



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

*Print Date: 4/15/22*

**Title:** NCEH DLS Laboratory Quality Assurance Programs

**Project Id:** 0900f3eb81e1b52e

**Accession #:** NCEH-DLSPB-9/30/21-dfba9

**Project Contact:** Linde J Parcels

**Organization:** NCEH/ATSDR/DLS/DLSPB

**Status:** Pending Regulatory Clearance

**Intended Use:** Project Determination

**Estimated Start Date:** 10/01/2021

**Estimated Completion Date:** 10/01/2024

**CDC/ATSDR HRPO/IRB Protocol #:**

**OMB Control #:**

**Source System #:** 2021-0086

## Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research / Other <i>45 CFR 46.102(l)</i> Quality Assurance / Improvement	11/16/21	Davis_Stephanie I. (sgd8) CIO HSC

PRA: PRA Applies	11/16/21	Davis_Stephanie I. (sgd8) CIO OMB / PRA
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## Description & Funding

### Description

**Priority:** Standard

**Date Needed:** 11/30/2021

**Determination Start Date:** 11/16/21

**Description:** The CDC DLS QA programs operate out of multiple laboratories within the Division. They establish the baseline measurements and provide calibration and/or QC samples that laboratories around the world rely on to develop and improve methods with acceptable levels of accuracy and reliability and, in some cases, meet certain required certifications or accreditation. Laboratories use DLS-developed samples to test the quality and accuracy of their methods/assays. Participating laboratories enroll in the DLS QA program that fits their needs (i.e.: external quality assurance/performance assessment, proficiency testing, accuracy-based monitoring, or standardization/harmonization). After the laboratories receive DLS QA samples and perform their measurements, they return test results to DLS. DLS then evaluates the data using statistical methods and reports back to the laboratories on their analytical performance. Laboratories may receive additional technical assistance (TA)/troubleshooting to improve their method performance as needed. DLS programs are offered at different frequencies.

**IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:** No

**IMS Activation Name:** Not selected

**Primary Priority of the Project:** Not selected

**Secondary Priority(s) of the Project:** Not selected

**Task Force Associated with the Response:** Not selected

**CIO Emergency Response Name:** Not selected

**Epi-Aid Name:** Not selected

**Lab-Aid Name:** Not selected

**Assessment of Chemical Exposure Name:** Not selected

**Goals/Purpose** Accuracy and reliability of laboratory tests is important to identify and to monitor exposures and health biomarkers, which in turn improves diagnosis and treatment. Laboratories that conduct biomonitoring or test for certain environmental or nutritional chemicals participate in quality assurance (QA) activities for many reasons: to assess internal test performance, calibrate methods to standards among other laboratories, receive certification of proficiency to comply with certain regulations, or simply improve quality. Participation may help a laboratory to verify the accuracy of their methods and results or ensure accurate and consistent test results across multiple laboratories.

Collectively, these programs improve the quality of laboratory tests that measure environmental exposures and chronic disease

<b>Objective:</b>	biomarkers (including nutritional indicators and hormones) to better inform critical patient care and public health decisions for an expansive host of health outcomes such as rare heritable disorders in newborns, endocrine disorders, maternal health and risk of birth defects, bone, kidney and cardiovascular disease, cancers (including breast cancer), diabetes, thyroid and hormone dysregulation.
<b>Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and /or decreasing disparities?:</b>	No
<b>Project does not incorporate elements of health equity science:</b>	Yes
<b>Measuring Disparities:</b>	Not Selected
<b>Studying Social Determinants of Health (SDOH):</b>	Not Selected
<b>Assessing Impact:</b>	Not Selected
<b>Methods to Improve Health Equity Research and Practice:</b>	Not Selected
<b>Other:</b>	Not Selected
<b>Activities or Tasks:</b>	All Work Onsite at CDC Facilities
<b>Target Populations to be Included/Represented:</b>	Other - Not Applicable
<b>Tags/Keywords:</b>	DLS 2021-0086
<b>CDC's Role:</b>	CDC is the sole institution conducting activity
<b>Method Categories:</b>	QA/QI
<b>Methods:</b>	<p>There are thirteen (13) DLS QA programs conducted by the following five DLS branches. These programs provide materials and test result analysis to laboratories for the purpose of improving and/or standardizing test performance. # Clinical Chemistry Branch (5): Lipid Standardization Program (LSP) for Clinical Biomarkers; Cholesterol Reference Method Laboratory Network (CRMLN); Accuracy-based Laboratory Monitoring Programs (AMP); Hormone Standardization (HoST) Program; Vitamin D Standardization Certification Program (VDSCP) # Nutrition Biomarkers Branch (3): Vitamin A Laboratory # External Quality Assurance (VITAL-EQA); Quality Assurance Method Performance Verification (MPV) for Folate Microbiologic Assay; Quality Assurance Method Performance Verification (MPV) for Micronutrients # Organic Analytical Toxicology Branch (1): Biomonitoring Quality Assurance Support Program (BQASP) # Inorganic Radiation and Analytical Toxicology Branch (3): Proficiency in Arsenic Speciation (PAsS) Program; Ensuring the Quality of Urinary Iodine Procedures (EQUIP); Lead and Multielement Proficiency (LAMP) Testing Program # Newborn Screening and Molecular Biology Branch (1): Newborn Screening and Quality Assurance Program (NSQAP) All thirteen (13) CDC quality assurance programs help improve the accuracy and reliability of tests performed by laboratories in patient care, research, commercial and public health settings. They also help to make measurement results among research studies and among clinical laboratories more comparable.</p> <p>Data will be collected electronically via email and online forms; data reporting forms are returned to DLS via Excel templates, PDFs, or web platforms. Laboratories that participate in the various programs are domestic and international and can include public health</p>
<b>Collection of Info, Data or Biospecimen:</b>	

