Laboratory Procedure Manual

Analyte: **Complete Blood Count**

Matrix: **Whole Blood**

Method: ***Beckman Coulter DxH-800*** **Analyzer**

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As performed by: The National Health and Nutrition Examination Survey
Mobile Examination Center

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Important Information for Users

The Nation Health and Nutrition Examination Survey periodically refines these laboratory methods. It is the responsibility of the user to contact the person listed on the title page of each write-up before using the analytical method to find out whether any changes have been made and what revisions, if any, have been incorporated.

Public Release Data Set Information

This document details the Lab Protocol for testing the items listed in the following table:

File Name	Variable Name	SAS Label
CBC_L	LBXMOPCT	Monocyte percent (%)
	LBXNEPCT	Segmented neutrophils percent (%)
	LBXEOPCT	Eosinophils percent (%)
	LBXBAPCT	Basophils percent (%)
	LBDLYMNO	Lymphocyte number (1000 cells/uL)
	LBDMONO	Monocyte number (1000 cells/uL)
	LBDNENO	Segmented neutrophils num (1000 cell/uL)
	LBDEONO	Eosinophils number (1000 cells/uL)
	LBDBANO	Basophils number (1000 cells/uL)
	LBXRBCSI	Red blood cell count (million cells/uL)
	LBXHGB	Hemoglobin (g/dL)
	LBXHCT	Hematocrit (%)
	LBXMCVSI	Mean cell volume (fL)
	LBXMCHSI	Mean Cell Hgb Conc. (g/dL)
	LBXMCH	Mean cell hemoglobin (pg)
	LBXRDW	Red cell distribution width (%)
	LBXPLTSI	Platelet count (1000 cells/uL)
	LBXMPSI	Mean platelet volume (fL)

Complete Blood Count

1. Introduction

A complete blood count (CBC) with automated differential is performed in duplicate on all study participants (SPs) aged 1 year and older. The CBC is performed on the Coulter® DxH 800 analyzer using the SP's EDTA blood tubes, which are obtained via the phlebotomy component.

Note: Run the CBC within 2 hours. If unable to run the CBC within 2 hours, store the 3- or 4-ml EDTA blood tube at room temperature for no more than 24 hours. After 24 hours, the blood will undergo changes that will render the WBC, RBC, HgB, and HCT results inaccurate.

There are three Coulter DxH 800 analyzers, one for each mobile examination center (MEC). The serial numbers and system IDs are represented in Table 6-1.

Table 1-1. Coulter DxH 800 analyzers serial numbers and system IDs

DxH 800 location	Serial number	System ID	IQAP ID
MEC 1	AU36520	3770768	32979-1-B3
MEC 2	AU32459	3702621	32979-1-B2
MEC 3	AU23263	3348667	32979-1-B1

1.2 Purpose and Principle of Test

The Coulter DxH 800 analyzer is a quantitative, automated hematology analyzer for in-vitro diagnostic use in screening patient populations in clinical laboratories. The UniCel DxH 800 Analyzer provides the following: CBC, Leukocyte 5-Part Differential (Diff), Reticulocyte (Retic), and Nucleated Red Blood Cell (NRBC) on whole blood.

Note: The NHANES study does not use the reticulocyte data, and the NRBC is used only for calculating a corrected white blood cell count.

The Coulter DxH 800 analyzer measures the following parameters:

WBC	White Blood Cell count
UWBC	Uncorrected White Blood Cell count
RBC	Red Blood Cell count (for Whole Blood and Body Fluids)
Hgb	Hemoglobin
Hct	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Conc.
RDW	Red Cell Distribution Width
RDW-SD	Red Cell Distribution Width-Standard Deviation
PLT	Platelet count
MPV	Mean Platelet Volume
NE	Neutrophil percent
LY	Lymphocyte percent
MO	Monocyte percent
EO	Eosinophil percent
BA	Basophil percent
NE#	Neutrophil absolute number
LY#	Lymphocyte absolute number
MO#	Monocyte absolute number
EO#	Eosinophil absolute number
BA#	Basophil absolute number
NRBC	Nucleated Red Blood Cell percent
NRBC#	Nucleated Red Blood Cell absolute numbe
RET	Reticulocyte percent
RET#	Reticulocyte absolute number
MRV	Mean Reticulocyte Volume
IRF	Immature Reticulocyte Fraction
TNC	Total Nucleated Cell (Body Fluids)
TNC	Total Nucleated Cell (Body Fluids)

1.2.1 Coulter Method

In 1956, Wallace Coulter described the Coulter Principle as follows: A suspension of blood cells is passed through a small orifice simultaneously with an electric current. The individual blood cells passing through the orifice introduce an impedance change in the orifice determined by the size of the cell.

Each cell suspended in a conductive liquid (diluent) acts as an insulator. As each cell passes through the aperture, it momentarily increases the resistance of the electrical path between the submerged electrodes on either side of the aperture. This causes a measurable electronic pulse. For purposes of counting, the vacuum used to pull the diluted suspension of cells through the aperture must be at a regulated volume. The number of recorded pulses indicates particle count, and the size of the electrical pulse is proportional to the cell volume. In addition, the system counts the individual cells and provides cell size distribution. The number of cells counted per sample is approximately 100 times greater than the usual microscope count, which reduces the odds of statistical error approximately 10 times.

1.2.2 VCSn Technology

Historically, Beckman Coulter analyzers housed a flow cell in a Triple Transducer Module (TTM), which was first introduced commercially in the 1980s. The TTM flow cell was the location for detection of the processed samples. The TTM produced three measurement signals—volume, conductivity, and light scatter.

The DxH 800 system replaces the TTM with the Multi-Transducer Module (MTM), which measures additional multiple angles of light scatter, a major improvement over the single light scatter measured by the TTM. All Diff, NRBC, and Retic analysis occurs in the Volume Conductivity and Scatter properties module. The VCSn module is responsible for controlled sample preparation and delivery of the prepared sample to the flow cell for analysis of the WBC differential, reticulocyte, and NRBC. The VCSn module includes the Air Mix and Temperature Control (AMTC) and the MTM.

In the flow cell, low-frequency direct current measures volume, while high-frequency (RF) current senses cellular internal content through measuring changes in conductivity.

The MTM uses a flow cell to pass particles through a sensing zone, one particle at a time, and a diode laser to illuminate the particles. The illuminated particles both scatter and absorb a portion of the incident light. Sensors strategically placed around the flow cell collect the scattered light of interest. An additional sensor placed in the laser path measures the amount of light removed due to light scatter and absorption. This measurement is called axial light loss.

1.2.3 Dataplot Development

The technician performs a series of operations on the stored digital raw values received from the flow cell to identify populations and calculate the frequency of cells within each population. The system produces the dataplot displays for visual representation of the differential, NRBC membership (types of cells), and density (concentration).

The DxH 800 system algorithm uses tools designed for finding optimal separation between overlapping clusters of data.

The algorithm can:

- Adapt to unusual population shifts and overlaps;
- Define highly irregular separation;
- Make subsequent analysis of the identified regions; and
- Correct deficiencies in separation.

In the dataplots, different colors represent different memberships. Shades of colors represent density: dark colors for low density and bright colors for high density, as shown in the following listing (see Section 6.19.4 for examples):

NRBC analysis		Diff analysis	
NRBC	Red	Lymphocyte	Blue
Other*	Green	Monocyte	Green
WBC	Blue	Neutrophil	Purple
		Eosinophil	Orange
		Basophil	White
		Non-White Cell	Red

* Others include RBC debris, PLT debris, etc.

1.2.4 Parameter Measurement, Derivation, and Calculation

Exhibit 6-1 lists each reportable parameter and the method used to obtain the results. A description of the method is also included.

Exhibit 1-1. Reportable parameters and analysis methods

Parameter (reporting units in US-1 format)	Method	Description
WBC	Coulter Principle	White Blood Cell Count or Leukocyte Count • Measure directly, multiplied by the calibration factor. • Corrected for interference if necessary. If no correction is required, then WBC = UWBC. • WBC = N x 10^3 cells/µL.
UWBC	Coulter Principle	Uncorrected White Blood Cell • Measure directly, multiplied by the calibration factor. • UWBC = N x 10^3 cells/µL.
RBC	Coulter Principle	Red Blood Cell Count or Erythrocyte Count • Measure directly, multiplied by the calibration factor. • Corrected for very high white count if necessary. • RBC = N X 10^6 cells/µL.
Hgb	Photometric Measurement	Hemoglobin or Hemoglobin Concentration • Transmittance of light at 525 nm through a lysed WBC solution in the Hgb cuvette, compared to the transmittance of the same light through a reagent blank. The system converts this ratio to the Hgb value using a calibration factor. • Weight (mass) of Hgb determined from the degree of absorbance found through photo current transmittance expressed in g/dl. • Corrected for WBC interference. • Hgb (g/dl) = [constant X $\log^{10}$ (Reference %T/Sample %T)].
Hct	Calculated	Hematocrit • The relative volume of packed erythrocytes to whole blood. • Hct (%) = RBC X MCV[10].
MCV	Derived from RBC Histogram	Mean Corpuscular Volume • The average volume of individual erythrocytes derived from the RBC histogram. • The system multiples the number of RBC in each channel by the size of the RBC in that channel. The products of each channel between 36 and 360 femtoliters (fL) are added. This sum is divided by the total number of RBC between 36 and 360 fL. The analyzer then multiplies by a calibration factor. • Corrected for WBC interference. • Expressed in fL.

The DxH 800 system includes a Specimen Processing Module (SPM), a Pneumatic Supply Module (PSM), and a system manager (SM), precisely integrated to provide process control, data consolidation, and cassette or single-tube delivery of specimens.

1.3 Components of DxH 800

1.3.1 The Specimen Processing Module

The SPM is made up of the following functional modules:

1.3.3.1 **Specimen Transport Module (STM).** The STM automatically transports specimens, delivering closed-vial and open-vial specimens, which accommodates a wide range of specimen tubes. The STM supports the following:

1.3.3.1.1 Operator loading and unloading of specimens;

1.3.3.1.2 Transport and queuing of specimens;

1.3.3.1.3 Mixing and presentation of specimens; and

1.3.3.1.4 A magnetic transport system to move cassettes containing specimens.

1.3.3.2 **Sample Aspiration Module (SAM).** The SAM aspirates from capped specimen tubes (presented via cassette or single-tube presentation) or open vials (single-tube presentation). Body fluids are presented via single-tube, while whole bloods can be presented in either presentation mode. The identification and integrity of samples are verified prior to delivery and transfer to the analytical modules within the system. The SAM design provides for two methods of sample delivery: sample segmentation and sample dispensing. In sample segmentation, aspirated sample is transferred through the Blood Sample Valve where it is segmented for whole blood CBC and body fluid. In sample dispensing, whole blood sample segments are dispensed via the aspiration probe into the mixing chambers on the AMTC for the WBC differential and NRBC analyses.

1.3.3.3 **VCSn Module.** The VCSn module provides the physical processing elements necessary for the differential and NRBC sample preparation and subsequent measurement. This module includes the Distribution Valve (DV), AMTC module, MTM and their associated electronics and fluidics. Samples prepared at the AMTC are delivered to the MTM where the sample detection occurs.

1.3.3.4 **CBC Assembly.** The CBC Assembly provides the physical processing elements necessary for CBC sample conditioning (combining of reagents and the sample segment, mixing, and incubation) and measurement via the aperture bath assemblies, the Hgb assembly, and the electrical signal conditioning circuits.

1.3.3.5 **Common Services Consist of the Electronic Supply Module, Pneumatic Services, and Reagent Services (Supply and Distribution).** Common services provide and monitor electronic power and supplies, and monitor the reagent and waste levels as well as the pressure and vacuum.

1.3.2 The System Manager

The DxH 800 SM is responsible for the following:

- Controlling processes, such as analytic and diagnostic procedures;
- Producing test results; and
- Managing data, such as test ordering, result, review and release, quality control, LIS interface, logging, and report generation.

The SM includes an LCD flat panel monitor with touchscreen capability, a computer with a CD/DVD RW drive running Microsoft Windows operating system, the DxH 800 software, a standard keyboard, and an optical mouse.

1.3.3 Pneumatic Supply Module

The PSM supplies vacuum and pressure to the SPM.

1.4 Special Safety Precautions

All specimens may be potentially positive for infectious agents, including HIV and Hepatitis B and C viruses. Observe standard precautions and any additional personal protective equipment requirements in place. **It is mandatory to wear gloves and a lab coat when handling all human blood products and Coulter controls.** Dispose of all biological samples in a biohazard container and wipe down all work surfaces with an approved disinfectant at the end of each appointment block. Clean all spills immediately and with an approved disinfectant. For additional requirements during the COVID-19 pandemic, refer to the NHANES COVID-19 Mitigation Protocols. Certain troubleshooting procedures on the Coulter require the use of a 5 percent – 6 percent bleach solution. The MEC supply of bleach is an 8.25 percent solution. To make 20 mL of a 5 percent – 6 percent bleach solution using the 8.25 percent bleach, add 5.5 mL of DiH^2O to 14.5 mL of the 8.25 percent bleach solution.

The MEC Working Safely with Hazardous Chemicals manual contains all Coulter safety data sheets (SDS).

1.5 Digital Interface with the Integrated Survey Information System (ISIS)

The DxH 800 SM transmits individual SP results to the MEC automated ISIS system. All SP results are reviewed at the DxH 800 SM monitor.

The ISIS hematology module in the laboratory application automatically receives the results, or results are transmitted manually to the hematology module. The laboratory application evaluates the data for completeness and accuracy. The final decision to accept or reject a result is the responsibility of the clinical laboratory scientist.

All data is backed up and stored at Westat's home office.

1.6 Specimen Collection and Preparation

1.6.1 Specimen Collection

1.6.1.1 The phlebotomist collects a 3- or 4-ml K2 EDTA (ethylene diamine-tetracetic acid) tube, used for a CBC on all SPs aged 1 year and older, following the established venipuncture protocol and procedures. (A 1%–2% dilution effect occurs in this liquid EDTA tube.)

1.6.1.2 Sample volume is 165µL of whole blood in the closed-vial mode or the single tube presentation mode. The minimum sample volume per tube in the closed-vial mode is 1-ml with the proper proportion of blood to anticoagulant.

1.6.2 Specimen Preparation

For SPs 1–2 years old, the K_2 EDTA blood sample is shared between blood processing and hematology. The shared EDTA blood tube is processed by the clinical laboratory scientist working in the blood specimen-processing workstation first by taking off whole blood required for various tests in the SP's profile, including the metal tests. This prevents any potential metal contamination from the Coulter needle. The clinical laboratory scientist working in the blood specimen-processing workstation places the specimen on a rocker until the clinical laboratory technologist working in the

hematology workstation can perform the CBC. The CBC should be run as soon as possible; there is no requirement to wait any length of time between drawing the blood and running the CBC.

- There is a dedicated tube drawn for the CBC on SPs aged 3 years and older.

1.7 Procedure for Microscopic Examination

Not applicable. Do not prepare differential microscopic slides.

1.7.1 Reagents and Supplies

DxH reagents, including storage and handling requirements, are listed below.

- Coulter DxH diluent (store at 2–40°C)
- Coulter DxH diluent is shipped in ready-to-use containers.
- Opened containers are stable for 60 days. Do not use this product beyond the expiration date.
- Coulter DxH diluent is a cyanide-free, isotonic-buffered saline solution.
- Coulter DxH diluent dilutes the specimen, is used for rinsing SPM components between sample analyses, and provides a sheath stream to transport the specimen through the flow cell.
- Coulter DxH Lyse reagent (store at 2–40°C)
- Coulter DxH Lyse reagent is shipped in ready-to-use containers.
- Opened containers are stable for 60 days. Do not use this product beyond the expiration date.
- Coulter DxH Lyse is a cyanide-free, CBC lytic reagent that lyses red blood cells for the white blood cell count and works in conjunction with Coulter DxH diluent to generate a stable hemoglobin measurement.
- Coulter DxH Cell Lyse is also used to lyse the red blood cells and discriminates nucleated red blood cells from white blood cells.
    - Coulter DxH Diff Pack (store at 2–25°C)
        - Coulter DxH Diff Pack is shipped in ready-to-use containers.
        - Opened containers are stable for 60 days. Do not use this product beyond the expiration date.
        - The Coulter DxH Diff Pack consists of the Erythrolyse Lytic reagent and StabliLyse Preservative reagent.
        - The Erythrolyse Lytic reagent is a cyanide-free lytic reagent that dilutes the blood sample and lyses red blood cells in preparation for white blood cell measurement in the flow cell.
        - The StabiLyse Preservative reagent neutralizes the Diff lytic reagent and preserves the white blood cells for measurement in the flow cell. Together, Erythrolyse and StabiLyse provide the five-part differential.

- Coulter DxH cleaner (store at 2–25°C)
  - Coulter DxH cleaner is shipped in ready-to-use containers.
  - Opened containers are stable for 3 months. Do not use this product beyond the expiration date.
  - DxH cleaner is a cyanide-free, aldehyde-free cleaning agent that degrades residual materials so that they may be flushed from the system with diluent.

Note: If any Coulter DxH reagent has been partially or completely frozen, allow the product to warm to room temperature. Mix product by gentle inversion prior to placement on the instrument.

DxH controls, including storage and handling requirements, are listed below:

- Coulter 6C cell control (store at 2–8°C)
  - The Coulter 6C cell control is an integrated control that enables monitoring of system performance and calibration status for all directly measured and calculated CBC, Diff, and NRBC parameters. Instructions for use are as follows:
  - Remove 6C cell control vials from refrigerator and warm at ambient temperature for 10 to 15 minutes.
  - Roll the tube slowly between the palms of the hands eight times in an upright position. Invert the tube and slowly roll between the palms of the hands eight times. Then gently invert the tube eight times. Repeat.
  - Run the controls in the cassette presentation on the instrument.
  - Return the control tubes to the refrigerator within 30 minutes.
- The Coulter LIN-X Linearity control (store at 2–8°C) is recommended for verification of the reportable range and linearity, and for calibration assessment of the WBC, RBC, HGB, and PLT parameters.
  - When analyzing LIN-X Linearity Controls patient flags will occur. These flags should be ignored if a numerical result is obtained. When voteout (- - - - -), incomplete computation (.....) or over range (+++++) flags occur, the sample should be repeated. Some levels may generate a non-blood (N) flag. DO NOT ignore System messages (R).
  - Remove Coulter Lin-X cell control vials from refrigerator and warm at ambient temperature for 15 minutes.

- Ensure there is sufficient reagent to complete the analysis.
- Roll the tube slowly between the palms of the hands eight times in an upright
- Then gently invert the tube eight times. Repeat mixing procedure three times. Temporarily disable the NRBC module.
- Run the Lin-X cell controls in consecutive order beginning with Level 0 and ending with Level 11. Run controls in cassette presentation on the instrument.
- Level 11 is used to clean the system. The values for this level are not recorded.

- How to run linearity in the MEC:
  - Run each level under a separate repeatability—this is useful since it will calculate the mean for that level of Lin-X.
  - Print out the summary report for each level of Lin-X.
  - Write the level number on the top of each summary report.
  - Document all values on the Coulter Lin-X Control Worksheet. Do not forget to record the kit lot number on the worksheet. This number is different from the lot number for each of the tubes.
  - Send worksheet, package insert, and summary reports in the end of stand box to the Lab Component Lead at the home office in Rockville, MD.

- Coulter Latron CP-X control (store at 2–30°C) is recommended for the verification of the system calibration status of the VCSn parameters. Coulter Latron CP-X control checks the alignment of the laser and the flow cell on the DxH 800.
  - Perform daily checks prior to running Latron control.
  - Gently mix Latron CP-X control by inversion five to eight times. Avoid foaming.
  - Run the controls in the cassette presentation on the instrument.
- Coulter S-CAL® Calibrator is traceable to reference methods and recommended for determining adjustment factors to ensure accurate SPM measurements of directly measured CBC parameters. Calibrator results should be monitored with Coulter 6C cell control.
  - Remove S-CAL from the refrigerator and warm at ambient temperature for 15 minutes.
  - Roll the tube slowly between the palms of the hands eight times in an upright position.

- Invert the tube and slowly roll between the palms of the hands eight times. Then gently invert the tube eight times. Repeat.
- Inspect the tube contents to determine if all cells have been uniformly distributed. Repeat the mixing procedure if contents have not been uniformly distributed.
- Complete entire procedure within 1 hour.

1.7.2 DxH 800 Supplies

- 3-ml K_2 EDTA BD Hemogard Vacutainer® tube;
- 4-ml K2 EDTA BD Hemogard Vacutainer® tube;
- Tube rocker;
- Bleach, 8.25 percent sodium hypochlorite;
- Bottled deionized water;
- Plastic squirt bottle;
- Cotton gauze pads;
- Three-hole paper punch;
- Notebook;
- Flashlight;
- Precision screwdriver set; and
- CD-RW.

1.8 Shutdown of DxH 800 System

The DxH 800 SPM, SM, and monitor are connected to an uninterruptible power supply. In the event of a power outage at your facility, the components will continue to operate for a short time so that you can shut down the system. The printer is connected to the back-up power supply. Shut down the SM as follows:

- Shut down the operating system by using the routine Windows application.
- Power off the computer. Powering off the computer also powers off the monitor. You do not need to power off the monitor separately. The computer does not need to be shut down on a routine basis. Power off the computer only when circumstances deem it necessary.

1.8.1 Daily Shutdown

Beckman Coulter recommends that the SPM remain in cleaner for at least 30 minutes every 24 hours. If the SPM has power and is in Shutdown but the pneumatics are off, automatic cycling occurs every 24 hours to prevent flow cell and sample line clogging.

- Shutdown can be initiated manually or automatically.
- Shutdown removes diluent from the UniCel DxH 800 and replaces it with cleaner.
- At the end of the time with cleaner, the cleaner is replaced with diluent. Then, the compressor automatically shuts off.

1.8.2 Shutdown at the Mobile Examination Center

- Shutdown will be set automatically.
  - Select Calendar icon on top of DxH monitor screen.
- From the Daily Checks screen, select the Shutdown button to display the Manual Shutdown dialog box.
  - Select Autoconfiguration at the bottom of the screen.
  - Select Configure Shutdown.
  - Check Enable Automatic Shutdown: Fill in hour **07,** Min **00.**
  - Daily.Coulter.
  - Make sure each of the 7 days is checked.
  - Time in cleaner **0** Hour(s) **30** Minutes.
  - Select OK.

- Daily Checks (formerly known as StartUp) (Menu>QA>Daily Checks) are programmed to immediately follow the StartUp.
  - Select Autoconfiguration at the bottom of the screen.
  - Select Configure Daily Checks.
  - Check Enable Automatic Daily Checks.
  - Choose radio button Perform Daily Checks after Shutdown.
  - Select OK.
- Latron CP-X control should be run immediately following daily checks.

1.8.3 Cancel Automatic Shutdown

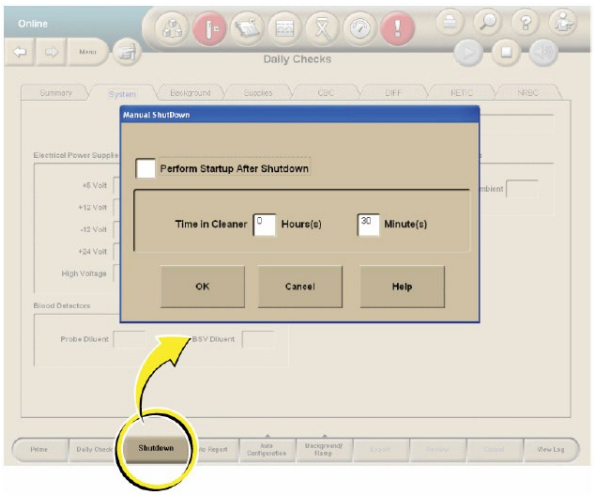
At certain times, automatic shutdown will have to be cancelled. To cancel automatic shutdown:

- From the Daily Checks screen, select Auto Configuration.
- Select Configure Shutdown.
- Remove the checkmark from the Enable Automatic Shutdown box.

To perform a manual shutdown when Auto Configuration is disabled, see the information that follows (Section 6.8.4).

1.8.4 Manual Shutdown of DxH Units

1.8.4.1 From the Daily Checks screen, select the Shutdown button to display the Manual Shutdown dialog box.



- Select the Perform Startup After Shutdown check box to automatically begin Daily Checks after shutdown.
- Type in Time in Cleaner 0 Hours and 30 Minutes check boxes to determine the time in cleaner.
- Select OK to begin shutdown or Cancel to exit the pop-up window without starting shutdown.

1.9 Log On as User

Logging on to the SM:

- Type your user name.
- Type your password. If you forgot it, ask one of the senior techs to reset it for you.

1.9.1 Entering New Operator

- Select Menu button in the upper-left corner of the DxH 800 screen.
- Then select **Setup** button.
- Select **Operators and Roles** button.
- Select **New Operator** button, enter all information. HINT: Do not enter the password you want to use; the first time you sign on you will be asked to change your password. Under operators access you need to select Level 3 to do all tasks on the DxH 800.

1.10 Run Daily Checks

- Select the Daily Checks button (Calendar icon) from the top of any screen to display the Daily Checks Summary screen with results of the most recent Daily Checks.
- Obtain printout of Daily Checks from printer, initial as “Reviewed by” and place in Hematology Log Book.
- If Daily Checks passed all criteria, run Latron Control.

- Running Daily Checks manually if Automatic Daily Check failed:
  - Select the Daily Checks button (Calendar icon) from the top of any screen to display the Daily Checks Summary screen with results of the most recent Daily Checks.
  - Select the Daily Checks button at the bottom of the screen. A DxH 800 dialog box displays the following:

"Are you sure you want to start a Daily Checks procedure?" Press OK to continue.

Select OK to run Daily Checks or select Cancel.

1.10.1 Daily Checks Screen

- The results of Daily Checks display on eight tabbed views: Summary (default view), System, Background, Supplies, CBC, Diff, Retic, and NRBC.
- When Daily Checks pass, the Daily Checks icon is neutral. Select the individual tabs to view those results.

If any of the Daily Checks do not pass, the following occurs:

- The Daily Checks icon is red.
- The problematic result is backlit in red on the Summary tab.
- The tab that contains the problematic result has a red indicator.
- If there are any failures, you must Review Daily Checks (Event Logs>General tab) to proceed with further analysis.
- The Daily Checks must pass or be reviewed in order to run specimens.
- From any tab on the Daily Checks screen, select the Review button on the local navigation bar to indicate that the Daily Checks results have been reviewed.

  Note: If Daily Checks pass, the Review button is disabled.
- You have to review only results that are questionable.
- Document on the Troubleshooting Log any action taken to troubleshoot the Daily Checks failure.

1.10.2 Additional Tasks From the Daily Checks Screen

- Select the Histogram button at the right of the screen on the Diff, Retic, or NRBC tabs to display the VCSn Ramp Tests Histogram screen.

  Note: The VCSn Ramp Tests Histogram screen is not for routine use; however, you may at some time be asked to access this screen when on the phone with a Beckman Coulter representative.

- Prime the SPM.
- Prime provides a method to remove cleaner in case an error occurred during a shutdown cycle.
- Select the Prime button at the bottom of the Daily Checks screen to prime the SPM.
- A DxH 800 dialog box will display the following message: "You have requested to perform a Prime Cycle."
- Select OK to continue or Cancel.

1.11 Quality Control

- Quality control is the routine monitoring of performance and service using commercial or patient controls.
- Controls have known characteristics when run on a given system and are analyzed periodically in the same manner that patient specimens are analyzed.
- The results of analyzed controls are then compared to the known characteristics using statistical methods.
- This comparison allows changes in the SPM performance to be detected.
- You can then take some action if the changes detected are significant.

1.11.1 Frequency of Performing Quality Control

- Beckman Coulter 6C cell control will be run at the beginning (8:30 am before SPs are processed), mid-point (1:30 pm), and at the end of each session (either 6:30 pm or 9:30 pm depending on the schedule). The time of the first run of the day of the 6C control QC performance is set to follow the preprogrammed Daily Checks of the analyzers and after the Latron run. After the QC has successfully passed and all parameters are within limits, the Start of Session QC tab must be updated to reflect successful performance of Beckman Coulter 6C controls.

- According to the manufacturer, each tube can be aspirated from 18 times within 16 days. The clinical laboratory scientist in WS 3 will record each time the QC vial is aspirated using the Coulter 6C Cell Control Open Vial Stability Monitoring Log (Exhibit 6-2). The clinical laboratory scientist in WS 3 will record why the QC was analyzed (QC run completed AM/PM/EVE, Precision Check, Concurrent Lot Testing, or Troubleshooting) and their initials each time the control or controls are analyzed. The header of the document will also be completed with pertinent information. The document will be housed on the WS 3 computer until completed and then sent to the Laboratory Component Lead as part of the end- of-stand QC.

    1. The same tray of the current lot number in use of 6C controls should be used until one or more levels of the QC have been analyzed the maximum number of times (18 occurrences in 16 days). Once one or more levels of the QC have been injected the maximum number of times, the *entire tray should be discarded* and a new tray should be used.

    2. If the 6C controls do not pass at the end of the session, troubleshooting will be performed. Once the QC passes, the CBC's for the session will be repeated. The results of the repeated CBCs will be sent to the Laboratory Component Lead for precision analysis and consultation with the Laboratory Director for a determination of notification of SPs with results not meeting the precision calculations.

       Note: The clinical laboratory scientist in WS 3 must be very careful not to use all of the sample from any of the SP's for the session as primes. **Samples from a previous session should be used whenever possible.**

Exhibit 1-2. Coulter 6C cell control open vial stability monitoring log

COULTER 6C CELL CONTROL OPEN VIAL STABILITY MONITORING LOG*

STAND #		STAND LOCATION		MEC #	
TEAM #		COULTER SYSTEM ID			
LOT #		BOX EXP. DATE		BOX OPEN DATE	

*Coulter 6C Cell Control has an open vial stability of 18 events over 16 days

			EVENTS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
PACK # 1	Set # 1 Open Date:	Level 1	Run																		
			Initials																		
		Level 2	Run																		
	Set # 1 Exp. Date:		Initials																		
		Level 3	Run																		
			Initials																		
PACK # 2	Set # 2 Open Date:	Level 1	Run																		
			Initials																		
		Level 2	Run																		
	Set # 2 Exp. Date:		Initials																		
		Level 3	Run																		
			Initials																		
PACK # 3	Set # 3 Open Date:	Level 1	Run																		
			Initials																		
		Level 2	Run																		
	Set # 3 Exp. Date:		Initials																		
		Level 3	Run																		
			Initials																		
PACK # 4	Set # 4 Open Date:	Level 1	Run																		
			Initials																		
		Level 2	Run																		
	Set # 4 Exp. Date:		Initials																		
		Level 3	Run																		
			Initials																		

RUN	
✓A	QC Run Completed AM
✓P	QC Run Completed PM
✓E	QC Run Completed EVE
P	Precision Check
CT	Concurrent Lot Testing
T	Troubleshooting

When one or more levels reaches 18 events, discard all 3 levels. Open a new set of QC to run start of session QC.

- Beckman Coulter 6C cell control is run in the cassette mode on the DxH analyzers.
- Beckman Coulter Latron CP-X control is run once each 24 hours following Daily Checks on the instrument and is run in the cassette mode on the DxH analyzers.
- Beckman Coulter Lin-X will be run once per year or at high elevation stands.
- Calibration with S-CAL will be performed at the start of every stand or when recommended to troubleshoot a problem.

1.11.2 Setting Up a Control File

- Entering 6C cell control lot numbers and expiration dates.

  Menu>QA>QC>More Options>QC Setup>New Control from Barcode>*Scan the 6C Cell Insert Barcode*>Select ALL & Auto Transmit>Select OK.

1.11.3 Setting Up a Latron Control File

- Entering Latron control lot numbers and expiration dates.

  Menu>QA>QC>More Options>QC Setup>New Control from Barcode>*Scan the Latron Insert Barcode*>Select ALL & Auto Transmit>Select OK.

1.11.4 Establishing Means and Standard Deviations (SDs) for Quality Control Material

- To be effective and evidence based, quality control ranges should be:
  - Developed using performance, bias, and precision of the test method;
  - Specific to the Coulter DxH 800, control level, and individual parameter; and
  - Designed to identify issues with the Coulter DxH 800.
- Manufacturer-assigned values should be used as a guide. Actual values for the mean and SD must be established by repeated testing on the instrument in the MEC where the data/information will be implemented. The mean should fall within the range published by the control manufacturer. Coulter's Hematology Interlaboratory Quality Assurance Program (IQAP) provides useful measures of the means and SDs observed in other laboratories using the Coulter DxH 800.
- At the start of a stand, use the manufacturer control published mean and SD until 20 runs have been performed on the control. After the 20 runs are completed, follow the steps below to establish the instrument-specific mean and SD for each level of the control.
- Procedure for establishing means and standard deviation (SD) requirements:
  - Analyze the new control a minimum of 20 times across multiple days. Testing conditions should mimic routine testing as closely as possible.

- View the mean and SD of the parameters using the QC menu on the DXH 800. Reviewing the Levey-Jennings plots for each of the parameters may identify drifts or shifts in the results over time, or a highly deviant result (see 6.11.10 for Levy-Jennings graph information). If no pronounced drifts, shifts, or outliers are seen, use the 20 data points to establish the mean and SD for the instrument (see Exhibit 6-3 for examples). Since the MEC laboratory runs multiple controls per day, the long-term SD may be underestimated and will need to be monitored.

  - This mean should be within the range stated on the control assay sheet and is considered the established target value.

  - Incorporate the SD range around the established target value and monitor throughout the dating of the product. Long-term sources of variability in the SD include different reagent bottles or lots, preventive maintenance, component replacement, and environmental factors.

  - The mean and SD measurements should be monitored and updated once sufficient data is collected.

  - When using the Coulter 6C assigned value or an instrument-specific mean, the instrument is considered well maintained and operating correctly if: (1) greater than or equal to 95 percent of the QC values fall within the EXPECTED RANGE of the Coulter assigned values, (2) QC values do not trend outside of the EXPECTED RANGE, and (3) control results with system messages and review flags, R, can be accepted except for the specific system event messages that indicate a hardware parameter is out of limit for some item such as voltage, temperature, or pressure.

- It is important to re-evaluate the criteria after a full lot of data has been compiled, and continue to evaluate on an ongoing basis to ensure that the control ranges are appropriate.

1.11.5 To Change the Mean and Standard Deviation (SD) on the Coulter

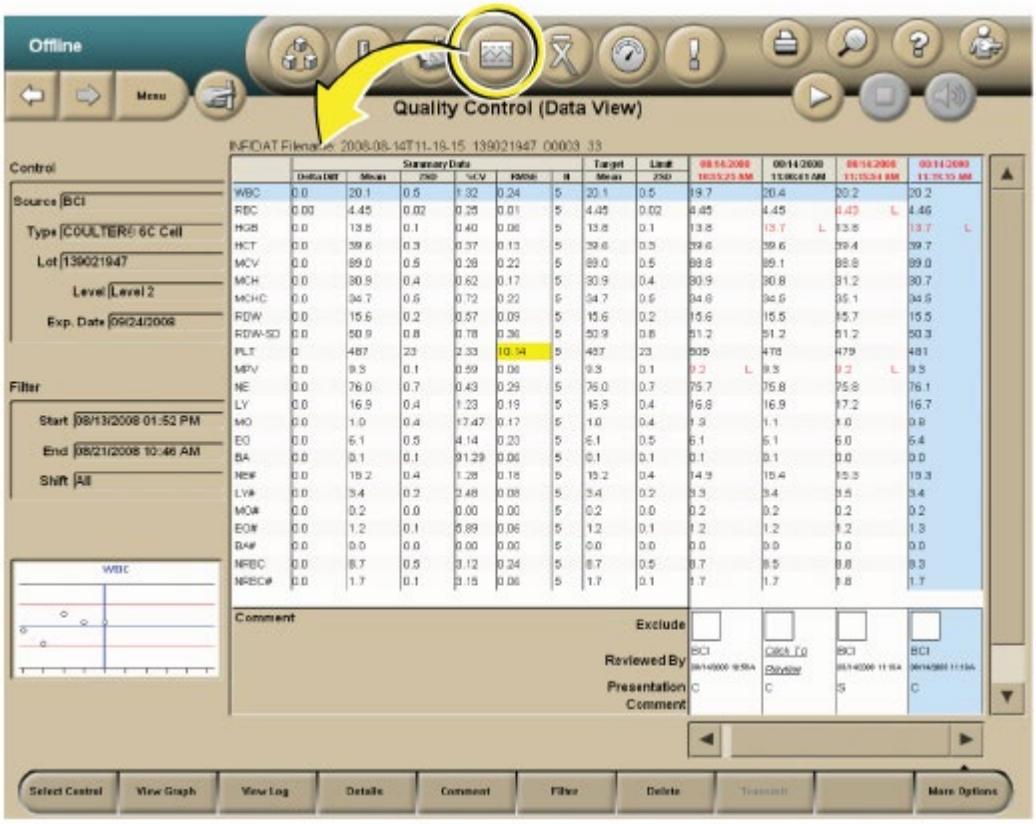
- Enter the QC menu selecting Data View.
- On the bottom of the screen, select More Options.
- Select QC Setup.
- Select Edit Control.
- Select Parameters.
- Edit the values needed and select Save.
- When given the option, select "Do not delete all runs."
- **Changes to means and SDs or calibration factors should only be made after consultation with the Laboratory Component Lead (Technical Consultant).**

1.11.6 What to do When a Control is Out of Range

- When a commercial control is out of range:
  - Ensure that the control material was mixed properly. If not, mix it according to the package insert.
  - Verify that the control was identified properly. If using a barcode reader, ensure that the barcode labels are clean and positioned correctly. If entering the ID manually, ensure that you typed the correct information.
  - Verify that the assigned setup information (assigned values and expected ranges) matches either the control package insert or your labs' established values. If they do not, contact a senior technologist to change the control's information to match.
  - If the problems above are ruled out, rerun the control to ensure that the problem was not a statistical outlier.
  - Ensure that the control material was not contaminated by running another vial or level of control.
  - Ensure that there are no errors during the cycle. If necessary, call Beckman Coulter for help in resolution.
  - Exclude the results on any out-of-range control by checking the Exclude box when reviewing that control.
  - Document action taken in the comment tab on the Coulter screen of affected control and the Troubleshooting Log.
- When Latron QC is out:
  - Ensure that the control setup information (assigned values and expected ranges) matches the package insert. If it does not, change the control information to match the package insert, then rerun the control.
  - Ensure that the Latron control is not contaminated, is properly mixed, is not expired, and you have a sufficient volume of sample.
- If necessary, use a new vial of control. Be sure to mix it according to the directions listed above.
- Ensure that the flow cell is clear by performing the flush flow cell procedure.
- Rerun the control. If the control is still outside the expected ranges, call Beckman Coulter.
- Document action taken in the Comment tab on the Coulter screen of Latron Control and in the Troubleshooting Log.
- Check the Exclude box on any Latron results that are out of range.

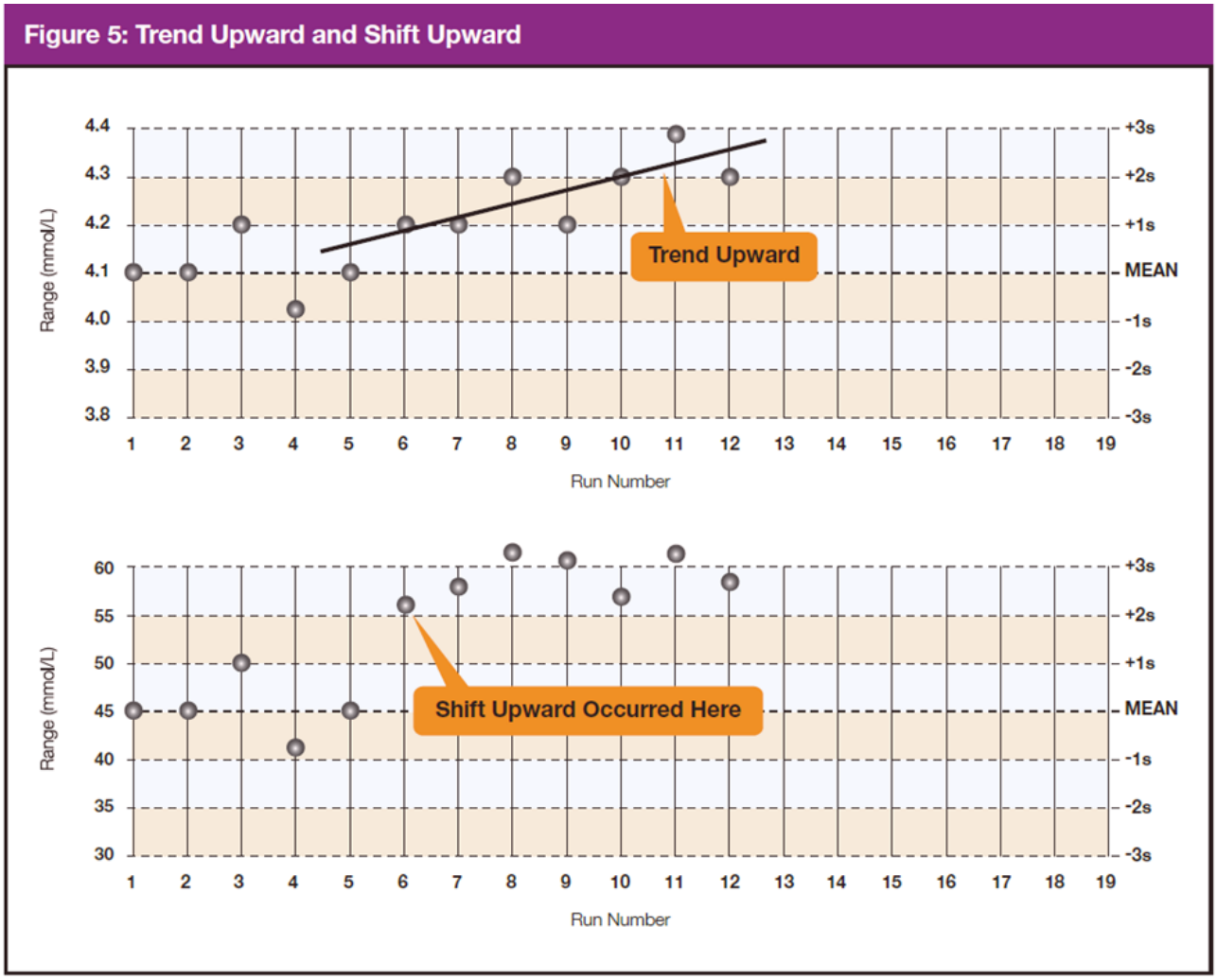
1.11.7 Viewing Control Files – Data View (Menu>QA>QC)

- To view control files on the Quality Control (Data View) screen, select the QC Status icon at the top of any screen.



- The Quality Control (Data View) screen displays the most recently analyzed control lot with the most recently analyzed run selected by default.
- If controls have not been reviewed, a dialog box displays a list of them.
- Out of control data as well as the date and time are displayed in red text.
- The Quality Control (Data View) screen includes summary data, configuration data, a filter section, QC run data, run status, and one thumbnail Levy-Jennings graph for the selected parameter (row).
- The chief clinical laboratory scientist will review QC on a weekly basis looking for any outlier results using the Westgard rules listed below. See examples of trends and shifts in QC data (Exhibit 6-3).

Exhibit 1-3. Examples of trends and shifts in QC data



Exhibits 1-4 through 1-8 present the Westgard rules as mentioned earlier.

Exhibit 1-4. Westgard Rule 1_{2s}

Rule 1_{2s}. A single control measurement exceeds 2 standard deviations (SD) of control limits either above or below the mean. This rule is used as a warning rule to trigger careful inspection of the control data.

