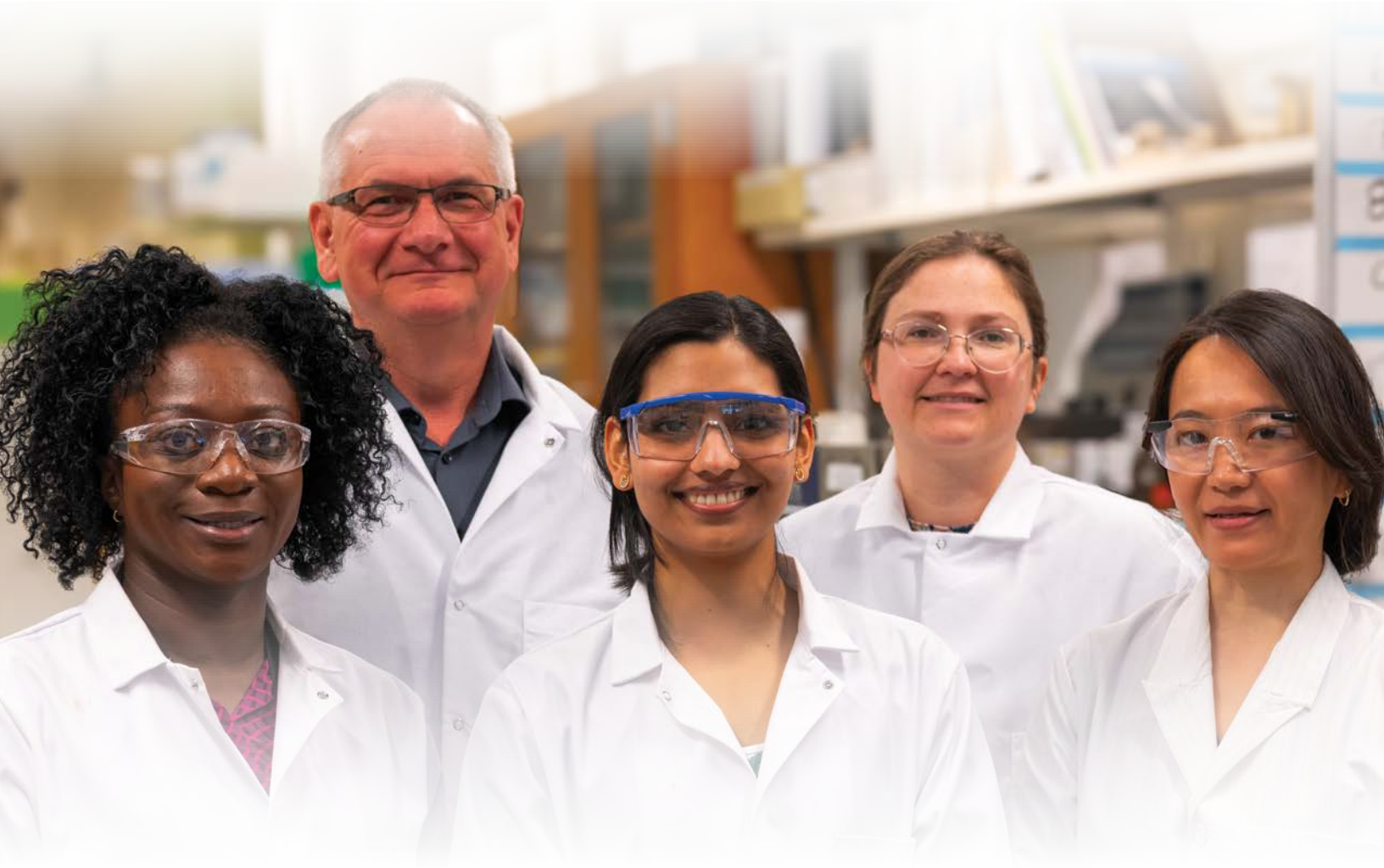


Division of Laboratory Sciences FY 2023 Annual Report





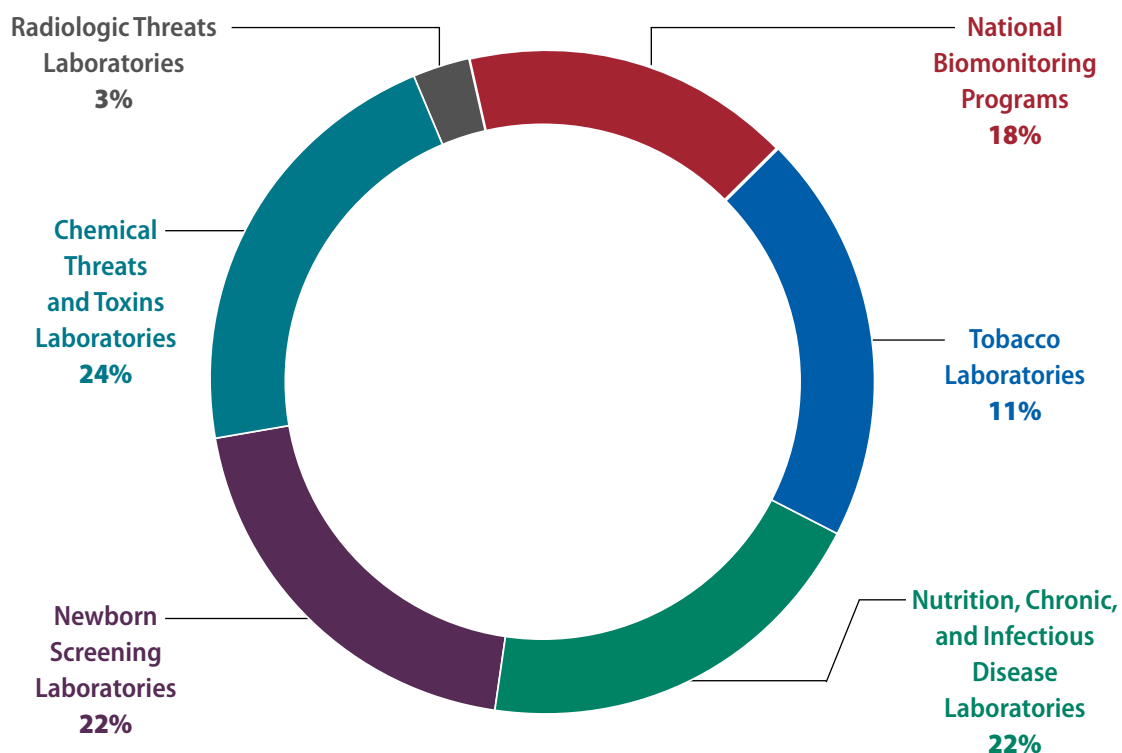
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Funding Overview—FY 2023

Funding Source	Amount
Direct Appropriated Funding—Environmental Health Laboratory	\$50,955,861
Financial support from other CDC programs	\$26,191,753
Financial support from other U.S. government agencies	\$18,077,424
Financial support from other sources (including user fees and gifts)	\$4,504,874
Total Dollars IN	\$99,729,912

Spending Overview—FY 2023





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 2023,



Quality Improvement

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



Formal Agreements

DLS maintained formal research agreements with **52 partner organizations**, including **10 international organizations**.



Funding Support

DLS provided funding support to **11 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.



What is biomonitoring? Biomonitoring combines **biology** and **monitoring**. Scientists at CDC's Division of Laboratory Sciences (DLS) **monitor** markers of environmental chemicals in **biological samples**. 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 help assess, track, and reduce exposure to environmental chemicals that may be harmful to people.

In addition, 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 is a tool to improve 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), a group of chemicals that have been widely used in industry and consumer products since the 1940s and remain 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), that better protect public health.

Supporting State Labs across the United States

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

FY 2023 Accomplishments

Studied U.S. population's exposure to hundreds of environmental chemicals

DLS continued to improve the *National Report on Human Exposure to Environmental Chemicals* by making it easier to use for all people. For instance, DLS expanded search capabilities by Chemical Abstracts Service Registry Number (CAS RN), added data export options, and updated terminology for demographic categories. The *Report* 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 10 new ones, and shares important information like

- The first nationally representative data for chlorinated tyrosines, which are biomarkers (short for biological markers) of chlorine gas exposure. These data can help improve the public health response to a chemical emergency involving chlorine by providing baseline information for comparison.
- More biomonitoring data for ethylene oxide, a cancer-causing chemical used to sterilize medical equipment, and to produce everyday consumer products like household cleaners, personal care items, and fabrics.
- New data showing that a representative sample of children 3 to 5 years of age had recently been exposed to pesticides like chlorpyrifos, an insecticide that is poisonous to the nervous system.
- New data showing that dioxins, furans, and dioxin-like polychlorinated biphenyls (PCBs) were present in adolescents and adults. The chemicals' presence is showing up decades after production of some of them—for instance, PCBs—was banned.

