboratory programs** and **two professional organizations** to strengthen national laboratory capability.

National Biomonitoring Program

Helping Lower People's Exposure to Harmful Chemicals

The National Biomonitoring Program provides laboratory science that improves the detection, diagnosis, treatment, and prevention of disease from exposure to environmental chemicals.

Biomonitoring combines **biology** and **monitoring**. DLS scientists ***monitor*** markers of environmental chemicals in ***biological sample***s. For example, DLS develops special laboratory methods and uses them to measure environmental chemicals in blood and urine from participants in the National Health and Nutrition Examination Survey (NHANES). NHANES is an ongoing survey that tracks the health and nutritional status of adults and children in the United States.

Scientists in the National Biomonitoring Program analyze and summarize these data in the *National Report on Human Exposure to Environmental Chemicals and Updated Tables*. The report provides the most thorough and up-to-date information on Americans' exposure, since 1999, to over 400 environmental chemicals. State and local public health researchers rely on the report to assess, track, and reduce exposure to environmental chemicals that may be harmful to people.

Every year, DLS biomonitoring activities support more than 75 studies of people whose health is at greater risk from exposure to harmful chemicals. The results of these studies can influence regulations and other actions to reduce exposures.

Benefits of Biomonitoring

In short, biomonitoring improves health and well-being. Scientists improve Americans' health by testing for exposure to harmful chemicals, helping other labs with the quality of their tests, and responding to public health emergencies. DLS biomonitoring measurements, for instance, showed widespread exposure among Americans to per- and polyfluoroalkyl substances (PFAS). This group of chemicals has been widely used in industry and consumer products since the 1940s and remains in the environment for a long time. These data, along with concerns about the health effects of some PFAS, prompted the Environmental Protection Agency (EPA) to issue updated drinking water health advisories for two PFAS, perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS).

Supporting State Labs across the United States

DLS provides funding for high-quality biomonitoring programs that help state laboratories detect harmful chemicals. DLS also offers training and performance evaluation to improve state laboratories' techniques.

FY 2024 Accomplishments

Reported latest data on human exposure to glyphosate and many other chemicals

The *National Report on Human Exposure to Environmental Chemicals* helps doctors, scientists, and public health officials track, respond to, and prevent harmful exposures. The latest version of the report includes data for more than 400 chemicals, including the herbicide glyphosate and metals and metalloids like cadmium.

Provided biomonitoring support for emergency public health responses across the United States

CDC used high-quality biomonitoring measurements to assess environmental exposures in communities affected by unexpected disasters and environmental emergencies, including

- PFAS, flame retardants, and metals in firefighters responding to the 2023 Maui wildfires
- Dioxins in residents near the East Palestine, Ohio, train derailment
- Lead and copper in children exposed to contaminated water in the U.S. Virgin Islands

Results help guide medical treatment and can be used to study health outcomes from environmental exposures.

Studied connection between pollutant exposure and prostate cancer in African men

CDC worked with the National Cancer Institute to learn about possible connections between exposures to organochlorine pesticides and prostate cancer in the Ghana Prostate Study. Men of African descent are known to have higher rates of the disease. Results from this study may shed light on ways to lower the rate of aggressive prostate cancer in this population. Rates are particularly high in Ghana, with its ongoing use of the insecticide dichlorodiphenyltrichloroethane (DDT) for malaria control and agricultural practices.

Supported technology innovation to reduce lead poisoning

CDC's National Biomonitoring Program scientists worked with other parts of the National Center for Environmental Health to support the Lead Detect Prize. This was a two-phase open innovation challenge with a $1 million prize pool to encourage scientists to develop better technology for measuring blood lead. Blood lead tests are the best way to find out if people have lead poisoning. Unique biomonitoring laboratory expertise can help ensure greater success with blood lead tests in the United States, especially for children.

Provided technical expertise to reduce chronic disease in Navajo children

CDC provided technical assistance to the University of New Mexico for the Navajo Birth Cohort Study/ Environmental Influences on Child Health Outcomes Study. The study of children in tribal communities examines possible links between uranium-mine waste exposure and health problems like nervous system developmental delays, obesity, and diabetes.

