CDC Lipid Standardization Program (CDC LSP) Sample Analysis Protocol and Data Submission Instruction Manual

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Website: https://www.cdc.gov/labstandards/csp/lsp.html

E-Mail: cdclsp@cdc.gov

Director, CDC Clinical Standardization Programs

Hubert W. Vesper, PhD

E-Mail: HVesper@cdc.gov

Lead, CDC Lipids Standardization Programs

Uliana Danilenko, PhD

E-Mail: UDanilenko@cdc.gov

GENERAL INFORMATION

Purpose

As part of the CDC's Clinical Standardization Programs, the Lipid Standardization Program (LSP) monitors the accuracy and precision of research and clinical laboratories over time. LSP provides blinded serum-based reference materials and evaluates the performance of participating laboratories. The reference values are assigned by the reference measurement procedures for total cholesterol (TC), total glycerides (TG), and high-density lipoprotein cholesterol (HDL-C) that are operated by the CDC Clinical Reference Laboratory (CRL). Routine values for additional analytes, apolipoprotein A1 (Apo A1) and apolipoprotein B (Apo B), are used for evaluation purposes only. Apo A1 and Apo B values are traceable to the candidate LC-MRM-MS-based reference measurement procedure (RMP) for apolipoproteins by the IFCC Working Group for Apolipoproteins by Mass Spectrometry (IFCC WG APO-MS). This protocol includes information on sample analysis and reporting on the CDC LSP website.

SAMPLE INFORMATION

Specimen Handling Information

LSP materials contain human serum only (100% Human Origin). No animal products or other human or animal tissues were used to manufacture these materials. All sera used to produce these materials have been tested for and determined to be free of human immunodeficiency virus (HIV) 1 & 2, hepatitis B virus (HBV), and hepatitis C virus (HCV). **No test method can offer complete assurance of the absence of HIV, HBV, HCV, or other infectious agents; therefore, all materials should be handled at the Biosafety Level 2.**

Observe universal precautions; wear protective gloves, laboratory coats, and safety glasses while handling LSP materials. The materials should only be used for quality assurance or research purposes as directed. Any residual samples should not be used for other purposes. These materials are for in-vitro use only.

LSP Materials Receipt

Each participant will receive 1.3 mL of sera per vial, blinded with a unique identifier. If this volume is not sufficient to measure all analytes enrolled, additional LSP materials may be obtained. All samples must be stored at -80° C upon receipt until the time of analysis.

Each sample box will contain one inverted vial to verify all samples have remained frozen during transit. Upon receipt, please inspect the content to confirm the integrity of the samples. Please contact the CDC LSP (cdclsp@cdc.gov) immediately if samples are received thawed, broken or if any discrepancies arise.

Box Information

Each box will contain samples for all 4 quarters for the year, 12 vials per quarter. See Figure 1 for an example of the box layout.

Run numbers and their respective quarters are indicated on the box layout. Vials are arranged by run number in sequential order for each quarter. Each sample must be analyzed according to the box layout. If vial positions are swapped, the participant must contact cdclsp@cdc.gov prior to analyzing the samples for an updated sample list.

The box top and box bottom are aligned with matching-colored dots. Carefully line up colored dots when replacing the cover.

RUN 1 QTR 1	RUN 2 QTR 1	RUN 3 QTR 1	RUN 4 QTR 1	RUN 5 QTR 1	RUN 6 QTR 1	RUN 7 QTR 1
RUN 8 QTR 1	RUN 9 QTR 1	RUN 10 QTR 1	RUN 11 QTR 1	RUN 12 QTR 1	RUN 1 QTR 2	RUN 2 QTR 2
RUN 3 QTR 2	RUN 4 QTR 2	RUN 5 QTR 2	RUN 6 QTR 2	RUN 7 QTR 2	RUN 8 QTR 2	RUN 9 QTR 2
RUN 10 QTR 2	RUN 11 QTR 2	RUN 12 QTR 2		RUN 1 QTR 3	RUN 2 QTR 3	RUN 3 QTR 3
RUN 4 QTR 3	RUN 5 QTR 3	RUN 6 QTR 3	RUN 7 QTR 3	RUN 8 QTR 3	RUN 9 QTR 3	RUN 10 QTR 3
RUN 11 QTR 3	RUN 12 QTR 3	RUN 1 QTR 4	RUN 2 QTR 4	RUN 3 QTR 4	RUN 4 QTR 4	RUN 5 QTR 4
RUN 6 QTR 4	RUN 7 QTR 4	RUN 8 QTR 4	RUN 9 QTR 4	RUN 10 QTR 4	RUN 11 QTR 4	RUN 12 QTR 4