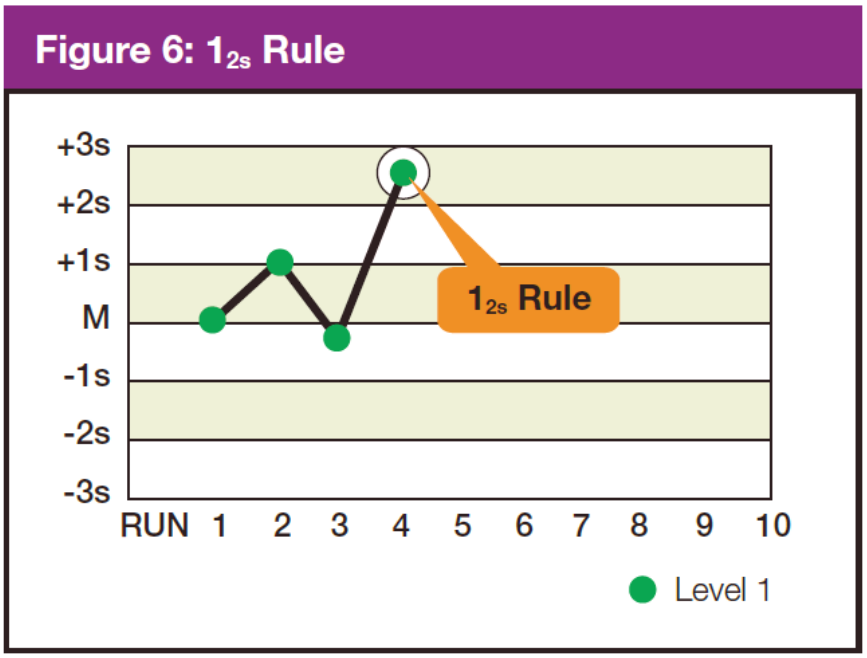


Exhibit 1-5. Westgard Rule 1_{3s}

Rule 1_{3s}. Identifies unacceptable random error or possibly the beginning of a large systematic error. Any QC outside ±3 SD violates this rule. A run is rejected when a single control measurement exceeds the mean ±3 control limits.

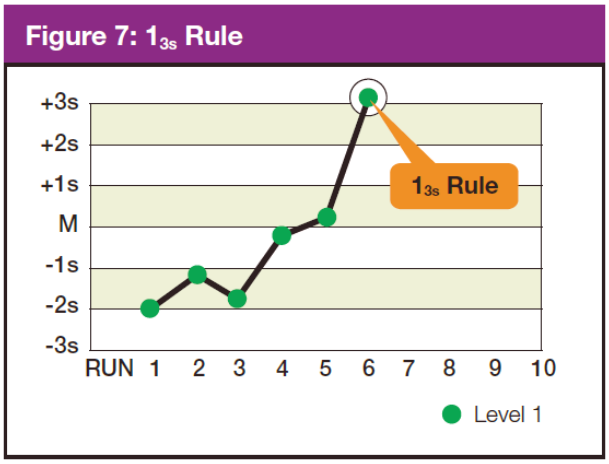


Exhibit 1-6. Westgard Rule 2_{2s}

Rule 2_{2s}. There are two rejection criteria for this rule: two consecutive QC results that are greater than 2 SD that are on the same side of the mean. Violation within the run indicates that systematic error is present and that it potentially affects the entire analytical curve. Violation across the run indicates that only a single portion of the analytical curve is affected by the error. The control run is rejected when two consecutive control measurements are greater than 2 SDs of control limits on the same side of mean within or across the run, with this rule.

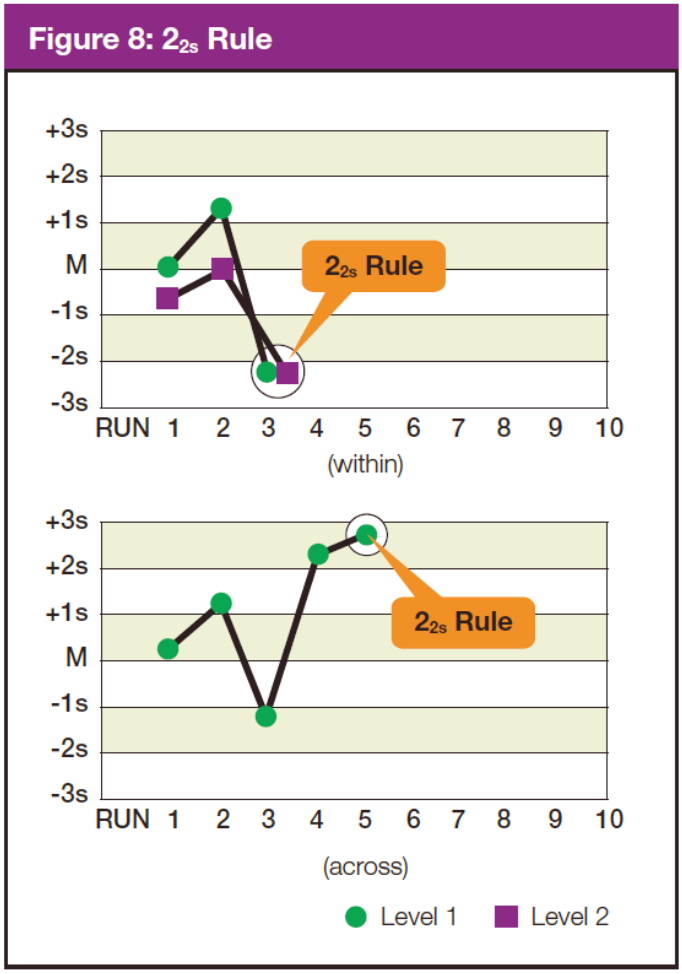
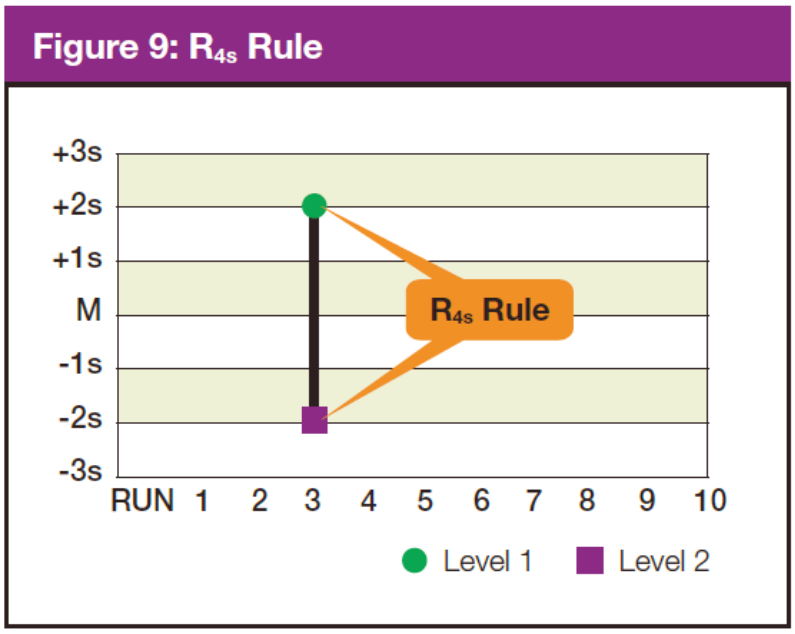


Exhibit 1-7. Westgard Rule$_{4s}$

Rule$_{4s}$. This rule rejects a run if there is at least a 4 SD difference between control values within a single run. For example, Level 1 control is + 2.9 SD above the mean and Level 2 is -1.4 SD below the mean. The total difference between the two control levels is greater than 4 SD. This rule identifies random error and is applied only within the current run.



Note: Violation of any of the following rules does not necessarily require rejection of the **analytical** run. These violations typically identify smaller systematic error or analytical bias that is not often clinically significant or relevant. Analytical bias may be eliminated by performing calibration or instrument maintenance.

Exhibit 1-8. Westgard Rule 4_{1s}

Rule 4_{1s}. This rule is violated with the fourth consecutive control measurement exceeding 1 SD on the same side of the mean. Troubleshooting action includes calling the Coulter hotline to see if other labs are reporting a bias with the same lot number of control. Perform any suggested diagnostic action or recalibrate if suggested by Coulter.

Figure 10: 4_{1s} Rule

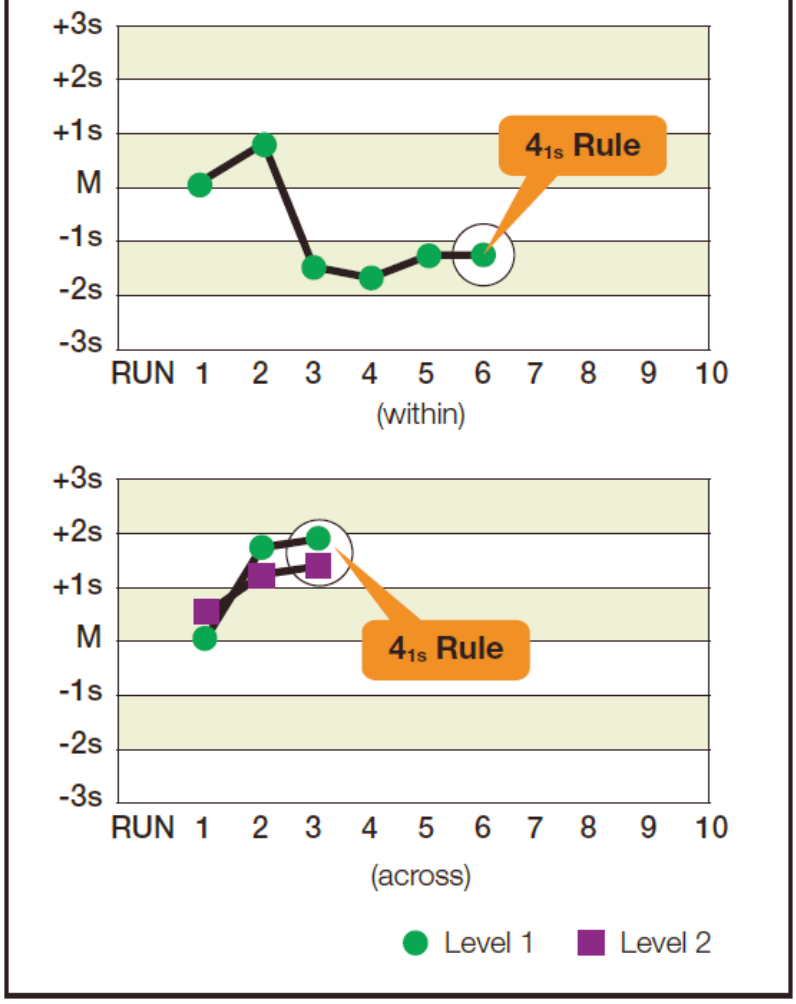


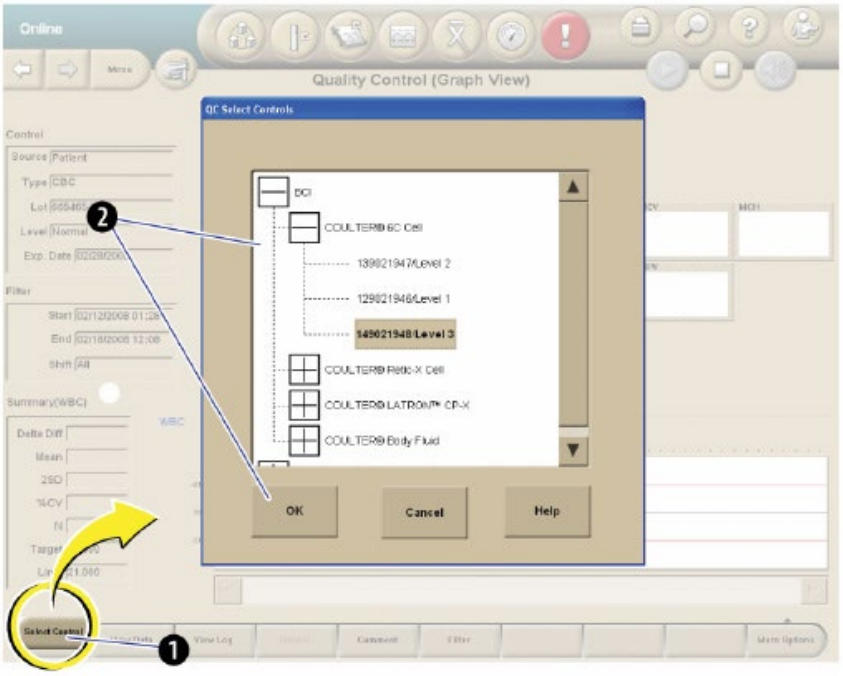
Table 1-2 lists the components seen on the QC Data View screen.

Table 1-2. Components on the QC data view screen

Component	Description
Delta Diff	The difference between the calculated mean and the assigned target of the parameter within the specified filter. Note: If the Extended QC is enabled and if Extended QC limits have been configured, and the equation below is greater than (absolute Delta Diff/BCI Target Value) x 100, and is greater than the Systematic Error limit, the Delta Diff will be highlighted in yellow for that parameter if N>=2 and N<15 or in red if N>=15. If the parameter's target is not applicable, N/A displays in this field.
Mean	The calculated mean of the included points within the specified filter.
25D	The calculated SD of the included points within the specified filter.
PercentCV	The calculated Coefficient of Variation of the included points within the specified filter. Note: If the Extended QC is enabled and Extended QC limits have been configured and the CV value is greater than the Random Error limit, the Percent CV will be highlighted in yellow for that parameter if N>=2 and N<15, or in red if N>=15.
RMSE	Root Mean Square Error (RMSE) displays when Extended QC is enabled. The RMSE is a Single Measurement Error. If the value exceeds the Single Measurement Error limit, the RMSE value will be highlighted in yellow for that parameter if N>=2 and N<15. The value is highlighted in red if N>=15. If the parameter's target is not applicable, NA displays in this field.
N	The number of included points within the specified filter.
Target	The assigned target of the parameter being used in your lab at the time of the control analysis. The target used by Extended QC will be based on what has been configured for traditional QC (either assigned or Mean to Target values).
(Assigned or Mean)	If Beckman Coulter or manually entered targets are used, the label below this heading reads "Assigned:" If means are used, the label below the heading reads "Means." If the parameter's target is not applicable, NA displays in this field.
Limit	The traditional expected limit of the parameter in use in your lab at the time of the control analysis.
(Manual, 2SD, or Lab)	If assigned limits are used, the label below this heading reads "Manual." If SDs or Lab Limits are used, the label below this heading reads "2SD" or "Lab," respectively.
Date/Time	The date and time of the control analysis.
Exclude	Allows you to exclude the results of that run from the control statistics calculations.
Reviewed By	Displays one of the following: • If the run has not yet been reviewed: A Click to Review link, which allows you to review the run. • If the run has been reviewed: The reviewer's user name and the review date and time.
Presentation	Displays the method of presentation for each run in the control file. • C = Cassette Presentation • S = Single-tube Presentation
Comment	A comment icon displays in this column if any comments have been added.
Ref. RBC	If the control type is a RETIC only, a Ref. RBC heading and numeric value display on the left side of the screen under the Summary Data columns. If the control is RETIC only and the Reference RBC Target and Limit are not sec, No Value will display in the Ref. RBC field.

1.11.8 Selecting a Control

- From the Quality Control (Data View) screen or the Quality Control (Graph View) screen, select the Select Control button on the local navigation bar to display the QC Select Controls dialog box.



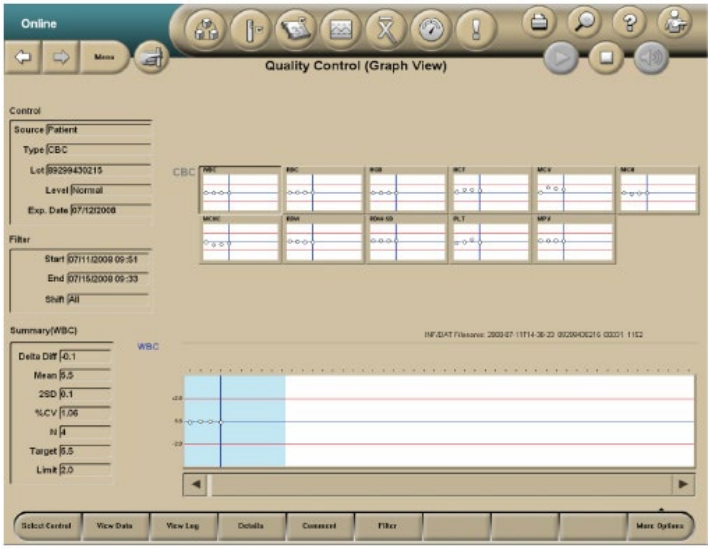
- Highlight the desired control and select OK.
- Exclude and rerun any control that is out of range. Document action taken to correct QC under comments on the Coulter screen in the affected control.

1.11.9 Viewing Control Files Graphically (Menu>QA>QC>View Graph)

From the Quality Control (Data View) screen, select the View Graph button OR select a parameter (row) and double-click the thumbnail Levey-Jennings graph.

The Quality Control (Graph View) screen displays the following:

- Up to 31 thumbnail Levey-Jennings graphs, one graph per parameter;
- An expanded Levey-Jennings graph for the selected parameter data; and
- Summary data for the selected parameter.



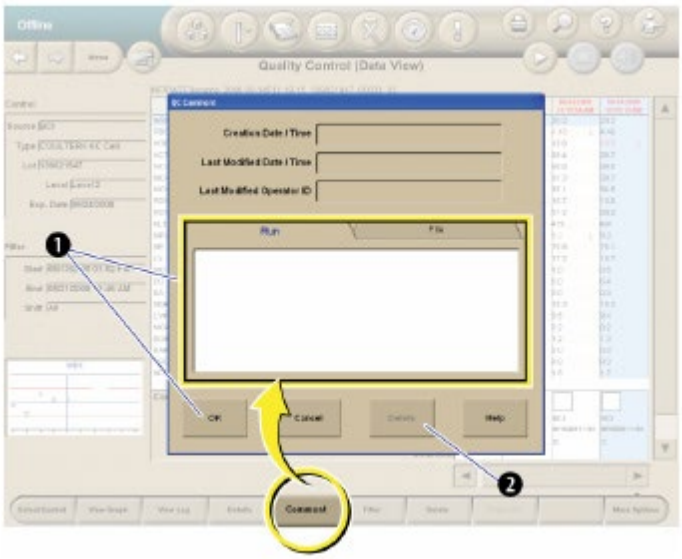
1.11.10 Using and Interpreting the Levey-Jennings Graphs

- The top half of the Quality Control (Graph View) screen displays all parameters associated with controls.
  - Levey-Jennings graphs display the latest run points for all parameters.
  - Each graph displays up to 10 points, and these change to reflect the scrolling of the expanded graph.
  - The points shown in the blue-shaded window of the expanded graph reflect those shown in the thumbnail graphs.
- The point cursor on the thumbnail graphs is synchronized with the selected run within the data grid and the point cursor in the expanded graph.
- If you select a thumbnail graph, it will be displayed in the expanded graph section on the lower half of the screen.
- Any thumbnail graph's border displays red if it contains a QC Out point.
  - Once all runs in a graph are reviewed, its border will return to normal color, but the QC Out point will remain red in the graph.
  - If the results violate the extended QC Single Measurement Error, the point will be yellow.
- The expanded Levey-Jennings graph at the bottom of the Quality Control (Graph View) screen displays all of the results for a selected parameter in the control file.
  - The blue-shaded window on the expanded graph, which contains up to 10 points and the point cursor, determines the points and cursor displayed in the thumbnail graphs.

- The point cursor is a blue vertical line on the graph that reflects the date selected in the Data View.
  - The cursor can be moved left or right by using the scroll bar or by selecting either the data points on the graph or the control run analysis Date/Times in the Data View table.
  - If the cursor moves to a point outside the window, the window shifts so that the new point displays in the window as the furthest right or left point.

1.11.11 Add, Modify, or Delete Comments to QC Results

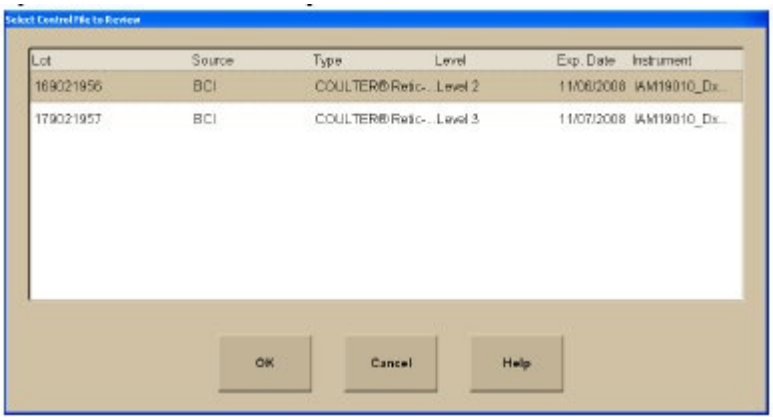
- From the Quality Control (Data View) or the Quality Control (Graph View) screen, select the Comment button to display the QC Comment dialog box.



- The Creation Date/Time, Modified Date/Time, and Last Modified Operator ID will not be populated until the entry of the comment has been completed.
- To add or modify a comment on a control run, select the Run tab, type in the text box, and select OK.
- To add or modify a comment on a control file, select the File tab, type in the text box, and select OK.
- To delete a comment, select the Delete button.

1.11.12 View Control Files Under Error Conditions

- Under Error conditions, the Quality Control Status icon at the top of the screen is red.
- If more than one lot triggered an error condition, the Select Control File to Review dialog box displays.
- All lots that are OUT are displayed on the dialog box.
- To review a specific log, select the lot and select the OK button.



1.12 Sample Analysis

1.12.1 Status

1.12.2.1 The SPM must be online to run samples.

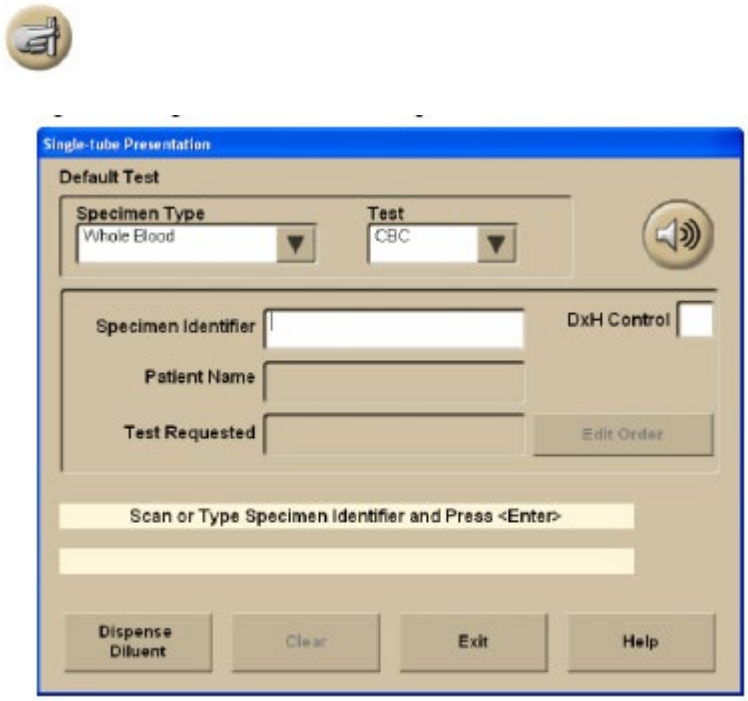
1.12.2.2 You can view the status of the SPM in the Status Mode area at the upper-left corner of any screen, except the Home screen.

1.12.2 Cassette Presentation

- Ensure that the SPM is set up for the appropriate test for your workflow.
- Ensure that specimens have been collected and stored properly.
- Load the specimens into the cassettes. Narrow tubes with small internal diameters will require manual premixing prior to analysis to ensure proper cell and plasma distribution and to avoid possible erroneous results. Premix these tubes before placing them in the cassette and then analyze the cassette by placing it in the Stat position of the input buffer.
- Place the cassettes in the input buffer to the right of the SPM. The SPM automatically begins cycling the cassettes.
- After the SPM cycles the samples, review the sample results at the SM. To avoid serious injury, do not place your hand through the cassette presentation opening on the SPM.

1.12.3 Single-Tube Presentation

- Ensure that your specimens have been collected and stored properly.



- Place the specimen on the barcode reader platform of the single-tube presentation station with the barcode facing the SPM to allow the single-tube presentation barcode reader to scan the specimen label. The barcode may also be scanned with the handheld scanner or the Specimen Accession Number may be typed into the Specimen Identifier field.

- Verify the Specimen Accession Number and test request. Acknowledging the ID that displays on the SM screen indicates that you accept either the barcode label read or the manual entry.
- Thoroughly mix the specimen.
- Place the specimen in the correct single-tube position.
- Do not place a closed tube or a 16-mm diameter tube in the right position of the single-tube presentation station. Doing so could cause incomplete aspiration and an erroneous result.

1.12.4 Handling Alarms

- An audible or visible alarm on the DxH 800 system should be addressed by reviewing the Event Logs on the History Log screen.
  - The Worklist-Custom tab can be used to select from predefined or user-defined filters to set the audible alarms.

1.13 Data Evaluation

1.13.2 Flags

Flags appear to the right of the result:

- For some parameters, flagging occurs as a result of the flagging or editing of other parameters.
- Flags in the following exhibit are shown in order of placement on screens and printouts, with the highest priority flags at the top within each space.
- A yellow background on the screen indicates that results were above or below a reference range.
- A red background on the screen indicates that results exceeded an action or critical limit or that another flag was present.
- Flags appear in one of four positions to the right of the result.
- The flags are listed in order of priority within each space. It is possible to have flags in each of the four positions.
- Refer to Exhibit 1-9 to interpret DxH flags.

Exhibit 1-9. Interpretation of DxH flags

Flag and position				Description
1	2	3	4	
e				Result calculated from a manually edited parameter.
+				Result above the measuring range.
-				Result below the measuring range.
R				Review the result. Special handling is required for editing a result flagged with R. Any parameter derived from an R-flagged parameter cannot be recalculated until that parameter is edited. R flags may also indicate that a System Message has occurred. Check the message area on the Patient Result screen and the History Log>General table for details.
	c	L		Low critical limit exceeded.
	c	H		High critical limit exceeded.
	a	L		Low action limit exceeded.
	a	H		High action limit exceeded.
		H		High reference range limit exceeded.
		L		Low reference range limit exceeded.
			P	Partial aspiration detected during sample analysis.
			N	Non-blood sample detected.
			D	Delta check triggered.

1.13.2 Codes

Codes appear in place of results when the system cannot generate results:

- Codes are also called nonnumeric results.
- Codes in the following table are shown in order of the placement on screens and printouts, with the highest priority flags at the top within each space.

Refer to the following list to interpret DxH codes.

= = = = = Analysis was disabled at the configuration level of the SM (Menu>Setup>System>Analysis).

For example:

IF NRBC is temporarily disabled, any results with an NRBC enumeration in the panel will display = = = = = in place of the NRBC values. The = = = = = persists in the database after the analysis has been re-enabled.

xxxxx Although available on a panel, this parameter was not enabled as a Test (Menu>Setup>Reporting>Tests) at the time of analysis; however, after this analysis, the parameter was enabled as a test.

For example:

Sample *A* was analyzed for a CR panel, but the IRF and MRV were not enabled as Tests.

Later, IRF and MRV were enabled as Tests; therefore, the system will not display the IRF and MRV parameters for CR panel results but, for Sample *A*, xxxxx displays in place of a value for those parameters.

::::: Flow cell clog was detected.

----- Total voteout occurred. No average histogram will appear for the affected parameter.

Incomplete computation.

May occur in place of calculated parameters because a voteout or over-range occurred for a primary parameter used in the calculation. Occurs when the instrument cover is opened.

+++++ Result exceeds the operating range.

????? Result is outside the range of values that can be formatted for

display. # # # # # Results were rejected.

1.13.3 Messages

Messages can be results-related or demographic- or status-related:

- Results-related messages:
    - Suspect messages (appear in red) are generated by internal algorithms to convey that a clinical condition may exist with a specimen based on an abnormal cell population or distribution.

      Refer to the *Unicel DxH 800 Help Manual* on board the analyzer for a detailed list of all Suspect messages.
    - System messages (appear in green) indicate an event occurrence that may affect the operation of a system, requires operator notification, or entry into a History Log.

      The majority of system messages are accompanied by an R (review) flag. Some are accompanied by N or P flags.

      Refer to the *Unicel DxH 800 Help Manual* onboard the analyzer for a detailed list of all system messages.
    - Definitive messages (displayed in blue) are displayed for results based on exceed limits configured as part of an individual flagging set.

      Definitive messages can be created by copying reference ranges, or by manual entry of your own message definition.

      Refer to definitive messages in the setup chapter of the onboard *Unicel DxH System Help Manual.*
- Demographic/status-related messages:
    - Exception messages.
    - If there are any exceptions for a specimen, a comments indicator displays in the System Status Message area below the patient demographics.
    - Select the Additional Data button to view the Exceptions.
    - System status messages indicate that the instrument was operating in some nonstandard state when a specimen was analyzed. These states are usually the result of some user action. They do not indicate that any problem was seen when the specimen was analyzed; instead, they indicate that the system was being operated in a manner in which some problems might not be detected.
    - Lab Action messages are triggered by Decision Rules programmed in the analyzer.

These messages are listed in the Lab Actions area of the Patient Results screen.

1.13.4 All Specimens

- Misleading results can occur if the specimen is not properly collected, stored, or transported. Beckman Coulter recommends that you follow Clinical Laboratory Standards Institute (CLSI) or equivalent procedures to ensure proper specimen collection, storage, and transport. Always follow the manufacturer's recommendations when using micro-collection devices for capillary specimen collection.

- Misleading results can occur if specimens contain clots. Always use good laboratory practices for inspecting specimens for clots and verifying results.

- Misleading results can occur if the specimen is not properly mixed. Always use good laboratory practices to ensure that specimens are appropriately mixed. Do not bypass or circumvent the automated mixing process used on the DxH 800.

- When running a test panel, with NRBC analysis enabled, the information from the analysis is used to supplement interference detection, flagging, and correction.

- **WBC and TNC**

  – NRBCs, giant platelets, platelet clumps, malarial parasites, precipitated elevated proteins, cryoglobulin, microlymphoblasts, very small lymphocytes, fragmented white cells, agglutinated white cells, lyse resistant red cells, unlysed particles greater than 35 fl in size.

  – Elevated WBC counts may have a carryover effect on subsequent leukopenic specimens, within the limits specified by Beckman Coulter. (See the Carryover section in the *Unicel DxH Help Manual* on board the analyzer.)

- **RBC**

  – Very high WBC count, high concentration of very large platelets, auto-agglutination.

  – If hemolysis is occurring in vivo, the instrument RBC may be flagged as low, reflecting the true circulating cells. If, however, the hemolysis is in vitro, the specimen may give falsely low RBC results. Cell counts due to in vitro hemolysis do not represent the number of circulating red blood cells.

- **HGB –** severe lipemia, heparin, certain unusual RBC abnormalities that resist lysing.

- **MCV –** very high WBC count, high concentration of very large platelets, auto-agglutination.

- **RDW –** very high WBC count, high concentration of very large platelets, auto-agglutination.

- **PLT –** giant platelets, platelet clumps, white cell fragments, electronic noise, very small red cells, and red cell fragments.

- **HCT –** known interferences related to RBC and MCV.

- **MCH –** known interferences related to HGB and RBC.
- **MCHC –** known interferences related to HGB, RBC, and MCV.
- **NRBC –** known interferences may be related to the following:
  - Lyse-resistant red cells,
  - Malarial parasites,
  - Very small or multi-population lymphocytes, or
  - Precipitated elevated proteins.
- **Differential**
  - Hypogranular granulocytes, agranular granulocytes, lyse-resistant red cells, very small or multi-population lymphocytes, elevated triglycerides, precipitated elevated proteins.
  - A transient basophilia may be observed in samples that have been exposed to high temperatures (90ºF or 32ºC). The temporary basophilia should resolve after stabilization at room temperature (72ºF or 22ºC).

1.14 Laser Safety

The Multi-Transducer Module contains a laser. A laser is a unique light source that exhibits characteristics different from conventional light sources.

The safe use of the laser depends upon familiarity with the instrument and the properties of coherent, intense beams of light. The beam can cause eye damage and instrument damage. There is enough power from the laser to ignite substances placed in the beam path, even at some distance. The beam might also cause damage if contacted indirectly from reflective surfaces (specular reflection). The laser on the DxH 800 is covered by a protective housing.

1.15 Calibration of the DxH 800

The S-CAL calibrator kit determines the adjustment factors for the calibration of the Coulter DxH 800. Calibration is a procedure to standardize the instrument by determining its deviation from calibration references and to apply any necessary correction factors. Calibration is performed in the closed-vial mode at ambient room temperature range (17–25°C, 63–77°F), using S-CAL as an alternative to whole blood.

1.15.1 Perform Calibration

- At the start of each stand, before you begin analyzing samples;
- After you replace any component dealing with dilution preparation, such as the BSV primary measurement, such as an aperture; and
- If your Beckman Coulter representative suggests that you calibrate.

1.15.2 Verify the Calibration of Your Instrument

- If controls show unusual trends or are outside limits; and
- When room temperature varies more than 10°F (5.5°C) from the room temperature during the last calibration.

1.15.3 Coulter Pre-Startup Procedure

Supply list: One diluent; one Cell Lyse; one Diff Pak; one cleaner; Latron; and 6C cell controls.

Arrangements for a Beckman Coulter representative to perform the necessary pre-startup procedures on the DxH 800, prior to the arrival of the team to the stand, will be made by the clinical laboratory scientist responsible for that MEC's coulter in advance. These pre-startup procedures for the representative will include:

- Removal of the travel brackets;
- Placement of all reagent lines in the reagents: diluent, Cell Lyse, Diff Pack, and cleaner (No RETICS!!!);
- Power up the analyzer;
- "*Wetting*" the analyzer (full prime of the system); and
- Flow cell adjustment.

A placard will be available for the representative (placed on the right side of the analyzer) with detailed instructions of the tasks that will need to be performed prior to the arrival of the team. The representative will be given the clinical laboratory scientist's number and email address in the event of any questions concerning the instructions.

1.15.4 Initial DxH 800 Startup

Perform a daily check after the instrument has been "Shutdown for at least 30 minutes." Select Menu>QA>Daily Checks>Daily Checks>OK.

Draw three 3-ml EDTA tubes from a person with a normal CBC.

Inventory all Coulter reagents – mark with received dates. (Once reagents have been opened, mark with an opened date and tech initials.)

- Log in to the DxH SM

BEFORE DELETING THE PREVIOUS STAND'S DATABASE OR CONTROL FILES, VERIFY WITH THE CHIEF CLINICAL LABORATORY SCIENTIST THAT IT IS OK TO PROCEED WITH THE FOLLOWING INSTRUCTIONS.

- **Delete the database from the previous stand –** Menu>Worklist>Custom>Advanced Search>Insert>Specimen>Analysis Date/Time>Between>Start Date/Time (*Enter MM/DD/YYYY & 24 HR hh:mm:ss that is at least 3 months prior to the current date*) and End Date/Time (*Enter MM/DD/YYYY & 24 HR hh:mm:ss that is 1 day before the current Setup date)*>Select OK>Select Save As *(*Create a Filter Name – Stand #*:* the stand you are getting ready to begin*)*>Search>Delete Order>Select All Test Orders in Current Filter>Select OK>Warning Box Will Appear, Select OK.

- **Delete previously used 6C cell control files –** Menu>QA>QC>More Options>QC Setup>Select Previous (Older) Control File (will be highlighted)>Delete Control>OK.

  You can only delete control files one at a time.

- **Enter reagent lot numbers and expiration dates –** Menu>Supplies>Setup>*Scan the Reagent Barcodes*>Select OK.

- **Enter 6C cell control lot numbers and expiration dates –** Menu>QA>QC>More Options>QC Setup>New Control from Barcode>Scan the 6C Cell Insert Barcode>Select ALL & Auto Transmit>Select OK.

- **Enter Latron control lot numbers and expiration dates –** Menu>QA>QC>More Options>QC Setup>New Control from Barcode>Scan the Latron Insert Barcode>Select ALL & Auto Transmit>Select OK.

- **Double click the Coulter icon on the desktop** and verify that the icon is in the taskbar (right corner of the screen).

- **Enter 6C Cell and Latron Control Lot Information into ISIS –** Right-click on the Lab Coulter icon in the taskbar>Select Expected Values>Scan the Insert Barcode>Press Tab Key>Verify ALL Values>Select OK. Perform for both 6C cell and Latron control file inserts.

- Place QC and Latron package inserts in the Coulter binder.

Storage, handling, and stability: Sealed vials are stable through the expiration date when stored at 2-8˚C (35-46˚F). S-CAL when opened is stable for 1 hour once the calibration procedure has started.

1.15.5 Repeatability, Carryover Check, and Calibration

Repeatability

Supply list: Two 3-ml EDTA tubes filled with normal blood.

Before you can start or restart the carryover process, the SPM must be **offline.**

Ensure that you have enough normal whole blood from a **single donor** for a minimum of 10 cycles, and delete any data on the Repeatability screen before starting a new study.

- Use two 3-ml EDTA tubes (aspiration probe damage can occur if a specimen tube is pierced more than five times).

- Select Menu>QA>Repeatability>Repeatability Setup:

  – Presentation: Cassette;

  – Test Panel: CD;

  – Number of Aspirations: 5; and

  – Select OK and follow the screen prompts.

- Place the two tubes in consecutive positions in a cassette, place the cassette in the input buffer, and select OK on the DxH dialog box to start the cycle.

- When the cycle has completed, review the results on the Repeatability screen. Use the scroll bar to review all the results. Verify the %CV and the Diff parameters (see limits below). Select Finish.

- Verify that the coefficient of variation (CV) does not exceed the established repeatability limits:
  - **WBC** 2.5
  - **RBC** 2.0
  - **HGB** 1.5
  - **MCV** 2.0
  - **PLT** 5.0
  - **MPV** 3.0
- Check the low to high difference (bottom line) for the **Diff** parameters with these limits:
  - **NE%** ≤ 4.8
  - **LY%** ≤ 4.8
  - **MO%** ≤ 3.2
  - **EO%** ≤ 1.6
  - **BA%** ≤ 1.6

  If any of the results are outside the limits, call Beckman Coulter customer service.
- If all the results are within these parameters: Print>Select "Finish" and proceed with Carryover Check.

Use the **%CV** line for CBC parameters only and the Diff line for the differential parameters only. Please see Chapter 1: System Overview – Performance Specifications and Characteristics section in the Help Menu of the *Unicel DxH 800 Help Manual* for additional information regarding repeatability limits for acceptability (Table 1-1 and Table 1-7).

1.15.6 Carryover

Supply list: One 3-ml EDTA tube filled with normal blood and three empty 3-ml EDTA tubes.

Note: Remove S-CAL from refrigerator to allow time to acclimate to room temperature. Before you can start or restart the carryover process, the SPM must be offline.

- Fill three empty 3-ml Vacutainer EDTA tubes with diluent. Select Single-Tube Presentation icon>Dispense Diluent**>**Select OK**.** Place one empty capped EDTA tube in the purple tube holder on the left side of the cradle; *1 ml of diluent is dispensed during this process*. Once completed, "Do you want to dispense more diluent in the same tube?" box will appear>Select No. Remove the filled EDTA tube, and repeat the above steps two more times to fill the two remaining empty EDTA tubes with diluent. Select Exit>"Are you sure you want to exit Single-tube Presentation?">Select Yes.
- Select Menu>QA>Carryover>Carryover Setup:
  - Presentation: Cassette;
  - Test Panel: CD; and
  - Select OK and follow the screen prompts.
- Select OK to start the carryover procedure.
- Place a cassette in the input buffer with one blood tube followed by three diluent tubes consecutively and select OK to start the carryover procedure.
- When carryover is complete, review the results on the Carryover screen. If any of the carryover results "FAIL," repeat the procedure.

If the carryover results "FAIL" after the second attempt, call Beckman Coulter customer service.

- If the status of all parameters is "PASS": Print.

When performing a carryover procedure, the calculated percent carryover and/or background for each parameter is compared to the carryover and background limits for acceptability.

See Chapter 1: System Overview – Performance Specifications and Characteristics section in the Help Menu of the *Unicel DxH 800 Help Manual* for additional information regarding carryover and background limits for acceptability (Table 1-12 and Table 1-13).

1.15.7 Calibration

Supply list: One S-CAL calibrator.

Note: Before you can start or restart the calibration procedure, the SPM must be offline.

- Allow **S-CAL** to warm to ambient (room) temperature for approximately 15 minutes.
- Select Menu **>**QA**>**CBC Calibration**>**Calibration Setup. You will be prompted by a dialog box that states: Existing data will be deleted. Select OK to continue.
  - Number of Aspirations: 11;
  - Presentation: Cassette; and
  - Calibrator Type: BCI.
- Select Upload>*Scan the S-Cal Insert Barcode*>Verify ALL Values>Select OK**.**
- Mix the **S-CAL** by hand by rolling the tube slowly between the palms of the hands eight times in an upright position. Invert the tube and slowly roll it again eight times. Gently invert the tube eight times. Repeat these actions. When all cells are uniformly distributed, place the calibrator in the cassette.
- Place the cassette in the input buffer and select OK to start calibration procedure.
- Exclude the first run by checking the box beside that run.
- Review the calibration results.
- If all the results are within the specified parameters: Print>Select Finish**.**
- If results recommend calibration (the boxes at the bottom of the calibration screen are check marked)>Select OK.

The background of the Factor %Diff, %CV, and Difference cells changes color when the presented value is out of the normal range as follows:

- Yellow for Difference indicates that the value is out of range, which means that calibration is recommended.
- Red applies only to the %CV and indicates that the statistical value is NOT within range and the system does NOT allow calibration.

When all results are acceptable, the Edit System Recommendations button at the bottom-right corner of the screen is enabled. This button allows the modification of the calibration recommended by the system by selecting or deselecting check boxes. Verify the calibration by running controls. Menu>QA>QC>Select Control>*Select the control that you want to view*>Select OK> Select "Reviewed By" to review controls>Print.

Note: Place all printed charts and control inserts into the DxH Logbook.

Below is an image of the NHANES Coulter Monitor icon. It must be open and running at the start of each session. This icon stores all DxH 800 runs in the ISIS database. Double-click on the Coulter icon so that it displays in the lower-right taskbar. Once the icon is displayed, the Coulter and the ISIS Laboratory application are communicating with each other.

1.16 Run Study Participant Samples

Exhibit 1-10 presents a picture of blood tubes.

Exhibit 1-10. Picture of tubes

- Place tube in the cassette and place in the SPM.
- Run all samples in duplicate. The DxH is set to automatically rerun SP samples in duplicate, but not controls.

  To set DxH 800 for automatic repeat of each SP sample, use the following sequence of steps:

  Menu>Set-up>Flagging/Rules>Rules>Select decision rule workbench tab (upper right)>Add Rules>Rule name: Type 'Repeat' at the *> Specimen Type: use drop-down menu and select whole blood>Rule description: Type automatic repeat if condition RBC<10>Additional test: Check Rerun box in additional test box>OK. Place analyzer offline>Activate Decision Rules tab (middle center tab)>Activate Rule (lower left).
- Run samples in the primary mode.

Check to make sure the printer is working properly. Operate the analyzer with the doors and panels closed. Monitor reagent levels.

1.16.1 Review Data and Transmit

- Review the data. Select Menu>Patient Results.
- Data from the Coulter DxH 800 are automatically transmitted to the ISIS system when the NHANES Coulter monitor icon has been opened on the ISIS screen.
- Use the Worklist screen to sort, retrieve, transmit, and archive data to CD. Transmit data from the Coulter DxH 800 to ISIS as necessary. Save all data to CD at the end of each stand.

1.16.1 Daily Shutdown

See Section 6.8, pages 6-13 to 6-15.

1.16.2 Prolonged Shutdown

1.16.2.1 If the instrument is going to be idle for more than 72 hours, as in summer or winter 2-week breaks, adjust the shutdown procedure as follows: Menu>QA>Daily Checks>AutoConfiguration>Configure Shutdown>Uncheck Daily, Check only boxes for every other day (Mon, Wed, Fri, Sun)>OK. Ensure that there is sufficient cleaner and diluent for shutdowns during the break time.

