

Division of Laboratory Sciences

2021 Select Accomplishments

National Biomonitoring Program

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

Assessed American's Exposure to Hundreds of Environmental Chemicals

DLS published the [Updated Tables, March 2021](#) to the *National Report on Human Exposure to Environmental Chemicals*. With this release, the report provided data for more than 400 chemicals: 73 reported for the first time or measured in a new matrix (serum, urine, or blood) and 108 updated since the *Updated Tables, January 2019*. The report includes Per- and Polyfluoroalkyl Substances (PFAS) replacement chemicals like GenX and ADONA, formaldehyde, and total testosterone. Nationally representative exposure data help physicians, scientists, and public health officials identify harmful exposures and ensure adequate nutrition levels.

Helped Reduce American's Exposure to PFAS from Food Packaging

DLS biomonitoring data showed widespread exposure among Americans to PFAS. These data, along with concerns about the health effects of these compounds, prompted the Food and Drug Administration (FDA) to ban manufacturers' use of certain PFAS in food packaging in 2016. As a result of DLS's laboratory science and FDA's action, two American manufacturers unveiled a new process for generating PFAS- and plastics-free packaging in August 2021, a move that will reduce harmful exposures and protect public health.

Provided Biomonitoring Data on the Harmful Impacts of Chlorpyrifos to Children that Informed EPA Ban

[EPA banned](#) the use of the widely used pesticide chlorpyrifos on all food crops in August 2021, citing DLS biomonitoring data that showed prenatal exposure to chlorpyrifos is linked with lower birth weight, reduced IQ, and other developmental problems in children.

Published Highly Impactful Data on PFAS Exposure and Cardiometabolic Risk in Children

DLS's measurements of four PFAS helped document an association between gestational exposure to some [PFAS and cardiometabolic risk for diabetes or heart disease, for example, in adolescence](#). Among hundreds of papers published in 2021, the National Institute of Environmental Health Sciences recognized these findings for their substantial scientific impact and public health relevance.

Ensured the Accuracy of Laboratory Testing for Arsenic, Mercury, Cadmium, and Uranium

DLS collaborated with the National Institute of Standards and Technology to evaluate the stability of standard reference materials for potentially harmful inorganic elements. Laboratories use these materials to validate analytical methods used to measure arsenic, mercury, cadmium, and uranium in urine. Accurate analytical measurements are essential to investigations of human exposures to these compounds.

Increased State Biomonitoring Capacity to Test for Mercury Exposures

DLS started an interlaboratory sample exchange program with Maine, Michigan, and New Jersey to help them develop and validate methods to identify different forms of mercury (mercury speciation). Accurate biomonitoring methods for mercury speciation are essential for identifying the source of potentially harmful mercury exposures.

Developed a Laboratory Test to Measure Fluoride in the U.S. Population

DLS developed a fluoride in urine test to assess the U.S. population's levels of fluoride. This data will be used to evaluate American's fluoride levels based on the CDC recommendations about the optimal levels of fluoride in drinking water needed to prevent tooth decay.

Provided Laboratory Data for the CDC's Childhood Blood Lead Reference Value

[CDC's Blood Lead Reference Value \(BLRV\)](#) is a screening tool to identify children who have higher levels of lead in their blood compared with most children. DLS provided the analytical data and calculated the new blood lead reference value for CDC's [2021 BLRV](#). This update helps promote additional progress in addressing longstanding disparities in lead exposure and blood lead levels in children.

Tobacco Laboratory

The Tobacco Laboratory provides laboratory science that helps reduce individual and population exposure to addictive and toxic substances from tobacco products.

Helped Determine the Effectiveness of *The Family Smoking Prevention and Tobacco Control Act of 2009* in Reducing American's Exposure to Chemicals in Cigarette Smoke

DLS measured levels of chemicals found in cigarette smoke in a special sample of U.S. adult cigarette smokers and nonsmokers and published the data as a part of CDC's [National Exposure Report](#). The sample provides a robust dataset for identifying changes in exposures of smokers following enactment of tobacco product standards under [The Family Smoking Prevention and Tobacco Control Act of 2009](#).

Assessed the Addictive Potential of E-Cigarettes and Heated Tobacco Products

DLS performed a comprehensive evaluation of the physical design properties and chemical composition of 144 new tobacco products, including e-cigarettes and heated tobacco products. Findings support FDA's regulatory efforts and suggest products are designed to appeal to first-time users and progress them to more addictive products through a combination of adding flavors, manipulating pH, and varying nicotine content.