Tobacco Laboratory

Smoking Out What Keeps People Hooked

The Tobacco Laboratory aims to reduce people's contact with addictive and toxic substances in tobacco products—from cigarettes to cigars to e-cigarettes. The laboratory develops special, high-quality lab tests that analyze addictive and toxic substances from tobacco products.

Tracking Trends in Tobacco Use

DLS measures harmful and addictive tobacco ingredients in NHANES participants.

Measurements of cotinine and 3-hydroxycotinine—markers of nicotine—in the national survey show that harmful exposures occur in both smokers and nonsmokers. For example, in the early 1990s the data revealed that 88% of nonsmoking Americans were exposed to tobacco smoke. This led to protective measures like smoking restrictions in public buildings.

DLS continues to support public health efforts by identifying groups who are at risk from secondhand smoke exposure, including children.

Offering Data Solutions

DLS shares baseline lab data that are important for science-based tobacco regulation by the U.S. Food and Drug Administration. The data include measurements of addictive and toxic substances in tobacco products, smoke, and in the urine and blood of tobacco users or persons in contact with secondhand smoke.

Every year DLS provides 700,000 analytical results for a population study on the behavioral and health effects of the 2009 Family Smoking Prevention and Tobacco Control Act. The law discourages minors and young adults from smoking.

FY 2024 Accomplishments

Developed new methods for studying tobacco product use and exposure

CDC developed new methods for measuring 10 monoaromatic amines and 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol (NNAL, a tobacco-specific nitrosamine) in urine. Monoaromatic amines and tobacco-specific nitrosamines are carcinogens found in tobacco smoke. We can use these methods to improve studies of general population exposure levels and associations with cancer risk. CDC also developed a method for measuring cotinine and hydroxycotinine in serum. Cotinine and hydroxycotinine are the primary metabolites of nicotine and serve as key biomarkers of secondhand smoke exposure in people. The new method is more sensitive and can detect exposures at even lower levels. This may be particularly useful when studying exposures among certain population groups, like children.

Supported investigation of suspected EVALI outbreak in Alaska

CDC provided support for research on e-cigarette or vaping use-associated lung injury (EVALI) cases in Alaska. Researchers discovered that contents in large-volume disposable e-cigarettes break down over time, contributing to higher levels of metals, excipients, and plasticizers in the aerosol deliveries. Excipients (sometimes referred to as "inactive ingredients") are additives included in products to give them different qualities, like texture or taste. Many of these "leached" chemicals are known inhalation irritants and can cause inflammation, which likely exacerbates existing health conditions.

Studied free/total nicotine in tobacco-free, nicotine pouch products

Nicotine-containing products, labeled as being "tobacco-free" nicotine (TFN), are marketed as alternatives to conventional tobacco products. Little is known about these emerging products and their contents. CDC measured nicotine, pH, and moisture levels in a range of products. Measured nicotine content was often less than the advertised levels. Although TFN products may lack many of the harmful chemicals and carcinogens found in conventional smokeless products, they do contain candy and fruit flavored additives. The flavors, along with the wide range of nicotine levels, could contribute to easier initiation and increased addictiveness.

Nutrition, Chronic, and Infectious Disease Laboratories

Measuring Important Markers of Nutrition and Diseases

The Nutrition, Chronic, and Infectious Disease Laboratories improve the laboratory detection and diagnosis of nutrition-related disease, heart disease, and other chronic diseases. The labs also support influenza and selected infectious disease projects.

Improving Nutritional Health and Well-Being

DLS provides a broad look at Americans' nutrition status—from salt intake to trans-fatty acid levels. DLS develops special lab tests and uses them to measure nutrition markers found in blood and urine samples from NHANES participants.

The Second National Report on Biochemical Indicators of Diet and Nutrition in the U.S. Population sums up information on 58 nutrition biomarkers that are important to human health. The report helps physicians, scientists, and public health officials improve Americans' health and well-being.

Improving Laboratory Methods and Health

Health professionals need accurate and precise laboratory measurements to correctly diagnose and treat disease. DLS develops and improves laboratory methods to measure biomarkers, or signs, for risk of heart disease, cancer, thyroid disease, diabetes, and other conditions. DLS also offers programs that help public health, patient care, and research labs, as well as test developers and manufacturers, to achieve accurate, consistent, and comparable test results.