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QTR 1 – PSxxx, QTR 2 – PSxxx, QTR 3 – PSxxx, QTR 4 – PSxxx

Figure 1: LSP box layout example

SAMPLE ANALYSIS PROTOCOL

1. Thawing and mixing
    a. Remove the vial for the appropriate run from the freezer and thaw to ambient temperature (25°C). If necessary, thawing may be done in a 25°C water bath for 30 minutes.
    b. To ensure homogeneity, thawing while mixing/rotating is recommended. Proper mixing techniques include the use of a hematological mixer, blood mixing wheel, or by swirling thoroughly. **Do not vortex or shake vigorously.**
    c. Prepare control materials according to the laboratory's protocol.
2. Analyze one sample in duplicate measurements in one run per week in sequential order for twelve weeks for each enrolled analyte. Each LSP sample must be analyzed at random intervals in conjunction with the laboratory's regular study and/or patient samples. LSP samples must be analyzed within their respective quarters.
3. Please follow the laboratory's standard protocol for quality controls.
4. Quarterly data submissions are due on the last day of every quarter. Please see below for the LSP quarter dates.

LSP Quarter Dates:

First Quarter: January 1 - March 31

Second Quarter: April 1 - June 30

Third Quarter: July 1 - September 30

Fourth Quarter: October 1 - December 31

LABORATORY DATA COLLECTION SYSTEM INSTRUCTION MANUAL

Please use the following link to access the LSP Data Submission Website (https://wwwn.cdc.gov/dlsdata/lspds/log_in.aspx). The log in page can be seen in Figure 2 below. To log in to the LSP website, enter the User ID and temporary password provided by the CDC LSP. Select the check box to accept the terms and conditions, and Log In. In the event the password is forgotten or unable to access the LSP website, contact cdclsp@cdc.gov for assistance.

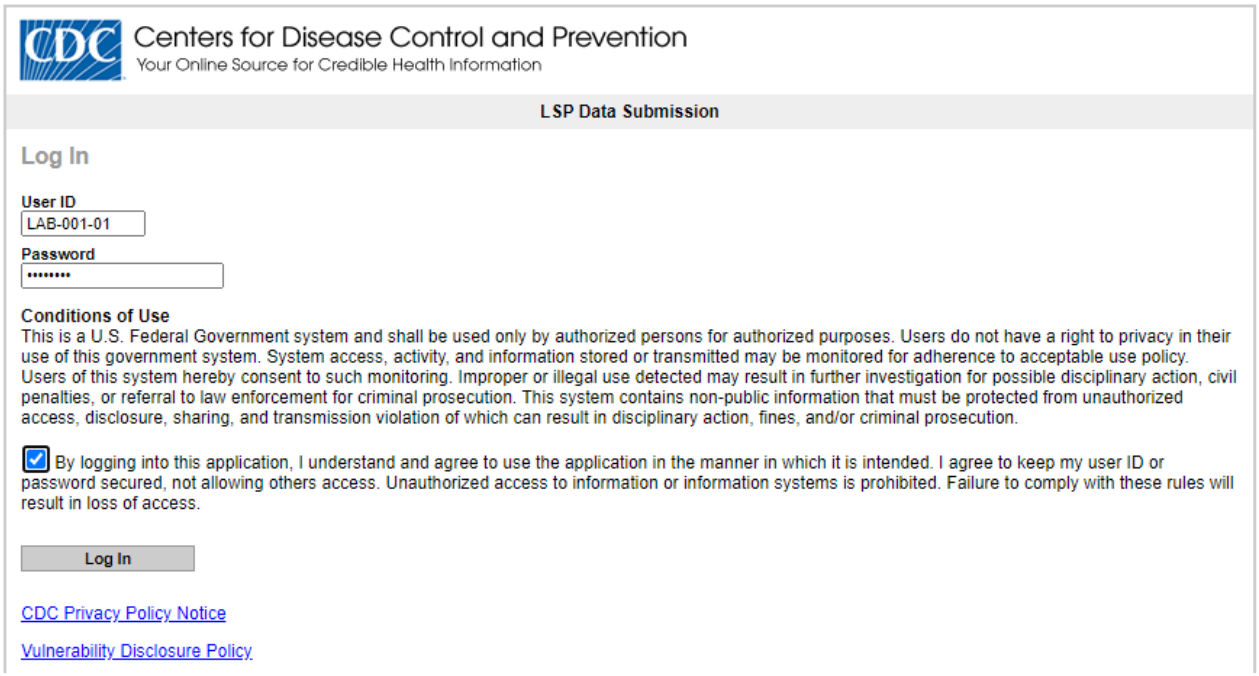

Figure 2: CDC Lipid Standardization Program Data Submission log-in page

The LSP home page is shown in Figure 3. This page consists of various tabs to be utilized when submitting LSP data as well as access to program-related materials and announcements.