1.16.3 Beginning and End of Stand Operations

- Beginning of stand:
    - Arrange for a Coulter service representative to remove all travel brackets and re-wet the system.
    - Follow procedure for Calibration, Repeatability, and Carryover Check.
- End of stand.
    - Call Coulter Support to have an engineer install the travel brackets and perform the travel shutdown procedure for the DxH 800. Before the engineer performs this service, the following tasks must be completed by the technologist assigned to the Coulter for that stand:
    - Select (QC Icon)>Select Control>Select 6C Cell Control Level 1>Transmit>Select All Runs in Current Control File>Select OK. The Coulter icon on the workstation computer will "flicker" to indicate the transmission of data. Once the flickering has stopped, repeat the same steps beginning with Select Control and transmit QC data for 6C Cell Control Levels 2 and 3, followed by the Latron Control File.
    - Select [QC Icon]>Select Control>Select 6C Cell Control Level 1>Select [Printer Icon]>Change Report Type to Summary Report>Select [Control Lot] and checkmark all Current Stand Controls (Both Latron and 6C Cell Files)>Select [Print] All Runs>Select [Print Options] Data Report and Graphical Report>Select Thumbnails>Select Print.
        - Clip all the reports together with a binder clip and place them in the end of stand FedEx Box.
    - DISC 1: IQAP
        - Export IQAP Data. Insert a blank disc into the disc drive. Select Menu>Set- up>Quality Control>IQAP Export>All DxH Control Lots>Multiple Shifts>CD Recorder>Start>Follow screen prompts.
        - Label the disk IQAP and include Stand # and MEC # and place the disc in the end of stand FedEx box.
    - DISC 2: LOGS
        - Export Log Data. Insert a blank disc into the disc drive. Select Menu>Logs>Export>Select ALL in (1) Event, (2) Data Summary, (3) Maintenance, and (4) Audit Logs>Select and Enter Date Range (Start of Stand to End of Stand)>Select Start. The disc will automatically eject out of the disc drive upon completion.
        - Label the disk **Logs** and include **Stand # and MEC #** and place the disc in the end of stand FedEx box.

- DISC 3: DATABASE

  Export Patient Log (Database). Insert a blank disc into the drive. Select Menu>Worklist>Custom>Advanced Search>Filter Name (Stand #)>Insert>Specimen>Analysis Date/Time>Between (Start of Stand to End of Stand)>OK>Search>Export>Type CSV>All Results in Current Filter>Destination CD Recorder (G:\\)>Select Start. The disc will automatically eject out of the disc drive upon completion.

  Label the disk Database and include Stand # and MEC # and place the disc in the end of stand FedEx box.

  Clean the aspiration probe. Select Menu>Maintenance>Clean Aspiration Probe>[Start]. Once procedure has completed, select Finish>[OK].

  Clean the BSV, the handheld barcode scanner, and the STM and wipe the analyzer's exterior with lint-free tissue and deionized water.

  - Complete the Hematology Maintenance Log and include all of the paperwork from the Hematology Notebook, including Daily Check logs, package inserts, precision checks, and calibration data. This information should be binder-clipped separately into the respective subsections and included in the end of stand FedEx box to the Laboratory Component Specialist at Westat. The box can now be sealed and sent with the rest of the shipment.

Service performed by a Beckman Coulter representative:

- In most cases the Facilities Equipment Specialist will discard all trash and empty reagent boxes after the representative has finished decommissioning the analyzer.

- In most cases the FES will strap down and secure the DxH and computer monitor for the impending travel.

1.17 Coulter Reportable Range of Results

Table 1-3 presents the Coulter reportable range of results.

Table 1-3. Coulter reportable range of results

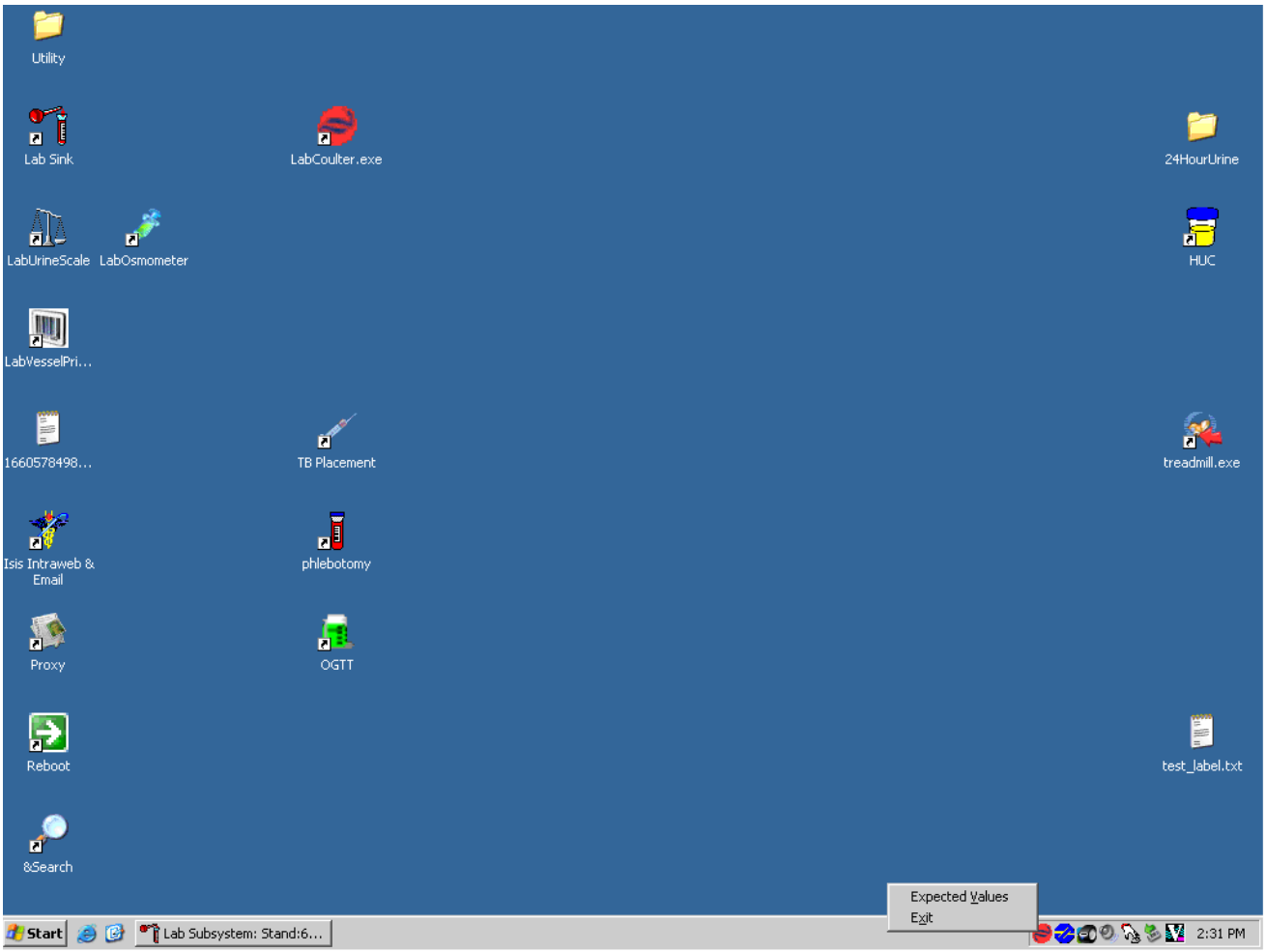
Parameter	Linearity	Limits: The greater of
WBC x 10^3 cells/µL	0 to 337.7	0.2 or 3.0%
RBC x 10^6 cells/µL	0 to 8.30	0.05 or 2.0%
Hgb g/d	0 to 24.3	0.2 or 3.0%
MCV fL	50.0 to 150.0	2.0 or 3.0%
Plt x 10^3 cells/µL	0 to 4897	10.0 or 7.0%
MPV fL	5.0 to 20.0	5.0%

1.18 Integrated Survey Information System

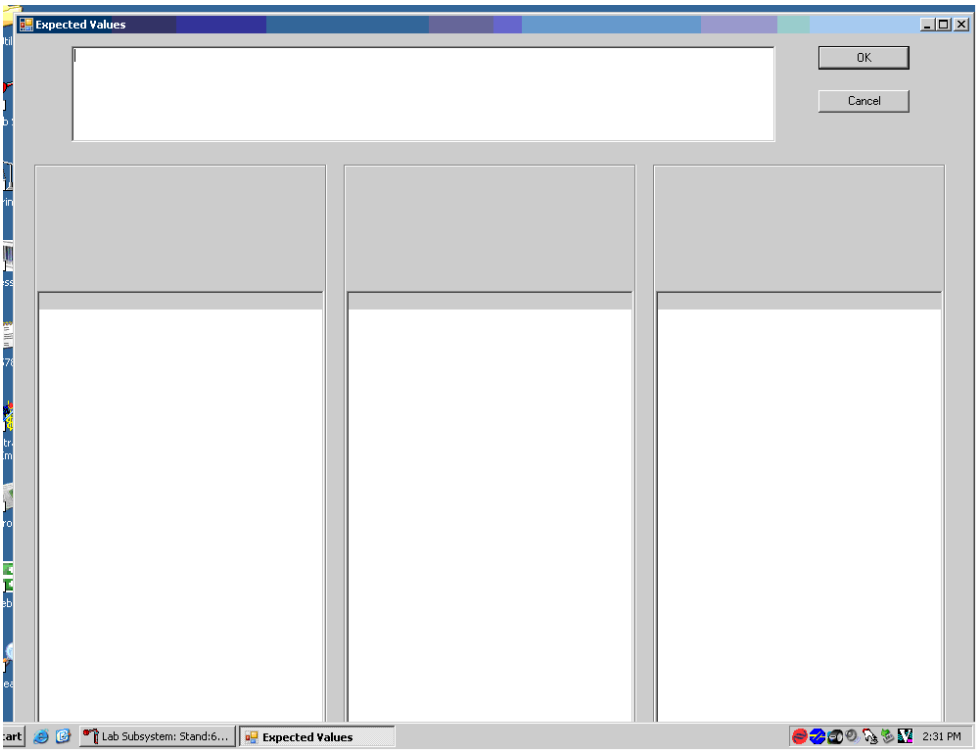
1.18.1 Record 6C Cell and Latron Lot Numbers in Integrated Survey Information System

The Integrated Survey Information System (ISIS) maintains the capability to download all 6C cell and Latron control data. The data are used to monitor quality control results. Upload or enter data for each lot number each time a new lot number is put into use. The ISIS uses the same 6C cell control package insert and Latron package insert as the DxH 800.

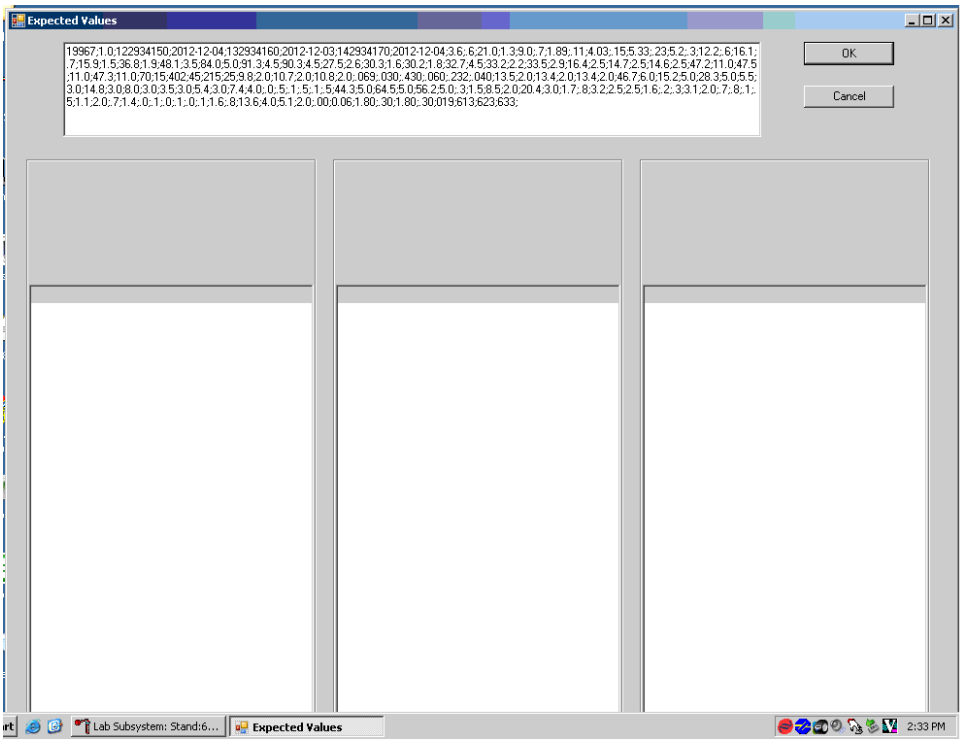
- Access the Coulter QC Lot Info module.
- Right-click on the Coulter icon in the bottom-right corner of window.



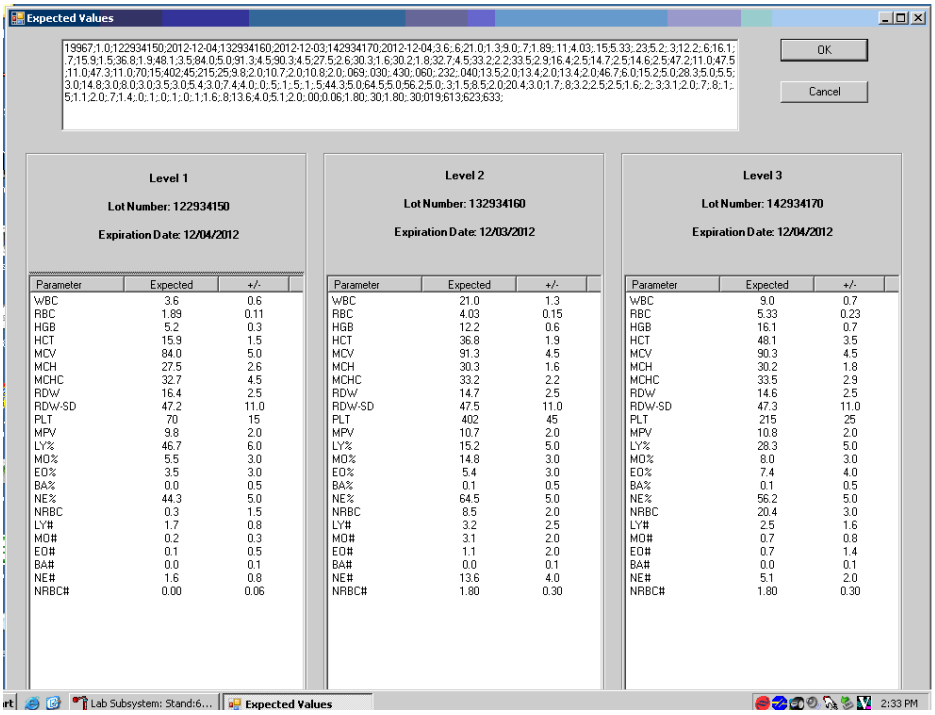
- Click on Expected Values to bring up the Coulter QC Input screen for 6C cell controls and Latron QC.



- Make sure cursor is in the top window, scan the barcode on the Coulter package insert, and wait until data fill in the top window.

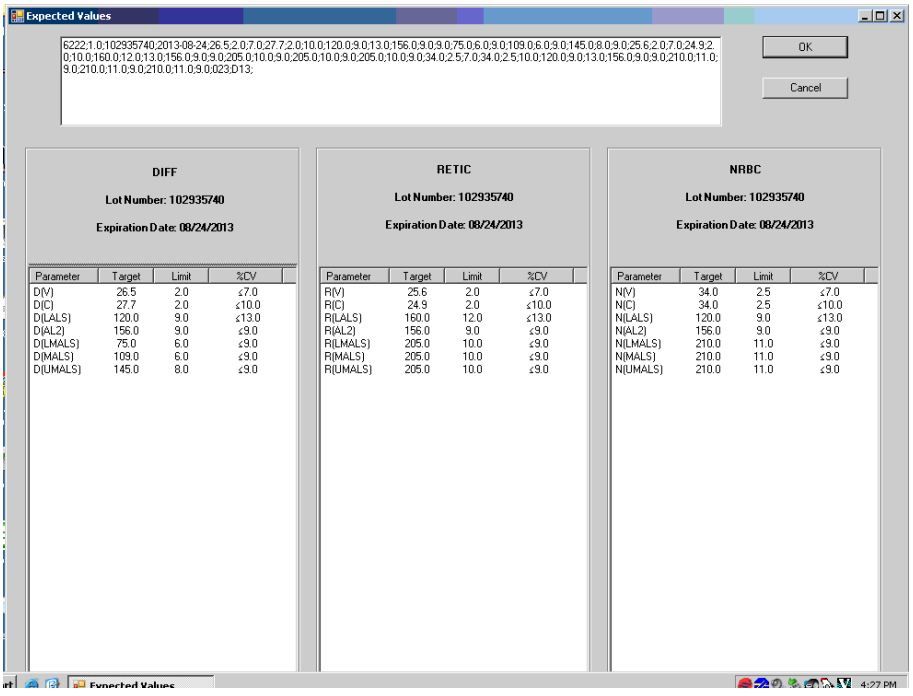


- Tab to populate the bottom windows for each level of 6C cell control.



- Below is a screenshot depicting Latron QC expected values for Diff, Retic, and NRBC.

  Check the expected values against the package insert and click OK to save and exit.



1.18.2 Interlaboratory Quality Assurance Program (IQAP)

All instruments participate in Coulter's IQAP program. The IQAP program includes saving results of 6C cell controls, transferring them to a CD, and sending them to Beckman Coulter, which compares the results to other laboratories. Beckman Coulter issues a report that contains a statistical analysis to evaluate performance. Perform this procedure at the end of each stand.

The procedure to download IQAP files to CD follows:

- Slide the CD into the drive and gently close CD holder.
- Menu>QA>QC>More options (bottom of screen)>Export.
- Type: CVS.
- Data Selection: All runs in current control file.
- Folder: CD Recorder Radio Button.

  Repeat for each of the three levels

  of QC.

1.18.2.1 Reviewing IQAP Peer Group Means (Chief Techs)

- Use the website https://qapweb.beckmancoulter.com/qapweb/.
- Log in.
- Choose the Analyzer (with note that B1 is MEC 3, B2 is MEC 2, B3 is MEC 1).
- Review active pool statistics. **(Note the number of labs in current pool. A small sample size can have a significant effect on data.)**
- Put in lot number of 1st level 6C.
- View report.

Note: Look at Mean and SD (not the assayed value), which is what is on the assay sheet we get. The Mean and SD are the averages for all the labs submitting data for this lot using 800 DXH. The shown SD is 2 SD from the peer mean.

- Select "BACK."
- Use same procedure for remaining lot #.
- Address concerns with the Lab Component Lead if any issues arise.

1.18.3 Proficiency Testing

Evaluation and participation in the College of American Pathologists (CAP) proficiency-testing program is part of the comprehensive quality control program. These survey materials are shipped three times per year and consist of five 3-ml whole blood specimens. Follow all CAP instructions in preparing the materials before performing the test. Run specimens in a manner identical to routine specimens. Fill out the CAP result form, make a copy for the log book, and send results to CAP.

After the assigned primary clinical laboratory scientist has tested and recorded results, other clinical laboratory scientists are to perform the testing and record their results without consultation with the primary tech. The secondary clinical laboratory scientist's results will be sent to the Laboratory Component Lead as a record of competency testing.

To make barcode labels:

- Select Utility on desktop.
- Select "Dymo test labels."
- Highlight the label shown:
    - Click on "Properties" in far upper right;
    - Symbology: Choose "code 128 Auto";
    - Data: Barcode delete "Click me" or "0000001" and type in proficiency sample number, i.e., FH6-01;
    - Align: Center;
    - Size: Medium; and
    - Show barcode text: Below.
- Print: Will print on Dymo label maker.
- Repeat for all five samples.
- Exit out and select "No" to "do you want to save?"

- To auto print results for proficiency samples:
- Select Menu>Set Up>Reporting>Auto Report.
- Check box "Print Lab Report as Each Analysis is Complete."
- Back out of setup.
- BE SURE to uncheck box after you have finished running samples and printing results.

Run proficiency samples in cassette (samples will be run twice under current setup and each result will print separately).

- Average results on NHANES Hematology CAP Results worksheet.
- Select Computer>MECSTAFF>Lab.
- Save as KitName-KitNumber_YYYY-MMDD_MEC#_Tech Initials_ P (for primary) or S (for secondary operator).
- Enter results on CAP paperwork.
- Enter results in CAP site on computer using your own personal CAP login:
  - Log in to the CAP site with individual account info;
  - Click on the e-lab solutions suite;
  - On the right side of the screen, click on the "Request access to laboratory data" link;
  - The screen will open that will ask you to enter the CAP number; and
  - Enter 6910001.

Have another tech proof your computer entry before submitting. Take a picture of your worksheet as a copy of your work and print for your records. Place your worksheet with indication of kit number, primary or secondary operator, your name and date in the Hematology log book to forward to the Laboratory Component Lead at end of stand, and also email the primary copy to the lead.

Record completion on your annual CAP survey Check Sheet. Indicate if you were primary or secondary operator.

1.18.4 Linearity for WBC, RBC, Hgb, and Plt Parameters

Lin-X™ (PN 628029) – The Lin-X linearity control verifies the reportable range of Coulter hematology system parameters for WBC, RBC, Hgb, and Plt.

Run the Lin-X survey material:

- At installation;
- At least yearly; and
- Whenever experiencing an altitude change of 1 mile or more between stands.

Principle – Lin-X linearity controls are human blood components from which repeated measurements verify the reportable range of Coulter hematology systems. Controls contain 12 vials, ranging from 0-12. Lin-X verifies the ranges for the following parameters: WBC, RBC, Hgb, and Plt.

To ensure the accuracy of linearity control ranges, Coulter system calibrates with S-CAL calibrator.

1.19 Interpretation of Results and Remedial Action

1.19.1 Sample Person Hemoglobin and Hematocrit Review and Remedial Actions

Review all results to make sure the hemoglobin and hematocrit are acceptable. The hematocrit should be approximately three times the hemoglobin. If an "H&H Does Not Match Flag" is displayed on both runs of an SP, repeat the run. Report out of range results if all runs are similarly flagged. Delete all but two of the runs before averaging.

1.19.2 SP Parameter Value Review and Remedial Actions

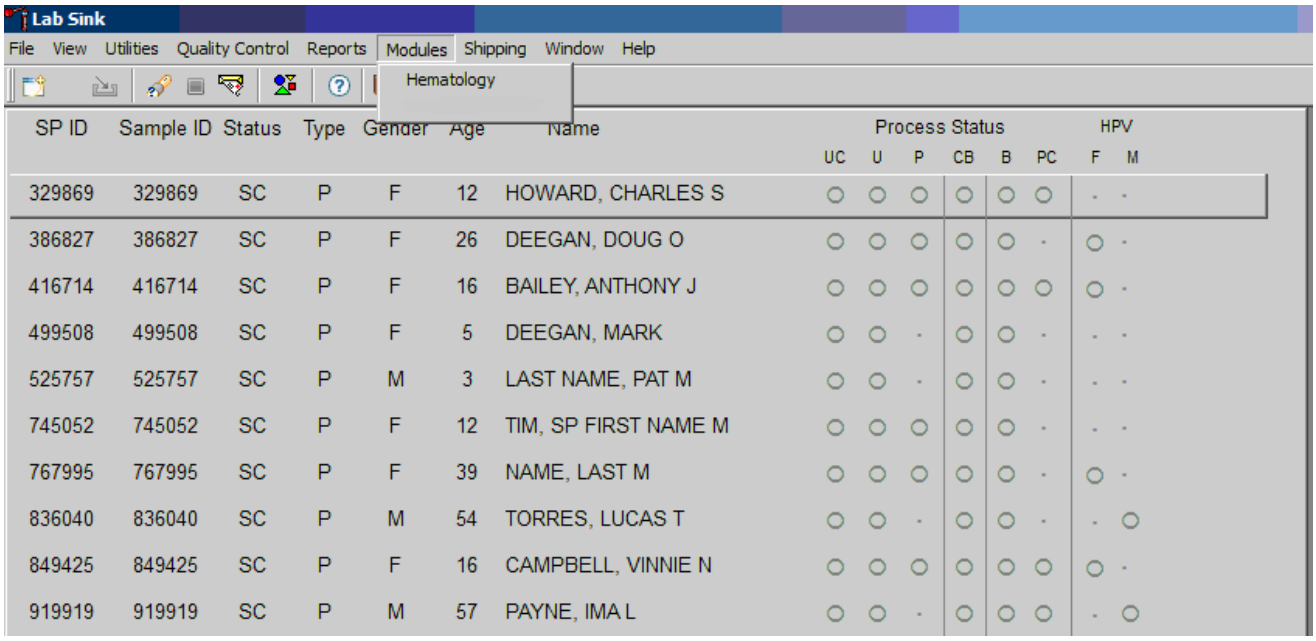
1.19.2.1 Access the Hematology module or reject a clotted blood tube

Open the Hematology module.

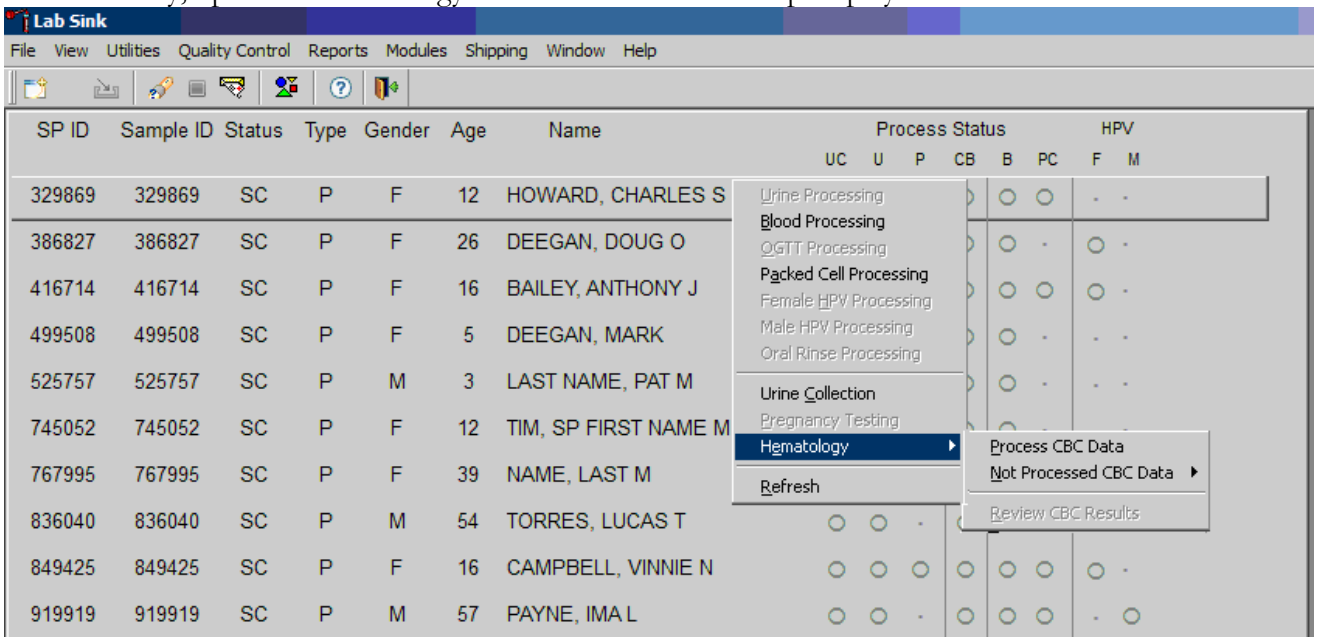
The Hematology module does not need to be open before running SP samples on the DxH 800. Note the red icon in the lower-right corner of the system tray.

This is the NHANES Coulter Monitor icon. It must be open and running at the start of each session. This icon stores all DxH 800 runs in the ISIS database. Double-click on the Coulter icon on the desktop to open the application.

Open the Hematology module: Direct the mouse arrow to Modules, in the top menu bar, left-click, drag the mouse arrow to Hematology, and right-click.

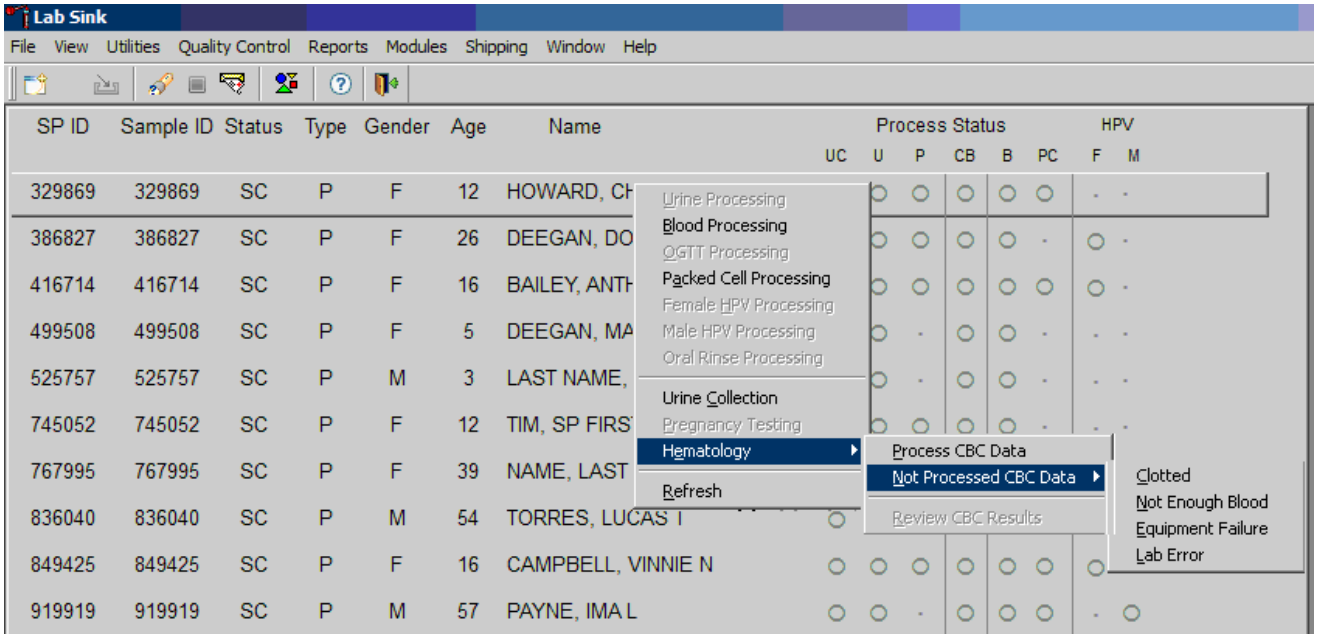


Alternatively, open the Hematology module from the heads-up display.



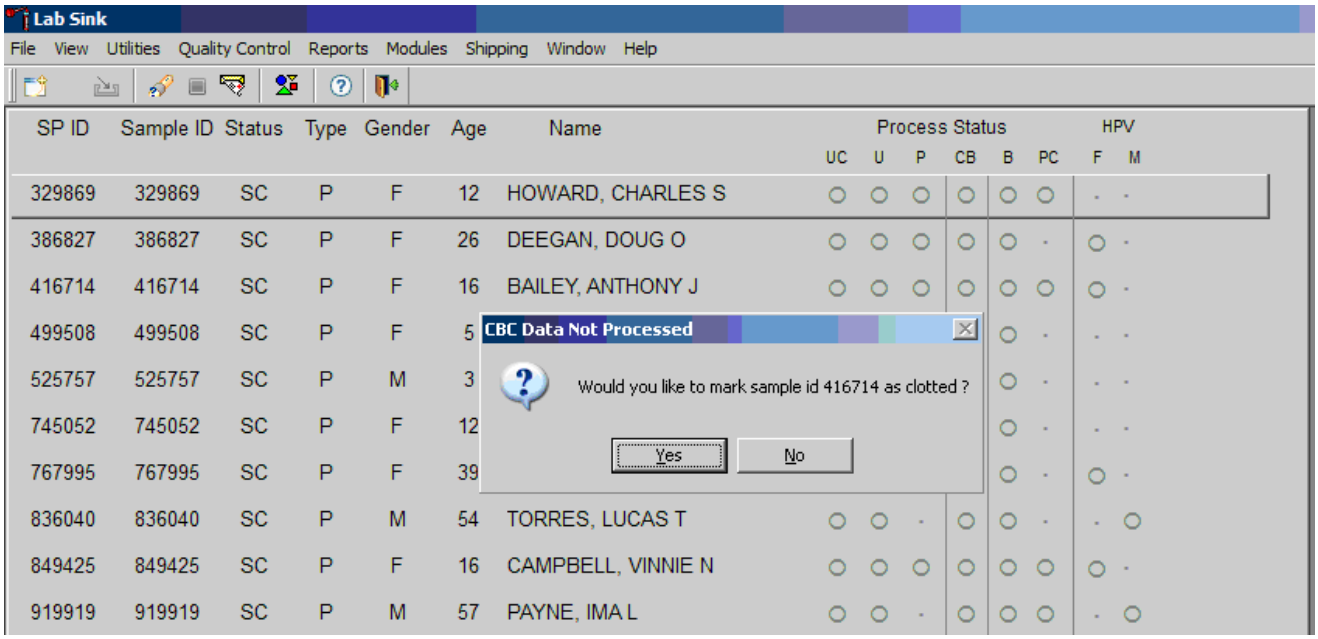
To access the Hematology module, direct the mouse arrow to any SP, right-click, drag the mouse arrow to Hematology, then to Process CBC Data, and right-click. Alternatively, use the arrow keys to move up and down the list until a particular SP is highlighted, right-click, drag the mouse arrow to Hematology then to Process CBC Data, and right-click.

Either open the module or reject the specimen and add a reason or comment for every CB record where blood was drawn in phlebotomy AND there are no CBC results.



Open the module (Process CBC Data) or record why the CBC is not being run (Not Processed CBC Data). Select or record a comment for every CBC that is not run. To complete opening or accessing the Hematology module, direct the mouse arrow to Process CBC Data and right-click. To record why a CBC is not being run, direct the mouse arrow to the exact SP's line on the heads-up display, right-click, drag the mouse arrow to Not Processed CBC Data, and drag the mouse arrow to the correct reason and right-click.

A pop-up window will display. Confirm the selection.

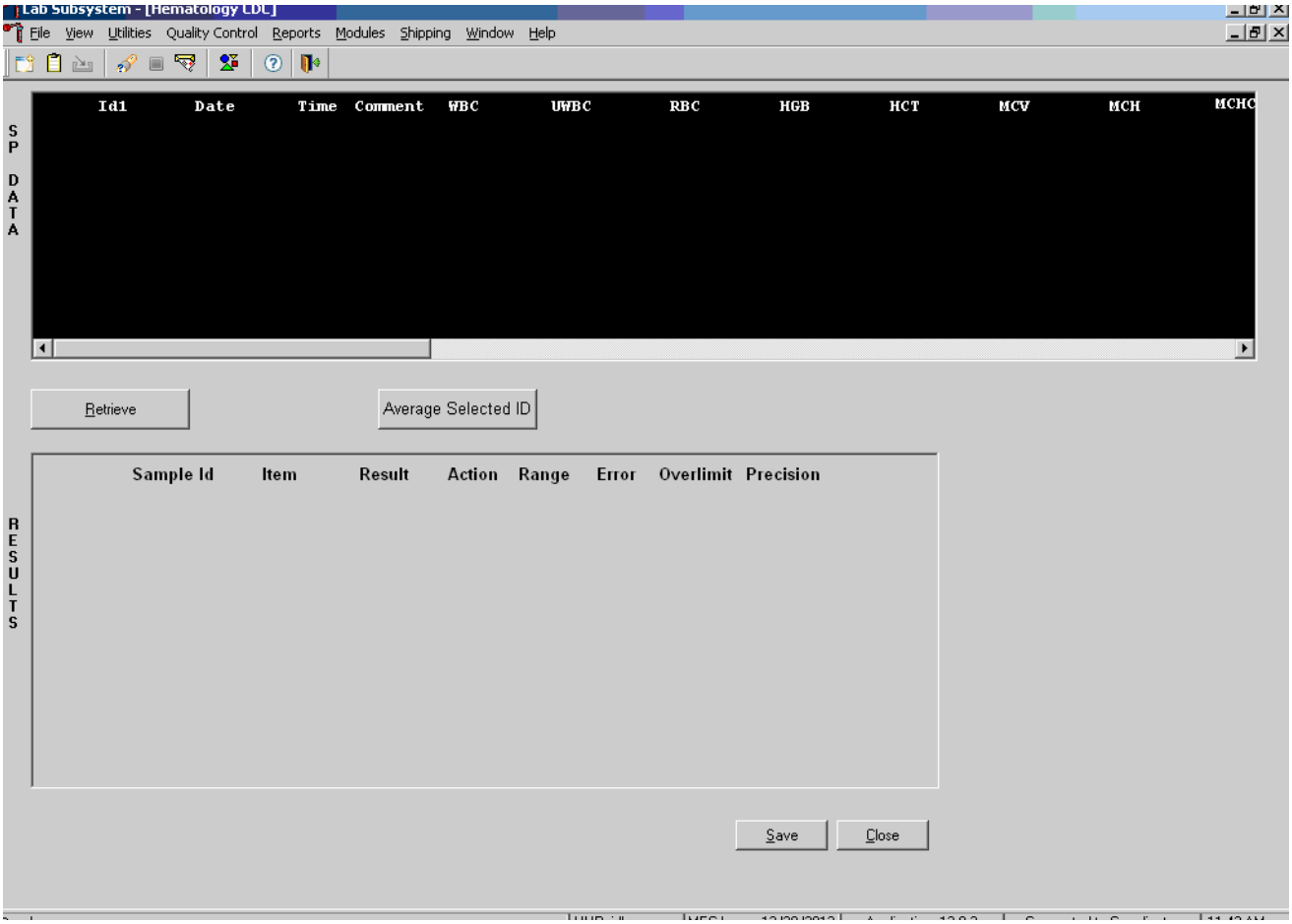


A CBC Data Not Processed message text box displays that asks, "Would you like to mark sample ID XXXXXX as Clotted/Not Enough Blood/Equipment Failure/Lab Error?" To record a "Yes" response, direct the mouse arrow to the Yes button and left-click, type [Y], or press Enter. To record a "No" response, direct the mouse arrow to the No button and left-click, or type [N]. If a "Yes" response is recorded, the comment is saved to the database. If a "No" response is recorded, no comment is saved to the database. If the record is marked with the selection in the database, the heads-up display updates to complete (the CB circle fills in black).

2. Hematology module overview

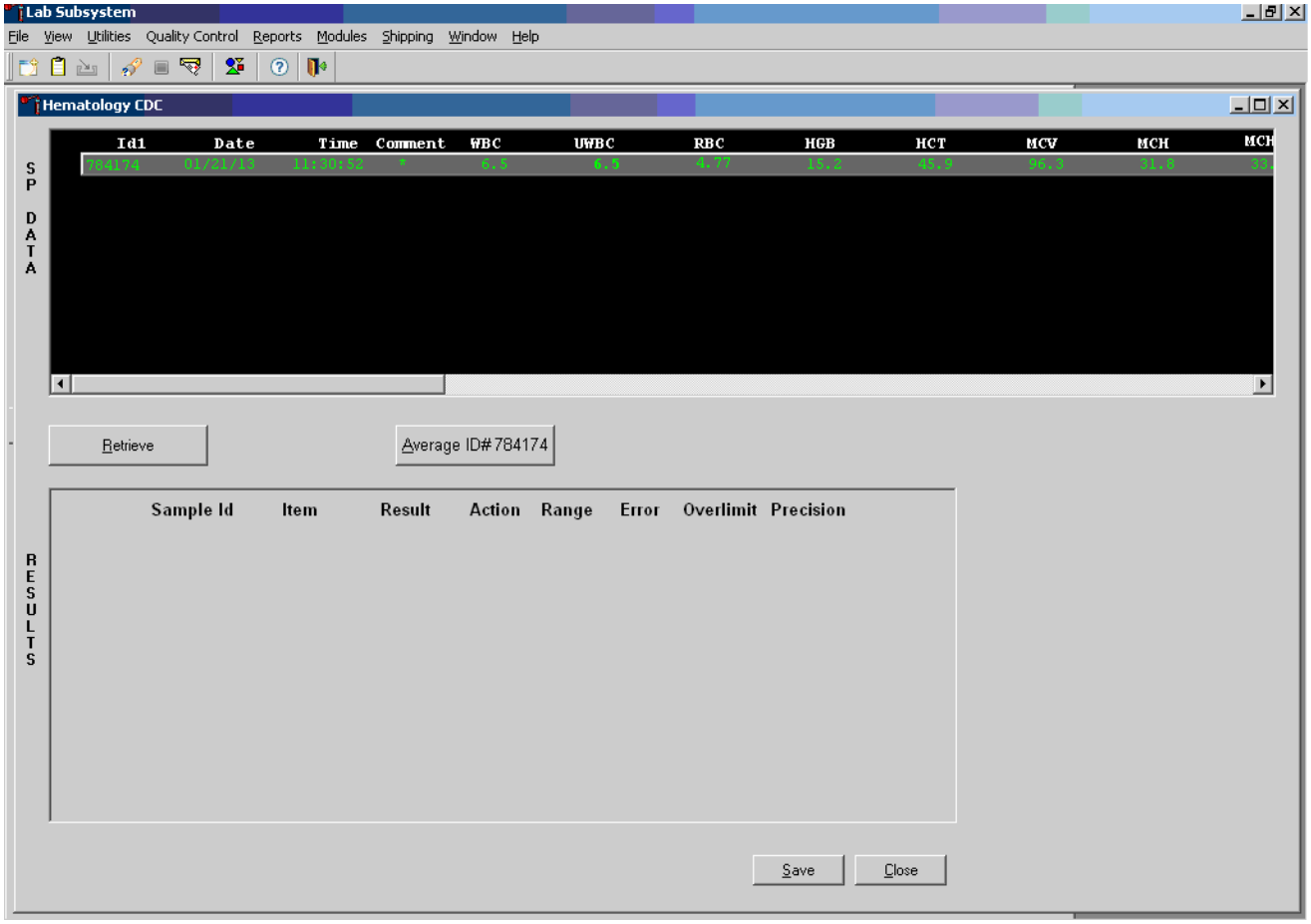
The CBC results are not automatically populated in the Hematology module. Use the Retrieve button to send the results from ISIS to the Hematology module. Select "Retrieve" after each run.

Make sure the Coulter DMS host computer icon (HC) is displaying an up arrow (↑) in the DMS bottom tile bar.



After data is retrieved, it displays in the top portion of the window, the SP Data section. This section includes the SP ID, the date and time the CBC was run, and columns for each parameter. The bottom portion of the window is the Results section. Results display after the Average Selected ID button is selected.

Review all Coulter data in the SP Data section after they are retrieved.

