



# Division of Laboratory Sciences

## FY 2022 Annual Report



**U.S. Department of  
Health and Human Services**  
Centers for Disease  
Control and Prevention



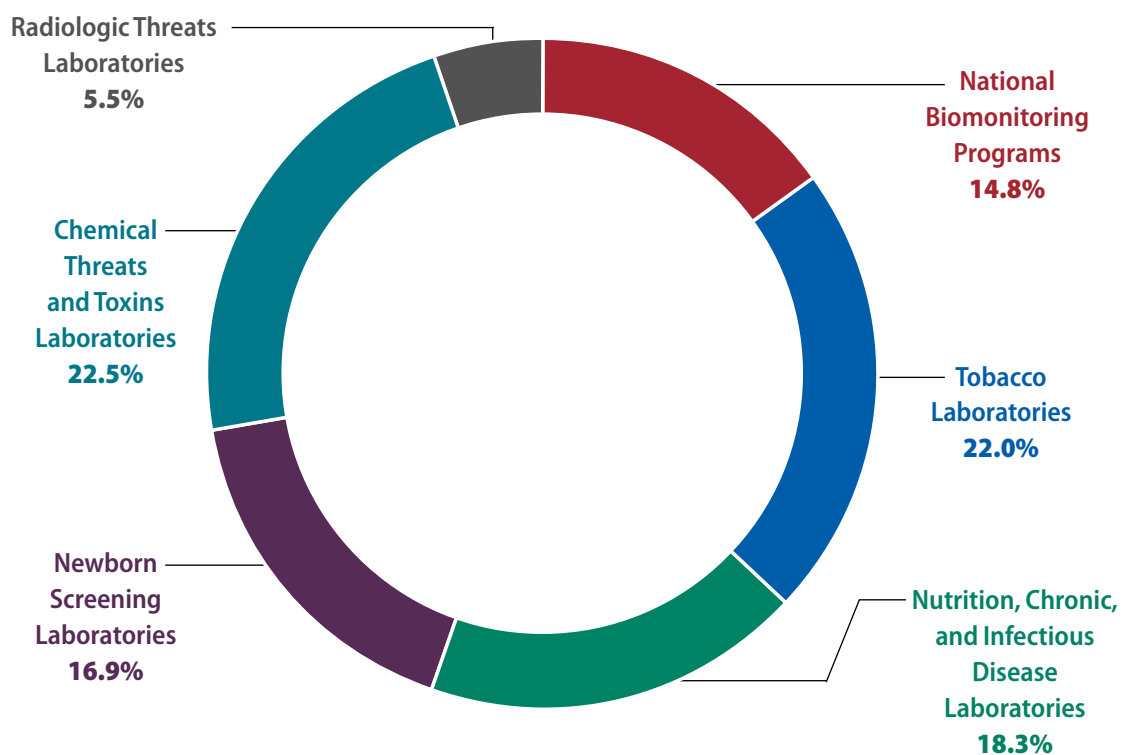
## Contents

Funding Overview—FY 2022 .....	5
Spending Overview—FY 2022 .....	5
National Biomonitoring Program .....	6
Tobacco Laboratory .....	8
Nutrition, Chronic, and Infectious Disease Laboratories .....	10
Newborn Screening Laboratories .....	12
Chemical Threat Agents and Toxins Laboratories .....	14
Radiologic Threats Agents Laboratory .....	16

## Funding Overview—FY 2022

<b>Funding Source</b>	<b>Amount</b>
Direct Appropriated Funding—Environmental Health Laboratory	\$ 48,956,224
Financial support from other CDC programs	\$ 28,118,151
Financial support from other U.S. government agencies	\$ 18,189,738
Financial support from other sources (including user fees and gifts)	\$ 9,840,582
<b>Total Dollars IN</b>	<b>\$ 105,104,695</b>

## Spending Overview—FY 2022





**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. Examples of FY 2022 involvements follow:



### **Quality Improvement**

DLS worked with over **2,000 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 **50 partner organizations**, including **8 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. They develop special laboratory methods and use 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 to over 400 environmental chemicals. Since 1999, state and local public health researchers have relied on the *Report* to help assess and reduce exposure to environmental chemicals that may be harmful to people.