Investigated Harm Reduction Among Smokers Switching to E-Cigarettes

DLS [completed multiple studies](#) that described harmful and addictive exposures in people who smoke both cigarettes and e-cigarettes and smokers who switched fully to e-cigarettes. Data show that harm reduction only happens when traditional cigarette smoking is reduced by 50%. FDA regulators can use this information as they develop policies to reduce harm from use of combustible tobacco products.

Improved the Understanding of Nicotine Dependence in Smokers

DLS applied new laboratory methods to evaluate used cigarette filters and found increased nicotine dependence with increased intensity of product use among smokers. [These data](#) showed a correlation between nicotine exposure biomarkers and common tobacco dependence metrics. Policy

makers and regulators can use [this information](#) to inform public health actions that address cigarette design manipulations that increase smoking intensity, nicotine delivery, and nicotine dependence.

Nutrition, Chronic, and Infectious Disease Laboratories

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

Improved the Understanding of Transmissibility of COVID-19 Variants

DLS completed [structural analysis of the SARS-CoV-2 D614G variant](#) and the original wild-type viral protein. Results showed that more infectious variants of the SARS CoV-2 virus have larger glycans in the receptor-binding domain compared to the original viral strain, causing major structural differences that may impact transmission, virulence, and vaccine efficacy. These important data helped CDC better understand and predict disease transmission.

Helped Expand the Reach of Folate Studies within Low-Resource Settings

DLS showed that folate forms measured by liquid chromatography tandem mass spectrometry in red blood cell lysates and whole blood lysates were comparable and stable for two years when stored frozen. [This finding](#) allows investigators to work with different blood matrices depending on field and study conditions, expanding the availability of important nutrition studies on neural tube defects or folate sufficiency in low-resource settings globally.

Improved the Understanding of Exposures to Aflatoxin in Uganda

DLS completed a [multinational laboratory project](#) to obtain country-wide estimates of exposure to aflatoxin, a potent carcinogen formed by mold on crops, in Uganda. Findings improve understanding of key geographic, demographic, and socioeconomic factors that may increase aflatoxin exposure risk.

Demonstrated the Effectiveness of Using Low-Cost Tests in International Micronutrient Surveys

DLS conducted a [study](#) that showed low-cost tests for iron and inflammation biomarkers, widely used in micronutrient surveys in low resource countries, performed acceptably over time and compared well with reference tests used in nationally representative U.S. studies like the National Health and Nutrition Examination Survey (NHANES). This information demonstrates that nutrition status data from different countries can be reliably interpreted alongside U.S. nutrition status data.

Established a New Partnership to Promote Accurate Lab Tests to Healthcare Insurance Providers

DLS Clinical Standardization Programs partnered with a private payer to expand the use of standardized lab tests. As a result, the payer modified policies to promote the use of standardized laboratory methods for vitamin D, testosterone, cholesterol, and others, and strongly recommended its providers and payers order and reimburse only “standardized” testosterone tests for laboratory evaluation of patients. Private payer support is critical for universal adoption of standardized tests for certain chronic disease biomarkers.

Expanded Use of CDC Test for Trans Fatty Acid to Reduce Cardiovascular Diseases Globally

DLS’s laboratory method for measuring trans-fatty acids (TFA) in people is now in use in India and Thailand, improving these countries’ laboratory capacity to measure this important chronic disease

biomarker. This method was also adopted by the World Health Organization (WHO). [Cardiovascular diseases](#) (CVD) are the leading cause of death globally. This work will enable other countries to better assess exposures to TFA and evaluate the impact of public health policies to minimize risks for CVD.

Improved the Accuracy of Cholesterol Tests from a Large Test Manufacturer

Data from DLS's Lipids Standardization Program helped identify a problem with the accuracy of cholesterol measurements from a major test manufacturer. DLS assisted the manufacturer in improving the accuracy and reliability of their measurements, which account for nearly a quarter of the cholesterol tests conducted in the United States. This early detection and intervention prevented misdiagnosis and misinterpretation of results for millions of total cholesterol tests performed annually.