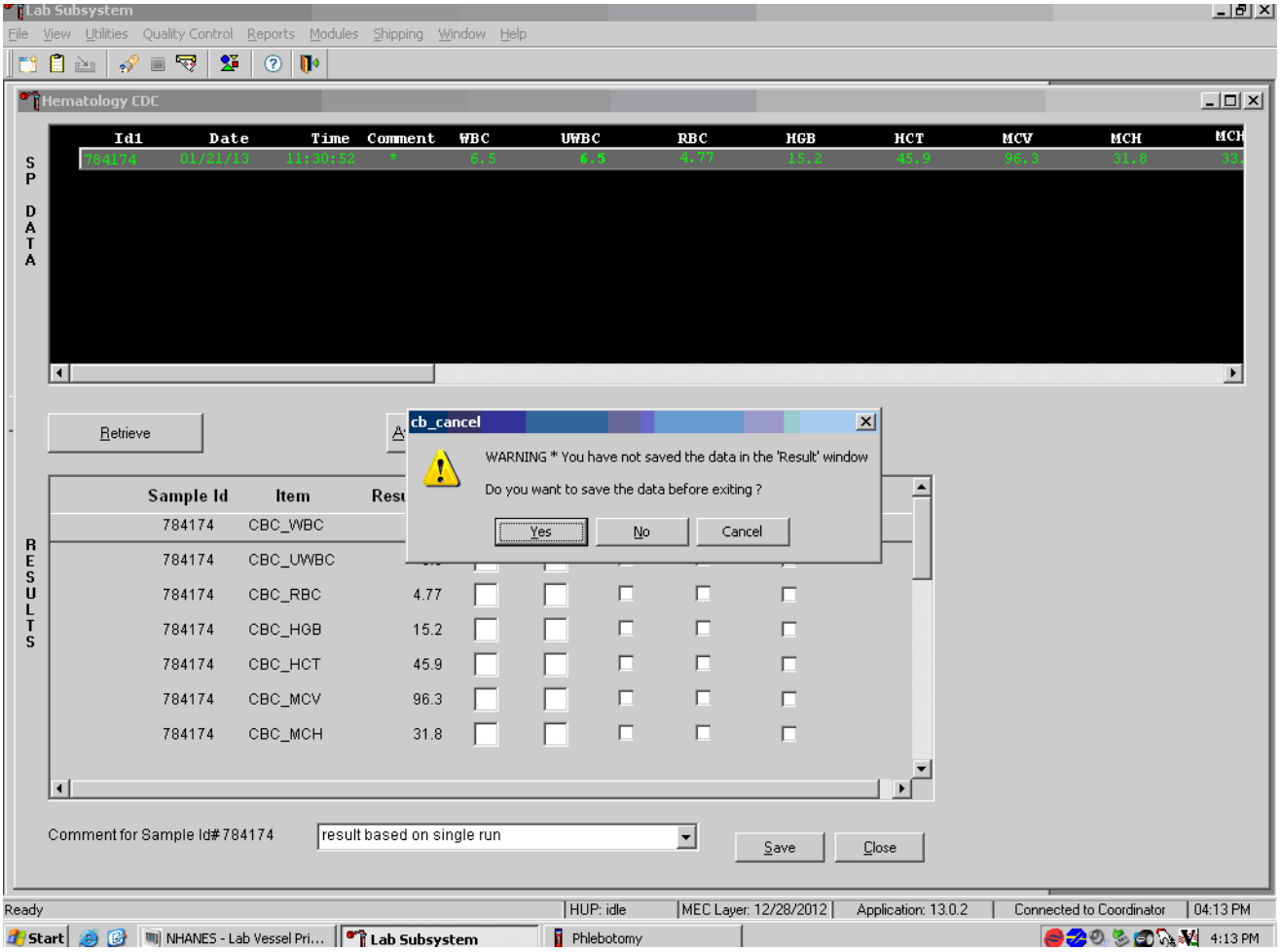


To view SP data for all parameters, direct the mouse arrow to the horizontal scroll bar at the bottom of the SP Data section and drag the scroll bar to the left or right. Alternatively, to view the SP data for all parameters, direct the mouse arrow to the small scroll arrows on the left and right edges of the horizontal scroll bar, and left-click.

Hematology Results Section Overview. The Result columns include: Sample ID, Item (CBC parameter), Result (Coulter data for a single run or the ISIS-averaged result for multiple runs), Action (CDC-established critical limits), Range (CDC-established reference ranges for both genders and four age groups), Error (Coulter-transmitted instrument errors), Overlimit (Coulter-transmitted result that exceeds the instrument's linearity limit), and Precision (CDC-established values for the difference between any two runs). Checkmarks display in boxes for parameters that have errors, are over limit, or for those that exceed precision limits. An "H" for "high" and "L" for "low" display for parameters that exceed action limits or reference ranges.

Average, Evaluate, and Save Results for All Parameters. The SP's results display in the bottom portion of the window after the Average Selected ID button is selected. To view results for all parameters, direct the mouse arrow to the vertical scroll bar at the right side of the Results section and drag the bar up or down. Alternatively, to view all the results, direct the mouse arrow to the small scroll arrows on the top and bottom edges of the vertical scroll bar, and left-click. Evaluate each parameter for error, overlimit, and precision checkmarks, and "H" or "L" action limit and reference range flags. To save the result to the database, direct the mouse arrow to the Save button and left-click. After results are saved, they are erased from the screen. To exit without saving the result to the database, direct the mouse arrow to the Cancel button and left-click.

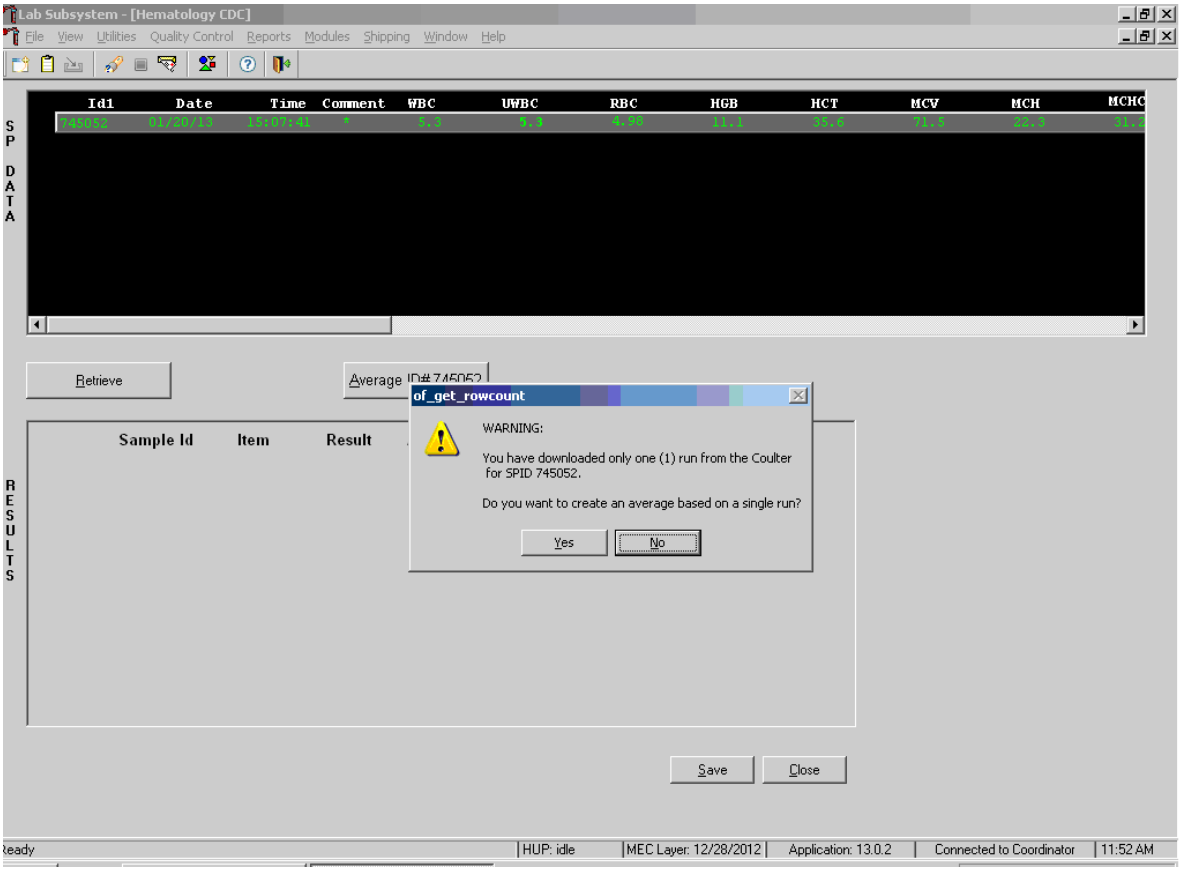
A warning text box displays if the Close button is selected before the results have been saved.



If the Close button is selected before the results are saved to the database, a warning message text box displays that states, "WARNING * You have not saved the data in the 'Result' window" and asks, "Do you want to save the data before exiting?" To record a "Yes" response, direct the mouse arrow to the Yes button and left-click, type [Y], or press Enter. To record a "No" response, direct the mouse arrow to the No button and left-click, or type [N]. To cancel the action, direct the mouse arrow to the Cancel button and left-click. If a "Yes" response is recorded, the CBC results are saved to the database and erased. If a "No" response is recorded, no results are saved to the database and the data in the Results section are erased. A Cancel response returns the screen to its previous state.

3. Running samples when only one run is possible

Save results where only one run was possible.



Run Samples in Duplicate Whenever Possible. If the whole blood is insufficient, it is acceptable to average and save only one run. To save results where only one run is possible, direct the mouse arrow to the Average Selected ID box and left-click. A warning message text box displays that states, "You have downloaded only one (1) run from the Coulter for SPID *XXXXXX*" and asks, "Do you want to create an average based on a single run?"

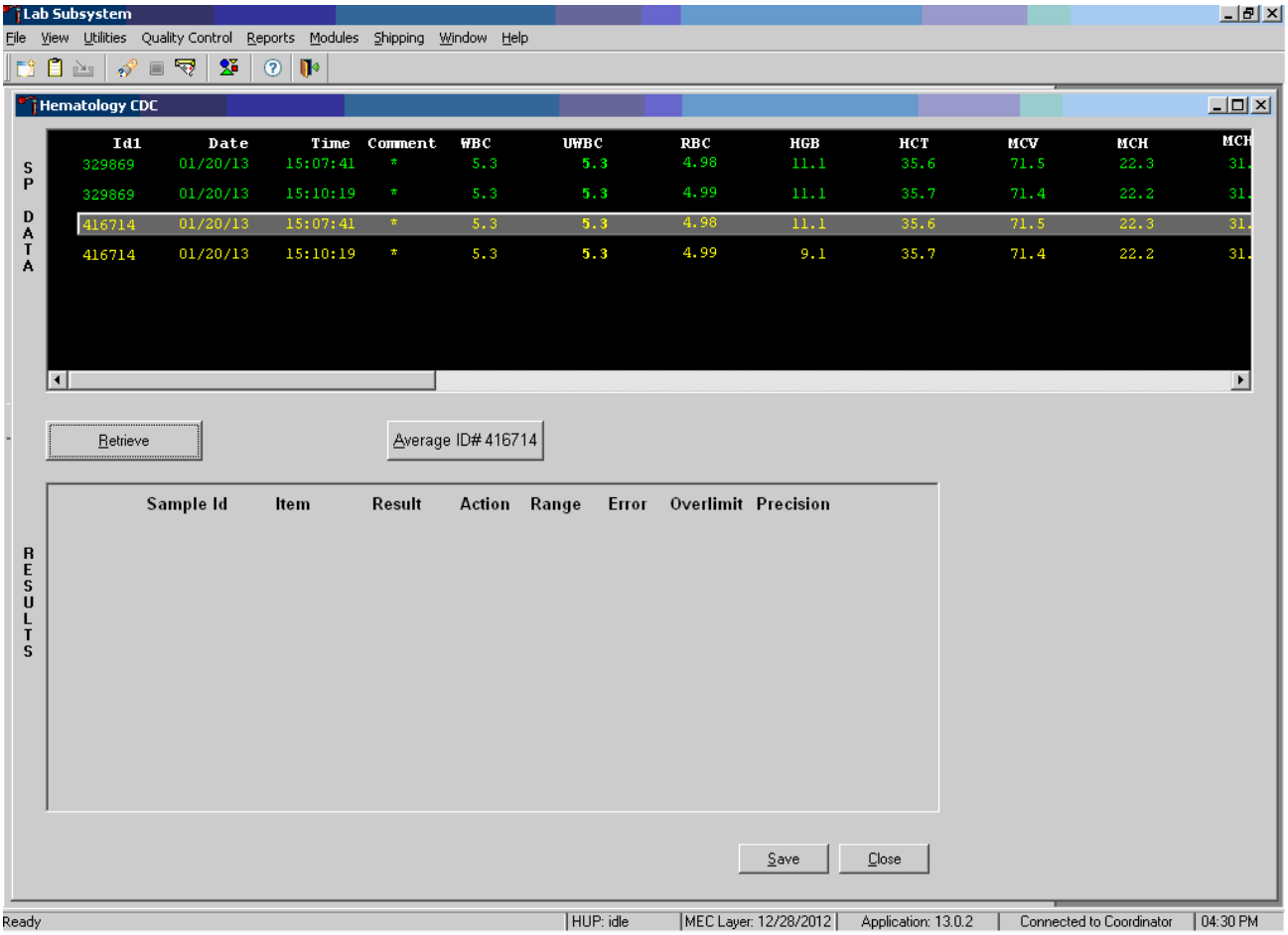
To record a "Yes" response, direct the mouse arrow to the Yes button and left-click or type [Y/y]. To record a "No" response, direct the mouse arrow to the No button and left-click, or type [N/n], or press Enter. If a "Yes" response is recorded,

the CBC results display in the bottom Results section of the window. A "No" response cancels the action and returns the window to its previous state.

For results where only one run was possible, the Comment box at the bottom of the window defaults to "result based on single run."

4. Running samples in duplicate

Run all samples in duplicate and average the data.



Whenever a sample is run in duplicate, both results display in the SP Data section. To average these two results, direct the mouse arrow to Average ID#*XXXXXX* button and left-click.

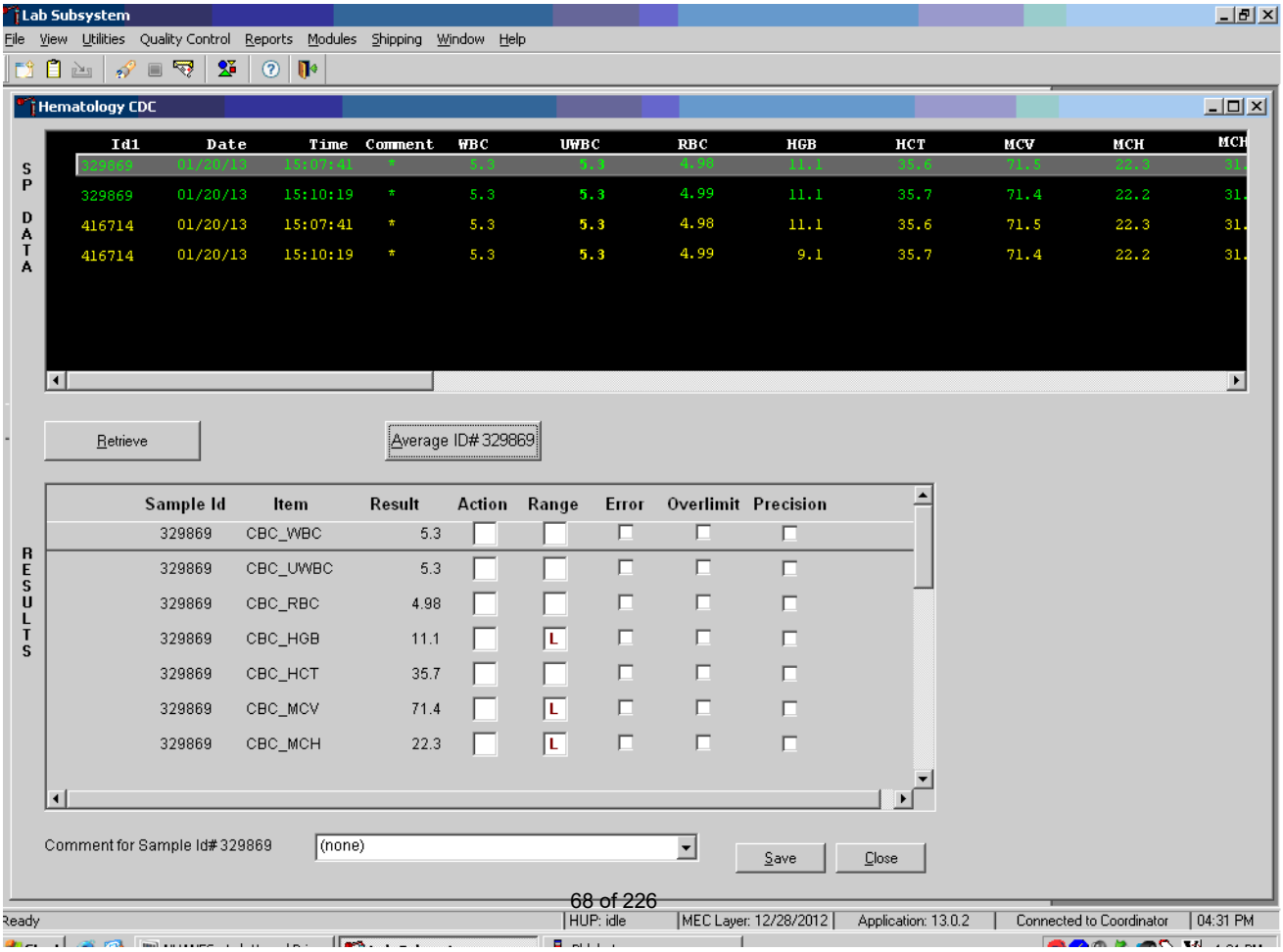
Results display in the lower section of the window.

The differences between duplicate values for WBC, RBC, Hgb, MCV, Plt, NE#, LY#, MO#, EO# and BA# are calculated and evaluated to determine if they are within the following CDC-established precision limits (Table 1-4).

Table 1-4. CDC precision limits

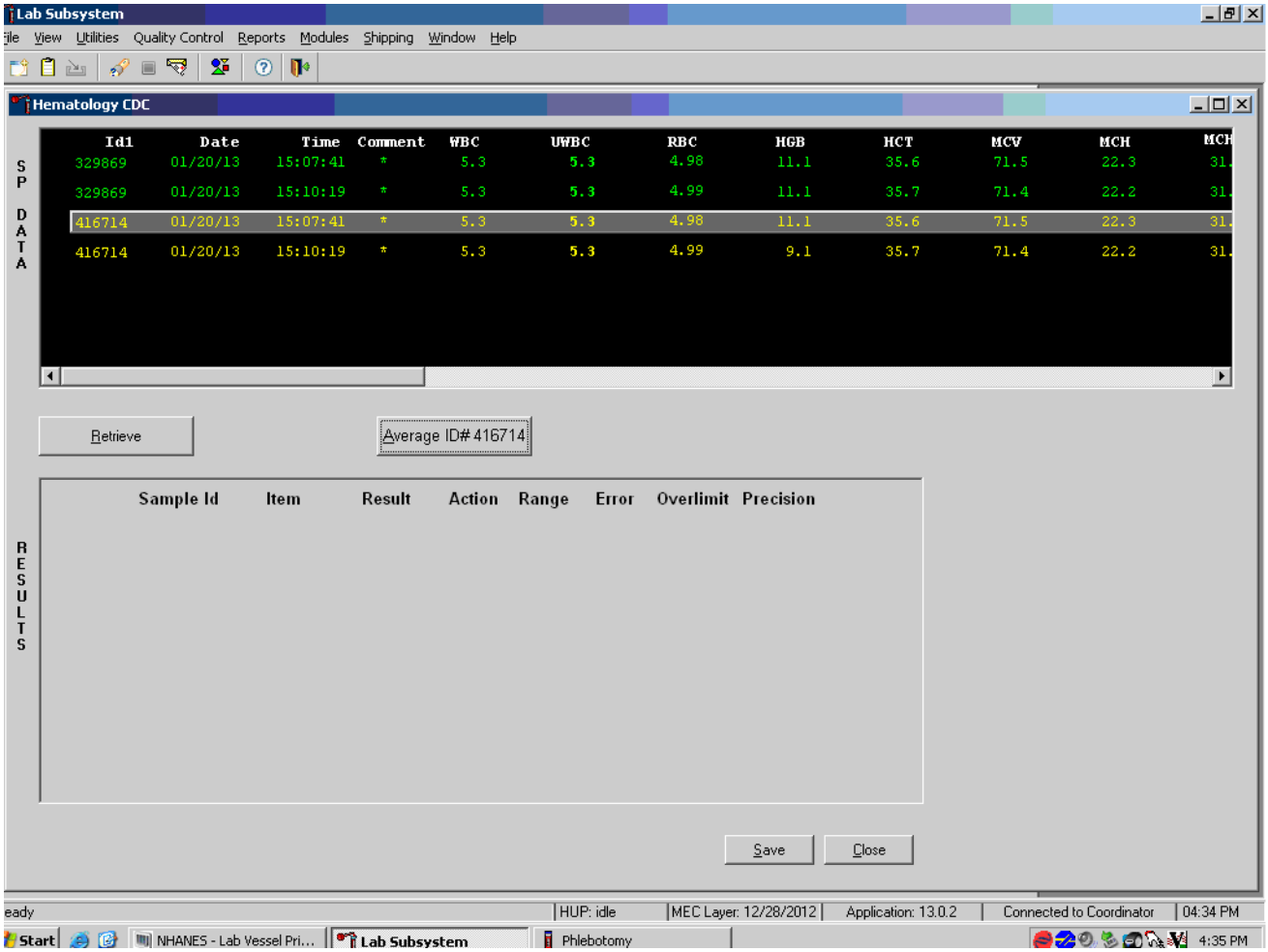
Test	Precision limits
WBC	±0.4 x 10^3
RBC	±0.1 x 10^6
Hgb	±0.4 g/dl
MCV	±2.2 fL
Plt	±23 x 10^3
NE#	±0.4 x 10^3
LY#	±0.2 x 10^3
MO#	±0.2 x 10^3
EO#	±0.2 x 10^3
BA#	±0.2 x 10^3

If RBC parameters are out of range, evaluate the data for drift. If drift is evident, evaluate the possibility of an instrument malfunction. If any WBC differential absolute number is out of range, check the WBC scattergram for abnormal cell population(s). Evaluate and save results when precision limits are not exceeded.



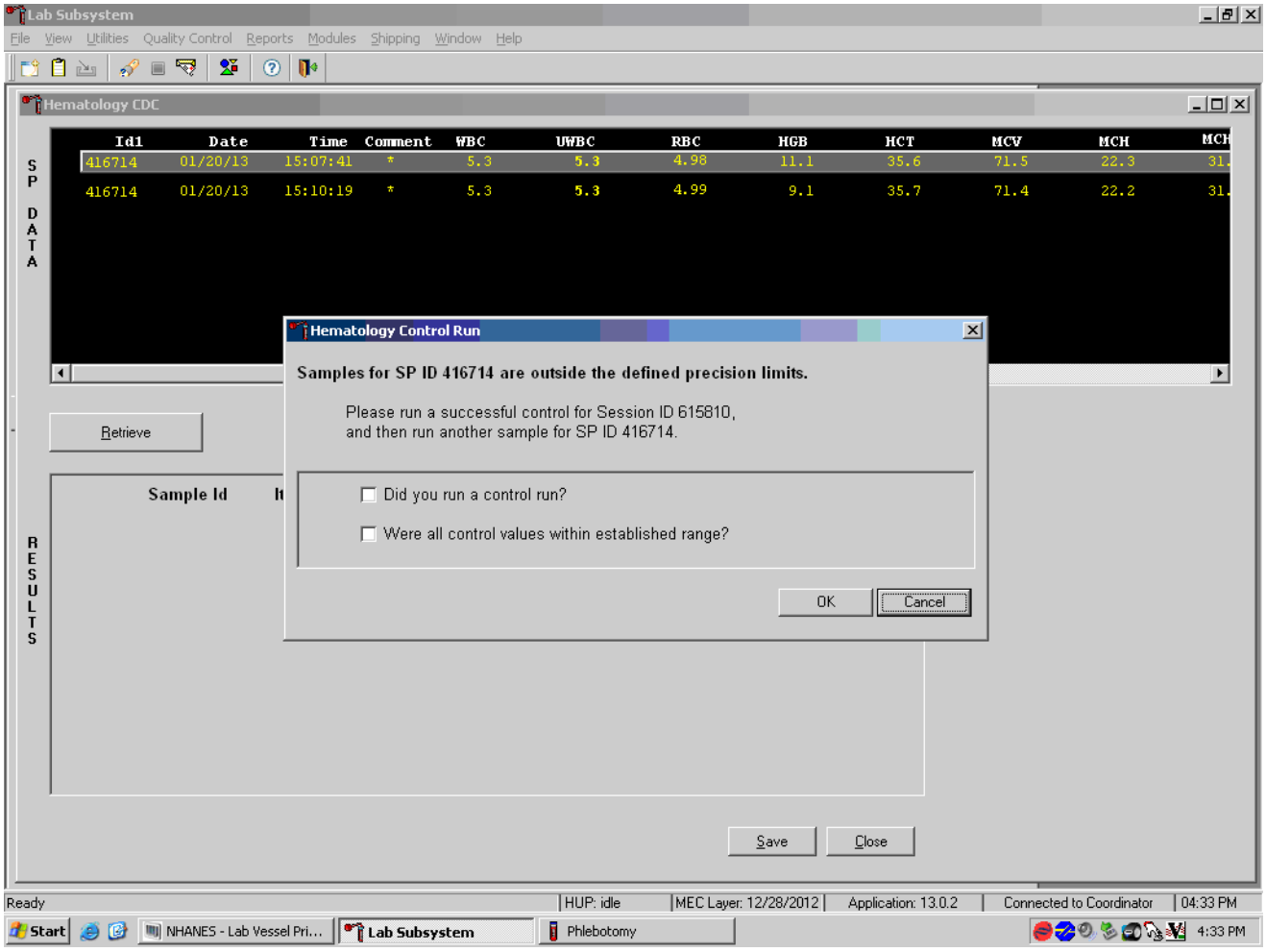
Evaluate results for all parameters. Evaluate each parameter for error, overlimit, and precision checkmarks, and "H" or "L" action limit and reference range flags. If there are no checkmarks in the Precision column (no precision limit was exceeded), save the results to the database. To save the results to the database, direct the mouse arrow to the Save button and left-click. After results are saved, they are erased from the screen. To exit without saving the result to the database, direct the mouse arrow to the Close button and left-click.

Average, evaluate, and rerun specimens that exceed precision limits.



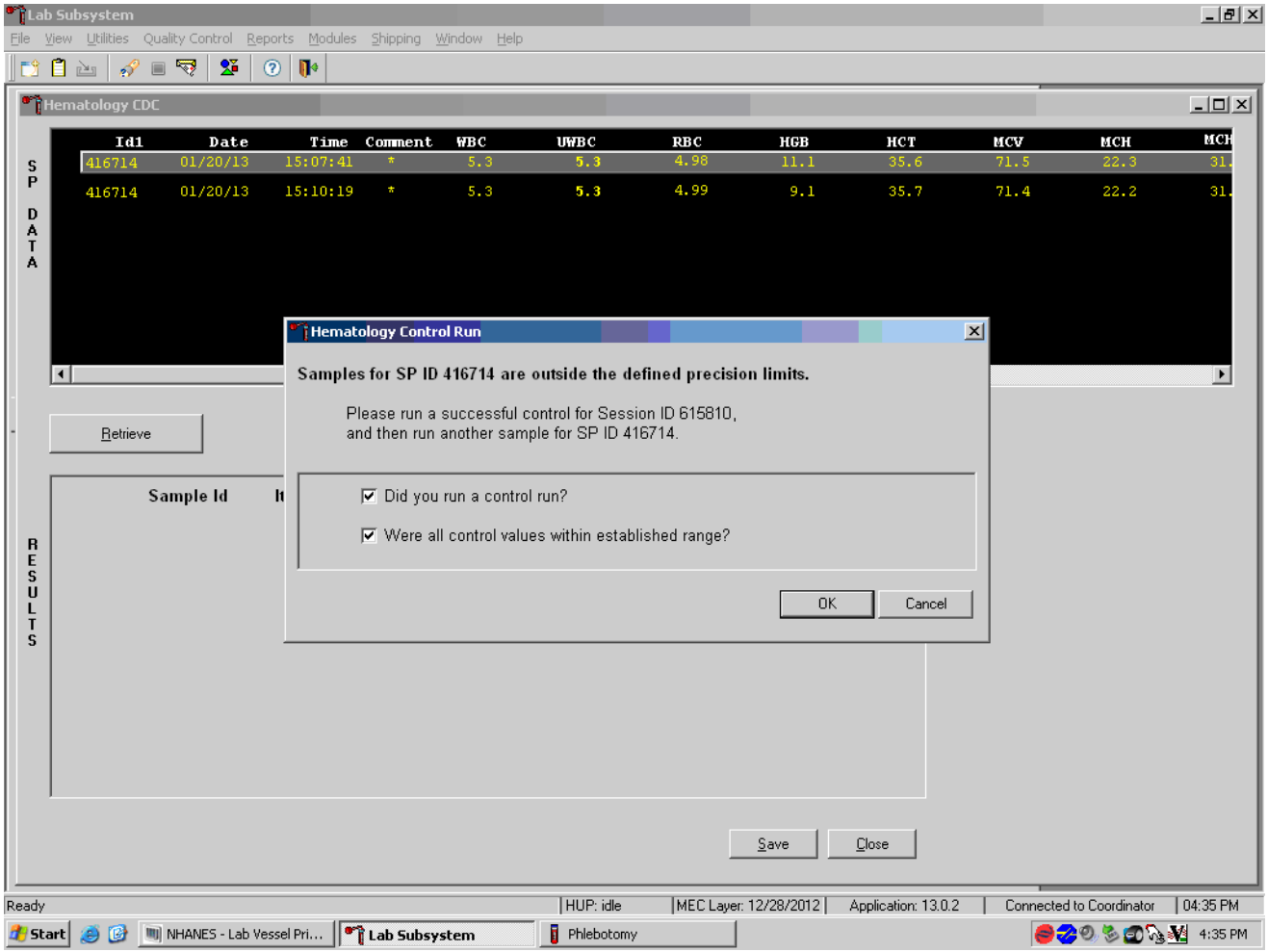
Average the two results by using the mouse to direct the mouse arrow to the Average ID#*XXXXXX* button and left-click. If, at this point, precision limits are exceeded for any individual parameter, the technologist is prompted to run a control and evaluate it to determine if all control values fall within the control's established range.

If any parameter exceeds its precision limit, the Hematology Control Run window displays.



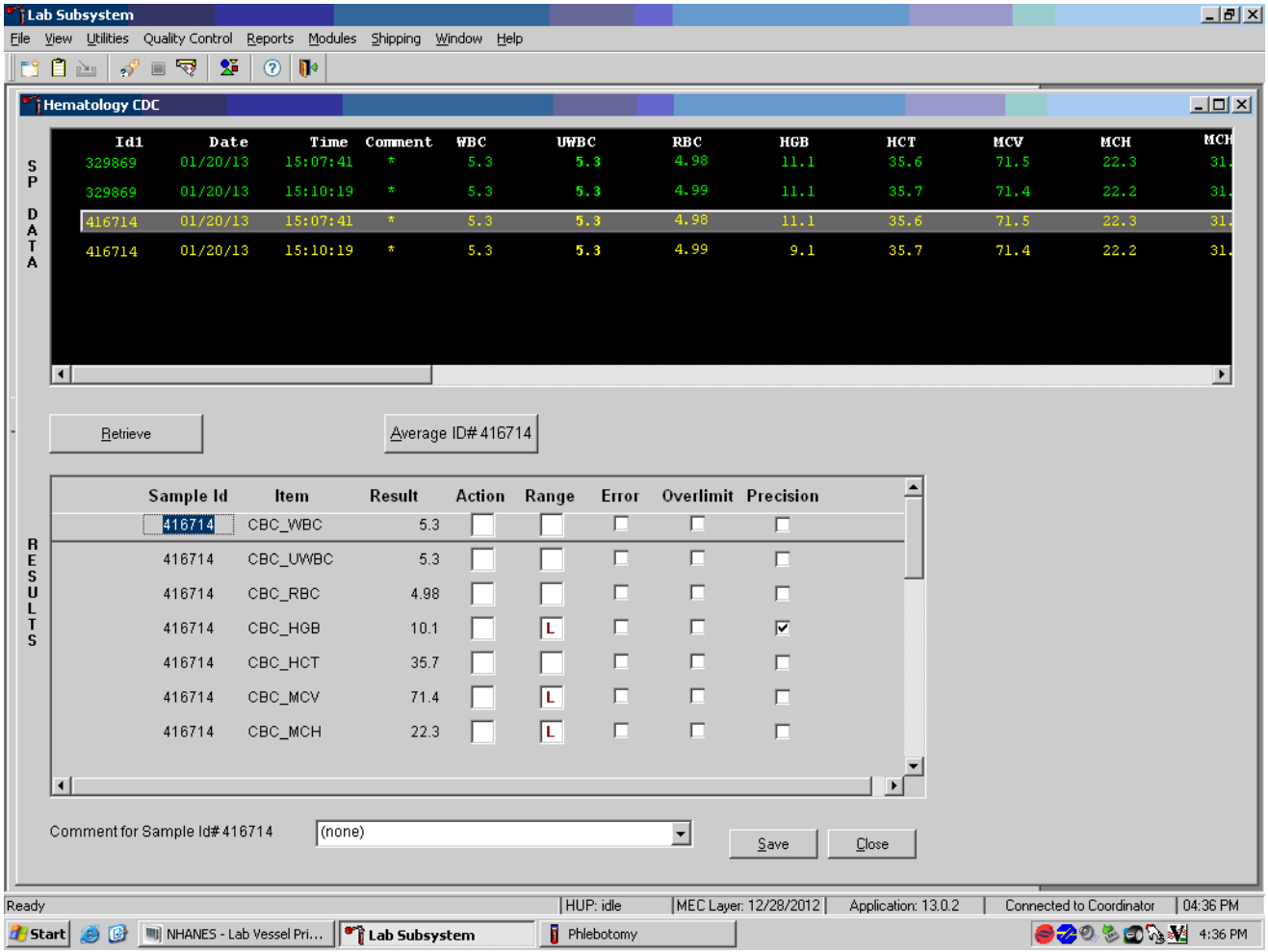
The Hematology Control Run window indicates that the "Samples for SP ID *XXXXXX* are outside the defined precision limits." It instructs the technologist to "Please run a successful control for Session ID *XXXXXX*, and then run another sample for SP ID *XXXXXX*." If it has been more than 30 minutes since running the sessions QC (all three levels of 6C cell control), run any one level of 6C cell control and evaluate the results. Respond to the two questions, "Did you run a control run?" and "Were all control values within established range?" To confirm these actions, direct the mouse arrow to each of the two check boxes and left-click to record the checkmarks.

Save the responses to the check box questions.



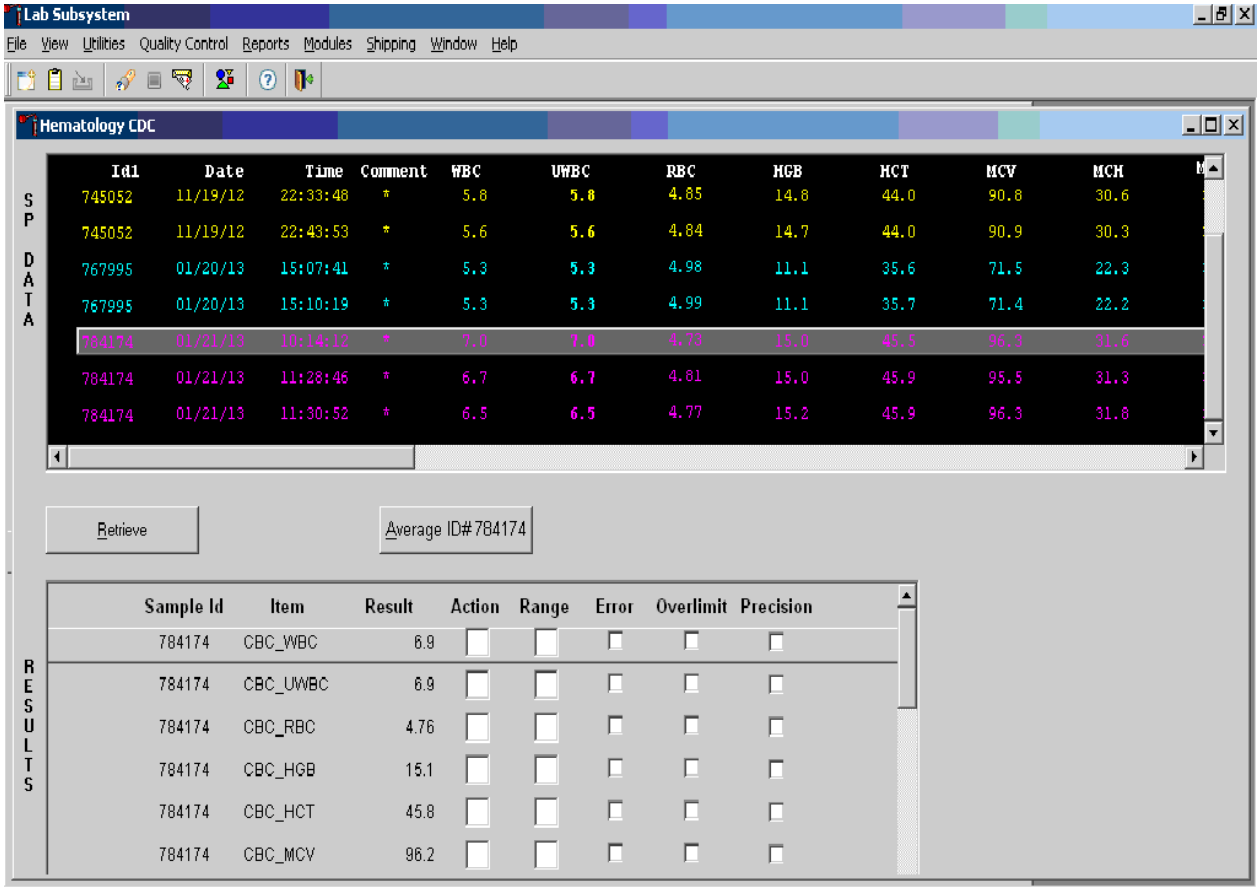
To save these responses to the database, direct the mouse arrow to the OK button and left-click or type Enter. To exit the Hematology Control Run window without saving the responses, direct the mouse arrow to the Cancel button and left-click. As soon as the OK button is selected, the averages display in the Results section of the window.

Evaluate the results displayed in the Results section of the window.

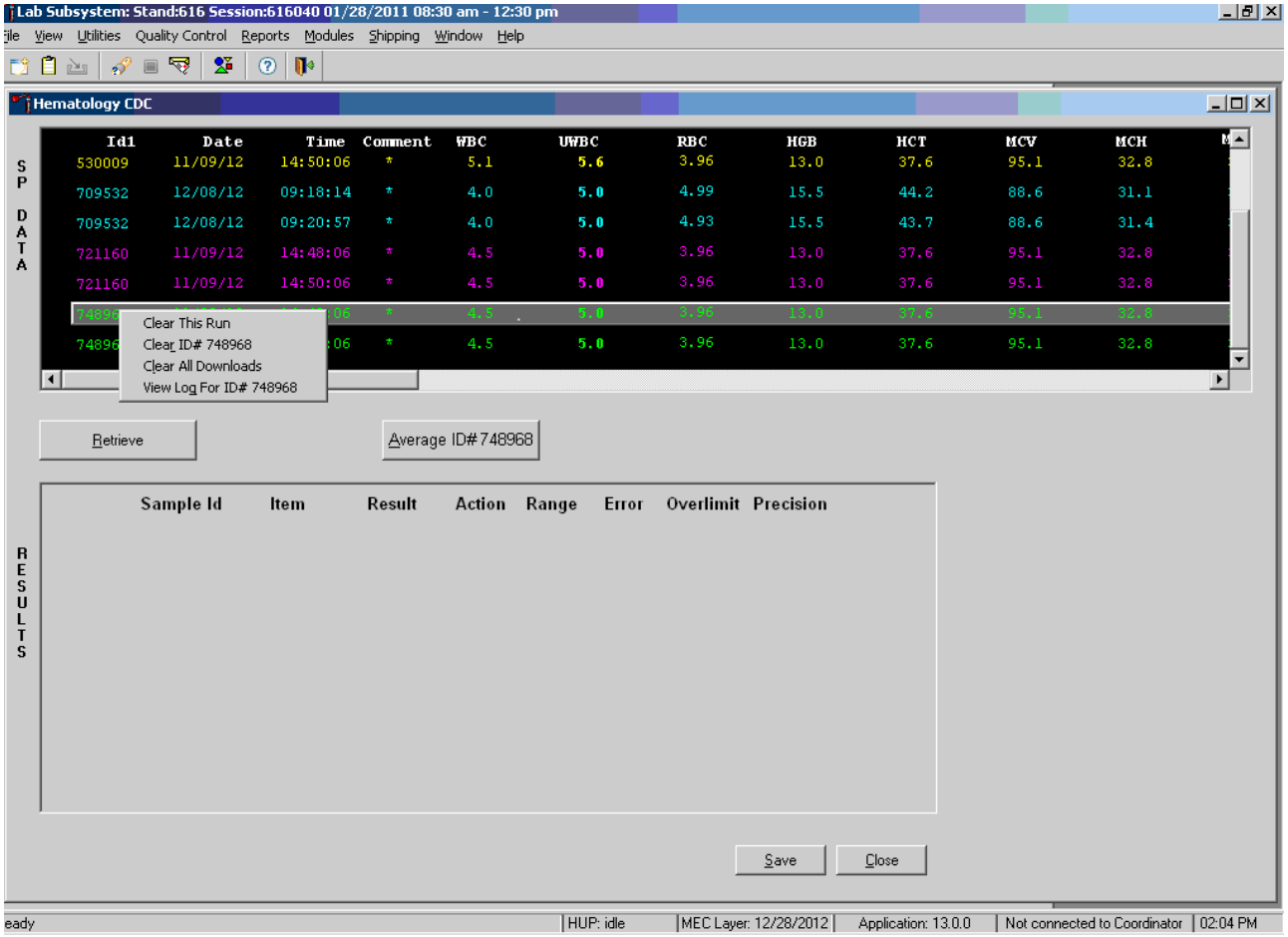


Evaluate each parameter for error, overlimit, and precision checkmarks, and "H" or "L" action limit, reference range flags, and comment in the above screen. Use the scroll bar to view all results. When there are checkmarks in any of the Precision columns, meaning that the precision limit was exceeded, rerun the blood sample a third time. If there is insufficient blood to run the CBC again (total of four runs, since the instrument is set to run all samples in duplicate), delete the run that caused the precision error. Save one run and comment based on a single run. (In the above example, delete the second run for SP 416714 and save the first run.) To save the results to the database, direct the mouse arrow to the Save button and left-click. After results are saved, they are erased from the screen. To exit without saving the result to the database, direct the mouse arrow to the Close button and left-click. Run one level of QC when precision limits are exceeded, before re-running the sample in duplicate. Remember to fill out the 6C spreadsheet to account for the extra run of that level of control.

Run the specimen again when any precision limit is exceeded or if one run has a comment and the second run does not.

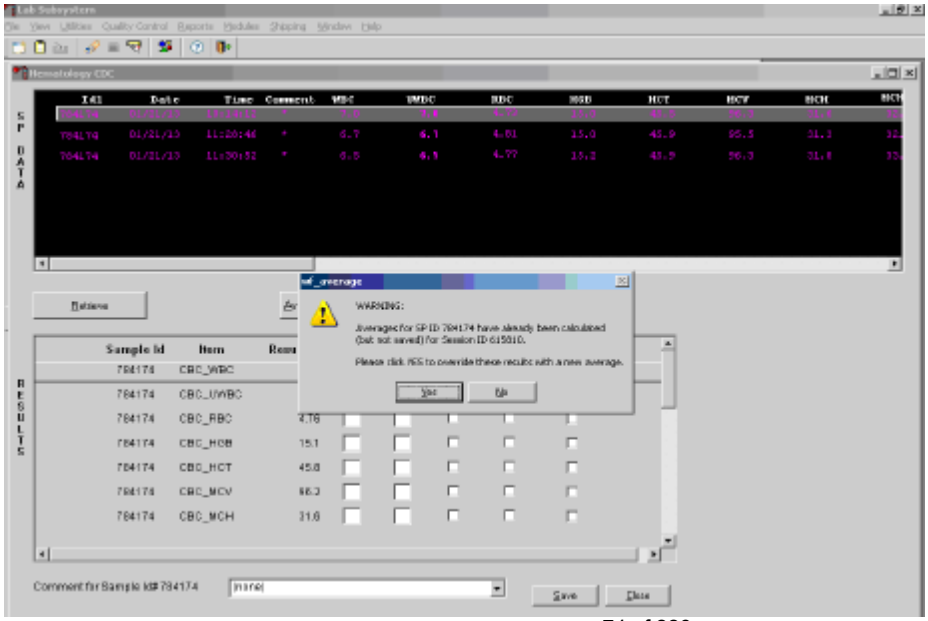


Run the blood sample again. Two additional results will be displayed. Whenever a sample is run more than once, all results in the SP Data section are displayed. Scroll through the top of the SP data window and determine which of the two runs match the best. Delete the two outlier runs, which could be the run that caused the precision error or the run that does not/does have a comment, and re-average the two remaining runs.



