DIVISION OF LABORATORY SCIENCES
2020 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.

Equipped States to Assess Exposures to Harmful Chemicals

As a part of longstanding support for state public health laboratories, CDC's Division of Laboratory Sciences (DLS) awarded New Hampshire, New Jersey, New York, Michigan, Iowa, and Minnesota a total of about $5 million each year for five years. These awards are a crucial component of assessing Americans' exposures to environmental chemicals through the National Biomonitoring Program and increase the capability of state public health laboratories to conduct high-quality biomonitoring studies and assess exposures of concern specific to their communities.

Improved Access to National Environmental Chemical Exposure Data

DLS and CDC's National Environmental Public Health Tracking Program collaborated to offer users of CDC's *National Report on Human Exposure to Environmental Chemicals* a way to view the report's static tables in dynamic, customizable charts and tables. The Biomonitoring: Population Exposures content area on the Environmental Public Health Tracking Network showcases the new functionality. Users can view updated years of data and create custom charts for environmental chemicals or their metabolites from nine environmental chemical groups.

Identified Higher PFAS Exposures in Communities with Contaminated Drinking Water

DLS biomonitoring measurements confirmed per- and polyfluoroalkyl substances (PFAS) serum concentrations that were higher than the general U.S. population in five communities near current or former military bases, all known to have had PFAS in their drinking water. These data, collected as part of ATSDR's Exposure Assessment, will inform future studies evaluating the impact of PFAS exposure on human health.

Better Understanding of Potential Links Between Pesticides Exposures and Children's Behavior

DLS characterized pesticides exposures in children from an area in Ecuador with one of the highest concentrations of flower plantations and use of pesticides in the Americas. DLS measurements will improve the understanding of the relationship between pesticide exposure and mental health symptoms and will assess, for the first time, potential transient neurobehavioral changes associated with pesticide exposures in children.

Assessed Longstanding and Emerging Great Lakes Contaminants in Susceptible Populations

DLS characterized exposures to persistent organic pollutants and polycyclic aromatic hydrocarbons in licensed anglers and in Burmese refugees and their descendants living in the Milwaukee area who eat fish from the area water bodies. Findings will increase awareness of chemical exposures among local fish consumers and the entire Great Lakes community. These data will also help inform local public health actions and safeguard people from harmful exposures in this area known for its heavy industrial, urban, and agricultural pollution.

Assessed Americans' Exposures to Ethylene Oxide

Using a recently developed CDC method, DLS measured ethylene oxide levels as hemoglobin adducts to assess the exposure of populations near medical equipment sterilizing facilities in Chicago. These measurements provided unique, direct comparison of exposure with U.S. population reference levels obtained from NHANES.

DLS also released new biomonitoring data for ethylene oxide hemoglobin adducts among cigarette smokers and non-smokers. These important data were provided as a standalone resource in advance of the next scheduled update to the *National Report on Human Exposure to Environmental Chemicals* to aid federal, state, and local public health agencies, and others currently investigating ethylene oxide.

Identified Methyl Mercury Poisoning from Skin Lightening Cream

DLS provided speciated mercury biomonitoring data that helped confirm toxic methylmercury exposure in two people that used skin lightening cream in California. Critical exposure information guided medical management of the exposed individuals and resulted in a revised public health alert related to skin lightening creams.

Improved Measurements of Potentially Harmful Inorganic Elements in People Around the World

DLS collaborated with the National Institute of Standards and Technology (NIST) to finalize Standard Reference Material (SRM) 955d. This SRM for toxic metals in human blood replaces an existing SRM to provide an expanded panel of elements, such as lead, in blood. It is used to assess the accuracy of analytical measurements used for biomonitoring, epi-aids, and other public health studies. SRM is commercially available, and can be used internationally to validate measurements of elements with significant public health importance.

Tobacco Laboratory

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

Identified Cause of National Lung Injury Outbreak

In response to the outbreak of electronic cigarette, or vaping, product use-associated lung injury (EVALI), DLS rapidly developed and applied 22 laboratory methods for measuring priority potential toxicants in EVALI-associated product emissions and bronchoalveolar lavage (BAL) fluid. After DLS data showed vitamin E acetate in product emissions, and in BAL fluid from nearly all case patients, DLS collaborated with external partners to show that e-cigarette emissions of vitamin E acetate caused lung injury in mice. These data conclusively established inhaled e-cigarette emissions of vitamin E acetate as the cause of the outbreak.

Lab Measurements Informed U.S Food and Drug Administration (FDA) Tobacco Regulation

DLS published 10 manuscripts and reported seven ISO 17025 methods related to harmful chemicals in tobacco products and electronic cigarette/vaping devices, helping fill major gaps in tobacco exposure science. These methods equip the FDA with valid and reliable analytical tests to measure harmful or potentially harmful constituents in tobacco products and support regulatory approaches to reduce the harm caused by tobacco products.

Better Understanding of Harmful Acrolein Exposures and the Risk of Cardiovascular Disease

DLS characterized harmful exposures related to smoking marijuana and tobacco as part of a longitudinal cohort study. DLS measurements improved understanding of the association between acrolein exposure and cardiovascular disease diagnosis. It showed that tobacco smokers had higher exposure to acrolein, a known carcinogen, than marijuana smokers.

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.

Developed Lab Test to Support COVID-19 Vaccine Development

DLS developed a reliable mass spectrometry method for detecting and quantifying antigens from SARS-CoV-2 to aid COVID-19 vaccine development and release. DLS also characterized the site-specific glycan content of the SARS-CoV-2 Spike protein to better understand vaccine efficacy and antibody-based COVID-19 medical countermeasures. These data can help identify the most effective, protective vaccines and inform the design of antibody treatments.