Expanded Global Availability of Important Reference Materials for Cardiovascular Disease Biomarkers

DLS partnered with the International Federation of Clinical Chemistry (IFCC), Laboratoire National de métrologie et d'essais (LNE), and the WHO, to make and distribute highly needed reference materials. This effort led to worldwide availability of reference materials for chronic disease biomarkers, which can be used to standardize tests and improve testing accuracy. DLS assigned cholesterol reference values to materials developed by the French metrological institute LNE and assisted the IFCC with developing reference materials for new and emerging CVD biomarkers, such as lipoproteins. DLS also responded on short notice to the closure of the only distributor of lipoprotein reference materials, by serving as the repository of these WHO materials.

Improved the Accuracy of Iron Status Biomarker Tests

DLS applied unique procedures to characterize reference materials for iron status biomarkers, enabling manufactures to correctly calibrate tests and substantially reduce variability in results. Iron deficiency is a major public health concern worldwide, so accurate and reliable measures of iron status are essential.

Newborn Screening Laboratories

The Newborn Screening Laboratories assure the early and accurate laboratory detection of treatable congenital disorders in newborns.

Improved Efficiency and Quality of the Newborn Screening Quality Assurance Program

DLS implemented a new online participant portal for the nearly 700 domestic and international laboratories that participate in the Newborn Screening Quality Assurance Program each year. This data modernization effort brings efficiency and reliability to the complex logistics associated with a program of this magnitude.

Developed a Sustainable Process to Provide Quality Assurance Materials that Improve Accuracy of Newborn Screening Tests

The Newborn Screening Quality Assurance Program provides quality assurance materials that improve the detection of diseases in newborns. For disorders detected by a molecular test, creating dried blood spot materials that mimic newborn samples is challenging because the diseases are rare and only limited quantities of blood are available from donors affected by the disease. DLS devised a process to sustainably grow large quantities of patient-derived transduced cell lines to create large-scale lots of dried blood spots that contain the genome from patients affected by specific diseases. In 2021, this new dried blood spot sample type was launched with great success for routine use to

detect spinal muscular atrophy and severe combined immunodeficiency. Also in 2021, this new sample type was successfully piloted for use in a small subset of newborn screening laboratories for cystic fibrosis detection.

Provided Molecular Testing Support to Newborn Screening Labs

DLS responded to more than 150 requests for assistance with molecular testing from 53 U.S. and international institutions, amounting to more than 600 hours of support. DLS provided help with new test implementation, troubleshooting, continuous quality improvement, sequencing technology, and molecular education for diseases such as severe combined immunodeficiency, spinal muscular atrophy screening, cystic fibrosis, and congenital adrenal hyperplasia.

Improved Capacity to Develop Quality Assurance Materials in Partnership with Patient and Family Blood Donors

DLS's newborn screening laboratories collaborated with the California Department of Public Health and the Sequoia Foundation to establish disease-specific donor repositories for creating quality assurance materials for laboratories that conduct molecular testing. Patient and family member blood donations were collected and stored as dried blood spots and cryopreserved or transduced for cystic fibrosis, spinal muscular atrophy (SMA), Pompe, Krabbe, Mucopolysaccharidosis type 1 (MPS 1), X-linked adrenoleukodystrophy (X-ALD) and medium-chain acyl-CoA dehydrogenase deficiency (MCAD). In 2021, the SMA patient sample repository for the SMN1 gene was completed.

Chemical and Radiologic Threat Agents and Toxins Laboratories

The Chemical Threat Agents and Toxins Laboratories provide laboratory support for the public health response to chemical threat agents and threats involving certain toxins. The Radiologic Threats Laboratory provides effective laboratory support for the public health response to radiologic threat agents.

Provided Consistent, High-Quality Laboratory Materials for Nationwide Chemical Emergency Preparedness

DLS strengthened the Laboratory Response Network for Chemical Threats by improving supply chain integrity for materials needed to respond to a chemical emergency. A consistent, high-quality supply of materials assures LRN-C labs in the United States and Puerto Rico can provide important lab results that identify exposed people, guide treatment, and prevent further exposures.

Developed a New Test to Detect Thorium-232, a Radiological Threat

DLS's Radiation Analytical Toxicology Laboratory developed an automated analytical method for the identification and quantification of the priority threat radionuclide thorium-232. This will enable DLS to rapidly test urine samples and determine the radiation dose and long-term health risk to people contaminated from a radiological incident. Accurate and rapid dose data are essential for effective prioritization of scarce medical countermeasures during a radiological emergency response.