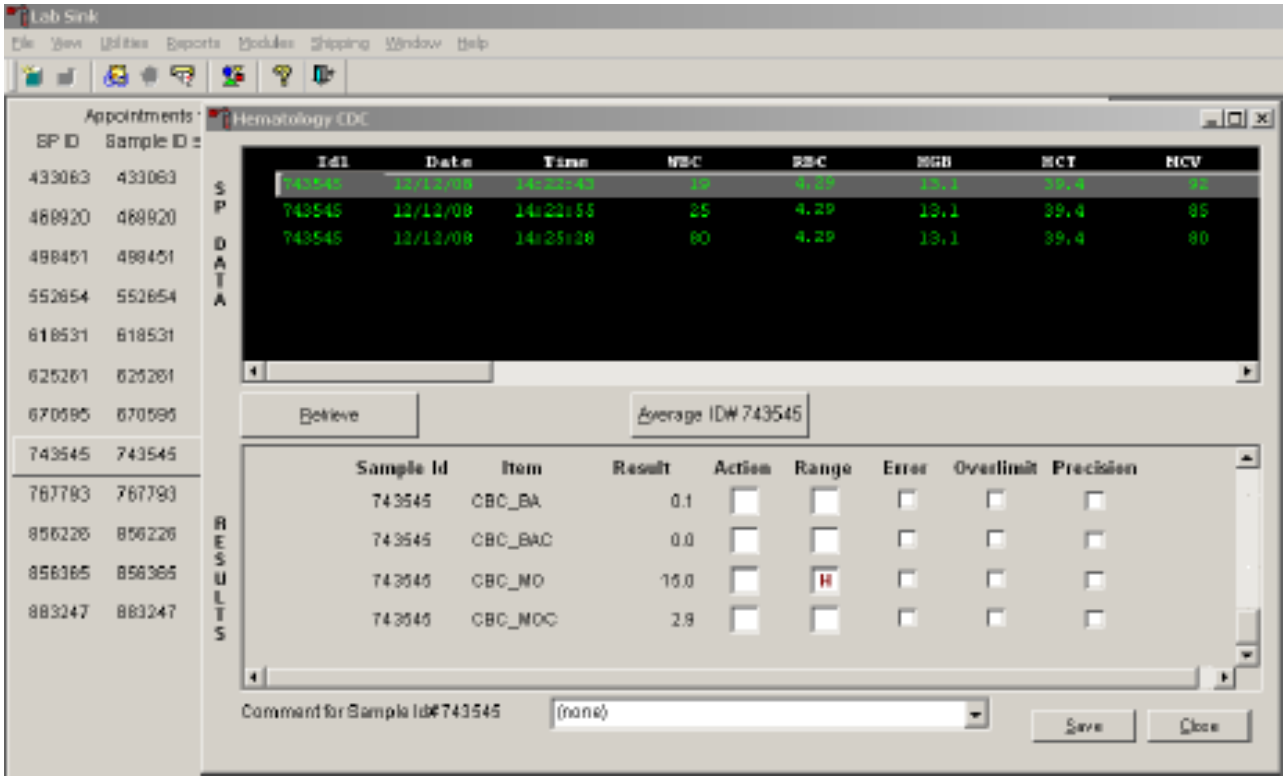
After clearing the outlier runs, re-average the two remaining runs and analyze the results.

Override the current averaged results with a new average.



Whenever a sample has previously been averaged, and a new average is calculated, a warning message text box displays stating, "Averages for SP ID *XXXXXX* have already been calculated (but not saved) for session ID *XXXXXX*." The text box instructs, "Please click YES to override these results with a new average." To override the current average with a new average, direct the mouse arrow to the Yes button and left-click, or press Enter. To exit or return to the previous screen containing the previous averages, direct the mouse arrow to the No button and left-click.

Evaluate the new results.

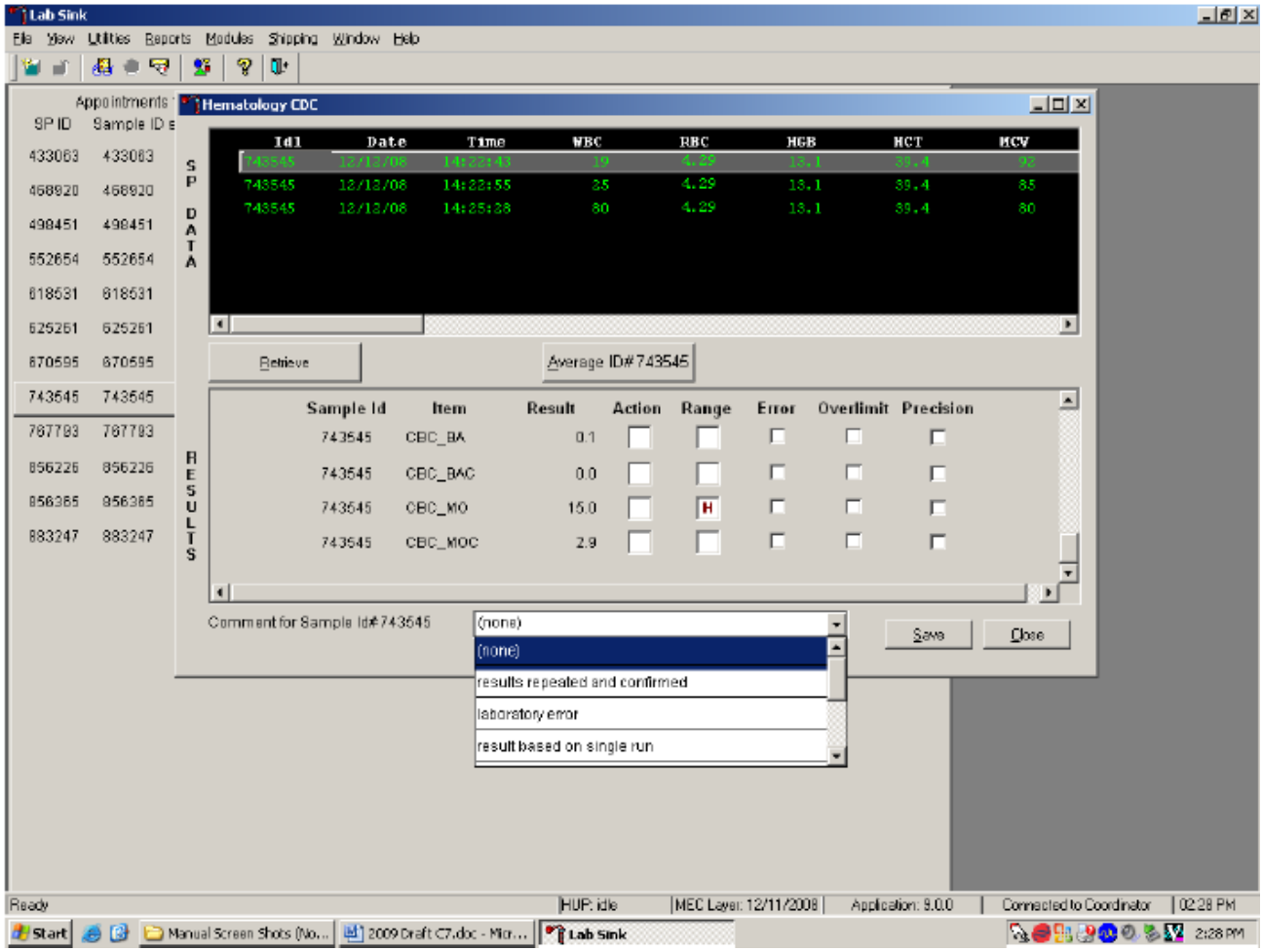


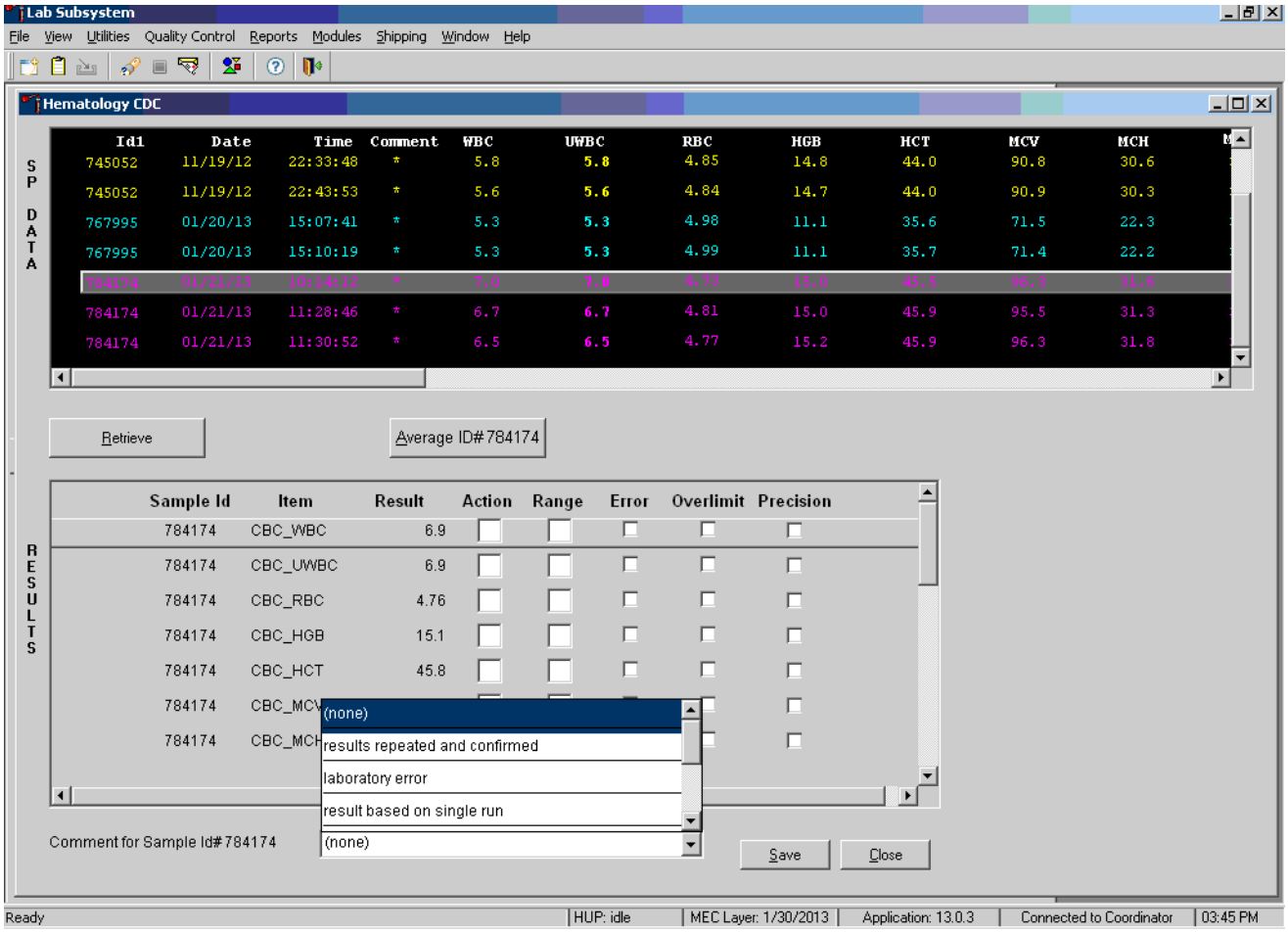
If all parameters of the two remaining runs now meet precision limits (there are no checkmarks in the Precision column), save the results to the database. To save the result to the database, direct the mouse arrow to the Save button and left-click. After results are saved, they are erased from the screen. To exit without saving the result to the database, direct the mouse arrow to the Close button and left-click.

If after four runs precision limits are still not met for any parameter, a comment is automatically attached to the results. Do not run a specimen more than four times.

5. Attaching comments to the results

Enter a comment for any run where results were repeated and confirmed, the equipment failed, or there was a laboratory error.





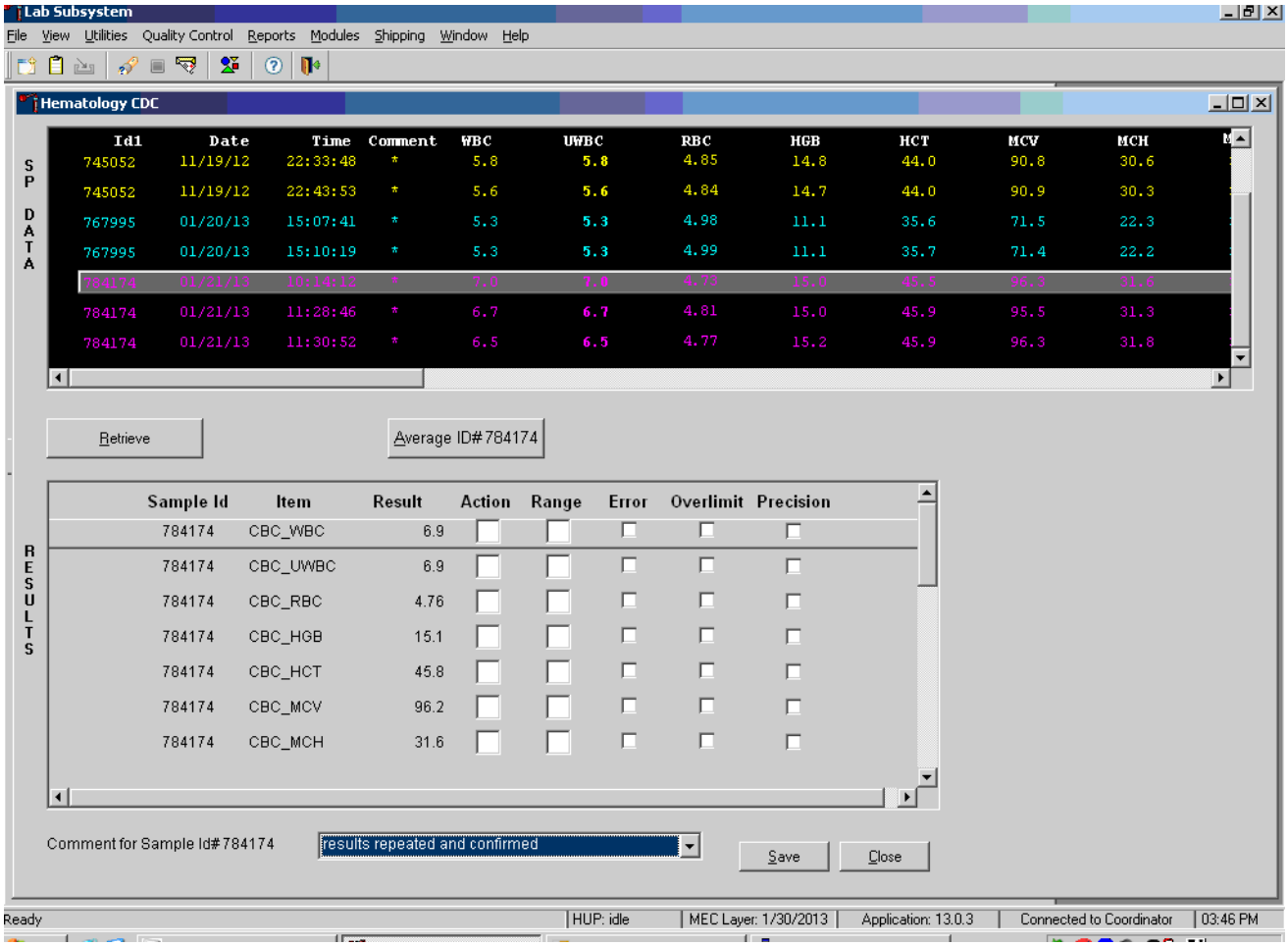
To attach a comment to the results in the database, direct the mouse arrow to the drop-down list on the Comment box, left-click to display the codes, drag the mouse arrow to the most appropriate choice, and left-click. Alternatively, to record a comment, direct the mouse arrow to the drop-down list on the Comment box, click to display the codes, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code, and when the correct choice is highlighted, left-click.

Exhibit 1-11 presents the comments for the samples and when they are to be used.

Exhibit 1-11. List of comments to be used

Comment	Use when
Results repeated and confirmed	Any parameter exceeded an action, range, or precision limit and the specimen (blood tube) was run more than once.
Laboratory error	There was a technologist error.
Result based on single run	The quantity of specimen is insufficient to run it more than once.
Equipment failure	The Coulter malfunctioned.
No diff results/diff vote out	The Coulter does not report parameter results for any part of the differential or the instrument reported a voteout for any of the differential parameters.
Clotted	The blood is clotted.
Not enough blood	There is insufficient blood to perform at least one complete aspiration.

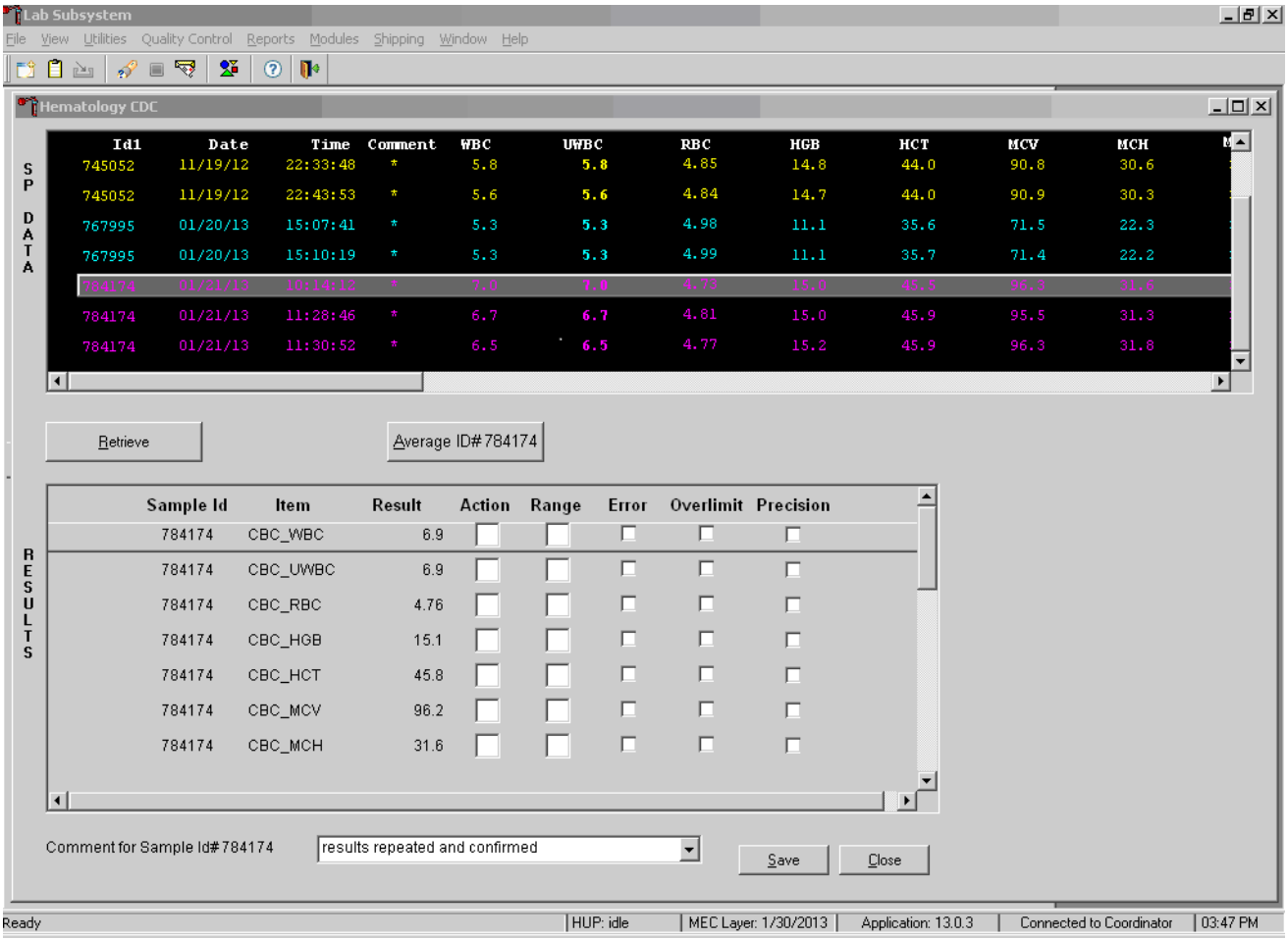
Save the result after attaching a comment.



Save the averaged result and update the comment by using the mouse to direct the mouse arrow to the Save button and left-click. To exit without saving any data to the database, direct the mouse arrow to the Close button and left-click.

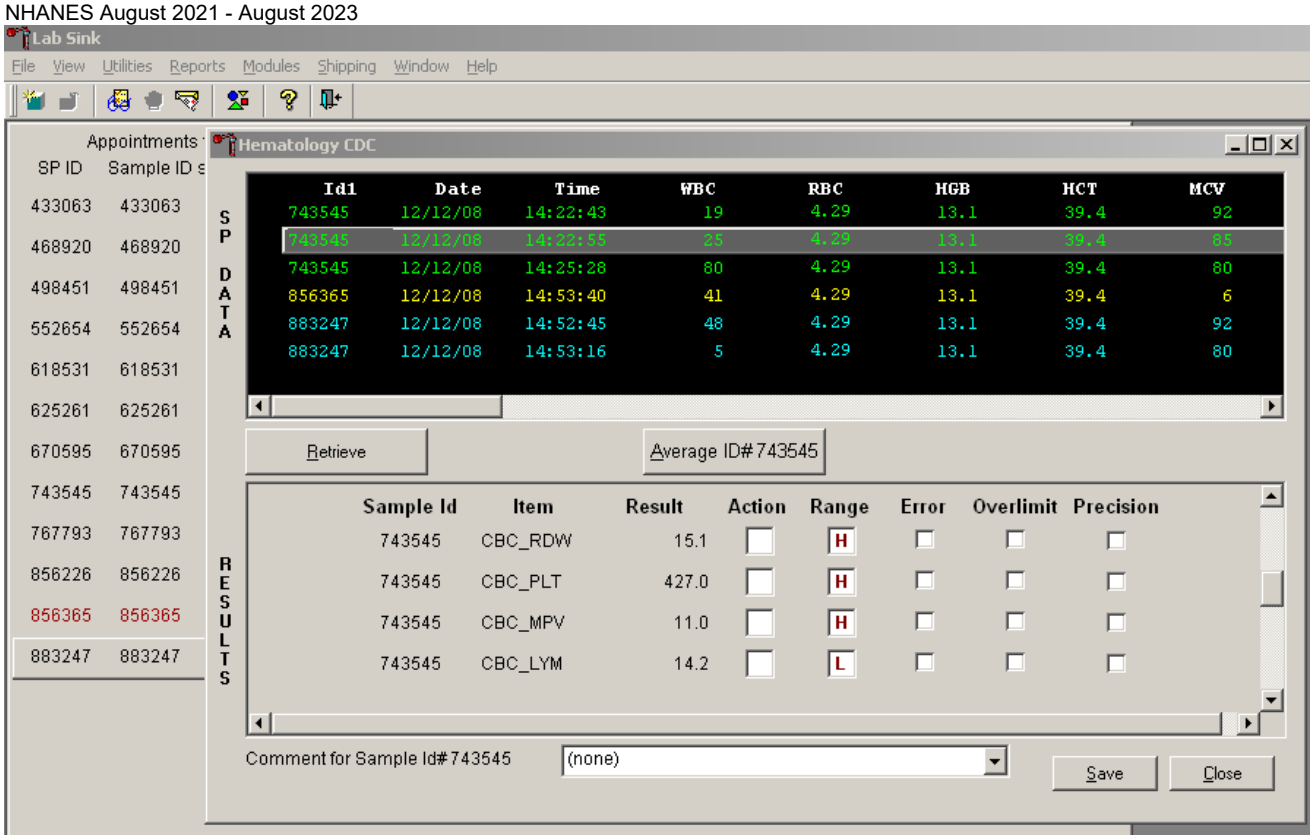
6. Using alternative data manipulation choices

Retain data for multiple SPs in the SP Data section of the window.



In general, run one SP in duplicate through the Coulter, retrieve the data, average the result, and save the data to the database. The Hematology module will display data for multiple SPs in the SP Data section. Each individual SP's results or pairs of results are displayed in a different color. To select or highlight any one SP, direct the mouse arrow to the row containing the correct SP ID and left-click.

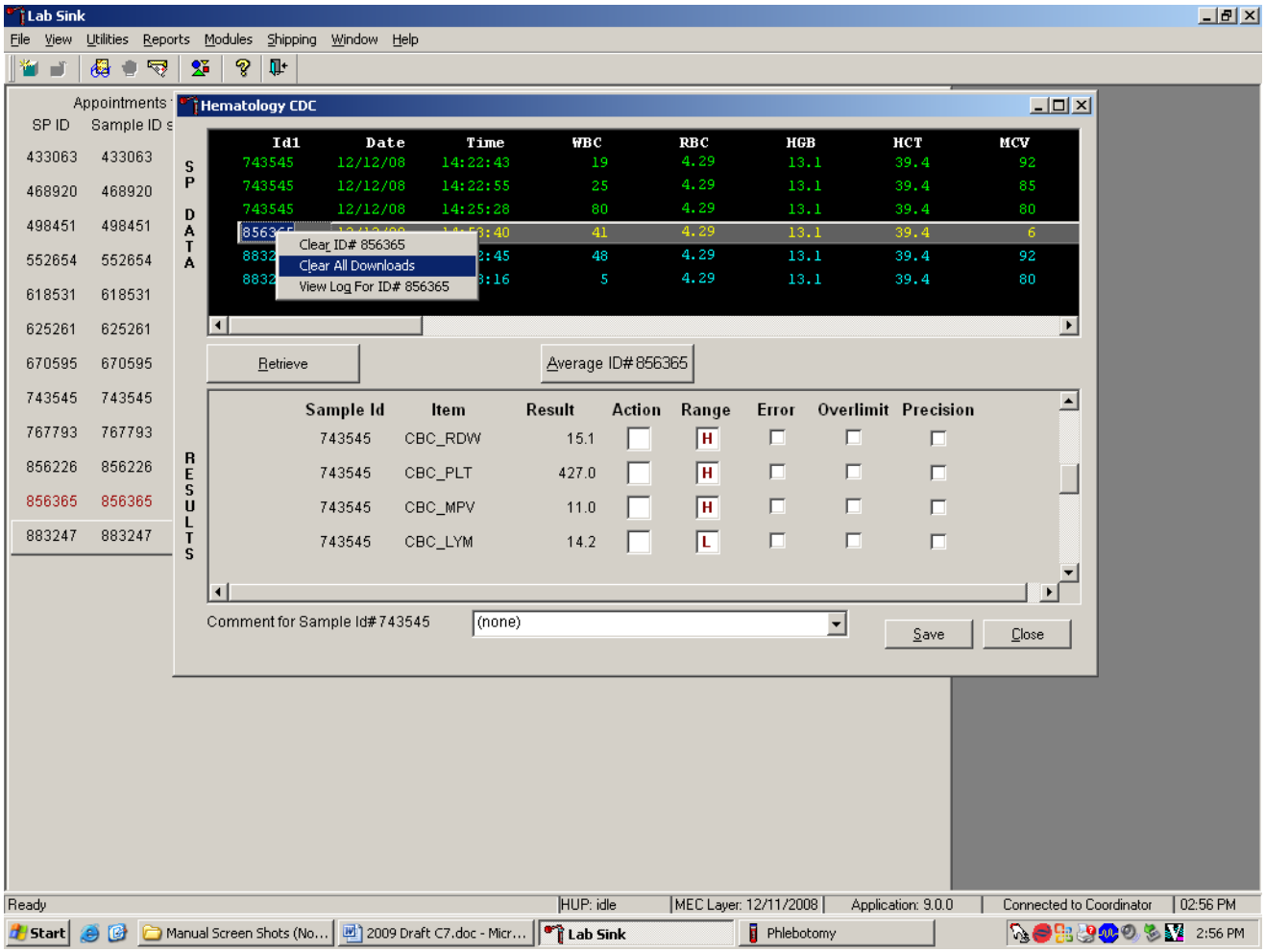
Average the results for one SP at a time.

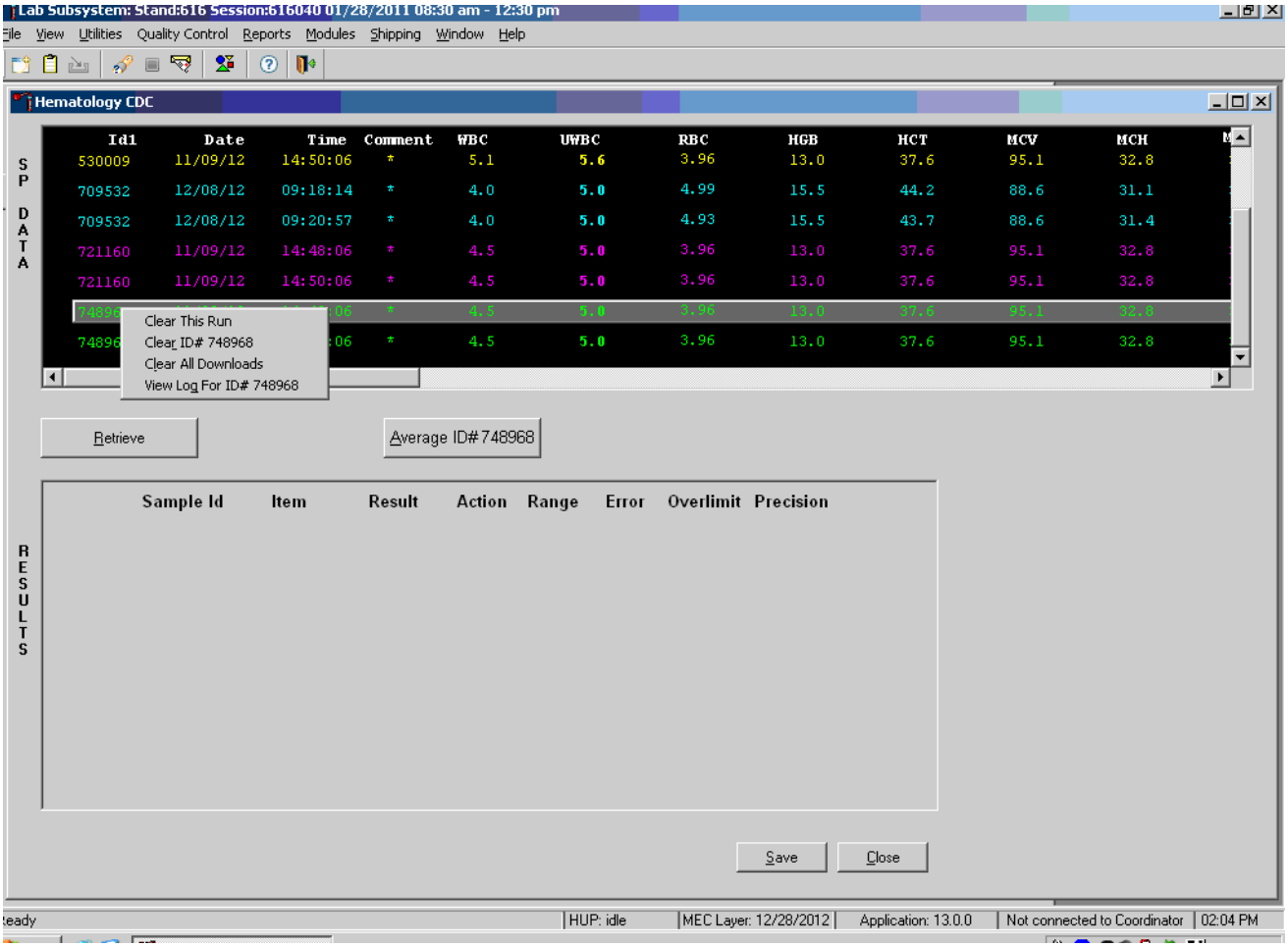


Evaluate each parameter for error, over limit, and precision checkmarks, and "H" or "L" action limit and reference range flags. If there are no checkmarks in the Precision column (no precision limit was exceeded), save the result to the database. To save the result to the database, direct the mouse arrow to the Save button and left-click. To exit without saving the result to the database, direct the mouse arrow to the Close button and left-click. If there are any precision checkmarks, run a 6C cell control, evaluate the control results, rerun the blood tube a third time, re-average, evaluate, and save the results.

Use alternative data manipulation choices as desired.

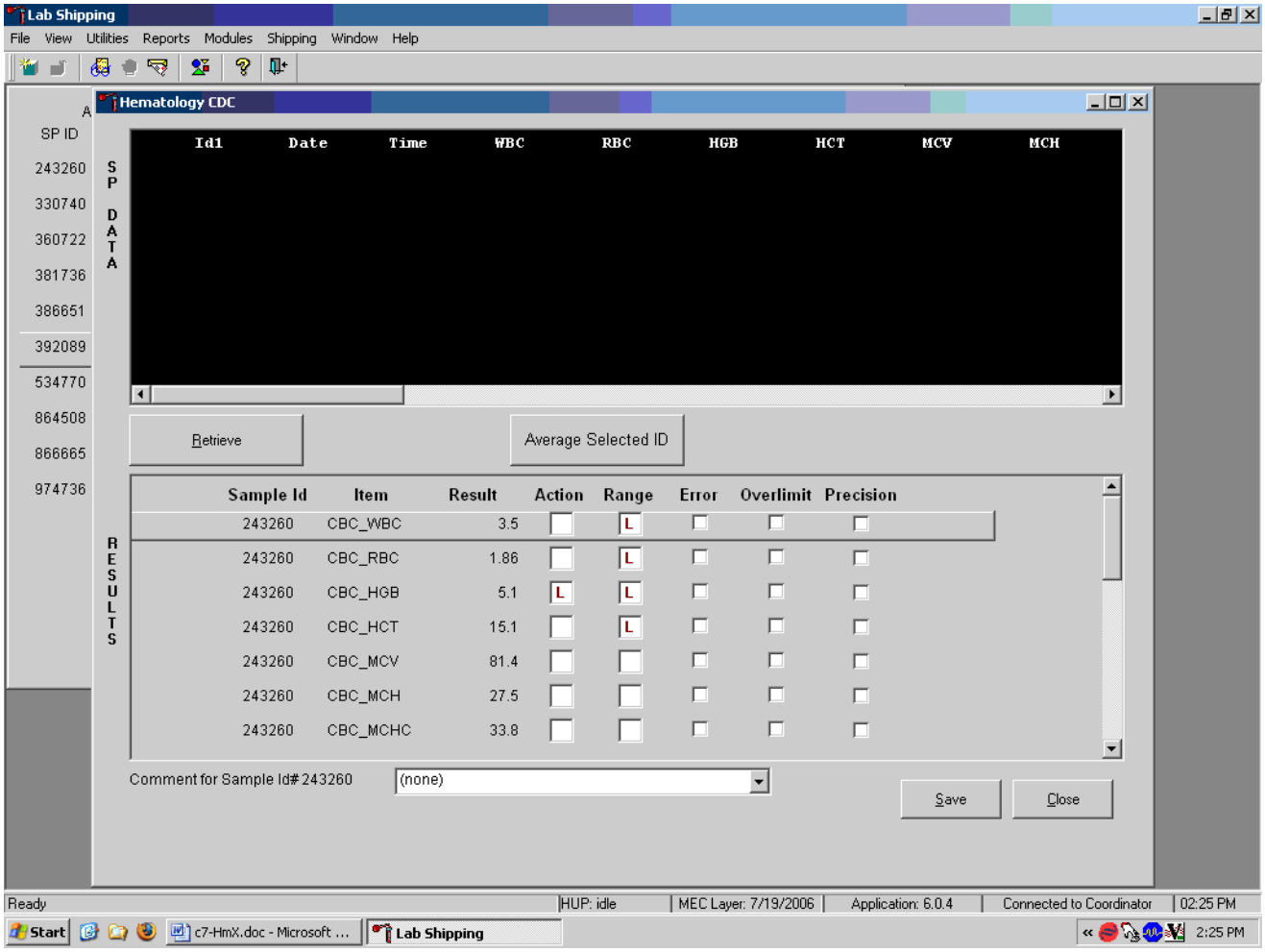
Use the "Clear All Downloads" function to delete all data for all SPs in the SP Data section.





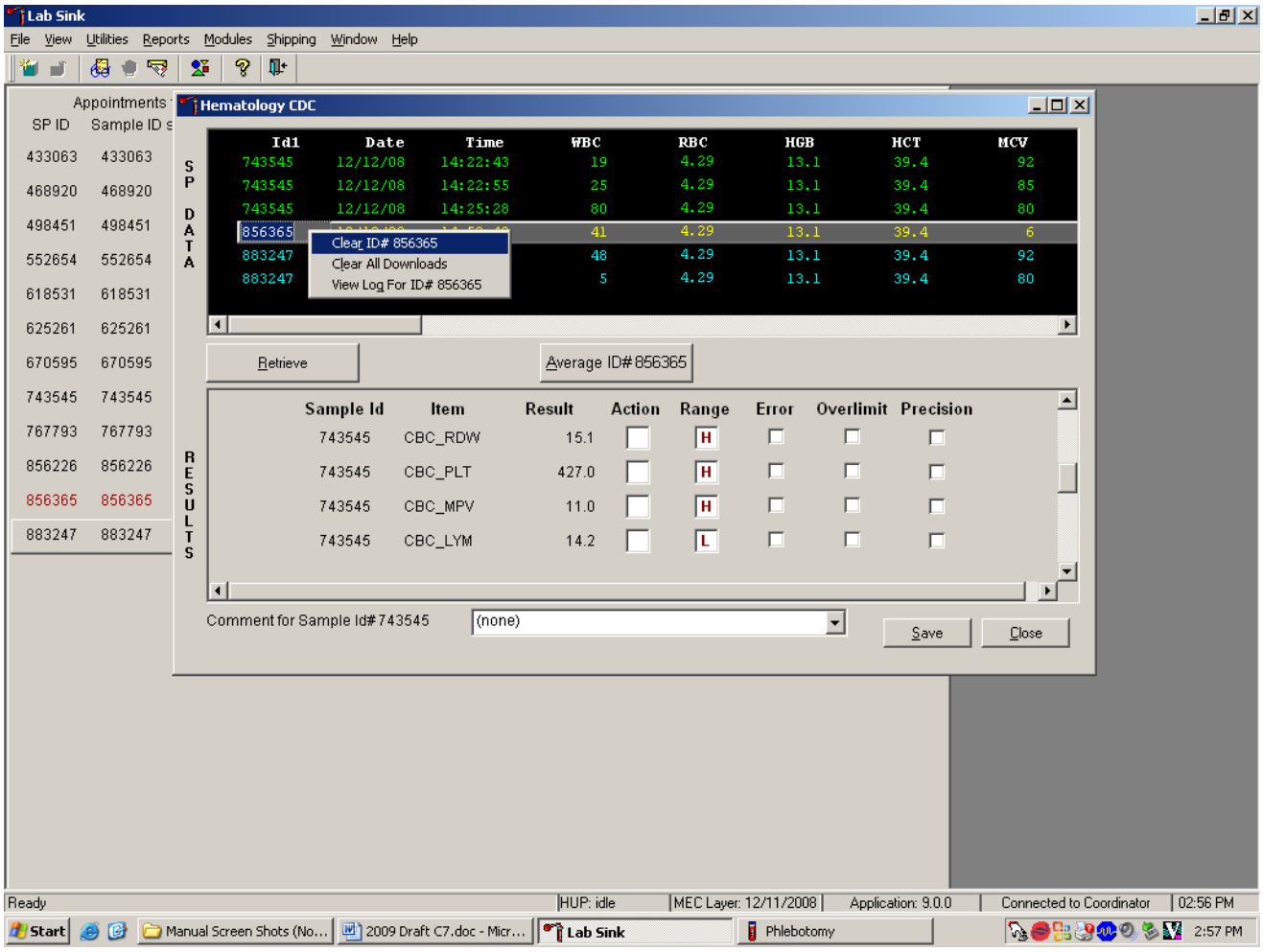
To clear all downloads from the SP Data section, direct the mouse arrow to any row in the SP Data section and right-click to display the alternative data manipulation choices. To select "Clear All Downloads," drag the mouse arrow to the Clear All Downloads choice and left-click.

Release the mouse button to clear all downloads.



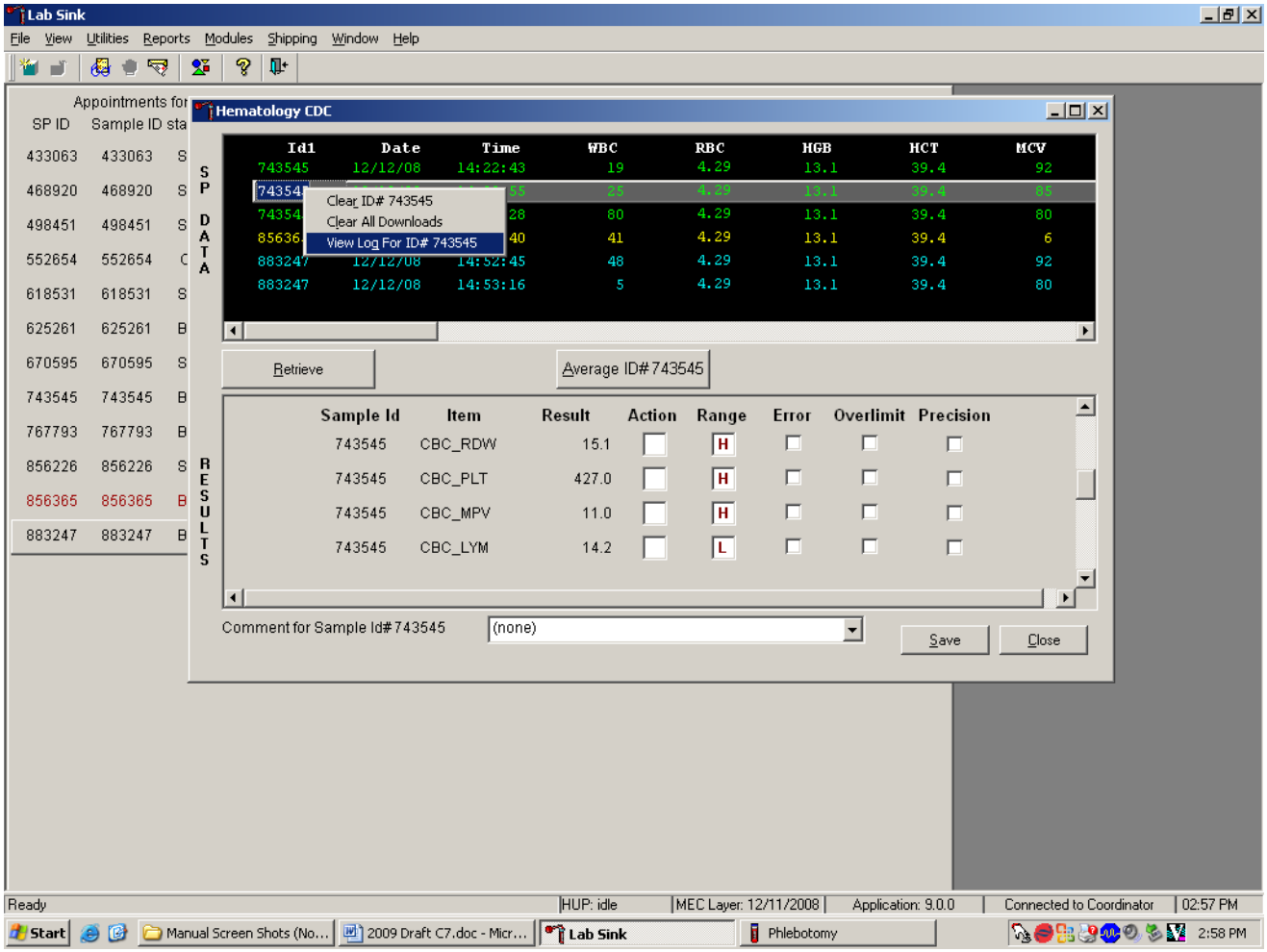
All data in the SP Data section are erased, but any averaged result remains in the Results section of the window. To clear the result section, close the Hematology module. To close the Hematology module, direct the mouse arrow to the Close button and left-click.