### **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 that Americans had widespread

exposure to Bisphenol A (BPA), a chemical often used in personal and consumer products. A daily diet of canned soup was shown to increase BPA exposure by more than 10 times the amount that someone would get by eating soup made of fresh ingredients. Shortly after this finding was reported, a major canned-soup manufacturer volunteered to remove BPA from its packaging.

## Supporting State Labs across the United States

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

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.

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## FY 2022 Accomplishments

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

The *National Report on Human Exposure to Environmental Chemicals* helps doctors, scientists, and public health officials track, respond to, and prevent harmful exposures. DLS created a new online format for the *Report* to give the public faster and easier access to the information.

The latest version of the *Report* includes data for more than 400 chemicals, including 5 new ones. Highlights from the most recent edition of the *Report* include:

- The first nationally representative data for urinary chromium. These data affect results of chromium biomonitoring in patients who have had joint replacement surgery.
- New biomonitoring data for ethylene oxide in the U.S. population. These data help federal, state, and local public health officials look at exposure trends in the U.S. population and evaluate health risks in communities with high exposure.
- New biomonitoring data for glyphosate in the U.S. population. According to these data, more than 80% of U.S. residents aged 6 years and older have had recent exposure to glyphosate. The chemical is the most widely used weed killer in the United States.
- The first nationally representative data for urinary 2-((isopropyl)phenyl)phenyl phosphate and urinary 4-((tert-butyl)phenyl)phenyl phosphate. These are metabolites of popular flame retardants and substances used in plastic. Metabolites are matter the body produces when breaking down a chemical or compound.

### Provided biomonitoring data for studying the cancer risks of exposure to per- and polyfluoroalkyl substances (PFAS)

DLS is working with the National Cancer Institute to learn whether exposure to perfluorooctanoic acid and other PFAS may be a cause of testicular cancer in U.S. Air Force servicemen and ovarian, endometrial, and prostate cancer in a large group of people in the U.S. Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial. The results will help inform future studies of perfluorooctanoic acid and other PFAS.

### Studied U.S. Army staff exposure to insecticides

All U.S. Army active-duty and reserve soldiers wear uniforms treated with permethrin to kill or repel mosquitoes and other insects. DLS biomonitoring data showed that soldiers wearing two types of permethrin-treated uniforms were exposed to the insecticide. These data will help the Army find ways to reduce soldiers' exposure to the insecticide while still offering effective protection from insect-borne diseases like malaria.

# Tobacco Laboratory

## Smoking Out What Keeps People Hooked



The CDC Tobacco Laboratory aims to help reduce people’s contact with addictive and toxic substances in different tobacco products—from cigars to e-cigarettes. The laboratory has expertise in measurement science, and has developed special, high-quality lab tests that analyze addictive and toxic substances from tobacco products.

### **Tracking Trends in Tobacco Use**

CDC’s Division of Laboratory Sciences (DLS) measures harmful and addictive tobacco ingredients in NHANES participants.

DLS measurements of cotinine and 3-hydroxycotinine—markers of nicotine—in the national survey have shown 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 offers baseline lab data that are important for science-based tobacco regulation by the Food and Drug Administration. 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.

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## FY 2022 Accomplishments

### Developed a smoking machine adapter to provide standard measurements from existing and emerging products

DLS developed an adapter to help provide standard measurements of substances and emissions from combustible tobacco products and electronic cigarettes with noncircular mouthpiece shapes. A universal adapter allows a smoking machine to puff all commonly used tobacco and e-cigarette products the same way. The adapter is an invaluable tool for studying and reducing people's exposure to harmful chemicals found in the products and their emissions.