Improved Understanding of Supplement Use and Vitamin D Levels in Americans

DLS investigated the relationship between total serum 25-hydroxyvitamin D and dietary and supplemental intake of vitamin D in the adult U.S. population. The study showed that changes in vitamin D supplementation explain changes in the vitamin D status biomarker between 2007-2010 and 2011-2014. Vitamin D status of the U.S. population is an important public health indicator and may be associated with immune function.

Created Better Tests for Aflatoxin B1

DLS implemented an improved LC-MS/MS method for measuring albumin-bound aflatoxin B1. The updated method is faster, more efficient, and requires less sample volume, thereby improving our laboratory capacity to address human aflatoxin exposure, a persistent public health threat in developing countries.

Created a New Quality Assurance Program to Improve Folate Test Results

DLS assessed the performance of folate and vitamin B12 assays in CDC's VITAL-EQA over a 10-year period. While most laboratories achieved acceptable precision for both analytes, participants continued to show larger assay differences for folate compared to vitamin B12. CDC is now offering a more comprehensive method performance verification program to improve measurement of folate and other key nutritional indicators.

Established Consistent, Trustworthy Results for Thyroid Function Tests in the U.S.

DLS collaborated with the North American Menopause Society to establish and develop reference intervals and with the American Thyroid Association to determine analytical performance criteria for thyroid function tests. These efforts will result in recommendations for establishing and implementing reference ranges generated with a standardized and certified assay that can be adopted by the clinical and research communities.

Newborn Screening Laboratories

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

Improved the Quality of Newborn Screening for Spinal Muscular Atrophy (SMA)

The Newborn Screening Quality Assurance Program (NSQAP) developed the first newborn screening proficiency testing program that utilizes transduced lymphocytes from SMA donor families. This source improves detection of SMA in newborns and expands the capability of DLS to support state newborn screening efforts.

Expanded Severe Combined Immunodeficiency (SCID) Quality Program Internationally

The SCID program was previously open only to domestic participants. In January 2020, the program was opened to all countries measuring the TREC analyte from dried blood spots to identify newborns at risk for SCID.

Harmonized Cystic Fibrosis and Galactosemia Newborn Screening Results Across States

DLS established cell repositories made from donor cystic fibrosis and galactosemia patients representing many different pathogenic disease-causing variants in order to create quality assurance programs for molecular testing of these two disorders. NSQAP adjusted its shipping schedule to ensure state newborn screening laboratories will receive critical quality assurance materials during the COVID-19 pandemic.

Chemical 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 selected toxins.

Improved the Detection of Lethal Ricin and Abrin Toxins

DLS developed a single method for detecting abrin and ricin toxins in environmental samples. Both toxins have identical mechanisms of toxicity and are impossible to differentiate based on symptoms. The new method will allow CDC to rapidly differentiate between the toxins, help confirm cause of illness in exposed people, and ensure proper treatment.

First-Ever Measurements of *B. Cereus* Biovar *Anthracis* Guided Life-Saving Medical Treatment

During a clinical case of infection with *Bacillus cereus (B. cereus)* biovar *anthracis*, DLS detected and measured the decline of anthrax lethal factor in serum and pleural fluid. This was the first time that toxins were measured in a case of inhalation anthrax resulting from toxigenic *B. cereus.* DLS data guided medical decisions and determined treatment efficacy, which included the first use of antitoxin Raxibacumab from the Strategic National Stockpile (SNS). Tests revealed that anthrax lethal factor was still present in pleural fluid after seven days, so the patient received a second dose of Raxibacumab. The patient survived the infection and is in recovery.

Provided Tools to Build Laboratory Capacity for Identifying Synthetic Opioids

DLS improved nationwide access to critical laboratory reference materials by distributing the Opioid Polysubstance Material Kit and the new Fentanyl Analog Screening Emergent Panel V3, part of the Traceable Opioid Material® Kits registered by HHS. DLS also created a free online resource that helps clinical laboratories confidently identify 213 synthetic opioid-related compounds using any high-resolution mass spectrometer. DLS evaluated 19 commercial immunoassays for detection of 30 fentanyl analogs, providing critical information for application and interpretation of these assays and guiding updates to improve rapid detection of novel synthetic opioids.

Developed a Lab Test to Detect Human Exposure to Harmful Algal Blooms

DLS developed new methods to measure human exposure to toxins present in harmful algal blooms. Sample analysis conducted with these new methods identified toxins in clinical specimens following inhalation exposures to blue-green algal blooms and red tides, which contained microcystins and brevetoxins.

Radiologic Threats Agents Laboratory

The Radiologic Threats Laboratory provides effective laboratory support for the public health response to radiologic threat agents.

Developed a Urine Lab Test for Gamma-Emitting Radionuclides

DLS developed an automated analytical method for the identification and quantification of the priority threat radionuclides Cs-137, Co-60, I-131, Ir-192, Mo-99 and Se-75. This will enable CDC to test urine samples and then determine the radiation dose of people contaminated from a radiological incident to determine if they need medical intervention to lower their long-term health risk.

Improved a Urine Lab Test for the Radiologic Threat Agent Sr-90

DLS enhanced the analytical method for the identification and quantification of Sr-90 by developing an automated pre-analytical system which eliminates a slow manual extraction system and the handling of concentrated acids, making the method faster and safer for laboratory staff. This method will enable more samples to be tested by fewer people during a response to a radiological incident to determine if they need medical intervention.

CS322282-A