Use the data manipulation functions to erase or delete one SP's data in the SP Data section.



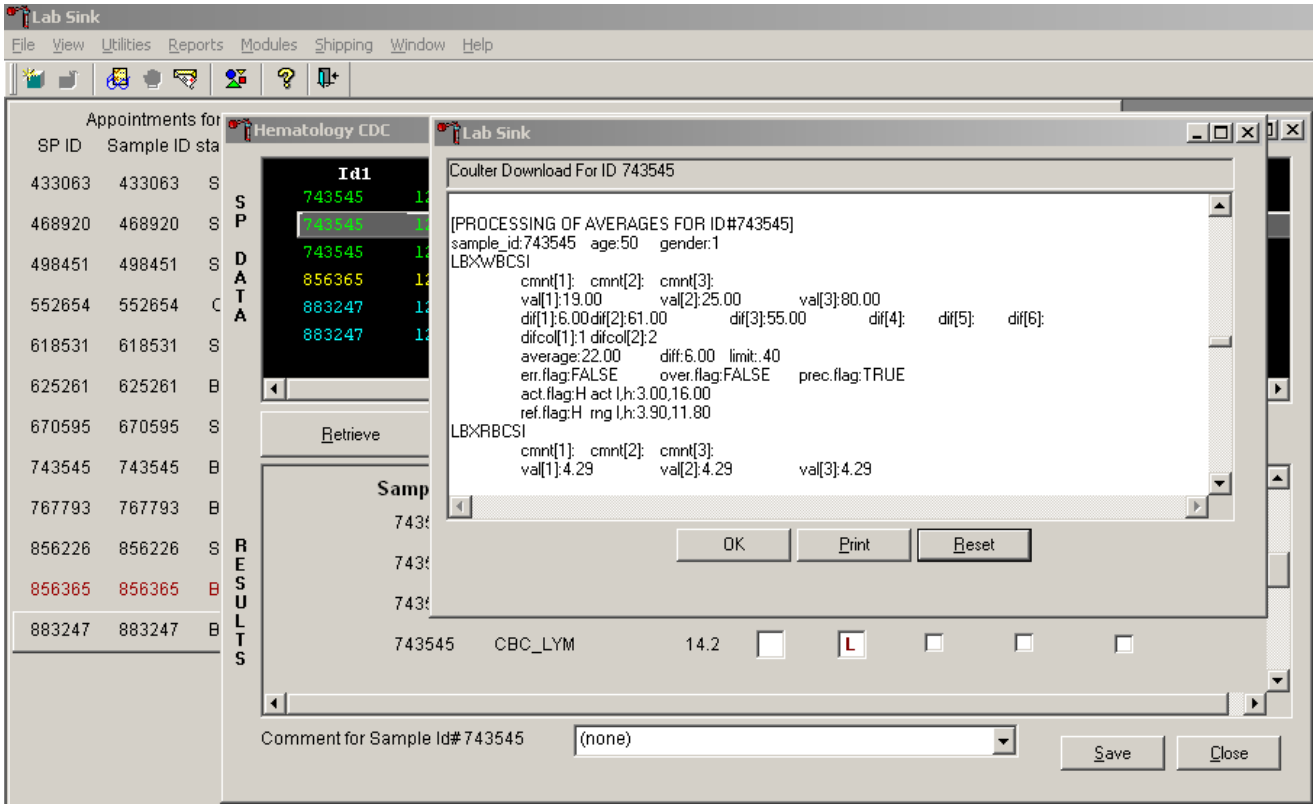
To clear the Coulter downloads for any one SP, direct the mouse arrow to the individual row in the SP Data section, right-click to display the alternative data manipulation choices, drag the mouse arrow to Clear ID#*XXXXXX*, and right- or left-click. Release the mouse button to clear this download. Retransmit, retrieve, average, and save the data.

Use the "View Log for ID# *XXXXXX*" choice to view all Coulter data, averages, and precision limit values for any SP.



To view the detailed log for any one SP's result, direct the mouse arrow to the individual row in the SP Data section and right-click to display the alternative data manipulation choices. Drag the mouse arrow to "View Log for ID*XXXXXX*" and release the mouse button to view the detailed log for this SP's results.

Review the SP's log.



The SP's log contains detailed information for each parameter and each run. When finished reviewing the information, direct the mouse arrow to the OK button to close the window. To print the log, drag the mouse arrow to the Print button and left-click. To clear the log and close the screen, direct the mouse arrow to the Reset button and left-click, or select Enter.

1.19.3 DxH 800 Suspect Messages

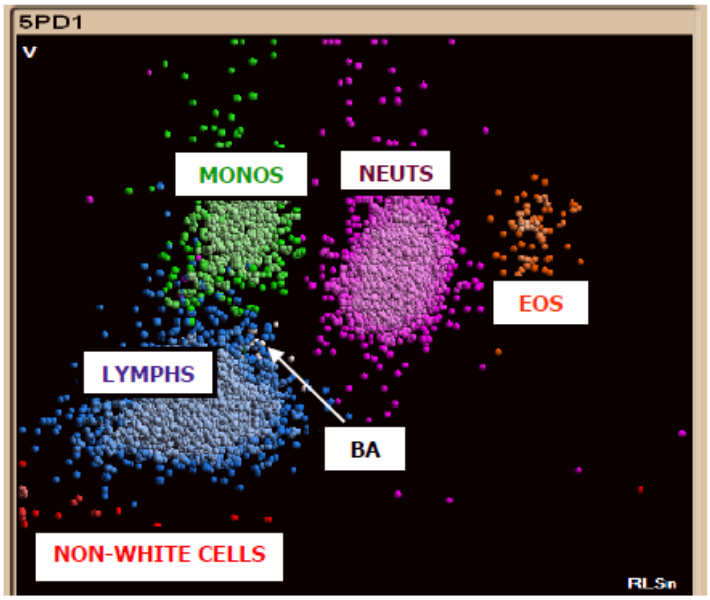
Suspect messages flag an abnormal cell distribution or population. The system generates these messages according to an internal algorithm. Specific suspect messages indicate some abnormalities that exhibit characteristic cluster patterns. Suspect messages indicate the possibility of a particular abnormality. Not every atypical scatterplot has a corresponding suspect message.

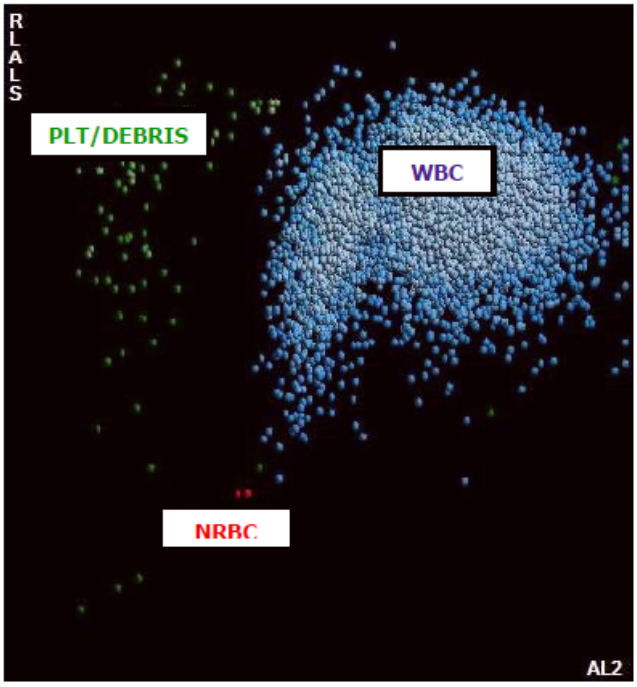
1.19.3.1 **Remedial Action.** Rerun the specimen. If the flag is "H&H Does Not Match," use the SP's EDTA sample from processing station, if available, as a check for proper tube filling. Delete all but two runs if flags are consistent, before averaging and accepting results.

1.19.4 DxH 800 Histogram Interpretations

Exhibit 6-12 presents UniCel DxH 800 Coulter cellular analysis system cell population.

Exhibit 6-12. Cellular analysis images





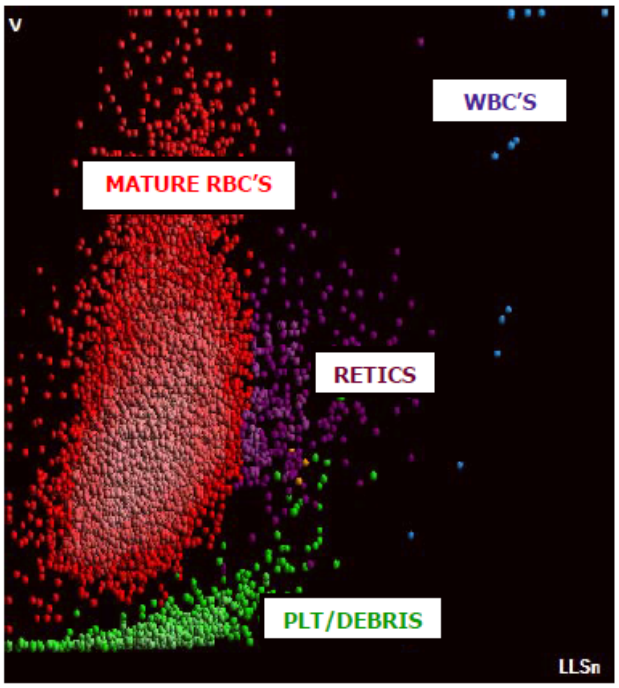


Exhibit 1-13 presents DxH system messages.

Exhibit 1-13. DxH system messages

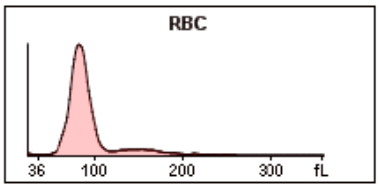
All System messages are accompanied by "R" (Review) flags. Exceptions are the System Messages associated with an Aspiration error (P Flag) and the Non-Blood Specimen message (N Flag).

SYSTEM MESSAGE DXH		SYSTEM MESSAGE DXH
WBC		**PLT**
Abn WBC Pattern		Platelet Clumps
Cellular Inter		PLT Carryover
System Event: WBC		PLT Inter: Debris
WBC Carryover		RBC-PLT Overlap
RBC		System Event: PLT
Abn RBC Pattern		**NRBC**
System Event: RBC		Abn NRBC Pattern
HGB		AL2 Blank Volt: N
HGB Inter: WBC		DataDisc: N
HGB Blank Shift		High Event Rate: N
System Event: HGB		Low AL2 Events: N
MCV		Low DC Events: N
MCV Inter: PLT		Low Event Rate: N
MCV Inter: WBC		Low Events: N
DIFF		NRBC Inter
Abn Diff Pattern		NRBC-LY Overlap
Aged Sample		System Event: N
Data Disc: D		**BF**
Excessive Debris: D		Abn TNC Pattern
High Event Rate: D		System Event: TNC
High OP Events: D		TNC Carryover
High RF Events: D		**P**
Low Event Rate: D		Bubbles
Low Events: D		Carryover
Low OP Events: D		No Aspiration
Low RMALS Events: D		Non-blood Specimen
MO-NE Overlap		Partial Aspiration
NE-EO Overlap		Range Error
System Event: D		Unknown Error
Undefined Pop: D		**::::: Code**
RETIC		Flow Cell Clog: D
Abn Retic Pattern		Flow Cell Clog: N
AL2 Blank Volt: R		Flow Cell Clog: R
Data Disc: R		
High Event: R		
Low Event: R		
Nucleated Cells		
RET Inter: Debris		
RET Inter: PLT		
RET-RBC Overlap		
System Event: R		

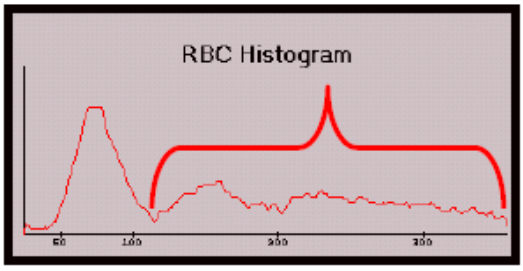
Exhibits 1-14, 1-15, 1-16, and 1-17 respectively present red blood cell histogram examples, white blood cell histogram examples, platelets histogram examples, and an image of better abnormal cell detection.

Exhibit 1-14. Red blood cell histogram examples

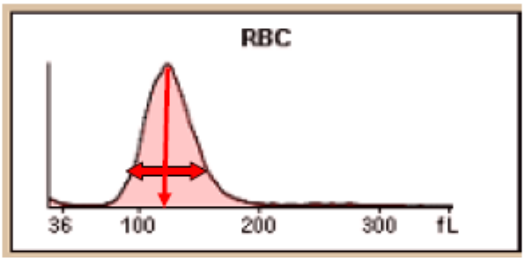
RBC Histogram Examples



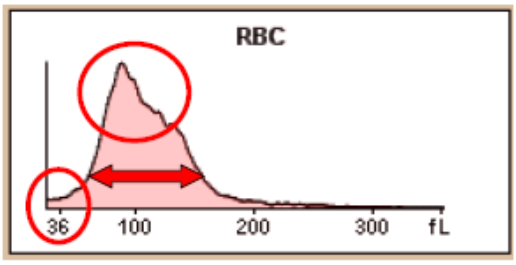
NORMAL



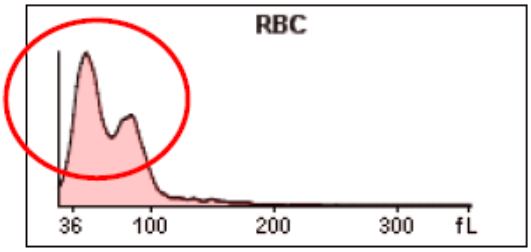
RBC AGGLUTININ



MACROCYTIC, Elevated RDW



RBC Fragments / DI RBC / Elevated RDW



DI RBCs, RBC Frags, Elevated RDW

Exhibit 1-15. White blood cell histogram examples

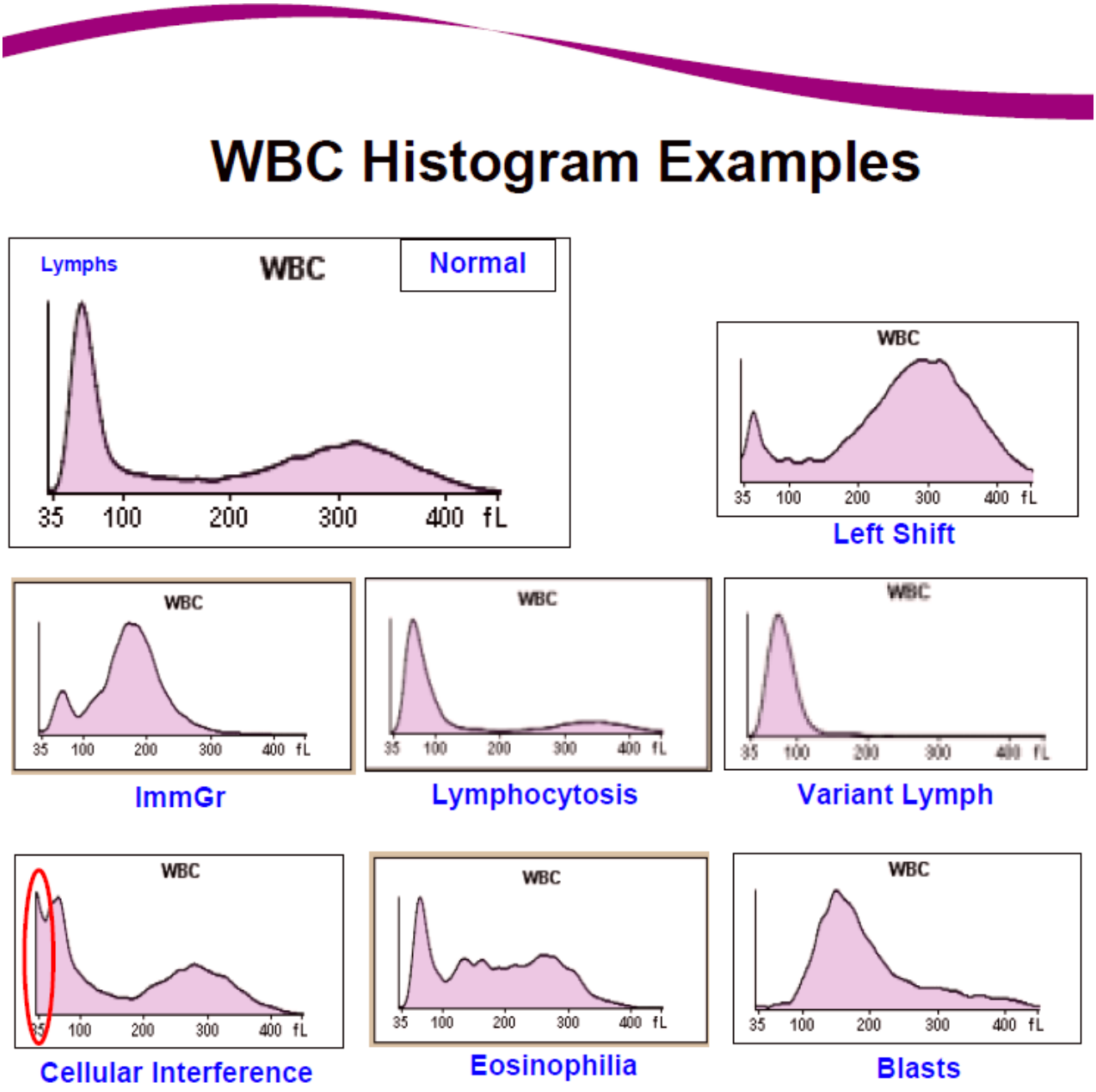
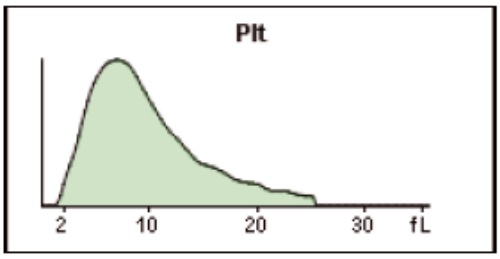


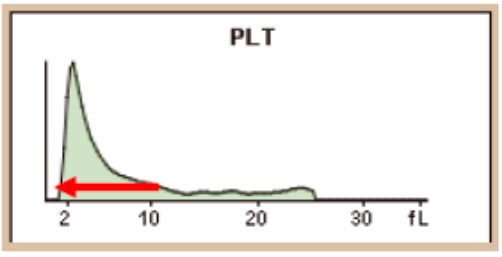
Exhibit 1-16. Platelets histogram examples

PLT Histogram Examples

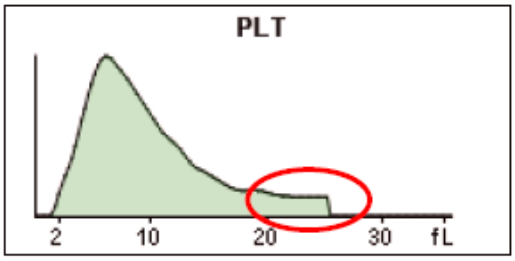
Normal



Small Platelets



Giant Platelets



RBC/PLT Overlap

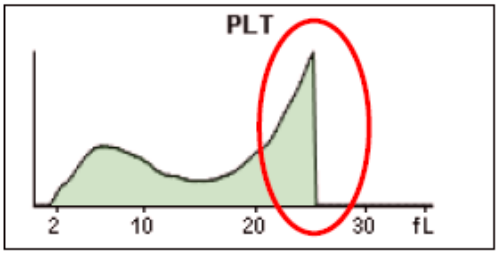
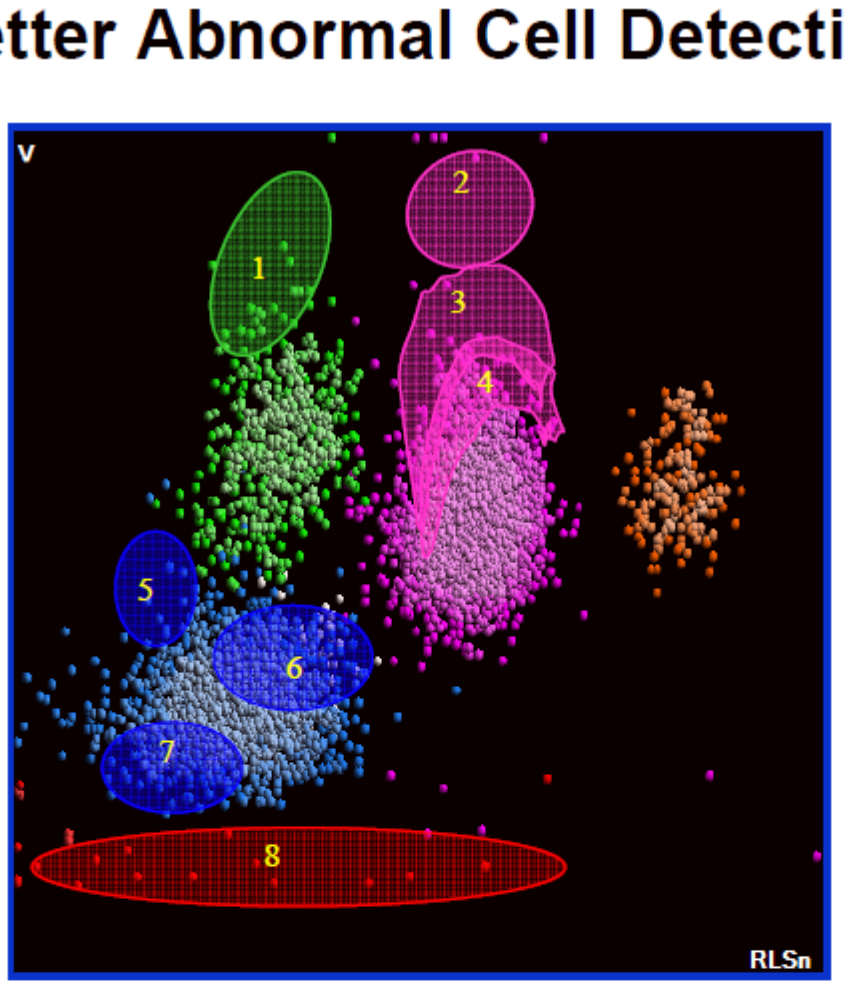
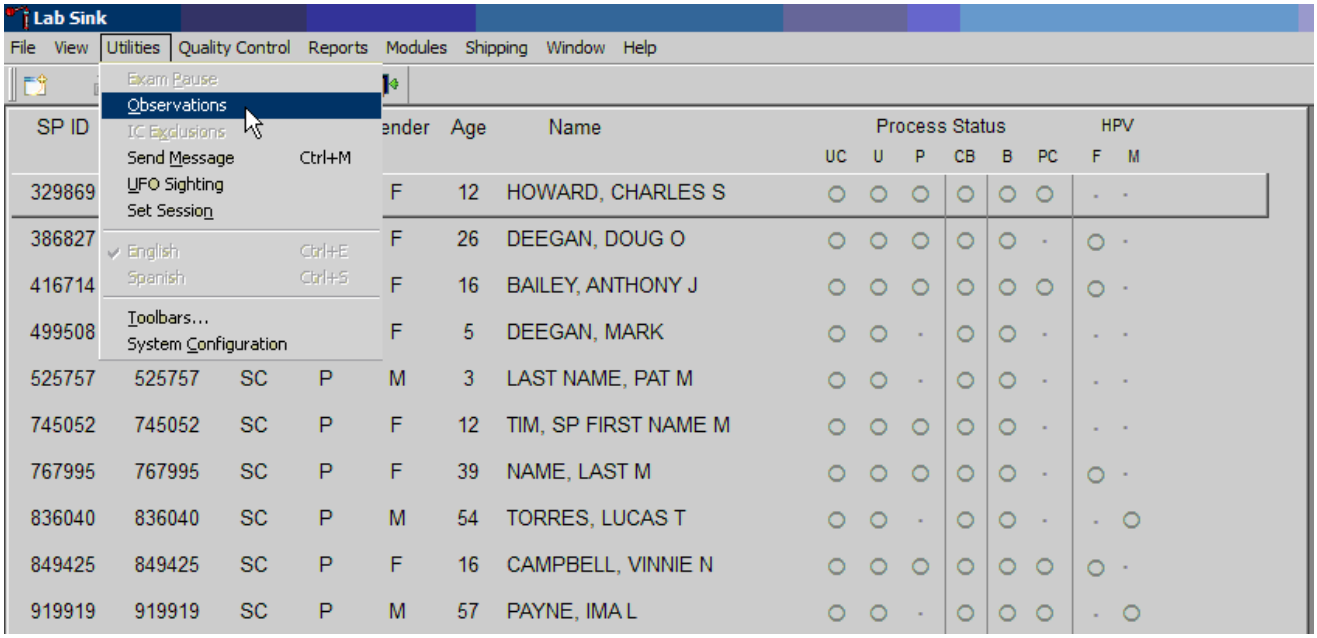


Exhibit 1-17. Image of better abnormal cell detection

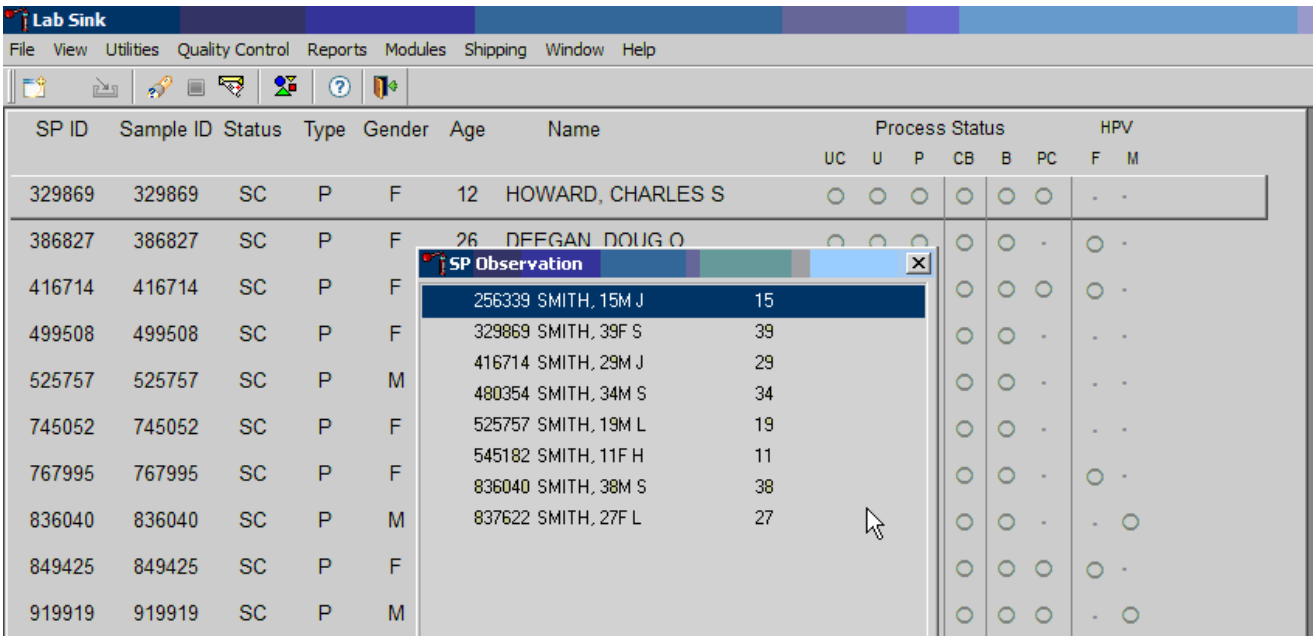


1.19.5 Clinician Review

The MEC clinician reviews and interprets all CBC results. Results outside action limits flash and transmit to the clinician immediately. The clinician determines if referral for the SP for treatment is necessary. The clinical laboratory scientist sends an observation to the clinician whenever a critical or action limit is detected for any CBC parameter.

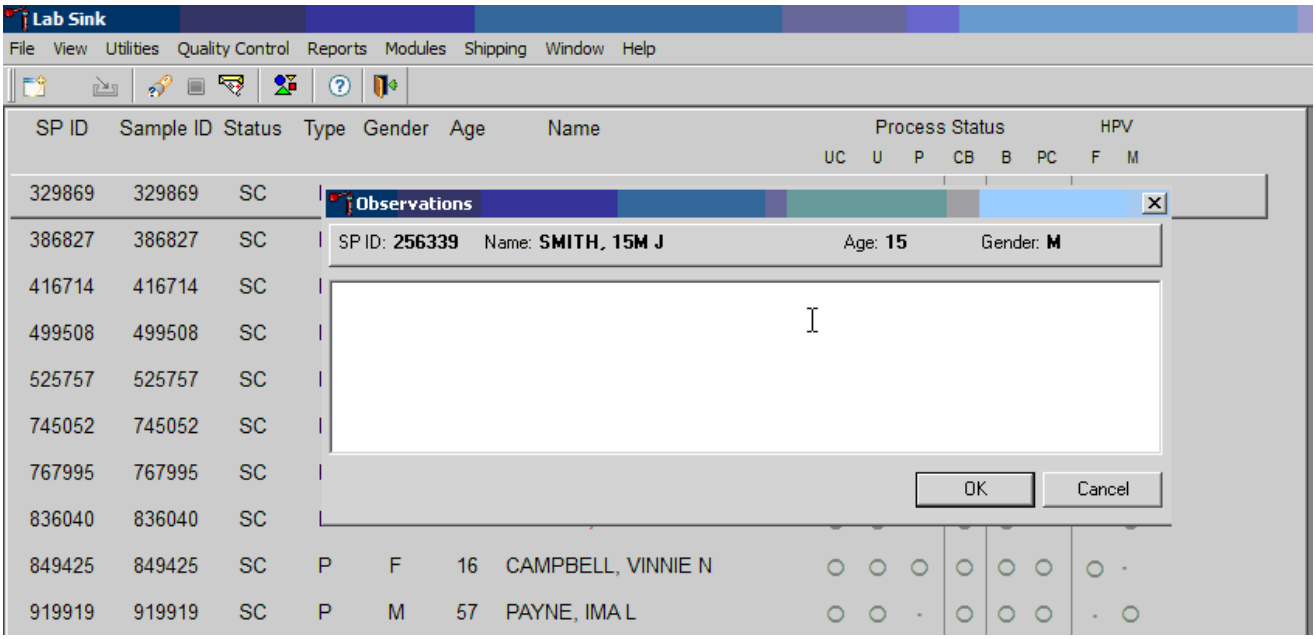


To access the observation function, direct the mouse arrow to Utilities in the menu bar, left-click, drag the mouse arrow to Observations, and left-click. Select or highlight the correct SP.



To select or highlight an SP, drag the mouse arrow to the correct SP and left-click or use the keyboard arrows to move up and down the list. Verify that the SP ID, name, and age are correct. Use the scroll bar to view the complete list of SPs. To continue, direct the mouse arrow to the OK button and left-click, or select Enter. To cancel these actions and exit the observation function, direct the mouse arrow to the Cancel button and left-click.

The observation window displays.



The observation window contains the SP ID, name, age, and gender. Type the observation using the keyboard. To send the observation to the clinician, direct the mouse arrow to the OK button and left-click, or select Enter. To cancel these actions or to exit the observation window without entering an observation, direct the mouse arrow to the Cancel button and left-click.

Enter the observation on an SP.

Document the date, time, responsible laboratory individual, person notified, and test results, including the parameter.

1.20 Limitations of Method: Specimen Rejection, Interfering Substances, and Conditions

This method limits samples to human whole blood.

1.20.1 Specimen Rejection

Reject clotted specimens and recollect if clinician requests.

1.20.2 Interfering Substances and Conditions

Because the Coulter directly measures RBC, WBC, Hgb, and Diff percent, it is most important to concentrate on analytes and substances that interfere with these parameters. The Coulter calculates HCT, MCH, MCHC, and DIFF # parameters. The Coulter derives MCV, RDW, PLT, and MPV from RBC or platelet histograms. The following are possible interfering substances or conditions:

- Abnormal BUN, glucose, or sodium levels could affect the MCV.
- Abnormal WBCs could affect lymphocytes, monocytes, and granulocytes.
- Abnormally small WBCs could affect white count, lymphocytes, monocytes, and granulocytes.
- Clumped platelets could affect white count, lymphocytes, monocytes, granulocytes, RBC, MCV, RDW, platelet count, and MPV.
- Cryofibrinogen and cryoglobulin crystals could affect white count, lymphocytes, monocytes, granulocytes, RBC, hemoglobin, platelet count, and MPV.
- An elevated WBC count could affect RBC, hemoglobin, MCV, RDW, platelet count, and MPV parameters.
- Fragile WBCs could affect white count, lymphocytes, monocytes, granulocytes, platelet count, and MPV.
- Giant platelets could affect white count, lymphocytes, monocytes, granulocytes, RBC, MCV, RDW, platelet count, and MPV.
- Hemolyzed specimens could affect RBC, hemoglobin, platelet count, and MPV.
- Lipemic specimens could affect MCV.
- Severely icteric plasma causes increased hemoglobin.
- Nucleated RBCs could affect the white count, lymphocytes, monocytes, granulocytes, and hemoglobin values.

- **WBC –** certain unusual RBC abnormalities that resist lysing, nucleated RBCs, fragmented WBCs, agglutinated WBCs, any unlysed particles greater than 35 fL, very large or aggregated platelets as when anticoagulated with oxalate or heparin, specimens containing fibrin, cell fragments, or other debris such as pediatric and oncology specimens.

- **RBC –** very high WBC count, high concentration of very large platelets, agglutinated RBCs, RBCs smaller than 36 fL, specimens containing fibrin, cell fragments, or other debris such as pediatric and oncology specimens.

- **Hgb –** very high WBC count, severe lipemia, heparin, certain unusual RBC abnormalities that resist lysing, or anything that increases the turbidity of the sample such as elevated levels of triglycerides.

- **MCV –** very high WBC count, high concentration of very large platelets, agglutinated RBCs, RBC fragments that fall below the 36-fL threshold, or rigid RBCs.

- **RDW –** very high WBC count, high concentration of very large or clumped platelets as in blood anticoagulated with oxalate or heparin, RBCs below the 36-fL threshold, two distinct populations of RBCs, RBC agglutinates, or rigid RBCs.

- **Plt –** very small red blood cells near the upper threshold, cell fragments, clumped platelets as with oxalate or heparin, platelet fragments, or cellular debris near the lower platelet threshold.

- **MPV –** known factors that interfere with the Plt count and shape of the histogram or known effects of EDTA.

- **Hct –** known factors that interfere with the parameters used for computation: RBC and MCV.

- **MCH –** known factors that interfere with the parameters used for computation: Hgb and RBC.

- **MCHC –** known factors that interfere with the parameters used for computation: Hgb, RBC, and MCV.

- Diff Parameters – known factors that affect the WBC count as listed above or high triglycerides that affect lysing.

1.21 Reference Ranges

Tables 1-5 and 1-6 respectively present references ranges for blood cell counts for males and females, by age.

Table 1-5. Reference ranges (males)

	1-5		6-18		19-65		66+	
Age in years	2.5	97.5	2.5	97.5	2.5	97.5	2.5	97.5
White blood cell count (SI)	4.3	14.6	3.6	11.5	3.9	11.8	3.8	12.1
Red cell count (SI)	3.98	5.3	4.14	5.78	4.18	5.86	3.57	5.67
Hemoglobin (g/dl)	10.7	14.2	11.9	16.9	13.1	17.5	11.4	17.1
Hematocrit (%)	32.1	41.7	35.3	49.9	38.7	51.4	33.9	50.9
Mean cell volume (fL)	68.2	88.8	75.6	94.6	79.8	99.1	81.4	102.7
Mean cell hemoglobin (pg)	22.3	30.6	25.0	32.3	26.3	34.0	26.3	35.0
MCHC (g/dl)	32.3	35.6	32.3	35.3	32.3	35.3	32.1	35.1
Red cell distribution width (%)	11.4	15.8	11.4	14.0	11.4	14.5	11.8	16.2
Platelet count (%) SI	212	546	179	439	152	386	124	384
Mean platelet volume (fL)	6.1	8.9	6.6	10	6.8	10.1	6.6	10.2
Nucleated red blood cells	0.1	8.3	0	0.6	0	0.6	0	0.6
Lymphocyte percent (%)	22.8	68.4	17.5	54.3	16.1	47.9	12.3	46.4
Lymphocyte Absolute	1.0	10.0	0.6	6.2	0.6	5.7	0.5	5.6
Monocyte percent (%)	4.6	15.2	4.8	13.7	4.4	13.5	4.6	14.0
Monocyte Absolute	0.2	2.2	0.2	1.6	0.0	1.6	0.2	1.7
Segmented neutrophils percent (%)	17.6	67.1	30.3	72.8	37.8	74.6	39.5	78.1
Segmented Neutrophils Absolute	0.8	9.8	1.1	8.4	1.5	8.8	1.5	9.5
Eosinophils percent (%)	0.7	11.3	0.7	11.5	0.7	8.5	0.6	8.8
Eosinophils Absolute	0.0	1.6	0.0	1.3	0.0	1.0	0.0	1.1
Basophils percent (%)	0.1	2.5	0.1	1.6	0.1	1.6	0.1	1.6
Basophils Absolute	0.0	0.4	0.0	0.2	0.0	0.2	0.0	0.2

Table 1-6. Reference ranges (females)

	1-5		6-18		19-65		66+	
Age in years	2.5	97.5	2.5	97.5	2.5	97.5	2.5	97.5
White blood cell count (SI)	4.3	14.0	3.9	12.2	4.1	12.9	4.0	11.6
Red cell count (SI)	3.96	5.28	3.84	5.24	3.64	5.2	3.51	5.34
Hemoglobin (g/dL)	11.0	14.2	11.2	15.1	10.6	15.6	10.9	15.9
Hematocrit (%)	32.5	41.9	33.5	44.6	32.0	45.9	32.8	47.0
Mean cell volume (fL)	70.2	89.1	74.7	94.9	74.6	98.2	80.3	100.6
Mean cell hemoglobin (pg)	23.3	30.8	24.5	32.6	24.3	33.8	26.4	34.5
MCHC (g/dl)	32.4	35.5	32.3	35.3	32.1	35.3	32.3	35.1
Red cell distribution width (%)	11.3	15.4	11.3	14.8	11.4	16.3	11.6	16.3
Platelet count (%) SI	215	547	190	446	168	441	155	428
Nucleated red blood cell (/100 WBC)	0.1	8.3	0	0.3	0	0.3	0	0.3
Mean platelet volume (fL)	6.1	8.9	6.6	10.0	6.8	10.2	6.7	10.5
Lymphocyte percent (%)	21.6	68.8	17.2	54.7	14.1	47.6	13.7	46.9
Lymphocyte Absolute	0.9	9.6	0.7	6.7	0.6	6.1	0.5	5.4
Monocyte percent (%)	4.2	14.4	4.3	12.7	3.8	11.6	4.4	12.8
Monocyte Absolute	0.2	2.0	0.2	1.5	0.2	1.5	0.2	1.5
Segmented neutrophils percent (%)	19.4	69.5	31.9	74.3	39.8	78.1	40.9	78.1
Segmented Neutrophils Absolute	0.8	9.7	1.2	9.1	1.6	10.1	1.6	9.1
Eosinophils percent (%)	0.6	9.9	0.6	9.9	0.6	7.3	0.6	7.5
Eosinophil Absolute	0.0	1.4	0.0	1.2	0.0	0.9	0.0	0.9
Basophils percent (%)	0.1	2.5	0.1	1.6	0.1	1.7	0.1	1.7
Basophils Absolute	0.0	0.4	0.0	0.2	0.0	0.2	0.0	0.2

Reference ranges for normal values were calculated from the NHANES data set (1999–2004) using 95 percent reference interval(s) determined nonparametrically, through ranking the observations and determining the lower (2.5th percentile) and the upper (97.5th percentile) reference limits. The nonparametric (ranking) method was used because most measured hematology parameters have a skewed, non-Gaussian distribution.

1.22 Action Limits

Action limits are a guide to inform the clinician that a CBC result(s) is/are abnormal. Since all specimens are run in duplicate, there is no reason to retest the sample.

- **WBC male and female (all ages)** **< or = to 3 x 10^3 µL or>or = to 16.0 x 10^3 µL**
- **Hgb male and female (<6 years)** **<6.5 g/dl or >14.5 g/dl**
- **Hgb female (>6 years)** **<6.5 g/dl or >16.0 g/dl**
- **Hgb male (>6 years)** **<6.5 g/dl or >18.0 g/dl**
- **PLT male and female (all ages)** **<50 x 10^3 µL or >800 x 10^3 µL**

Possible causes of abnormal parameters:

- High RBC, Hgb, or HCT—dehydration, polycythemia, shock, chronic hypoxia;
- Low RBC, Hgb, or HCT—anemia, thalassemia, and other hemoglobinopathies;
- Low MCV—microcytic anemia;
- High MCV—macrocytic anemia, liver disease;
- Low WBC—sepsis, marrow hypoplasia;
- High WBC—acute stress, infection, malignancies;
- Low platelets—risk of bleeding; and
- High platelets—risk of thrombosis.

1.23 Specimen Storage and Handling During Testing

Specimen storage:

- Store specimens capped and place on a rocker at room temperature until processed. If specimens are not analyzed during the session due to excessively high room temperature, place all specimens in a biohazard bag and place bag in a cabinet of a cool room. Retrieve from this area when specimens can be run—then mix the specimens well before running.
- Run within 24 hours of drawing.

1.24 Alternative Method for Performing Test or Storing Specimens if Test System Fails

There is no alternative method for this test. Store EDTA tube at room temperature for no more than 24 hours. Restore the instrument to functionality and then run the specimen after thorough mixing.

1.25 Test Results Reporting System: Protocol for Reporting Action Limits

Results outside the action limits are brought to the clinician's attention by sending the clinician an observation and requesting a decision on "course-to-follow."

All records, including QA/QC data, will be maintained for 6 years. Use only numerical identifiers for SP results.

1.26 Quality Control Summary Statistics and Graphs

Chapter 10 includes a separate detailed description of the comprehensive quality control plan. Monitor 6C cell control results for bias and maintain results for the entire study period. Compare all three instruments using the CAP proficiency results.

1.27 Troubleshooting

If the background fails:

1.27.1 If WBC, RBC, Plt fails—zap apertures, prime sweep flow several times, shutdown as last resort.

1.27.2 If Differential fails—flush the flow cell.

1.27.3 If Hgb fails—clean BSV, Prime CBC Module, perform Hgb blank verification, Shutdown.

If the Latron fails:

- D or N(AI2) and/or D or N(Lals) out—unlock DV x 3, flush flow cell x 3.

1.28 Setting Shift Times

From Main Screen>Click on X with Bar over it (top Menu)>XB setup(Bottom screen)>"Shifts" Tab>In "Multiple Shifts" type 08:00:00 in shift one start box>Type in 13:00:00 in Shift 2 box>Type in 23:00:00 in Shift 3 box >The "to" boxes will auto fill >Save.