Improving Flu Vaccines and COVID Tests

DLS methods to measure flu proteins have helped improve the accuracy and quality of flu vaccines. This has reduced the time it takes for the vaccines to become available. DLS recently built on its success in this area with new ways to measure the SARS-CoV-2 proteins that guide vaccine and diagnostic test development. The proteins are from a strain of coronavirus that causes COVID-19.

FY 2024 Accomplishments

Improved measurements to diagnose vitamin B1 deficiency

CDC developed a method to measure blood levels of thiamine diphosphate, an indicator of how much vitamin B1 people have in their bodies. A diet that is high in carbohydrates but low in sufficient nutrients can cause thiamine deficiency. This sign of malnutrition can affect the nervous and cardiovascular systems. The chemical behavior and stability of thiamine diphosphate make its measurement and analysis challenging. CDC will use this new method in the upcoming National Health and Nutrition Examination Survey cycle to look at the vitamin B1 status of the U.S. population for the first time.

Provided data on caffeine to guide studies on its health effects

CDC measured caffeine and 13 caffeine metabolites (substances the body makes when it breaks down caffeine) in over 4,200 urine samples from the National Health and Nutrition Examination Survey 1999-2000 and 2001-2002 cycles. This information, plus previous data up to 2014, provide a 16-year span of nationally representative exposure data to use in studying caffeine's effects on health.

Provided critical lab support to advance studies of nutrition status in Tanzania

CDC provided expert advice to the Tanzania Food and Nutrition Center to ensure high-quality laboratory data for a national nutrition survey. This comprehensive, time-sensitive quality review of laboratory data supported the center in its largest and most important public health project ever. The data will help inform policies to reduce malnutrition in the population.

Improved measurements to help reduce chronic disease

CDC developed cutting-edge laboratory methods that will improve the early diagnosis and treatment of major chronic diseases. A new method for measuring levels of four angiotensins (hormones that help regulate blood pressure) will enhance studies of high blood pressure risks. In addition, a new method for measuring parathyroid hormone will improve the detection of kidney and bone diseases.

Supported national and global public health efforts to improve heart health

CDC produced new data on the levels of trans fatty acids consumed by the U.S. population. These unsaturated fatty acids come from either industrial or natural sources. CDC's data will provide critical information on how effective Food and Drug Administration policies are in reducing trans fatty acids intake. CDC's research also helps the global community. International laboratories are using CDC's methodology to improve protocols for measuring trans fatty acids in people and food. Public health officials can learn how effective policies are in reducing trans fatty acids intake, with the aim of improving people's cardiovascular health.

Strengthened emergency response preparedness for future pandemics

To support the nation's emergency response preparedness, CDC created a new method for assessing the strength and security of mRNA vaccines. mRNA vaccines can be quickly manufactured and are important for public health responses to emerging infectious diseases like COVID-19. The new method will be critical for monitoring the dependability of mRNA vaccines in reserve in case of future pandemics.

Newborn Screening Laboratories

Making Big Footprints in Babies' Health

The Newborn Screening Laboratories help assure the early and accurate detection of treatable newborn diseases.

CDC's Newborn Screening and Molecular Biology Branch has the only laboratory in the world devoted to ensuring accurate newborn screening tests. The laboratory strengthens newborn screening test results for certain genetic, metabolic, and endocrine diseases in every state and more than 80 countries.

Every state in the United States screens newborns for many serious but treatable congenital diseases. These include spinal muscular atrophy, cystic fibrosis, sickle cell disease, endocrine diseases, multiple inborn errors of metabolism, lysosomal storage diseases, and severe combined immunodeficiencies. Early, accurate testing helps babies get diagnosed and receive appropriate and timely treatment.

Early Diagnosis Is Key

DLS supports state newborn screening programs with training, technical help, test development, and quality assurance materials so they achieve accurate test results. For example, DLS's Newborn Screening Quality Assurance Program creates about 1 million dried blood spots to simulate the sample types that newborn screening laboratories test. Laboratories use these sample spots to make sure their tests are accurate. Each year, the process helps ensure the early, correct identification and treatment of congenital disease in more than 6,000 American babies who otherwise may have died or had severe developmental disabilities.