Figure 3: CDC Lipid Standardization Program Data Submission Home page

The Sample Set tab contains the Sample Set Editor where sample sets are created for the respective pool series. This is shown in Figure 4 below. The complete list of active and inactive sample sets are listed in their respective drop-down lists.

Figure 4: CDC Lipid Standardization Program Sample Set Editor page

Select "Create a New Sample Set", the appropriate pool series and enter the vial barcode IDs for each run as shown in Figure 5. The Sample Set Name should include the pool series or quarter and the assay used to analyze the samples. Laboratories that receive multiple sample boxes per quarter may identify each sample set by a different name (i.e., PS167 Assay 1; PS167 Assay 2)

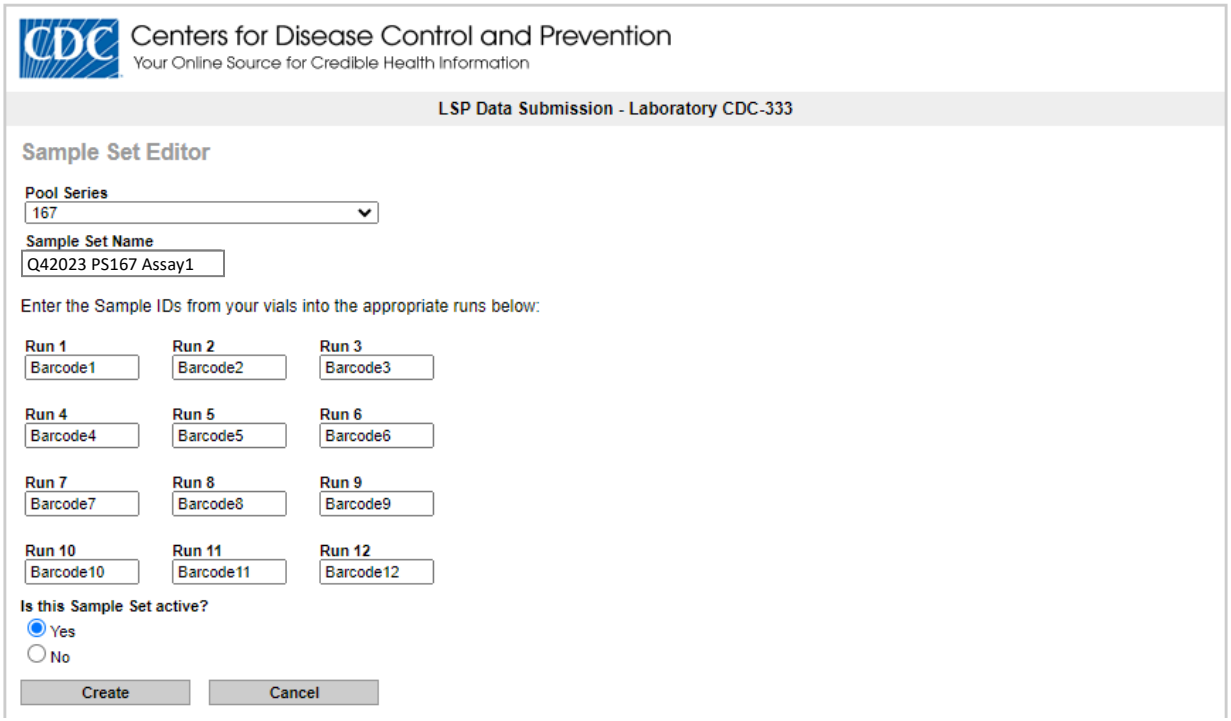

Figure 5: Creating a new sample set.

The sample set must be made active by selecting "Yes" to see the Sample Set listed on the Data Sheet Editor. Select Create to create the sample set.

Once the sample set is created, the instrument profile must be created as shown in Figure 6. This contains information about the instrument used to analyze LSP samples. Multiple instrument profiles can be created according to the laboratory. Be sure to activate all instrument profiles used in LSP. If the instrument isn't listed

in the drop-down list, contact cdclsp@cdc.gov to request the instrument and manufacturer name be added to the list.