### Promoted health studies of smoke exposure from burned products

DLS used a new smoke exposure biomarker to study the difference between users of burned (for example, cigars) and non-burned (for instance, e-cigarette) products. The studies help inform the public and policy makers about the harms of smoke exposure from tobacco and cannabis products. The data will be used to support action to reduce disease and death from burned products.

### Published scientific findings on the increased use of nonburning tobacco and vaping devices

DLS spearheaded a special edition of *Frontiers in Chemistry*, "Analytical Methods for Elucidating Harmful Exposures Related to Vaping" (2021, Volume 9, Impact Factor 5.5, 81k views as of October 26, 2022). The 24 peer-reviewed articles discuss the characteristics of e-cigarette and vaping products, so that future outbreaks of lung injury associated with them can be quickly controlled.





# 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**

CDC's Division of Laboratory Sciences (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 DLS 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 (short for biological marker) 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.



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## FY 2022 Accomplishments

### Improved understanding of how COVID-19 spreads

DLS analyzed the structure of the spike protein from the original SARS-CoV-2 strain and its viral variants. Scientists learned that the more infectious variants of the virus have different structures, which may affect their spread, the severity of infections, and vaccine effectiveness. These data helped CDC understand and predict how COVID-19 spreads and improve vaccines and treatments.

### Improved international studies of micronutrient status

Working together with the U.S. Agency for International Development, DLS created a training curriculum to help prevent malnutrition in Tanzania. The curriculum supports the Tanzania Food and Nutrition Center in checking and controlling micronutrient deficiencies.

During a two-week visit to Tanzania, DLS provided training on laboratory methods and quality assurance. DLS guidance will lay the foundation for future high-quality measurements and help build micronutrient assays into the Tanzania Demographic Health Survey.

### **Studied field sampling challenges in laboratory measurements of aflatoxins**

DLS studied how field sampling challenges, like transportation, storage, collection, processing, and sample type substitution affect the accuracy of measurements of serum aflatoxin B1-lysine. The serum can point to exposure to aflatoxin, a poisonous metabolite. Field conditions are often less than ideal in developing countries, where outbreaks are more likely to occur.

### **Reassessed vitamin C status of the U.S. population**

DLS assessed vitamin C levels in the U.S. population in NHANES 2017-2018 and found that they have remained stable since the last survey in 2005-2006.

People whose diets were low in recommended nutrients, and who smoked, had vitamin C deficiencies, pointing to the importance of nutrition and lifestyle in overall health (Powers et al., *Journal of Applied Laboratory Medicine* 2022).

### **Improved screening for heart disease risk in lower-income countries**

DLS boosted laboratory screening ability for heart disease risk in two lower-income countries by introducing point-of-care testing for blood lipids. DLS also helped train 40 biochemists and medical technologists in laboratory quality principles and point-of-care testing and management.

### **Published an evaluation of reference intervals to improve health diagnoses in children**

Reference intervals are a set of values that a doctor uses to interpret a patient's test results. They are important for measuring health and detecting diseases in children.

DLS looked at lab data for seven chronic disease biomarkers in children and noted differences in how data are used to make healthcare decisions. DLS is addressing these variations by developing accurate reference intervals to ensure correct pediatric health care.

### **Improved measurements for diagnosing and treating thyroid disorders**

DLS created a new way to make reference measurements of free thyroxine, an important gauge of thyroid function. Reference measurements are standards that are used to ensure accuracy in patient care, public health, and clinical research.

DLS studied more than 20 assays from major manufacturers around the world and noted inconsistencies that could lead to the incorrect diagnosis or treatment of patients. These findings help health care professionals better understand and interpret free thyroxine test results.

### **Evaluated commercial screening tests for heart disease risk**

DLS analyzed the performance of major commercial lipoprotein A (Lp(a)) assays. This new biomarker is used to screen for heart disease risk. Scientists noticed that measurement changes are only slightly affected by Lp(a) polymorphisms. Their finding paves the way for broad use of this biomarker in heart disease risk assessment.