DLS, the Association of Public Health Laboratories, and other partners develop and host yearly training on newborn screening methods for state public health laboratories. DLS also gives funding to help state laboratories test for new diseases, including those recently added to the Recommended Uniform Screening Panel (RUSP), a national list of 37 disorders for newborn screening at birth.

Improving Tests for Newborn Screening

DLS develops and improves newborn screening tests and provides technical assistance for both biochemical and molecular laboratory testing to detect newborn disease. Since 2011, the Newborn Screening Molecular Assessment Program has provided 29 on-site assessment visits to state newborn screening laboratories.

FY 2024 Accomplishments

Developed a screening method for Krabbe disease

CDC developed a method to test for psychosine, a second-tier biomarker used to screen for Krabbe disease, a brain disorder that can be fatal if untreated. CDC is poised to support state programs as they incorporate screening for this disease, which was recently added to the RUSP. The panel lists disorders that the Department of Health and Human Services recommends states screen for as part of their universal newborn screening programs.

Improved ability to detect rare diseases in babies early

CDC launched new programs to assure the quality of newborn screening tests:

- CDC's new routine molecular external quality control program for cystic fibrosis will greatly improve early detection of this disease. The program is helping 31 U.S. public health programs and four Canadian newborn screening programs embrace new detection technologies.
- CDC's new CRISPR/Cas9 genome editing workflow creates custom cell lines. It also piloted a combined external quality control program designed to improve detection of spinal muscular atrophy and severe combined immunodeficiency. Forty-six laboratories, representing 36 domestic state newborn screening programs and six Canadian provinces, enrolled in the pilot program. This broad participation paves the way for the first direct comparison of T-cell receptor excision circle test performance nationally.
- CDC developed unique proficiency testing and linearity materials for lysosomal storage disorders. The innovative, sustainable approach expanded the panel from three to seven disorders. The result is a greater capacity and accuracy to test and find answers for these rare genetic conditions.

Discovered a blood biomarker that may decrease false positive newborn screening test results in premature babies

CDC found that testing for the novel biomarker N-acetyl tyrosine can help identify newborns who are receiving total parenteral nutrition while in the hospital. Total parenteral nutrition is frequently given to premature babies as a nutritional supplement and includes fluid, electrolytes, sugars, amino acids, and vitamins. However, its components can complicate interpretation of newborn screening test results, increasing the frequency of false positives (results showing a given condition exists when it does not). Adding this biomarker to existing first-tier newborn screening tests will improve the screening of premature babies and alleviate concerns about additional testing, follow-up with medical staff, and added stress to new parents.

Strengthened national capacity for newborn screening emergency preparedness

CDC updated the national contingency plan (CONPLAN) for newborn screening. States, regions, or consortia of states can use CONPLAN to ensure continuity of critical operations in the event of a public health emergency. CONPLAN Version III further defines newborn screening system partners and their roles and clarifies the potential role of emergency management assistance compact. It also advises these partners on pre-event and post-event activities for a newborn screening emergency response.

Emergency Response Laboratories

How CDC Prepares for and Responds to Emergencies

The Emergency Response Laboratories support the nation in public health responses to chemical terrorism, toxins, radiologic threats, and opioids.

DLS is ready 24/7 to quickly find and help people at risk of contact with harmful chemicals during a public health emergency.

Detecting New and Likely Chemical Threats

DLS develops and performs unique laboratory tests, such as the Rapid Toxic Screen, to assess chemical exposure in people during a public health emergency or terrorist event. With the Rapid Toxic Screen, DLS can analyze urine and blood at the scene of chemical threats.

Within 36 hours of receiving samples, DLS can detect up to 150 chemical agents in 40 samples. After identifying the chemicals causing problems, DLS can measure up to 1,000 patient samples per day during an emergency. This information helps public health officials quickly figure out where the risks are, ensure the right treatment, and prevent added contact with harmful chemicals.

DLS has used the Rapid Toxic Screen to detect sulfur mustard exposure, ricin, and other potential warfare agents. DLS's ability to screen deters the use of these chemicals.