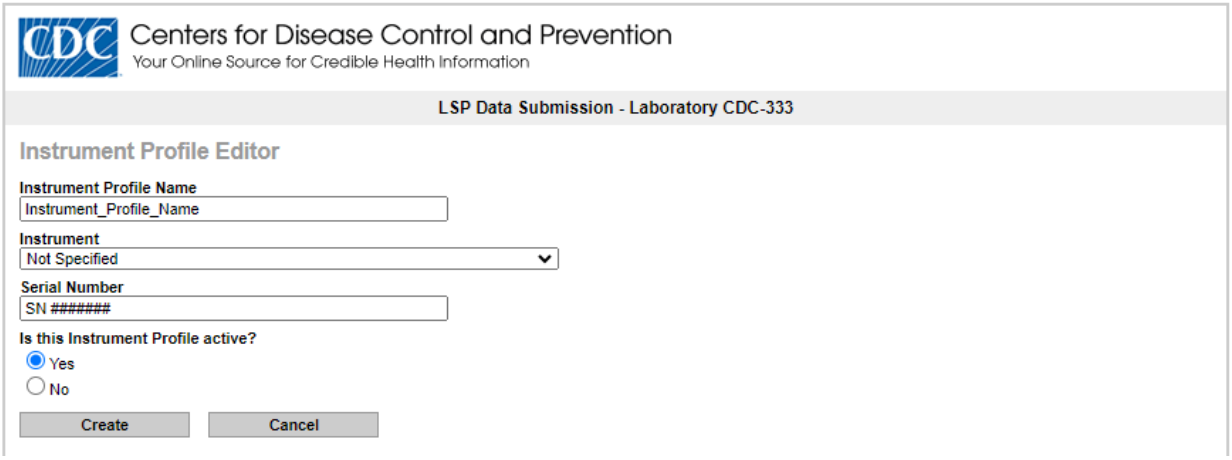

Figure 6: Creating a new instrument profile.

To submit data, select the Data Sheets tab to view data sheets that are in progress, submitted and accepted as shown in Figure 7 below.

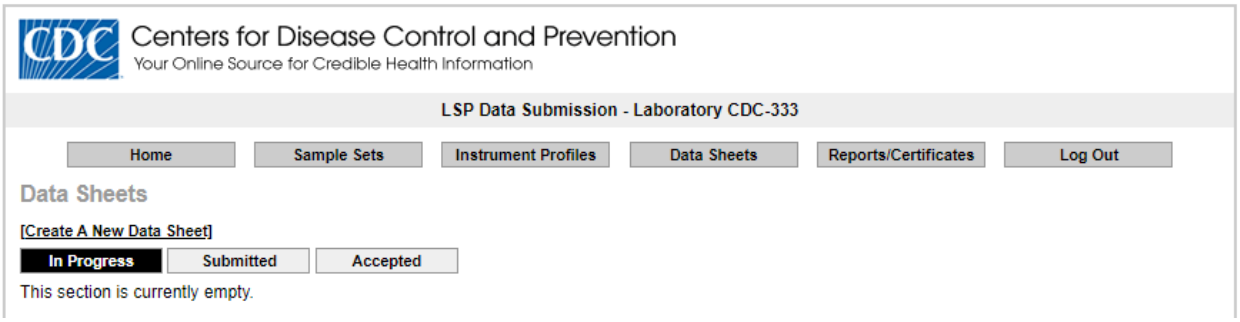

Figure 7: CDC Lipid Standardization Program Data Sheet page

Select “Create a New Data Sheet” to navigate to the Data Sheet Editor shown in Figure 8. Select the Sample Set created from the drop-down list. This will pre-populate the sample ID barcodes in the Sample ID column for their respective run numbers. Edits to existing data sheets can be done in the Data Sheet Editor as well.