# 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 to be diagnosed and receive appropriate and timely treatment.

### **Early Diagnosis Is Key**

The Division of Laboratory Science (DLS) supports state newborn screening programs with training, technical help, test development, and quality assurance materials so they achieve accurate test results. As an 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 money to help state laboratories test for new diseases, including those recently added to the nation's Recommended Uniform Screening Panel for newborns.

### **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.

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## **FY 2022 Accomplishments**

### **Created and distributed newborn screening quality assurance materials worldwide**

The Newborn Screening Quality Assurance Program provided dried blood spot quality assurance materials for 16 proficiency-testing and 11 quality-control programs in 670 newborn screening laboratories in 88 countries. The materials cover the core and secondary conditions listed on the Recommended Uniform Screening Panel. The Recommended Uniform Screening Panel is a national guideline for newborn screening. These services help ensure the early and accurate identification of babies with life-threatening or disabling conditions.

### **Developed new screening assays to identify babies with conditions faster**

DLS developed a newborn screening assay that can screen for 11 disorders at the same time. This single assay can replace multiple assays that newborn screening laboratories use and reduce the number of false positives.

### **Provided molecular testing support to the newborn screening community**

The Molecular Quality Improvement Program responded to 109 requests for technical assistance from 32 U.S. and 19 international newborn screening programs or stakeholders. The program provided critical support with using new assays, troubleshooting, continuous quality improvement, and molecular education—all to help screening programs for spinal muscular atrophy, severe combined immunodeficiency, cystic fibrosis, and congenital adrenal hyperplasia.

### **Improved screening for spinal muscular atrophy worldwide**

In January 2022, DLS expanded its newest molecular proficiency testing program, on Spinal Muscular Atrophy, to include international newborn screening labs. Spinal Muscular Atrophy is a serious disorder that causes progressive, severe muscle weakness and tone leading to significant developmental delay. Enrollment in the testing program rose from 28 U.S. programs to 78 international programs. This greatly improves programs' abilities to quickly diagnose babies born with Spinal Muscular Atrophy. Left untreated with this disorder, children often die before age 2.

# 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.

The Division of Laboratory Sciences (DLS) maintains 24/7 capability to quickly find and help people at risk of contact with harmful chemicals during a public health emergency. DLS's 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 fight biological and chemical threats and assist with other public health emergencies. To ensure effective action in case of 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. This linking of different laboratories is a new approach to public health preparedness.

## **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.

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## **FY 2022 Accomplishments**

### **Reported new national data to improve response to chemical emergencies**

DLS measured and reported data for butyrylcholinesterase in NHANES samples for the first time. These baseline measurements from the general population will improve public health response to large-scale chemical emergencies. The measurements will help CDC set reference ranges deemed normal for cholinesterase. The reference ranges can help public health officials determine if people were exposed to nerve agents.

### **Provided data to help opioid epidemic response efforts**

DLS measured and reported data for fentanyl analogs, metabolites, and related compounds as part of the National HIV Behavioral Surveillance: Injection Drug Use – Round 5 (NHBS-IDU5). This project, done with CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, provides a snapshot of new fentanyl exposure for people who inject drugs.



# 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**

The Division of Laboratory Sciences (DLS) maintains the 24/7 capability 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 actively participating in 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.

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## FY 2022 Accomplishments

### Improved ability to detect exposure to unhealthy radioactive materials

DLS created new automated methods to identify and quantify priority threat radionuclides californium-252, curium-244, americium-241, plutonium-239, neptunium-237, thorium-232, and uranium-238. These approaches will allow DLS to rapidly test urine samples and learn the radiation dose and possible long-term health risks to people exposed to such toxic threats. DLS will be able to quickly detect exposure to most radionuclides of greatest concern.





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