1.29 Reference

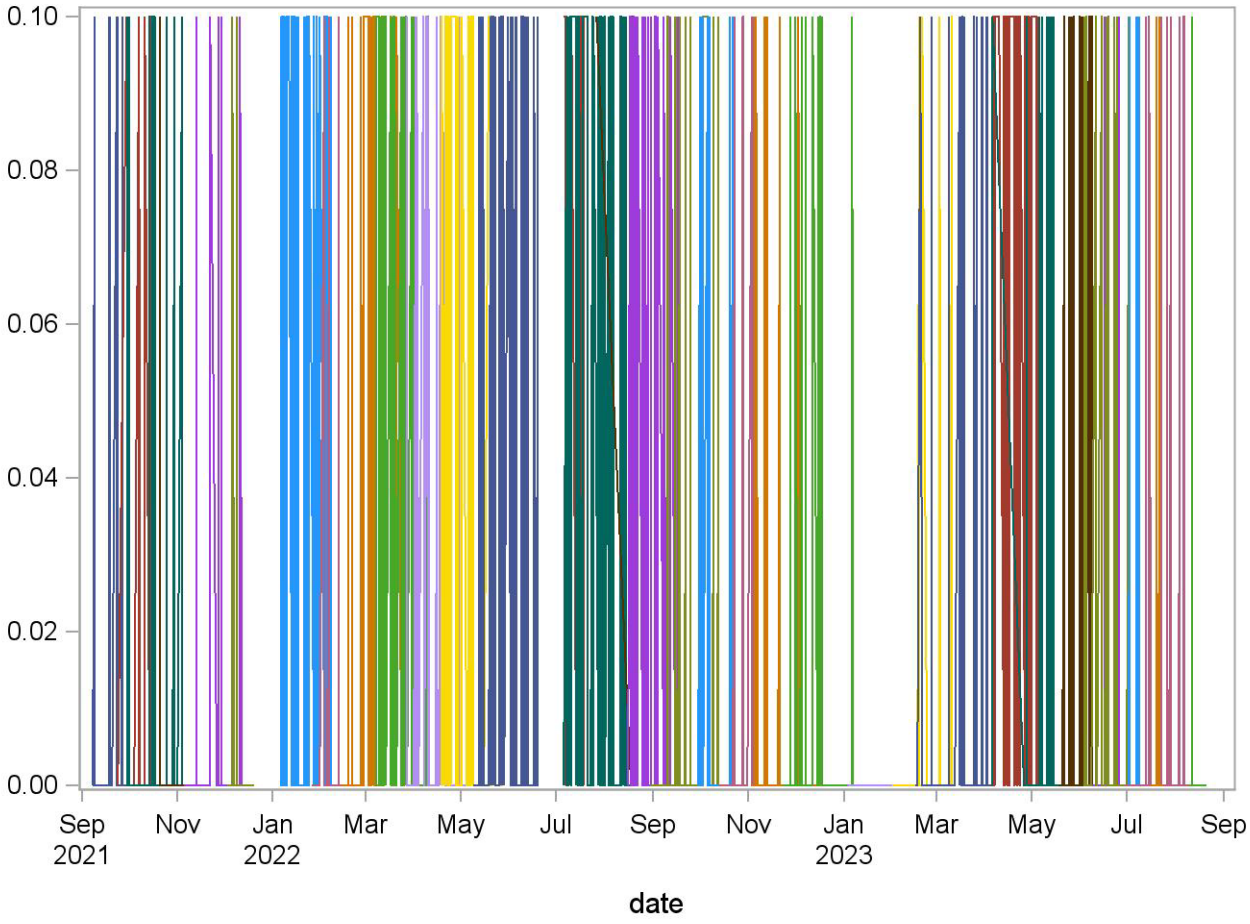
UniCe11 DxH 800 Coulter Cellular Analysis System Instructions for Use. Beckman Coulter, Inc. Fullerton, CA 92835. www.BeckmanCoulter.com

1.30 Summary Statistics and QC Graph

Please see following pages.

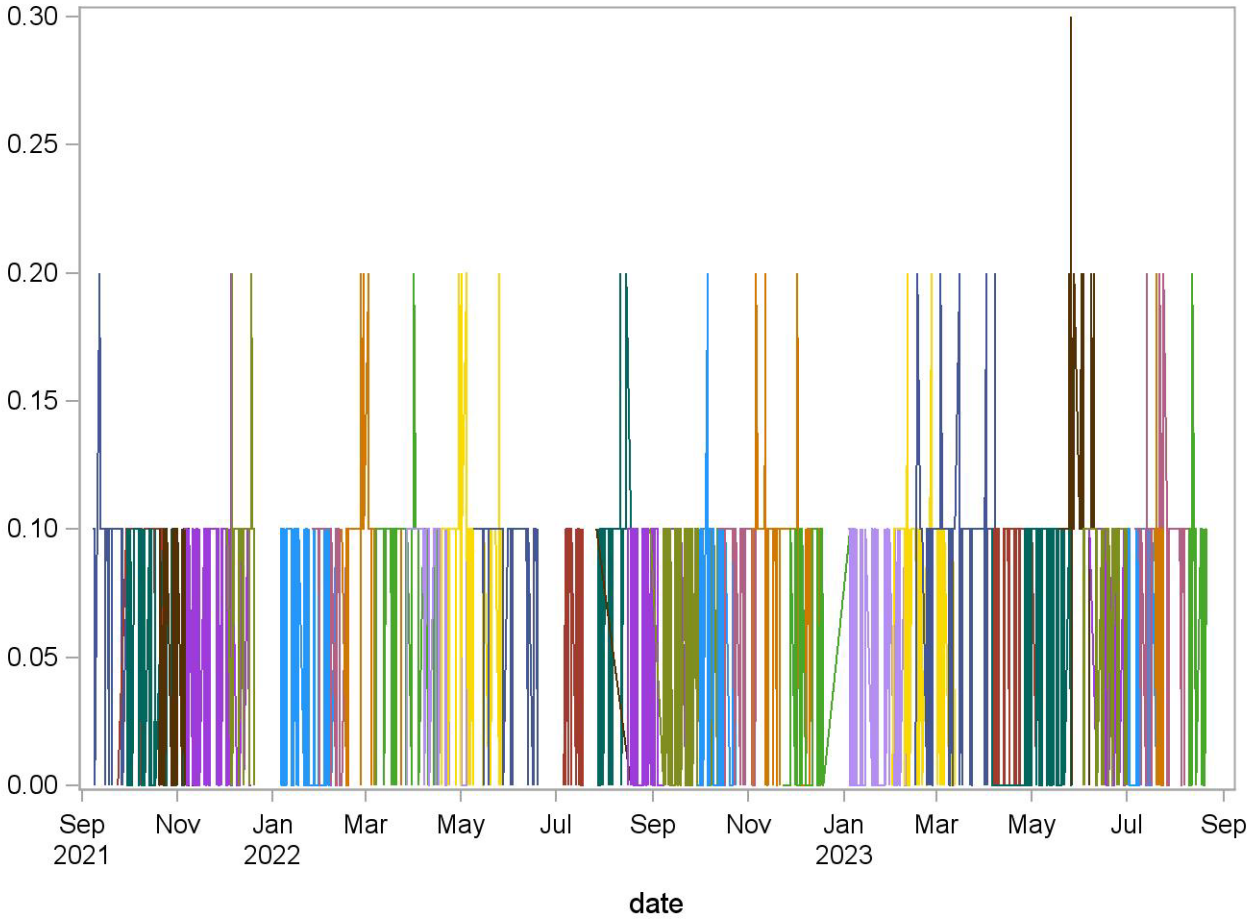
August 2021 – August 2023 Summary Statistics and QC Chart
LBCBAP1 (Basophils (%) (Lvl 1))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
12317388	48	08SEP21	03OCT21	0.0146	0.0357	244.6
12317389	54	24SEP21	23OCT21	0.0111	0.0317	285.5
12317393	107	30SEP21	06NOV21	0.0112	0.0317	282.7
12317395	56	20OCT21	14NOV21	0.0018	0.0134	748.3
12317399	142	05NOV21	18DEC21	0.0035	0.0185	525.3
12317402	41	03DEC21	20DEC21	0.0049	0.0218	447.1
12317408	127	06JAN22	11FEB22	0.0362	0.0483	133.2
12317412	52	26JAN22	19FEB22	0.0058	0.0235	408.1
12317416	131	14FEB22	25MAR22	0.0237	0.0427	180.3
12317418	85	08MAR22	16APR22	0.0318	0.0468	147.4
12317423	77	28MAR22	06MAY22	0.0221	0.0417	189.1
12317426	90	19APR22	28MAY22	0.0367	0.0485	132.2
12317431	78	09MAY22	19JUN22	0.0346	0.0479	138.3
12317435	32	06JUL22	19JUL22	0.0625	0.0492	78.7
12317439	126	06JUL22	18AUG22	0.0381	0.0488	128.0
12317440	12	27JUL22	21AUG22	0.0333	0.0492	147.7
12317444	130	16AUG22	25SEP22	0.0208	0.0407	196.1
12317448	116	30AUG22	13OCT22	0.0112	0.0317	282.7
12317451	66	30SEP22	24OCT22	0.0136	0.0346	253.6
12317457	67	13OCT22	06NOV22	0.0090	0.0288	321.3
12317460	146	03NOV22	18DEC22	0.0075	0.0265	351.5
12317463	54	23NOV22	08JAN23	0.0185	0.0392	211.7
12317468	132	04JAN23	12FEB23	0.0000	0.0000	.
12317472	87	01FEB23	13MAR23	0.0069	0.0255	369.6
12317475	136	16FEB23	08APR23	0.0140	0.0348	249.1
12317480	122	06APR23	07MAY23	0.0631	0.0484	76.8
12317483	108	06APR23	27MAY23	0.0102	0.0304	298.3
12317485	87	18MAY23	10JUN23	0.0356	0.0482	135.2
12317490	65	03JUN23	02JUL23	0.0185	0.0391	211.8
12317489	51	07JUN23	07JUL23	0.0098	0.0300	306.3
12317494	73	30JUN23	11AUG23	0.0123	0.0331	268.5
12317491	57	02JUL23	21JUL23	0.0088	0.0285	325.4
12317495	28	16JUL23	24JUL23	0.0071	0.0262	367.2
12317499	44	10AUG23	21AUG23	0.0023	0.0151	663.3


0.10
0.08
0.06
0.04
0.02
0.00
Sep
2021
Nov
Jan
2022
Mar
May
Jul
Sep
Nov
Jan
2023
Mar
May
Jul
Sep
date