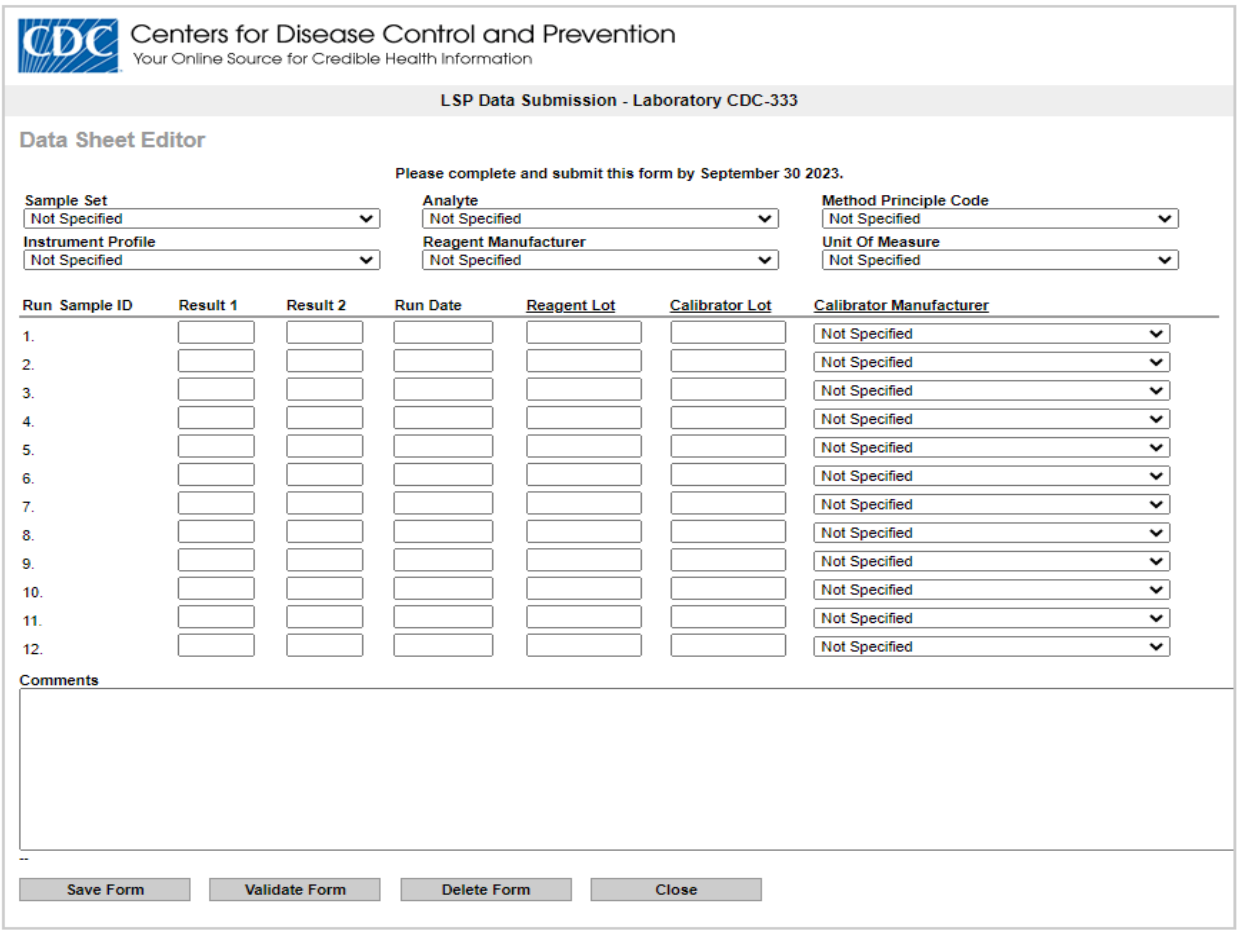

Figure 8: CDC Lipid Standardization Program Data Sheet Editor page

In the Data Sheet Editor, describe the assay, reagent, method, etc. used to analyze the LSP samples. Please note, the Method Principal Code options may vary depending on which analyte is selected. If a manufacturer is not listed, please contact cdclsp@cdc.gov to request the manufacturer be added to the drop-down list.

Enter the results into the Result 1 and Result 2 columns for each run. If a sample cannot be analyzed, enter an asterisk (*) for the results and provide a justification in the comments section. **Please note, incomplete data will not receive an LSP report or certificate. Reference values will be provided to the participant for internal comparison.**

If the same reagent Lot, calibrator lot and calibrator manufacturer are used for each run, enter the information in run 1 and double-click on each of the column headers to fill the information for all twelve runs.

It is recommended to review all data sheets for accuracy before submitting. Select “Validate Form” to run the error check. Error icons will be shown for each field that requires attention, and more information about the errors can be obtained by hovering over each error icon.

The Data Sheet Editor will automatically save the information entered every three minutes. Data sheets can be saved manually by selecting “Save Form” at any time.

To delete a data sheet, select “Delete Form”. Please note, deleted data sheets cannot be recovered.

If no errors are found, select “Submit Form” to submit the data to the CDC LSP. Multiple data sheets can be created for the enrolled analytes by following these steps.

If issues arise, contact cdclsp@cdc.gov for assistance.