laboratories, research laboratories, commercial laboratories, and diagnostic test manufacturers. They can be associated with medical schools, hospital systems, state health departments, universities/academic institutions, ministries of health, nonprofit organizations.

Collectively, these programs improve the quality of laboratory tests that measure environmental exposures and chronic disease biomarkers (including nutritional indicators and hormones) to better inform critical patient care and public health decisions for an expansive host of health outcomes such as rare heritable disorders in newborns, endocrine disorders, maternal health and risk of birth defects, bone, kidney and cardiovascular disease, cancers (including breast cancer), diabetes, thyroid and hormone dysregulation.

**Expected Use of Findings/Results and their impact:**

**Could Individuals potentially be identified based on Information Collected?** No

## Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Funding Intramural	Project Funding and Partners				1762845.00

## HSC Review

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### HSC Attributes

Quality Assurance / Improvement Yes

## Regulation and Policy

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**Do you anticipate this project will be submitted to the IRB office** No

**Estimated number of study participants**

**Population - Children**

Protocol Page #:

**Population - Minors**

Protocol Page #:

**Population - Prisoners**

Protocol Page #:

**Population - Pregnant Women**

Protocol Page #:

**Population - Emancipated Minors**

Protocol Page #:

**Suggested level of risk to subjects**

**Do you anticipate this project will be exempt  
research or non-exempt research**

### **Requested consent process wavers**

<b>Informed consent for adults</b>	No Selection
<b>Children capable of providing assent</b>	No Selection
<b>Parental permission</b>	No Selection
<b>Alteration of authorization under HIPPA Privacy Rule</b>	No Selection

### **Requested Waivers of Documentation of Informed Consent**

<b>Informed consent for adults</b>	No Selection
<b>Children capable of providing assent</b>	No Selection
<b>Parental permission</b>	No Selection

### **Consent process shown in an understandable language**

<b>Reading level has been estimated</b>	No Selection
<b>Comprehension tool is provided</b>	No Selection
<b>Short form is provided</b>	No Selection
<b>Translation planned or performed</b>	No Selection
<b>Certified translation / translator</b>	No Selection
<b>Translation and back-translation to/from target language(s)</b>	No Selection
<b>Other method</b>	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or behavioral outcome	No Selection
Registerable clinical trial	No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	No Selection
Human genetic testing is planned now or in the future	No Selection
Involves long-term storage of identifiable biological specimens	No Selection
Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Institutions yet to be added .....

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Linde Parcels	09/13/2024				Project Officer		404-498-5892	DLS POLICY BRANCH
Yan Ding	03/01/2024	07/02/2024			Project Officer		770-488-7934	DIVISION OF LABORATORY SCIENCES

## Data

**DMP**

**Proposed Data Collection Start Date:** 9/30/21

**Proposed Data Collection End Date:** 9/30/24

**Proposed Public Access Level:** Non-Public

Non-Public Details:

Reason For Not Releasing Data: Other - QA/QC

Public Access Justification: QA/QC

<b>How Access Will Be Provided for Data:</b>	Project data is not public health data
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### Plans for Archival and Long Term Preservation:

## Spatiality

Spatiality (Geographic Locations) yet to be added .....

## Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									



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