Helping People at Risk of Radiation Exposure

DLS is always ready to quickly find people at risk of contact with harmful radiation. DLS developed the Urine Radionuclide Screen to identify people's contact with alpha-, beta-, and gamma-emitting radionuclides that often cannot be detected by conventional means. With this process, DLS can screen more than 1,000 samples for above-normal amounts of radioactivity within 24 hours. The information helps public health officials determine when people are at risk, ensure effective treatment, and prevent additional harmful contact.

DLS used the Urine Radionuclide Screen to measure radiation exposures in federal workers returning to the United States from Japan after the 2011 Fukushima Daiichi Nuclear Power Plant radiation release. Test results showed low levels of radionuclides, posing no threat to health after the nuclear disaster.

Improving Botulism, Anthrax, and Ricin Tests

DLS develops unique mass spectrometry-based methods to rapidly and accurately detect and diagnose diseases caused by dangerous toxins. These include tests to better detect unsafe human exposure to botulism, anthrax, and ricin.

Strengthening National Preparedness

DLS helps prepare a wide variety of public health laboratories to detect biological and chemical threats and assist with other public health emergencies. To prepare for an emergency, DLS provides quality control materials, performance testing, and training to hundreds of participants in the national Laboratory Response Network for Chemical Threats. The network includes state and local public health labs.

DLS also helps strengthen public health preparedness for threats of radiological or nuclear terrorism by leading a pilot Radiological Lab Response Network. This group of state public health labs has the equipment and trained personnel to provide vital surge capability during a large-scale emergency. DLS provides these labs with technical assistance and reference materials for method development and validation.

FY 2024 Accomplishments

Improved laboratory capabilities for Novichoks

CDC developed new laboratory test methods and identified new biomarkers that confirm exposures to Novichoks, a class of nerve agents that can be used to cause harm. These new methods were successfully used for the Organisation for the Prohibition of Chemical Weapons Biomedical Proficiency Test Program. They improve laboratory emergency response capabilities for chemical weapons that have the potential to cause mass casualties.

Advanced national public health efforts to improve overdose surveillance

CDC provided technical assistance and support to laboratories participating in the CDC Overdose Data to Action Program. These efforts ensure harmonized and comprehensive data collection for national opioids overdose surveillance. CDC was also an integral part of a Brown University surveillance study involving the illicit use of opioids, including fluorofentanyl, a more lethal analog of fentanyl. CDC also directed the release of the Emerging Drug Panel Kits, a product of the Traceable Opioids Materials Kits, to provide nationwide access to laboratory reference materials for testing novel substances associated with overdose to improve reporting of drug uses.

Developed response capabilities to identify unknown toxins and metabolites

CDC developed discovery capabilities for emerging toxins and novel metabolites using high-resolution mass spectrometry. These methods allow us to identify previously unknown microcystin analogs and primary metabolites of anatoxin exposures, which can be toxic to humans and animals. This work is foundational for supporting emergency response to new and emerging chemical threats.

Advanced nationwide rapid emergency response capabilities

CDC completed cross-laboratory evaluation of high-resolution identification tools to assess rapid transfer and detection capabilities across five LRN-C laboratories. This evaluation is the first step in establishing agile response method distribution in real time for emerging threats.

Improved tests for exposure to ricin and abrin

Ricin and abrin are plant toxins with the potential for use in bioterrorism. CDC developed, validated, and published a new, less expensive method for extracting ricin and abrin from complex samples such as white powders. This method can also be applied to tests for similar toxins. This innovation in efficiency allows scientists to detect and differentiate ricin and abrin in a single analysis.

Boosted public health preparedness for radiological attacks

CDC improved the sensitivity of methods for detecting harmful radionuclides, including Po-210, Sr-90, Ir-192, and Cs-137, at lower levels. This innovation strengthens public health preparedness and emergency response capabilities in radiological attacks with materials intended to do harm.

Strengthened national capacity to identify radiation exposure

DLS performed a pilot study to increase state public health laboratories' capacity to measure radioactive materials like gross beta and Cs-137 in urine. This capability is critical during radiation emergencies, when people are exposed to harmful levels of radiation. DLS helped partner labs develop and validate their radiobioassay methods, strengthening the nation's capacity for rapid screening in emergencies.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