Supported a pilot study of East Palestine, Ohio, residents' exposure to hazardous chemicals after a train derailment

The February 2023 incident involved a train carrying hazardous chemicals. After the accident, emergency response officials evacuated residents and did a controlled burn of vinyl chloride, which several of the train cars were carrying. DLS assisted the University of Kentucky by measuring levels of dioxins and dioxin-like chemicals, which were associated with the derailment and the cleanup, in the blood of residents who took part in a pilot exposure study. Results showed that dioxin levels of those individuals sampled were within the normal range.

Looked at exposure to PFAS as a risk for kidney cancer

DLS partnered with the National Cancer Institute to study PFAS exposure in a racially and ethnically diverse population. Results showed some PFAS may be associated with increased kidney cancer risk, highlighting the need for more studies of PFAS exposures in racially and ethnically diverse populations..

Helped provide information to communities about health effects of PFAS exposure through drinking water

As a part of the [Multi-site Health Study](#) conducted by the Agency for Toxic Substances and Disease Registry (ATSDR), DLS measured PFAS in the serum of participants from seven affected communities across the United States with contaminated drinking water.

Analyzed nearly 10,000 urine and blood samples for research on chelation therapy and heavy metals

DLS provided technical assistance to Mount Sinai Medical Center for a clinical trial to learn whether intravenous chelation therapy along with multivitamins will reduce the risk of major heart attack and stroke in patients who have already had a heart attack and who also have type 2 diabetes. Chelation therapy is a method for removing heavy metals, such as mercury or lead, from the blood.

Shared new data on people's exposure to acrylonitrile and ethylene oxide

This information, gathered in collaboration with ATSDR, helps us learn more about the link between genetic makeup and the efficiency of detoxification in the body. Differences in detoxification efficiency among different populations may help identify groups that are more vulnerable to health effects from ethylene oxide exposure.



Tobacco Laboratory

Smoking Out What Keeps People Hooked

The Tobacco Laboratory aims to reduce people’s contact with addictive and toxic substances in different 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 (FDA). The data include measurements of addictive and toxic substances in tobacco products and smoke and in urine and blood from 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 aims to help discourage minors and young adults from smoking.

FY 2023 Accomplishments

Discovered that select flavors in little cigars dramatically affect the amount of nicotine and tar delivered to smokers

These data will help FDA develop effective regulations to lower nicotine and tar exposure for established tobacco users and reduce smoking’s appeal for new users.

Studied how e-cigarettes release certain addictive and harmful chemicals into the air

In collaboration with the National Institute on Drug Abuse, DLS provided measurements of standardized research e-cigarettes, which will serve as a reference point for different clinical studies examining e-cigarette use.

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.

A report called *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 2023 Accomplishments

Reported on global laboratory performance for multiple measures of health and nutrition status over a 10-year period

More than half of the participating laboratories achieved acceptable test performance. DLS's external quality assessment program is a valuable tool for laboratories with limited resources to track their performance over time.

Measured folate in 10,000 blood-based samples for a United Kingdom nutrition survey

This provided about 31,000 laboratory results over 15 years for the National Diet and Nutrition Survey, which assesses the diet, nutrient intake, and nutritional status of the general population of the United Kingdom. DLS measurements helped assess the folate status in the population, which informed folic-acid fortification policy in the United Kingdom.

Improved measurements to diagnose and treat thyroid problems

DLS developed a more accurate and sensitive way to measure free thyroxine, an important marker for assessing thyroid function. Scientists applied the method to find out how accurate and reliable clinical blood tests for thyroid problems were. Study data showed inaccuracies in thyroxine measurement—with a high likelihood to affect disease diagnosis. DLS informed the scientific community about its findings and is now collaborating with the American Thyroid Association to promote the use of standardized assays for accurate testing.

Generated first-time data on biotin levels in blood that will guide future research

DLS developed a new sensitive method for measuring biotin in human serum that will allow assessment of biotin status in the U.S. population and provide new insights on how biotin levels affect the reliability of certain clinical immunoassays, such as COVID-19 antibody tests. DLS used its method to generate first-time data on biotin levels in blood among the T cell and Antibody Profiles Post-SARS-CoV-2 Infection or Vaccination Study (TAPPS) cohort. Findings will provide a basis for future research on biotin levels in the general U.S. population.

Improved measurements to diagnose and treat heart disease

DLS substantially improved measurements of blood lipids, such as total cholesterol, impacting about 95% of all total cholesterol measurements conducted in the United States. In addition, DLS supports lipoprotein testing to improve cardiovascular disease prevention globally by serving as the only supplier and distributor of reference materials for apolipoprotein A1 and apolipoprotein B worldwide.

Showed how patients' inaccurate self-reporting of statin use to help lower cholesterol might skew studies of cardiovascular disease risks and outcomes

DLS collaborated with Duke University on a study assessing the effects of statin use on various lipid metabolism-related biomarkers. Results showed that inaccurate self-reporting of statin use is common and must be accounted for in studies of cardiovascular disease risk management, as well as other confounding factors such as age.

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 in every state and more than 80 countries. The laboratory strengthens newborn screening test results for certain genetic, metabolic, and endocrine diseases.

Every state in the U.S. 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. The process helps assure 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 - 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 2023 Accomplishments

Improved screening for a rare disease

The Newborn Screening Quality Assurance Program launched a pilot and then implemented a proficiency testing program to screen for guanidinoacetate methyltransferase deficiency. This deficiency, which affects the brain and muscles, was recently added to the Recommended Uniform Screening Panel. The availability of this new program allows newborn screening programs to comply with federal standards and helps ensure the early and accurate identification of babies with this rare disease.

Developed new ways to identify children with cystic fibrosis faster

DLS launched the first molecular quality control program to help detect DNA sequence changes that can cause cystic fibrosis. Thirty-two U.S. public health programs and three Canadian newborn screening programs received DLS-created dried blood spots representing the most common gene variants in people with cystic fibrosis. These materials greatly enhance detection of the disease.

Developed new screening methods to identify more affected babies faster

DLS developed and published several new testing methods for newborn screening to streamline work and reduce turnaround time:

- A new test that greatly improves the sensitivity and specificity of screening for homocystinuria, a rare genetic disease. This significant accomplishment will reduce the rate of false negatives (currently estimated at 50 percent) and false positives.
- A new assay that assesses 19 biomarkers to concurrently detect 11 newborn disorders. The single assay can replace multiple assays currently used by newborn screening laboratories and will reduce the number of false positives.
- A new method that screens simultaneously for seven lysosomal storage disorders, which are inherited metabolic diseases. The method uses an innovative technique shown to be better than current approaches.

Chemical Threat Agents and Toxins Laboratories

How CDC Prepares for Chemical Terrorism

The Chemical Threat Agents and Toxins Laboratories support the nation in public health responses to chemical terrorism and other emergencies involving select toxins.



DLS is ready 24/7 to quickly find and help people at risk of contact with harmful chemicals during a public health emergency. DLS' Chemical Threat Agents and Toxins Laboratories carry out this mission in several ways.

Detecting New and Likely 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 from people at the scene of chemical threats.

Within 36 hours of CDC 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 poisoning, and other potential warfare agents. DLS's ability to screen deters the use of these chemicals.

A New Approach to 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.

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.



FY 2023 Accomplishments

Updated kits to improve lab detection of manmade opioids

Laboratories play a key role in the U.S. response to the opioid overdose epidemic. That's why DLS is expanding their ability to detect emerging opioids and other drugs of concern through Traceable Opioid Material® Kits (TOM Kits®). DLS updated the kits to include a total of 80 emerging drug threats listed by the U.S. Drug Enforcement Administration. In addition, high-resolution mass spectral libraries are posted on the DLS website to help communities responding to the opioid epidemic.

Developed a method to detect more than 100 natural toxins in human urine

This new approach pinpoints toxins from plants, mushrooms, and fungi in human urine. DLS designed the method to help avert new chemical threats, and to support public health efforts in suspected poisoning incidents and outbreak investigations.

Radiologic Threats Agents Laboratory

Staying Ready for a Radiological Emergency

The Radiologic Threat Agents Laboratory supports public health responses to radiologic emergencies—or cases in which radioactive material is released into the environment.



Radiologic emergencies may be intentional or unintentional. For instance, intentional emergencies can include someone purposely contaminating food and water with radioactive material. Unintentional emergencies can include nuclear reactor accidents.

Helping People at Risk of Contact

DLS is ready 24/7 to quickly find people at risk of contact with harmful radiation. DLS developed the Urine Radionuclide Screen as a way 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.

As an example, 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.

Strengthening National Preparedness

DLS helps strengthen public health preparedness to counter threats of radiological or nuclear terrorism by leading a pilot Radiological Lab Response Network. The group comprises state public health labs that have 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 2023 Accomplishments

Improved ability to respond to radiological emergencies

DLS joined 10 other response network labs to participate in an emergency preparedness exercise led by the Integrated Consortium of Laboratory Networks. The exercise was designed to test and evaluate their responses in a disaster. Participants in the drill were asked to process mock "samples" they received when biological and radiological agents were released over a broad area. The labs verified sharing capabilities through a data portal and combined their sample receipt and preparation approaches into a reference process flowchart. The exercise will help DLS to quickly detect exposure to threat agents of greatest concern.



HS