August 2021 – August 2023 Summary Statistics and QC Chart
LBCBAP2 (Basophils (%) (Lvl 2))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
13318388	49	08SEP21	03OCT21	0.0796	0.0456	57.2
13318389	53	24SEP21	23OCT21	0.0774	0.0423	54.6
13318393	109	30SEP21	06NOV21	0.0339	0.0476	140.1
13318395	57	20OCT21	14NOV21	0.0456	0.0503	110.2
13318399	143	05NOV21	18DEC21	0.0490	0.0515	105.3
13318402	40	03DEC21	20DEC21	0.0900	0.0441	49.0
13318408	128	06JAN22	11FEB22	0.0484	0.0502	103.6
13318412	53	26JAN22	19FEB22	0.0774	0.0423	54.6
13318415	130	14FEB22	25MAR22	0.0915	0.0353	38.6
13318418	85	08MAR22	16APR22	0.0859	0.0383	44.6
13318423	80	28MAR22	06MAY22	0.0825	0.0382	46.3
13318426	89	19APR22	28MAY22	0.0899	0.0453	50.4
13318430	78	09MAY22	19JUN22	0.0885	0.0322	36.3
13318435	32	06JUL22	19JUL22	0.0594	0.0499	84.0
13318440	12	27JUL22	21AUG22	0.0583	0.0515	88.3
13318439	47	28JUL22	18AUG22	0.0872	0.0448	51.4
13318444	131	16AUG22	25SEP22	0.0641	0.0481	75.1
13318448	119	30AUG22	13OCT22	0.0655	0.0477	72.8
13318451	67	30SEP22	24OCT22	0.0463	0.0532	114.9
13318458	67	13OCT22	06NOV22	0.0791	0.0410	51.8
13318460	142	03NOV22	18DEC22	0.0859	0.0405	47.2
13318463	55	23NOV22	08JAN23	0.0382	0.0490	128.4
13318468	131	04JAN23	12FEB23	0.0305	0.0462	151.4
13318472	89	01FEB23	13MAR23	0.0753	0.0483	64.2
13318475	141	16FEB23	08APR23	0.0865	0.0435	50.2
13318480	127	06APR23	07MAY23	0.0780	0.0416	53.4
13318483	110	06APR23	27MAY23	0.0618	0.0488	79.0
13318485	86	18MAY23	10JUN23	0.1070	0.0400	37.4
13318490	66	03JUN23	02JUL23	0.0742	0.0441	59.4
13318489	52	07JUN23	07JUL23	0.0615	0.0491	79.8
13318491	57	02JUL23	21JUL23	0.0544	0.0503	92.4
13318494	66	06JUL23	11AUG23	0.0803	0.0503	62.6
13318495	28	19JUL23	24JUL23	0.0786	0.0568	72.3
13318499	45	10AUG23	21AUG23	0.0689	0.0514	74.7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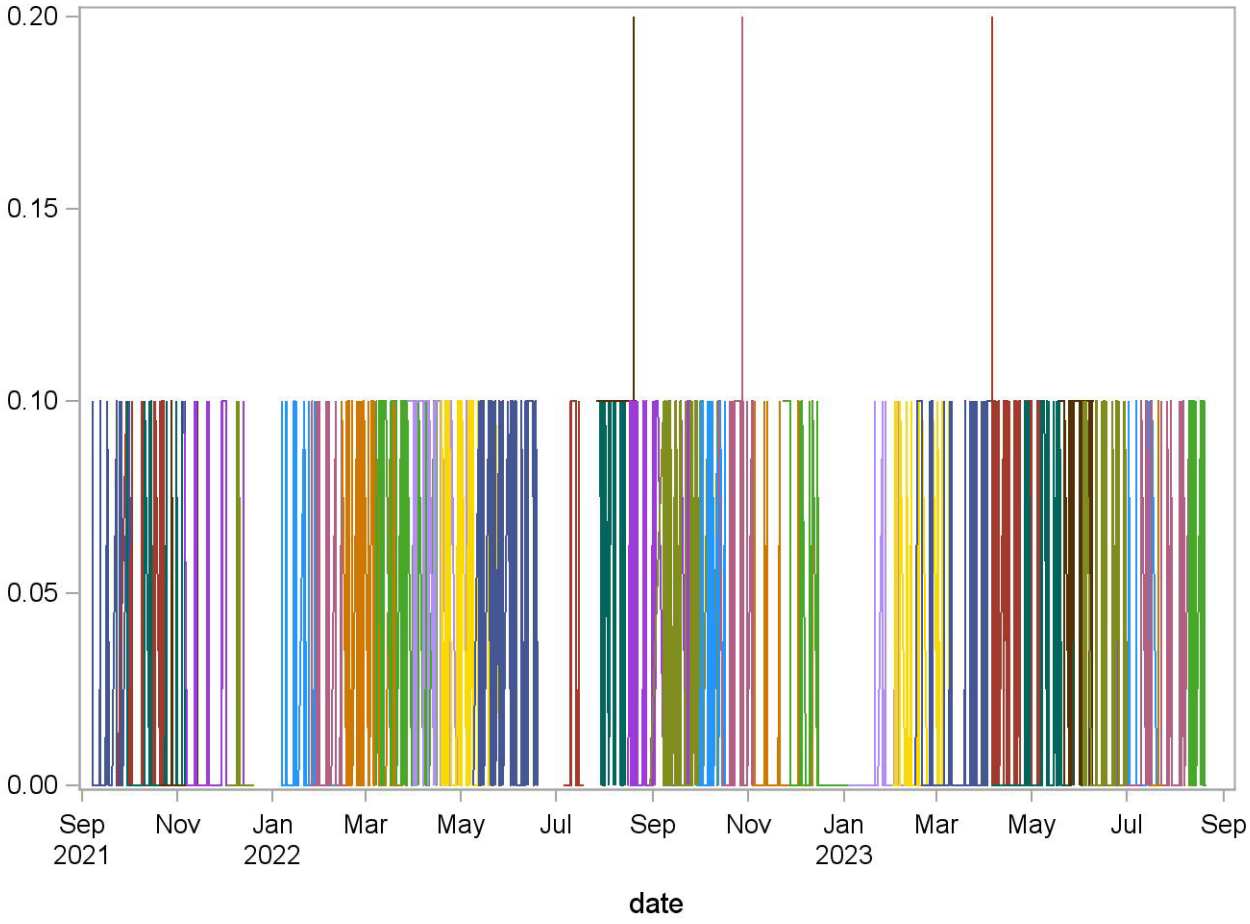
August 2021 – August 2023 Summary Statistics and QC Chart
LBCBAP3 (Basophils (%) (Lvl 3))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
14319388	50	08SEP21	03OCT21	0.0220	0.0418	190.2
14319389	53	24SEP21	23OCT21	0.0208	0.0409	197.3
14319393	109	30SEP21	06NOV21	0.0092	0.0290	316.1
14319395	56	20OCT21	14NOV21	0.0054	0.0227	424.1
14319399	141	05NOV21	18DEC21	0.0078	0.0269	345.0
14319402	41	03DEC21	20DEC21	0.0049	0.0218	447.1
14319408	128	06JAN22	11FEB22	0.0102	0.0303	298.6
14319412	53	26JAN22	19FEB22	0.0264	0.0445	168.5
14319416	131	14FEB22	25MAR22	0.0351	0.0479	136.5
14319418	85	08MAR22	16APR22	0.0600	0.0493	82.1
14319423	77	28MAR22	06MAY22	0.0675	0.0471	69.8
14319426	87	19APR22	28MAY22	0.0517	0.0503	97.2
14319430	78	09MAY22	19JUN22	0.0538	0.0502	93.2
14319435	32	06JUL22	19JUL22	0.0156	0.0369	236.1
14319440	12	27JUL22	21AUG22	0.0750	0.0622	82.9
14319439	45	28JUL22	15AUG22	0.0644	0.0484	75.1
14319445	133	16AUG22	25SEP22	0.0331	0.0472	142.8
14319448	116	30AUG22	13OCT22	0.0319	0.0468	146.8
14319451	70	30SEP22	24OCT22	0.0271	0.0448	165.0
14319457	67	13OCT22	06NOV22	0.0343	0.0509	148.3
14319460	144	03NOV22	18DEC22	0.0056	0.0230	413.7
14319463	54	23NOV22	08JAN23	0.0167	0.0376	225.7
14319468	130	04JAN23	12FEB23	0.0046	0.0211	456.4
14319472	87	01FEB23	13MAR23	0.0184	0.0390	211.9
14319475	136	16FEB23	08APR23	0.0243	0.0430	177.3
14319480	121	06APR23	07MAY23	0.0587	0.0511	87.1
14319483	110	06APR23	27MAY23	0.0173	0.0380	219.9
14319485	89	18MAY23	10JUN23	0.0685	0.0467	68.1
14319490	66	03JUN23	02JUL23	0.0318	0.0469	147.5
14319489	51	07JUN23	07JUL23	0.0098	0.0300	306.3
14319494	70	30JUN23	11AUG23	0.0271	0.0448	165.0
14319491	57	02JUL23	21JUL23	0.0211	0.0411	195.4
14319495	28	16JUL23	24JUL23	0.0107	0.0315	294.0
14319499	46	10AUG23	21AUG23	0.0304	0.0465	152.9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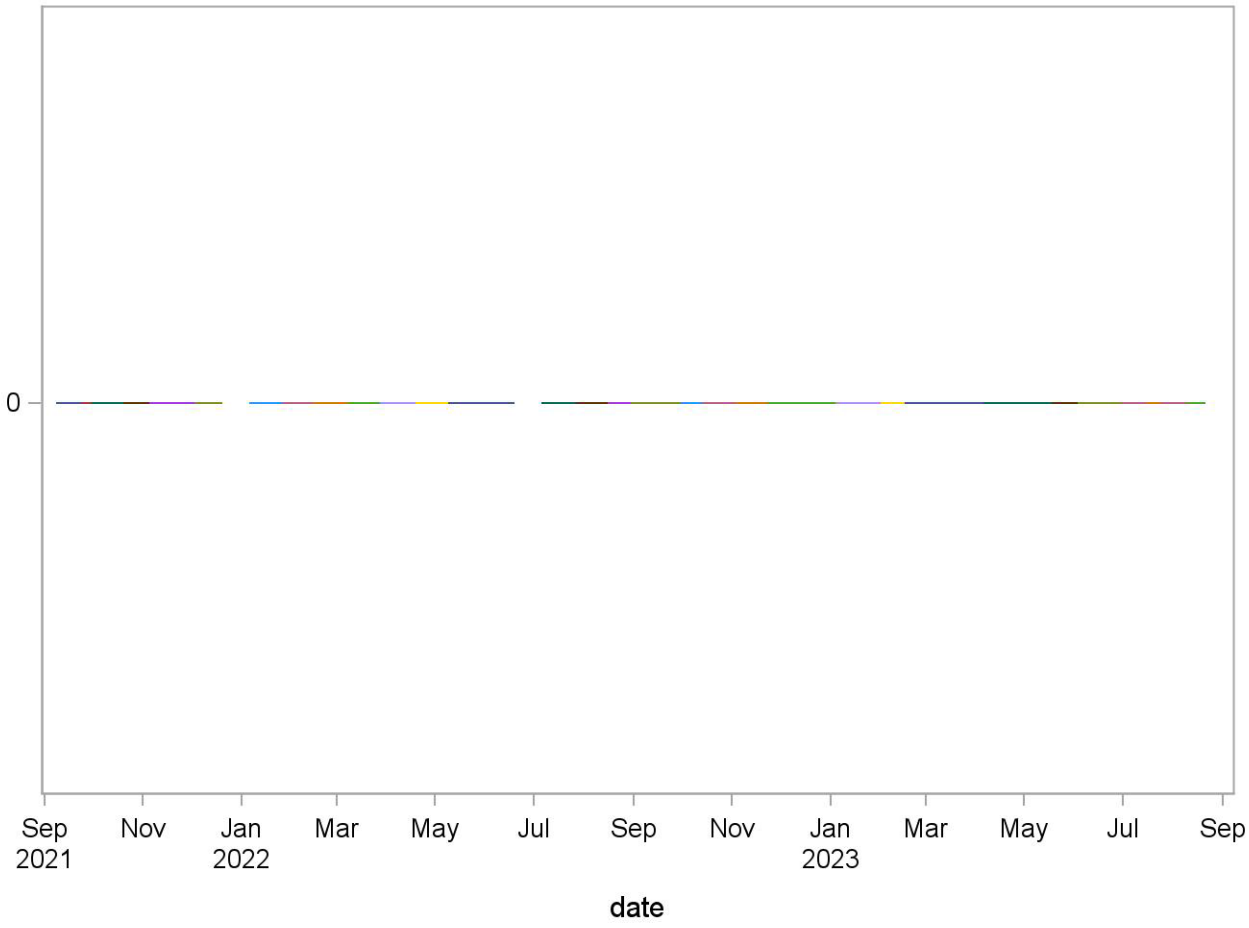
August 2021 – August 2023 Summary Statistics and QC Chart
LBCBAN1 (Basophils No.(10^3 cells/uL) (Lvl 1))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
12317388	48	08SEP21	03OCT21	0.0000	0.0000	.
12317389	54	24SEP21	23OCT21	0.0000	0.0000	.
12317393	107	30SEP21	06NOV21	0.0000	0.0000	.
12317395	56	20OCT21	14NOV21	0.0000	0.0000	.
12317399	142	05NOV21	18DEC21	0.0000	0.0000	.
12317402	41	03DEC21	20DEC21	0.0000	0.0000	.
12317408	127	06JAN22	11FEB22	0.0000	0.0000	.
12317412	52	26JAN22	19FEB22	0.0000	0.0000	.
12317416	131	14FEB22	25MAR22	0.0000	0.0000	.
12317418	85	08MAR22	16APR22	0.0000	0.0000	.
12317423	77	28MAR22	06MAY22	0.0000	0.0000	.
12317426	90	19APR22	28MAY22	0.0000	0.0000	.
12317431	78	09MAY22	19JUN22	0.0000	0.0000	.
12317435	32	06JUL22	19JUL22	0.0000	0.0000	.
12317439	126	06JUL22	18AUG22	0.0000	0.0000	.
12317440	12	27JUL22	21AUG22	0.0000	0.0000	.
12317444	130	16AUG22	25SEP22	0.0000	0.0000	.
12317448	116	30AUG22	13OCT22	0.0000	0.0000	.
12317451	66	30SEP22	24OCT22	0.0000	0.0000	.
12317457	67	13OCT22	06NOV22	0.0000	0.0000	.
12317460	146	03NOV22	18DEC22	0.0000	0.0000	.
12317463	54	23NOV22	08JAN23	0.0000	0.0000	.
12317468	132	04JAN23	12FEB23	0.0000	0.0000	.
12317472	87	01FEB23	13MAR23	0.0000	0.0000	.
12317475	136	16FEB23	08APR23	0.0000	0.0000	.
12317480	122	06APR23	07MAY23	0.0000	0.0000	.
12317483	108	06APR23	27MAY23	0.0000	0.0000	.
12317485	87	18MAY23	10JUN23	0.0000	0.0000	.
12317490	65	03JUN23	02JUL23	0.0000	0.0000	.
12317489	51	07JUN23	07JUL23	0.0000	0.0000	.
12317494	73	30JUN23	11AUG23	0.0000	0.0000	.
12317491	57	02JUL23	21JUL23	0.0000	0.0000	.
12317495	28	16JUL23	24JUL23	0.0000	0.0000	.
12317499	44	10AUG23	21AUG23	0.0000	0.0000	.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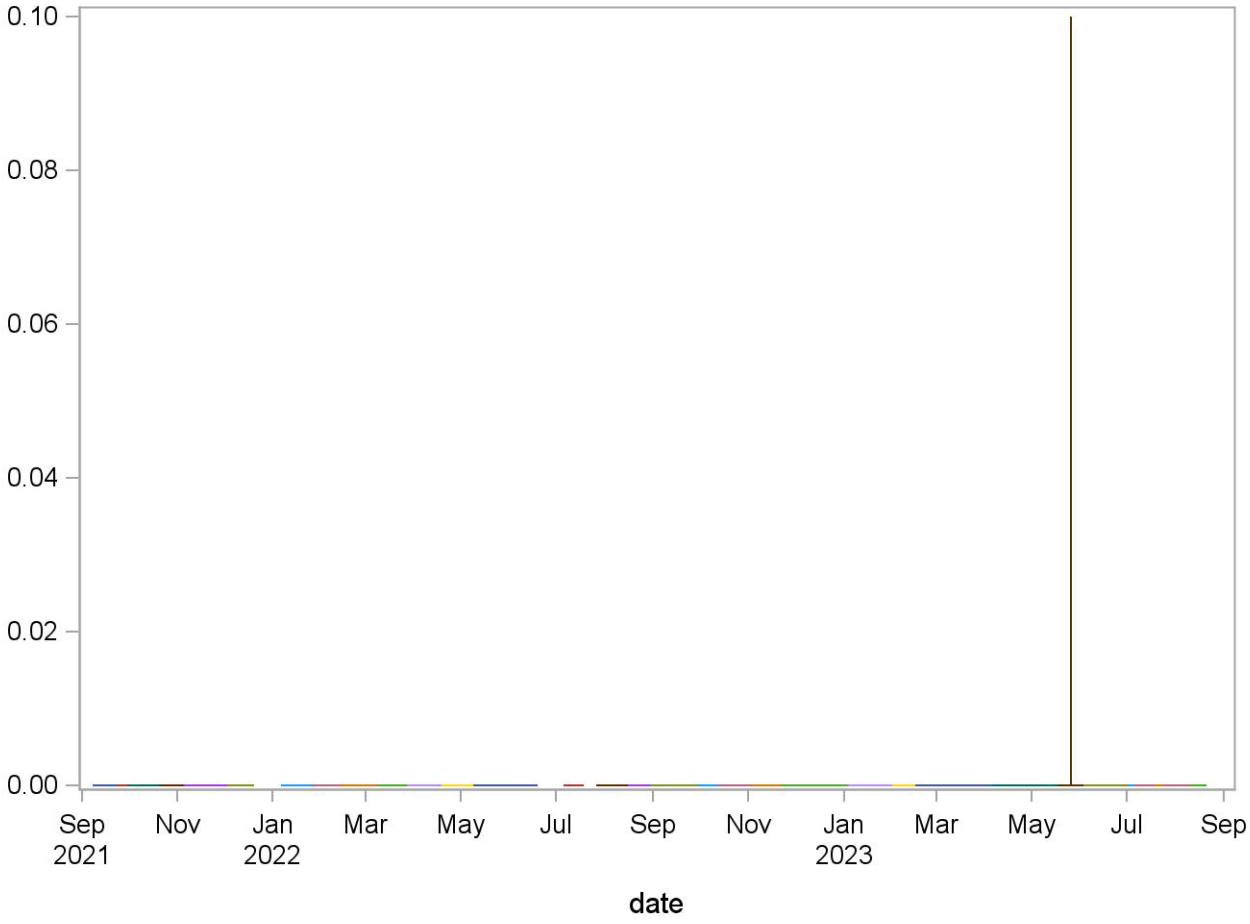
August 2021 – August 2023 Summary Statistics and QC Chart
LBCBAN2 (Basophils No.(10^3 cells/uL) (Lvl 2))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
13318388	49	08SEP21	03OCT21	0.0000	0.0000	.
13318389	53	24SEP21	23OCT21	0.0000	0.0000	.
13318393	109	30SEP21	06NOV21	0.0000	0.0000	.
13318395	57	20OCT21	14NOV21	0.0000	0.0000	.
13318399	143	05NOV21	18DEC21	0.0000	0.0000	.
13318402	40	03DEC21	20DEC21	0.0000	0.0000	.
13318408	128	06JAN22	11FEB22	0.0000	0.0000	.
13318412	53	26JAN22	19FEB22	0.0000	0.0000	.
13318415	130	14FEB22	25MAR22	0.0000	0.0000	.
13318418	85	08MAR22	16APR22	0.0000	0.0000	.
13318423	80	28MAR22	06MAY22	0.0000	0.0000	.
13318426	89	19APR22	28MAY22	0.0000	0.0000	.
13318430	78	09MAY22	19JUN22	0.0000	0.0000	.
13318435	32	06JUL22	19JUL22	0.0000	0.0000	.
13318440	12	27JUL22	21AUG22	0.0000	0.0000	.
13318439	47	28JUL22	18AUG22	0.0000	0.0000	.
13318444	131	16AUG22	25SEP22	0.0000	0.0000	.
13318448	119	30AUG22	13OCT22	0.0000	0.0000	.
13318451	67	30SEP22	24OCT22	0.0000	0.0000	.
13318458	67	13OCT22	06NOV22	0.0000	0.0000	.
13318460	142	03NOV22	18DEC22	0.0000	0.0000	.
13318463	55	23NOV22	08JAN23	0.0000	0.0000	.
13318468	131	04JAN23	12FEB23	0.0000	0.0000	.
13318472	89	01FEB23	13MAR23	0.0000	0.0000	.
13318475	141	16FEB23	08APR23	0.0000	0.0000	.
13318480	127	06APR23	07MAY23	0.0000	0.0000	.
13318483	110	06APR23	27MAY23	0.0000	0.0000	.
13318485	86	18MAY23	10JUN23	0.0012	0.0108	927.4
13318490	66	03JUN23	02JUL23	0.0000	0.0000	.
13318489	52	07JUN23	07JUL23	0.0000	0.0000	.
13318491	57	02JUL23	21JUL23	0.0000	0.0000	.
13318494	66	06JUL23	11AUG23	0.0000	0.0000	.
13318495	28	19JUL23	24JUL23	0.0000	0.0000	.
13318499	45	10AUG23	21AUG23	0.0000	0.0000	.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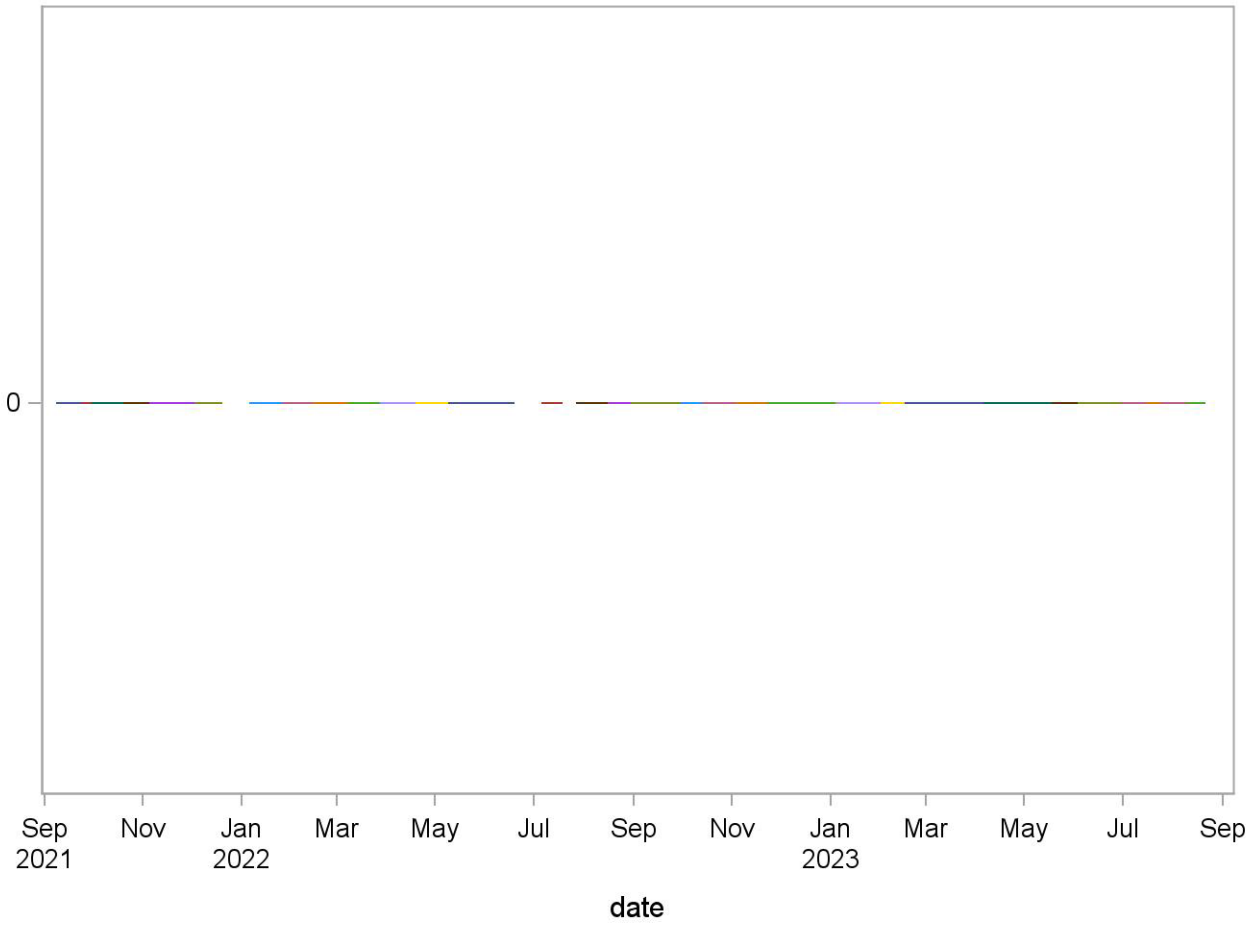
August 2021 – August 2023 Summary Statistics and QC Chart
LBCBAN3 (Basophils No.(10^3 cells/uL) (Lvl 3))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
14319388	50	08SEP21	03OCT21	0.0000	0.0000	.
14319389	53	24SEP21	23OCT21	0.0000	0.0000	.
14319393	109	30SEP21	06NOV21	0.0000	0.0000	.
14319395	56	20OCT21	14NOV21	0.0000	0.0000	.
14319399	141	05NOV21	18DEC21	0.0000	0.0000	.
14319402	41	03DEC21	20DEC21	0.0000	0.0000	.
14319408	128	06JAN22	11FEB22	0.0000	0.0000	.
14319412	53	26JAN22	19FEB22	0.0000	0.0000	.
14319416	131	14FEB22	25MAR22	0.0000	0.0000	.
14319418	85	08MAR22	16APR22	0.0000	0.0000	.
14319423	77	28MAR22	06MAY22	0.0000	0.0000	.
14319426	87	19APR22	28MAY22	0.0000	0.0000	.
14319430	78	09MAY22	19JUN22	0.0000	0.0000	.
14319435	32	06JUL22	19JUL22	0.0000	0.0000	.
14319440	12	27JUL22	21AUG22	0.0000	0.0000	.
14319439	45	28JUL22	15AUG22	0.0000	0.0000	.
14319445	133	16AUG22	25SEP22	0.0000	0.0000	.
14319448	116	30AUG22	13OCT22	0.0000	0.0000	.
14319451	70	30SEP22	24OCT22	0.0000	0.0000	.
14319457	67	13OCT22	06NOV22	0.0000	0.0000	.
14319460	144	03NOV22	18DEC22	0.0000	0.0000	.
14319463	54	23NOV22	08JAN23	0.0000	0.0000	.
14319468	130	04JAN23	12FEB23	0.0000	0.0000	.
14319472	87	01FEB23	13MAR23	0.0000	0.0000	.
14319475	136	16FEB23	08APR23	0.0000	0.0000	.
14319480	121	06APR23	07MAY23	0.0000	0.0000	.
14319483	110	06APR23	27MAY23	0.0000	0.0000	.
14319485	89	18MAY23	10JUN23	0.0000	0.0000	.
14319490	66	03JUN23	02JUL23	0.0000	0.0000	.
14319489	51	07JUN23	07JUL23	0.0000	0.0000	.
14319494	70	30JUN23	11AUG23	0.0000	0.0000	.
14319491	57	02JUL23	21JUL23	0.0000	0.0000	.
14319495	28	16JUL23	24JUL23	0.0000	0.0000	.
14319499	46	10AUG23	21AUG23	0.0000	0.0000	.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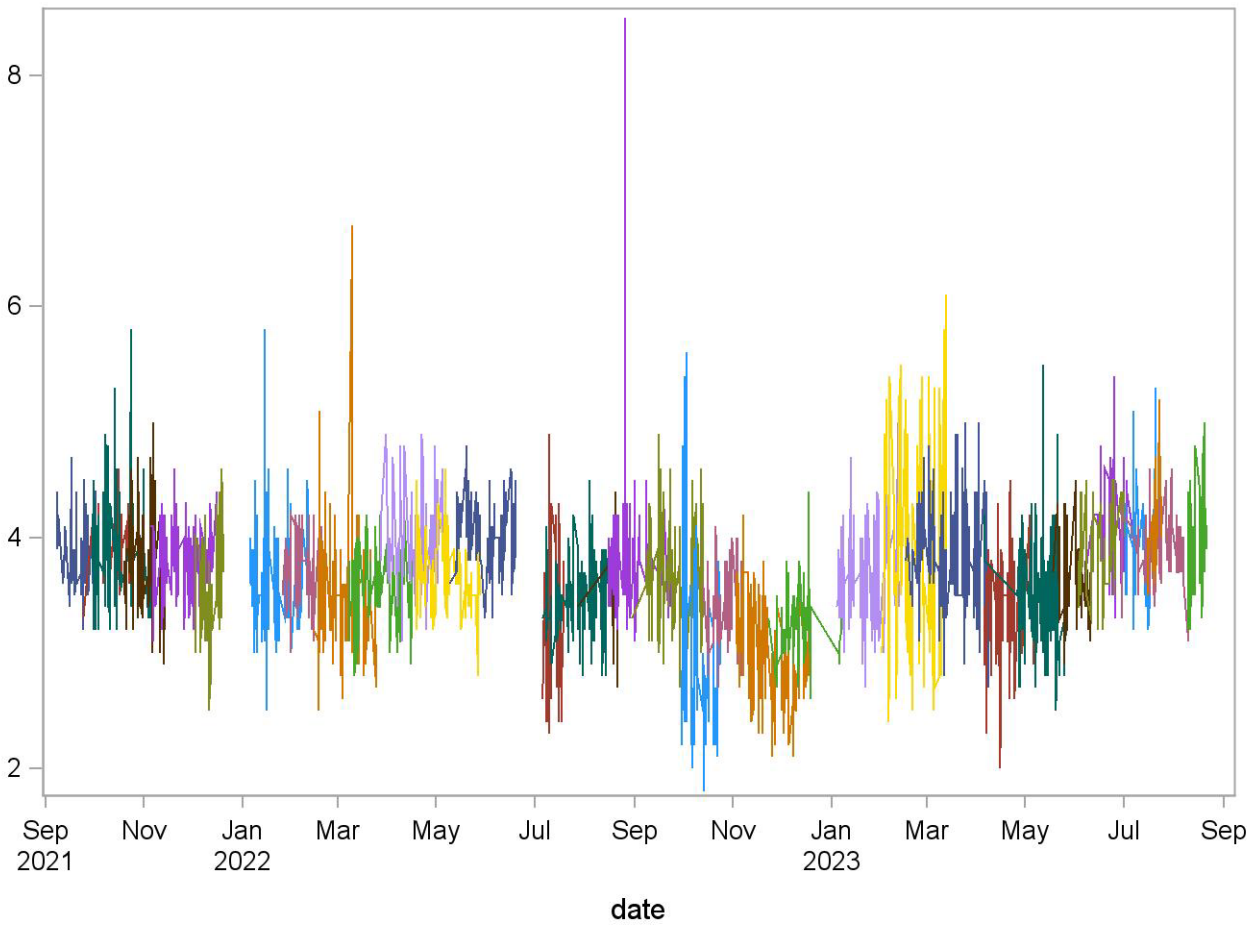
August 2021 – August 2023 Summary Statistics and QC Chart
LBCEOP1 (Eosinophils (%) (Lvl 1))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
12317388	48	08SEP21	03OCT21	3.9000	0.3339	8.6
12317389	54	24SEP21	23OCT21	3.8870	0.2503	6.4
12317393	107	30SEP21	06NOV21	3.8374	0.4373	11.4
12317395	56	20OCT21	14NOV21	3.7179	0.4436	11.9
12317399	142	05NOV21	18DEC21	3.8239	0.2679	7.0
12317402	41	03DEC21	20DEC21	3.4732	0.4472	12.9
12317408	127	06JAN22	11FEB22	3.6087	0.4293	11.9
12317412	52	26JAN22	19FEB22	3.7481	0.3165	8.4
12317416	131	14FEB22	25MAR22	3.4885	0.4752	13.6
12317418	85	08MAR22	16APR22	3.5671	0.3209	9.0
12317423	77	28MAR22	06MAY22	3.9506	0.4041	10.2
12317426	90	19APR22	28MAY22	3.6733	0.3031	8.3
12317431	78	09MAY22	19JUN22	4.0410	0.3180	7.9
12317435	32	06JUL22	19JUL22	3.2063	0.6734	21.0
12317439	126	06JUL22	18AUG22	3.4754	0.3116	9.0
12317440	12	27JUL22	21AUG22	3.4667	0.4519	13.0
12317444	130	16AUG22	25SEP22	3.7969	0.4984	13.1
12317448	116	30AUG22	13OCT22	3.6560	0.3990	10.9
12317451	66	30SEP22	24OCT22	2.9788	0.7947	26.7
12317457	67	13OCT22	06NOV22	3.4060	0.3325	9.8
12317460	146	03NOV22	18DEC22	3.0089	0.3886	12.9
12317463	54	23NOV22	08JAN23	3.2556	0.3272	10.0
12317468	132	04JAN23	12FEB23	3.6583	0.3659	10.0
12317472	87	01FEB23	13MAR23	3.9276	0.9243	23.5
12317475	136	16FEB23	08APR23	3.8294	0.4590	12.0
12317480	122	06APR23	07MAY23	3.3566	0.4004	11.9
12317483	108	06APR23	27MAY23	3.4426	0.4764	13.8
12317485	87	18MAY23	10JUN23	3.6161	0.3053	8.4
12317490	65	03JUN23	02JUL23	3.9600	0.3367	8.5
12317489	51	07JUN23	07JUL23	4.0627	0.4069	10.0
12317494	73	30JUN23	11AUG23	3.9192	0.3003	7.7
12317491	57	02JUL23	21JUL23	3.9684	0.4050	10.2
12317495	28	16JUL23	24JUL23	4.1429	0.3805	9.2
12317499	44	10AUG23	21AUG23	3.9045	0.4209	10.8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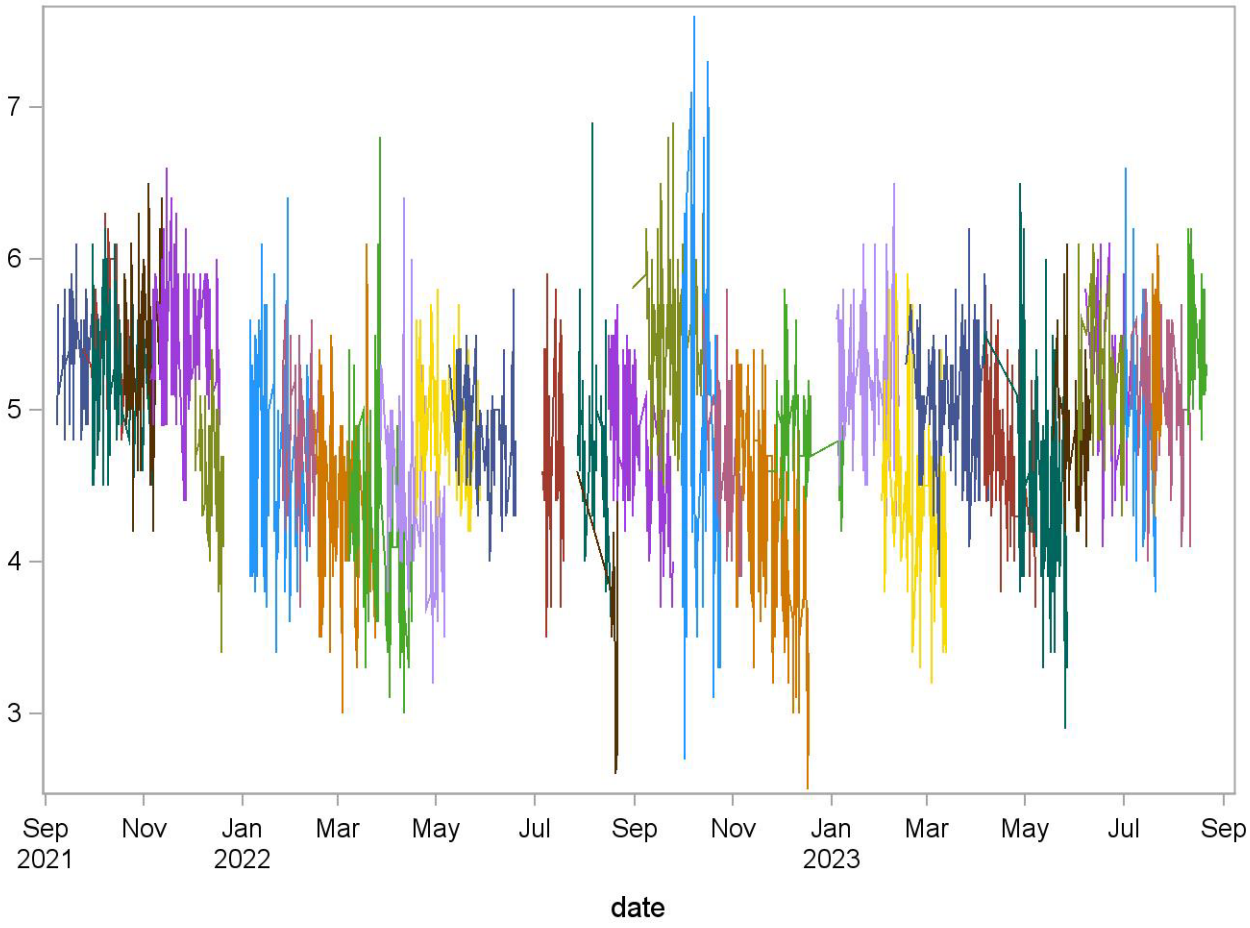
August 2021 – August 2023 Summary Statistics and QC Chart
LBCEOP2 (Eosinophils (%) (Lvl 2))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
13318388	49	08SEP21	03OCT21	5.3918	0.3207	5.9
13318389	53	24SEP21	23OCT21	5.4472	0.3495	6.4
13318393	109	30SEP21	06NOV21	5.2486	0.4165	7.9
13318395	57	20OCT21	14NOV21	5.3018	0.5143	9.7
13318399	143	05NOV21	18DEC21	5.4490	0.3690	6.8
13318402	40	03DEC21	20DEC21	4.5800	0.4177	9.1
13318408	128	06JAN22	11FEB22	4.5609	0.5176	11.3
13318412	53	26JAN22	19FEB22	4.7585	0.4249	8.9
13318415	130	14FEB22	25MAR22	4.3331	0.4936	11.4
13318418	85	08MAR22	16APR22	4.2035	0.6244	14.9
13318423	80	28MAR22	06MAY22	4.4288	0.5249	11.9
13318426	89	19APR22	28MAY22	4.9416	0.3605	7.3
13318430	78	09MAY22	19JUN22	4.8244	0.3594	7.4
13318435	32	06JUL22	19JUL22	4.7000	0.6466	13.8
13318440	12	27JUL22	21AUG22	3.6583	0.7763	21.2
13318439	47	28JUL22	18AUG22	4.7617	0.5286	11.1
13318444	131	16AUG22	25SEP22	4.8153	0.4449	9.2
13318448	119	30AUG22	13OCT22	5.4126	0.4814	8.9
13318451	67	30SEP22	24OCT22	4.6522	1.0929	23.5
13318458	67	13OCT22	06NOV22	4.6985	0.4191	8.9
13318460	142	03NOV22	18DEC22	4.2761	0.6327	14.8
13318463	55	23NOV22	08JAN23	4.8673	0.3570	7.3
13318468	131	04JAN23	12FEB23	5.2023	0.3767	7.2
13318472	89	01FEB23	13MAR23	4.4371	0.5476	12.3
13318475	141	16FEB23	08APR23	5.0340	0.3944	7.8
13318480	127	06APR23	07MAY23	4.6835	0.4103	8.8
13318483	110	06APR23	27MAY23	4.4791	0.6348	14.2
13318485	86	18MAY23	10JUN23	4.8849	0.4097	8.4
13318490	66	03JUN23	02JUL23	5.2076	0.3840	7.4
13318489	52	07JUN23	07JUL23	5.1462	0.4750	9.2
13318491	57	02JUL23	21JUL23	5.0053	0.6457	12.9
13318494	66	06JUL23	11AUG23	5.0652	0.4013	7.9
13318495	28	19JUL23	24JUL23	5.1000	0.4513	8.8
13318499	45	10AUG23	21AUG23	5.5156	0.3561	6.5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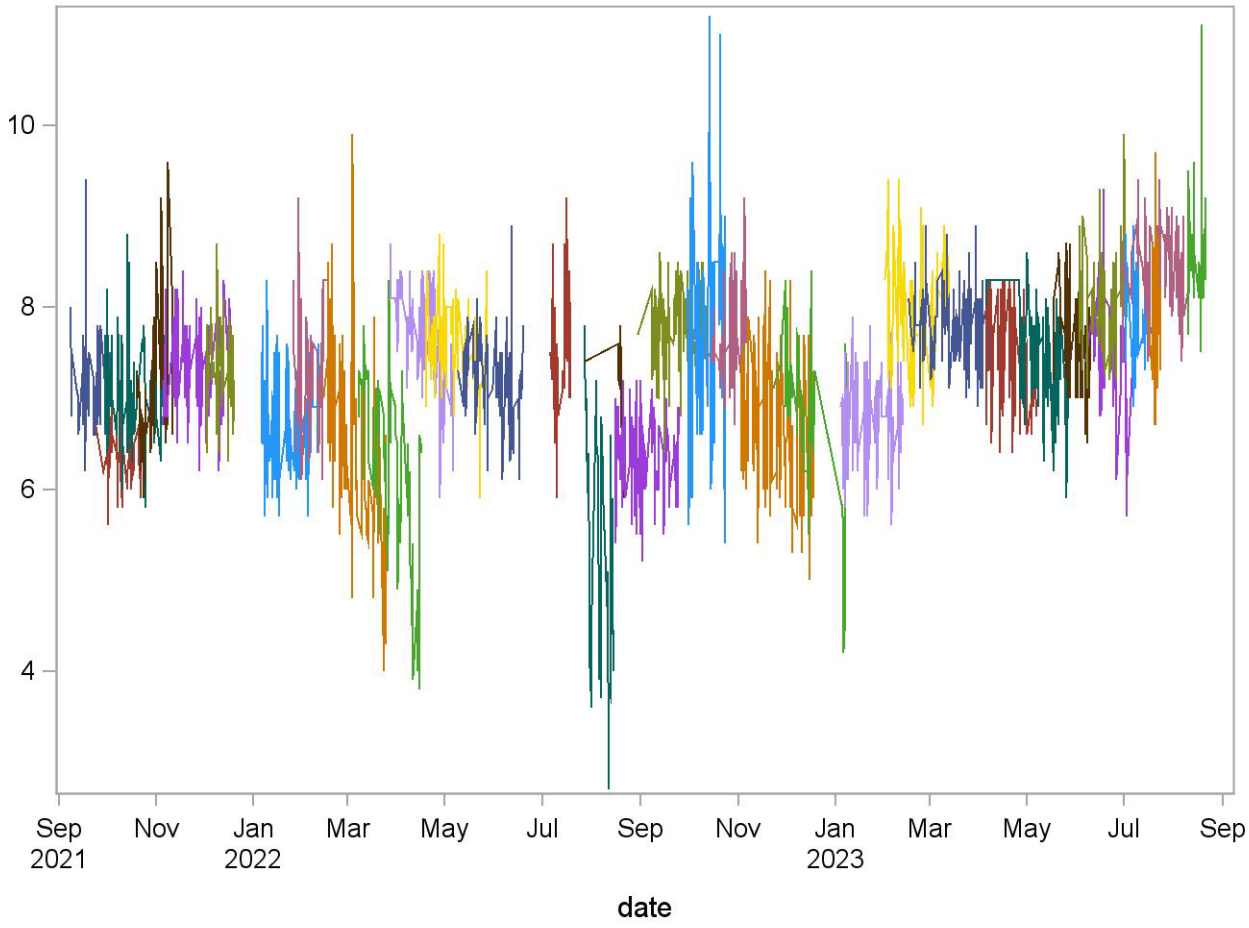
August 2021 – August 2023 Summary Statistics and QC Chart
LBCEOP3 (Eosinophils (%) (Lvl 3))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
14319388	50	08SEP21	03OCT21	7.1980	0.5408	7.5
14319389	53	24SEP21	23OCT21	6.3962	0.3524	5.5
14319393	109	30SEP21	06NOV21	7.0615	0.5219	7.4
14319395	56	20OCT21	14NOV21	7.1804	0.6919	9.6
14319399	141	05NOV21	18DEC21	7.3560	0.4186	5.7
14319402	41	03DEC21	20DEC21	7.3244	0.5272	7.2
14319408	128	06JAN22	11FEB22	6.7570	0.5190	7.7
14319412	53	26JAN22	19FEB22	7.3170	0.6139	8.4
14319416	131	14FEB22	25MAR22	6.6374	0.8769	13.2
14319418	85	08MAR22	16APR22	6.2365	0.9615	15.4
14319423	77	28MAR22	06MAY22	7.6416	0.5599	7.3
14319426	87	19APR22	28MAY22	7.5034	0.4363	5.8
14319430	78	09MAY22	19JUN22	7.2244	0.4923	6.8
14319435	32	06JUL22	19JUL22	7.5594	0.6848	9.1
14319440	12	27JUL22	21AUG22	6.8167	0.6686	9.8
14319439	45	28JUL22	15AUG22	5.1489	1.2814	24.9
14319445	133	16AUG22	25SEP22	6.3451	0.4063	6.4
14319448	116	30AUG22	13OCT22	7.7138	0.4265	5.5
14319451	70	30SEP22	24OCT22	7.5443	1.2208	16.2
14319457	67	13OCT22	06NOV22	7.6552	0.4803	6.3
14319460	144	03NOV22	18DEC22	6.7194	0.6804	10.1
14319463	54	23NOV22	08JAN23	6.8259	0.8594	12.6
14319468	130	04JAN23	12FEB23	6.8131	0.4591	6.7
14319472	87	01FEB23	13MAR23	7.9586	0.5862	7.4
14319475	136	16FEB23	08APR23	7.7816	0.3824	4.9
14319480	121	06APR23	07MAY23	7.5273	0.4608	6.1
14319483	110	06APR23	27MAY23	7.3645	0.4909	6.7
14319485	89	18MAY23	10JUN23	7.6517	0.4715	6.2
14319490	66	03JUN23	02JUL23	8.0379	0.5232	6.5
14319489	51	07JUN23	07JUL23	7.4843	0.6323	8.4
14319494	70	30JUN23	11AUG23	8.4171	0.4571	5.4
14319491	57	02JUL23	21JUL23	7.9105	0.4920	6.2
14319495	28	16JUL23	24JUL23	7.8000	0.7449	9.5
14319499	46	10AUG23	21AUG23	8.5739	0.5756	6.7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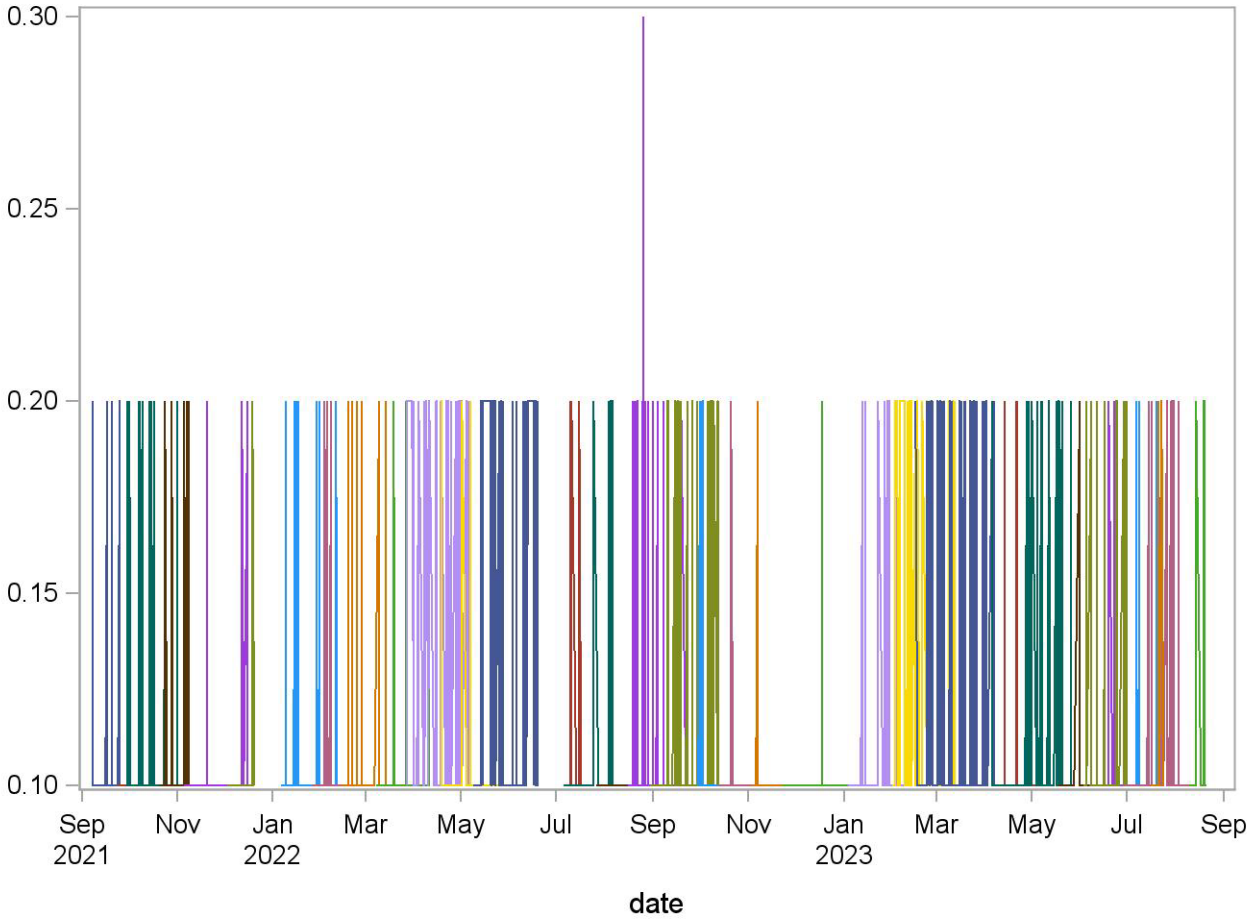
August 2021 – August 2023 Summary Statistics and QC Chart
LBCEON1 (Eosinophils No.(10^3 cells/uL) (Lvl 1))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
12317388	48	08SEP21	03OCT21	0.1125	0.0334	29.7
12317389	54	24SEP21	23OCT21	0.1000	0.0000	0.0
12317393	107	30SEP21	06NOV21	0.1121	0.0328	29.3
12317395	56	20OCT21	14NOV21	0.1089	0.0288	26.4
12317399	142	05NOV21	18DEC21	0.1021	0.0144	14.1
12317402	41	03DEC21	20DEC21	0.1024	0.0156	15.2
12317408	127	06JAN22	11FEB22	0.1063	0.0244	22.9
12317412	52	26JAN22	19FEB22	0.1058	0.0235	22.3
12317416	131	14FEB22	25MAR22	0.1053	0.0226	21.4
12317418	85	08MAR22	16APR22	0.1035	0.0186	17.9
12317423	77	28MAR22	06MAY22	0.1377	0.0488	35.4
12317426	90	19APR22	28MAY22	0.1044	0.0207	19.8
12317431	78	09MAY22	19JUN22	0.1436	0.0499	34.8
12317435	32	06JUL22	19JUL22	0.1094	0.0296	27.1
12317439	126	06JUL22	18AUG22	0.1032	0.0176	17.1
12317440	12	27JUL22	21AUG22	0.1083	0.0289	26.6
12317444	130	16AUG22	25SEP22	0.1138	0.0368	32.4
12317448	116	30AUG22	13OCT22	0.1216	0.0413	34.0
12317451	66	30SEP22	24OCT22	0.1076	0.0267	24.8
12317457	67	13OCT22	06NOV22	0.1015	0.0122	12.0
12317460	146	03NOV22	18DEC22	0.1007	0.0083	8.2
12317463	54	23NOV22	08JAN23	0.1019	0.0136	13.4
12317468	132	04JAN23	12FEB23	0.1068	0.0253	23.7
12317472	87	01FEB23	13MAR23	0.1391	0.0491	35.3
12317475	136	16FEB23	08APR23	0.1301	0.0461	35.4
12317480	122	06APR23	07MAY23	0.1033	0.0179	17.3
12317483	108	06APR23	27MAY23	0.1148	0.0357	31.1
12317485	87	18MAY23	10JUN23	0.1011	0.0107	10.6
12317490	65	03JUN23	02JUL23	0.1169	0.0378	32.3
12317489	51	07JUN23	07JUL23	0.1098	0.0300	27.4
12317494	73	30JUN23	11AUG23	0.1151	0.0360	31.3
12317491	57	02JUL23	21JUL23	0.1088	0.0285	26.2
12317495	28	16JUL23	24JUL23	0.1107	0.0315	28.4
12317499	44	10AUG23	21AUG23	0.1068	0.0255	23.9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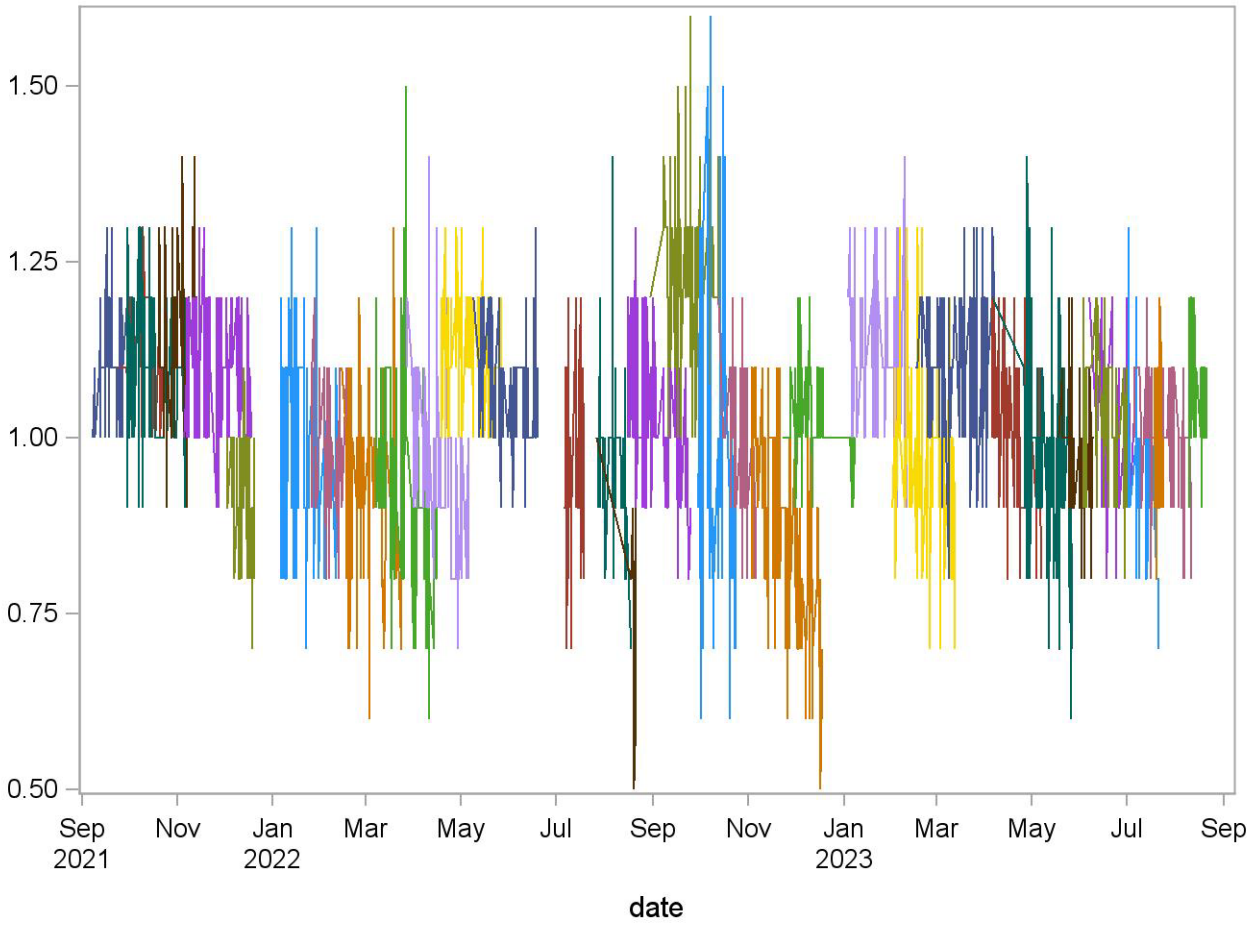
August 2021 – August 2023 Summary Statistics and QC Chart
LBCEON2 (Eosinophils No.(10^3 cells/uL) (Lvl 2))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
13318388	49	08SEP21	03OCT21	1.1163	0.0800	7.2
13318389	53	24SEP21	23OCT21	1.1151	0.0794	7.1
13318393	109	30SEP21	06NOV21	1.1028	0.0947	8.6
13318395	57	20OCT21	14NOV21	1.1298	0.1085	9.6
13318399	143	05NOV21	18DEC21	1.0916	0.0800	7.3
13318402	40	03DEC21	20DEC21	0.9125	0.0883	9.7
13318408	128	06JAN22	11FEB22	0.9594	0.1153	12.0
13318412	53	26JAN22	19FEB22	0.9717	0.0885	9.1
13318415	130	14FEB22	25MAR22	0.9223	0.1109	12.0
13318418	85	08MAR22	16APR22	0.9118	0.1392	15.3
13318423	80	28MAR22	06MAY22	0.9775	0.1211	12.4
13318426	89	19APR22	28MAY22	1.1225	0.0822	7.3
13318430	78	09MAY22	19JUN22	1.0718	0.0836	7.8
13318435	32	06JUL22	19JUL22	0.9594	0.1388	14.5
13318440	12	27JUL22	21AUG22	0.7750	0.1815	23.4
13318439	47	28JUL22	18AUG22	0.9596	0.1097	11.4
13318444	131	16AUG22	25SEP22	1.0305	0.0984	9.5
13318448	119	30AUG22	13OCT22	1.2227	0.1131	9.2
13318451	67	30SEP22	24OCT22	0.9552	0.2251	23.6
13318458	67	13OCT22	06NOV22	0.9881	0.0993	10.0
13318460	142	03NOV22	18DEC22	0.8817	0.1324	15.0
13318463	55	23NOV22	08JAN23	1.0418	0.0786	7.5
13318468	131	04JAN23	12FEB23	1.1221	0.0897	8.0
13318472	89	01FEB23	13MAR23	0.9652	0.1280	13.3
13318475	141	16FEB23	08APR23	1.0986	0.0910	8.3
13318480	127	06APR23	07MAY23	1.0157	0.0938	9.2
13318483	110	06APR23	27MAY23	0.9573	0.1404	14.7
13318485	86	18MAY23	10JUN23	0.9860	0.0883	9.0
13318490	66	03JUN23	02JUL23	1.0136	0.0875	8.6
13318489	52	07JUN23	07JUL23	1.0173	0.1004	9.9
13318491	57	02JUL23	21JUL23	0.9649	0.1246	12.9
13318494	66	06JUL23	11AUG23	0.9985	0.0850	8.5
13318495	28	19JUL23	24JUL23	0.9750	0.1005	10.3
13318499	45	10AUG23	21AUG23	1.0689	0.0763	7.1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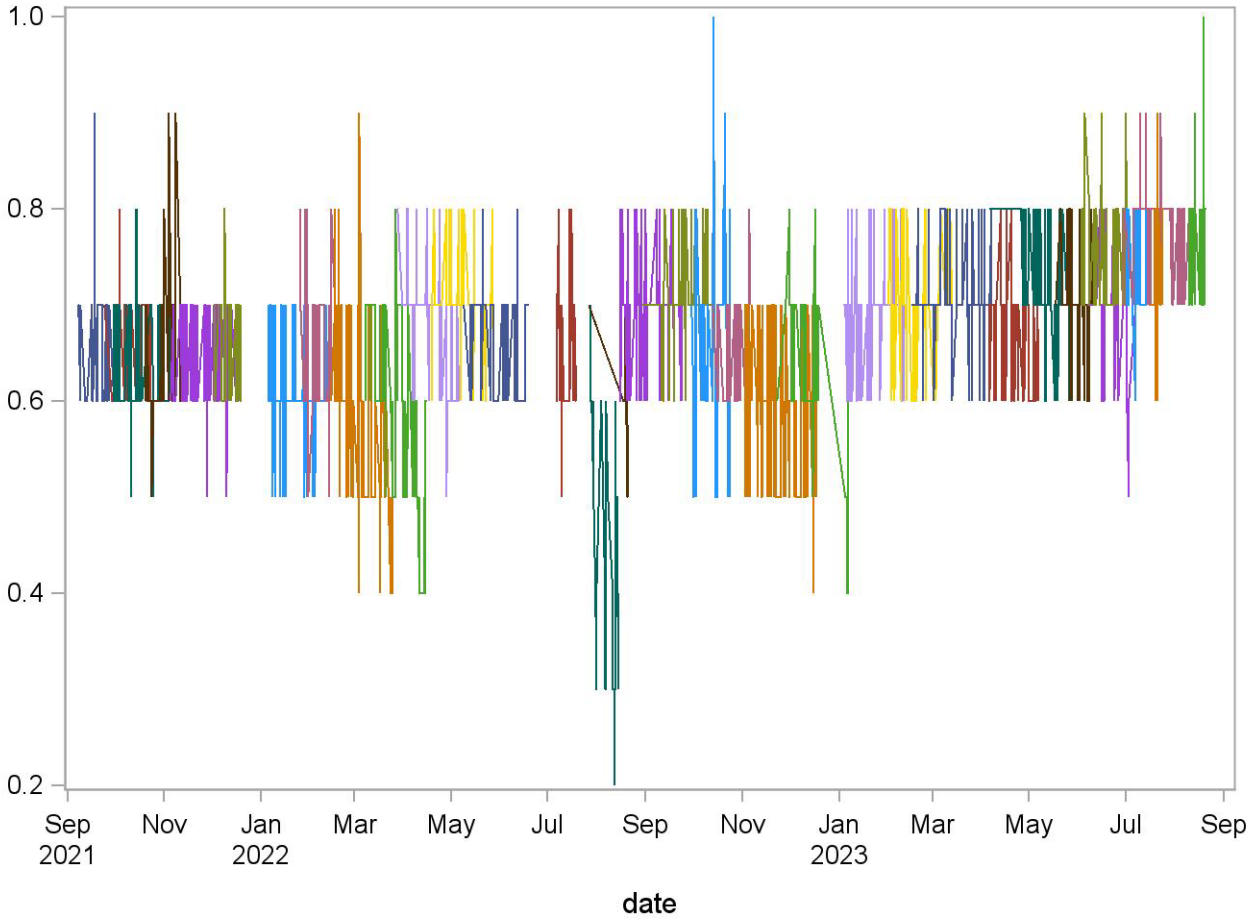
August 2021 – August 2023 Summary Statistics and QC Chart
LBCEON3 (Eosinophils No.(10^3 cells/uL) (Lvl 3))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
14319388	50	08SEP21	03OCT21	0.6480	0.0614	9.5
14319389	53	24SEP21	23OCT21	0.6528	0.0541	8.3
14319393	109	30SEP21	06NOV21	0.6394	0.0561	8.8
14319395	56	20OCT21	14NOV21	0.6536	0.0762	11.7
14319399	141	05NOV21	18DEC21	0.6426	0.0524	8.2
14319402	41	03DEC21	20DEC21	0.6634	0.0581	8.8
14319408	128	06JAN22	11FEB22	0.6125	0.0547	8.9
14319412	53	26JAN22	19FEB22	0.6434	0.0694	10.8
14319416	131	14FEB22	25MAR22	0.5939	0.0839	14.1
14319418	85	08MAR22	16APR22	0.5929	0.0949	16.0
14319423	77	28MAR22	06MAY22	0.6857	0.0601	8.8
14319426	87	19APR22	28MAY22	0.7023	0.0431	6.1
14319430	78	09MAY22	19JUN22	0.6731	0.0501	7.4
14319435	32	06JUL22	19JUL22	0.6531	0.0718	11.0
14319440	12	27JUL22	21AUG22	0.5833	0.0718	12.3
14319439	45	28JUL22	15AUG22	0.4422	0.1234	27.9
14319445	133	16AUG22	25SEP22	0.6917	0.0537	7.8
14319448	116	30AUG22	13OCT22	0.7043	0.0445	6.3
14319451	70	30SEP22	24OCT22	0.6500	0.1032	15.9
14319457	67	13OCT22	06NOV22	0.6537	0.0532	8.1
14319460	144	03NOV22	18DEC22	0.5951	0.0713	12.0
14319463	54	23NOV22	08JAN23	0.6370	0.0896	14.1
14319468	130	04JAN23	12FEB23	0.6869	0.0576	8.4
14319472	87	01FEB23	13MAR23	0.7046	0.0627	8.9
14319475	136	16FEB23	08APR23	0.7066	0.0425	6.0
14319480	121	06APR23	07MAY23	0.6802	0.0459	6.7
14319483	110	06APR23	27MAY23	0.7136	0.0533	7.5
14319485	89	18MAY23	10JUN23	0.7079	0.0505	7.1
14319490	66	03JUN23	02JUL23	0.7500	0.0588	7.8
14319489	51	07JUN23	07JUL23	0.6824	0.0555	8.1
14319494	70	30JUN23	11AUG23	0.7786	0.0508	6.5
14319491	57	02JUL23	21JUL23	0.7333	0.0512	7.0
14319495	28	16JUL23	24JUL23	0.7286	0.0713	9.8
14319499	46	10AUG23	21AUG23	0.7674	0.0634	8.3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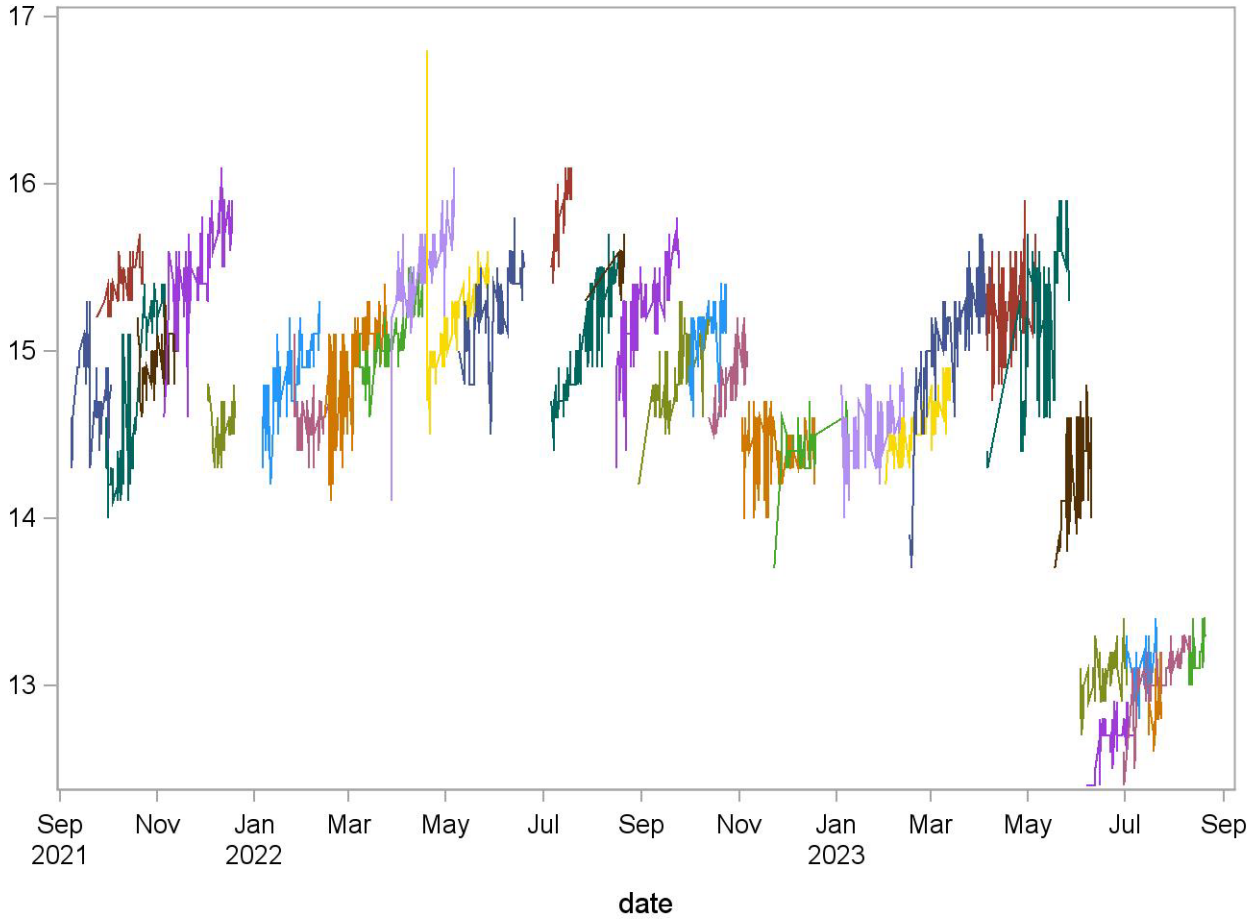
August 2021 – August 2023 Summary Statistics and QC Chart
LBCHCT1 (Hematocrit (%) (Lvl 1))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
12317388	48	08SEP21	03OCT21	14.7625	0.2321	1.6
12317389	54	24SEP21	23OCT21	15.4148	0.1156	0.7
12317393	107	30SEP21	06NOV21	14.7346	0.4630	3.1
12317395	56	20OCT21	14NOV21	14.9464	0.1501	1.0
12317399	142	05NOV21	18DEC21	15.4254	0.2699	1.7
12317402	41	03DEC21	20DEC21	14.5561	0.1379	0.9
12317408	127	06JAN22	11FEB22	14.7992	0.1966	1.3
12317412	52	26JAN22	19FEB22	14.5827	0.1438	1.0
12317416	131	14FEB22	25MAR22	14.8313	0.3123	2.1
12317418	85	08MAR22	16APR22	15.0800	0.1938	1.3
12317423	77	28MAR22	06MAY22	15.4909	0.2525	1.6
12317426	90	19APR22	28MAY22	15.1744	0.2815	1.9
12317431	78	09MAY22	19JUN22	15.2705	0.2336	1.5
12317435	32	06JUL22	19JUL22	15.8219	0.2090	1.3
12317439	126	06JUL22	18AUG22	15.1230	0.2923	1.9
12317440	12	27JUL22	21AUG22	15.5083	0.1311	0.8
12317444	133	16AUG22	25SEP22	15.2098	0.2546	1.7
12317448	116	30AUG22	13OCT22	14.8664	0.2097	1.4
12317451	66	30SEP22	24OCT22	15.0833	0.2181	1.4
12317457	67	13OCT22	06NOV22	14.8522	0.1491	1.0
12317460	146	03NOV22	18DEC22	14.3959	0.1639	1.1
12317463	54	23NOV22	08JAN23	14.4278	0.1433	1.0
12317468	132	04JAN23	12FEB23	14.4977	0.1714	1.2
12317472	87	01FEB23	13MAR23	14.5609	0.1512	1.0
12317475	137	16FEB23	08APR23	15.1628	0.3101	2.0
12317480	122	06APR23	07MAY23	15.2418	0.2215	1.5
12317483	108	06APR23	27MAY23	15.0917	0.4416	2.9
12317485	87	18MAY23	10JUN23	14.2989	0.2508	1.8
12317490	65	03JUN23	02JUL23	13.0415	0.1391	1.1
12317489	51	07JUN23	07JUL23	12.7078	0.1214	1.0
12317494	73	30JUN23	11AUG23	13.0370	0.2112	1.6
12317491	57	02JUL23	21JUL23	13.0912	0.1243	0.9
12317495	28	16JUL23	24JUL23	12.8571	0.1289	1.0
12317499	44	10AUG23	21AUG23	13.1727	0.1065	0.8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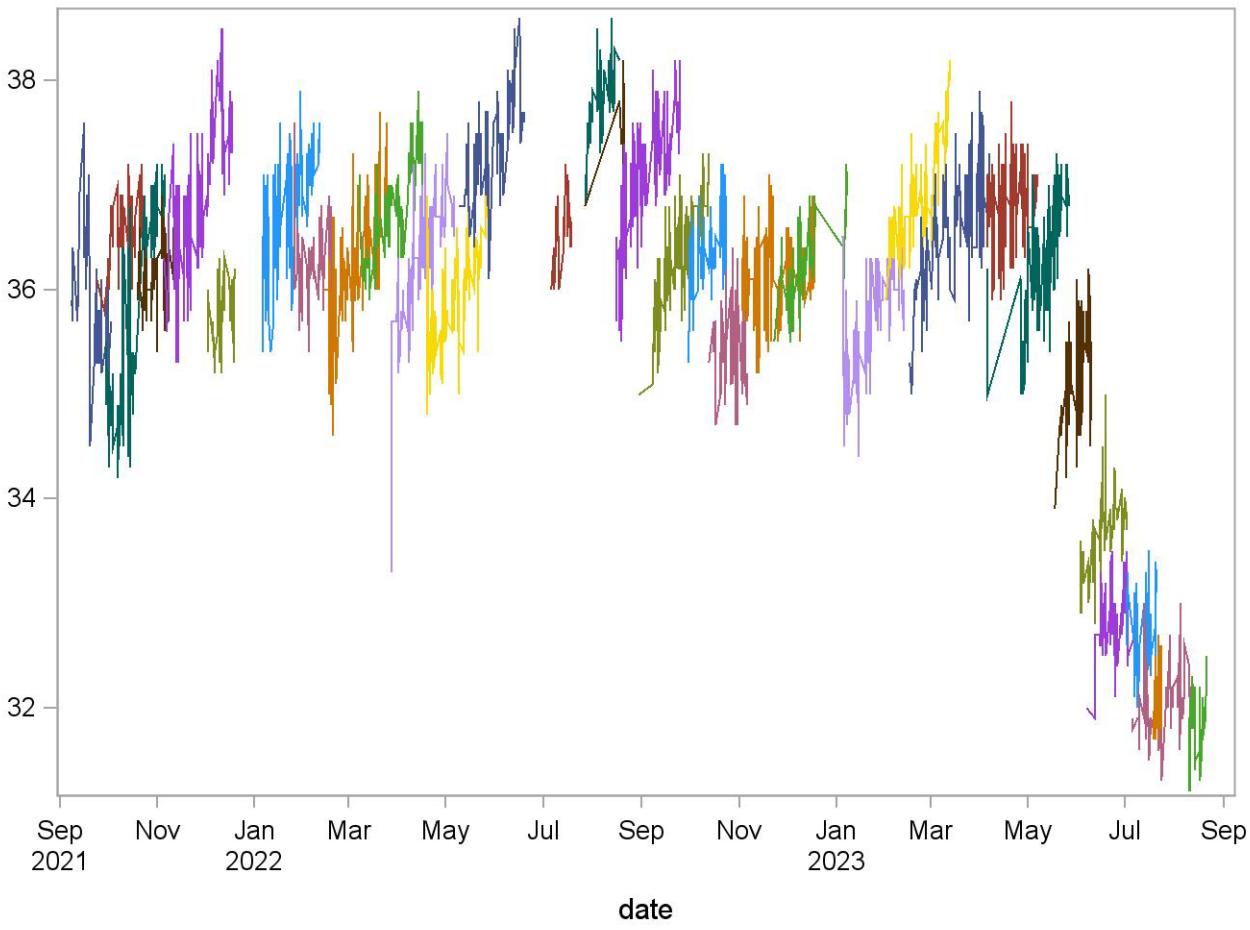
August 2021 – August 2023 Summary Statistics and QC Chart
LBCHCT2 (Hematocrit (%) (Lvl 2))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
13318388	49	08SEP21	03OCT21	35.9551	0.6468	1.8
13318389	53	24SEP21	23OCT21	36.5283	0.3313	0.9
13318393	109	30SEP21	06NOV21	35.7165	0.8696	2.4
13318395	57	20OCT21	14NOV21	36.1228	0.3036	0.8
13318399	143	05NOV21	18DEC21	36.7273	0.6571	1.8
13318402	40	03DEC21	20DEC21	35.8075	0.3083	0.9
13318408	128	06JAN22	11FEB22	36.6977	0.4983	1.4
13318412	53	26JAN22	19FEB22	36.2755	0.4090	1.1
13318415	130	14FEB22	25MAR22	36.1208	0.5693	1.6
13318418	85	08MAR22	16APR22	36.7376	0.4429	1.2
13318423	81	28MAR22	06MAY22	36.3247	0.6394	1.8
13318426	89	19APR22	28MAY22	35.9281	0.4993	1.4
13318430	78	09MAY22	19JUN22	37.3808	0.4781	1.3
13318435	32	06JUL22	19JUL22	36.5531	0.3331	0.9
13318440	12	27JUL22	21AUG22	37.5000	0.3542	0.9
13318439	47	28JUL22	18AUG22	37.8149	0.3470	0.9
13318444	131	16AUG22	25SEP22	37.0176	0.4871	1.3
13318448	119	30AUG22	13OCT22	36.3042	0.4684	1.3
13318451	67	30SEP22	24OCT22	36.3537	0.3590	1.0
13318458	67	13OCT22	06NOV22	35.4761	0.4015	1.1
13318460	142	03NOV22	18DEC22	36.0831	0.3628	1.0
13318463	55	23NOV22	08JAN23	36.2382	0.4262	1.2
13318468	131	04JAN23	12FEB23	35.5786	0.4997	1.4
13318472	89	01FEB23	13MAR23	36.8989	0.5280	1.4
13318475	141	16FEB23	08APR23	36.6702	0.5062	1.4
13318480	127	06APR23	07MAY23	36.8205	0.3672	1.0
13318483	110	06APR23	27MAY23	36.1682	0.5676	1.6
13318485	86	18MAY23	10JUN23	35.1907	0.4402	1.3
13318490	66	03JUN23	02JUL23	33.6045	0.3920	1.2
13318489	52	07JUN23	07JUL23	32.8173	0.3552	1.1
13318491	57	02JUL23	21JUL23	32.7193	0.3791	1.2
13318494	66	06JUL23	11AUG23	32.0409	0.3374	1.1
13318495	28	19JUL23	24JUL23	32.0714	0.2967	0.9
13318499	45	10AUG23	21AUG23	31.7444	0.3223	1.0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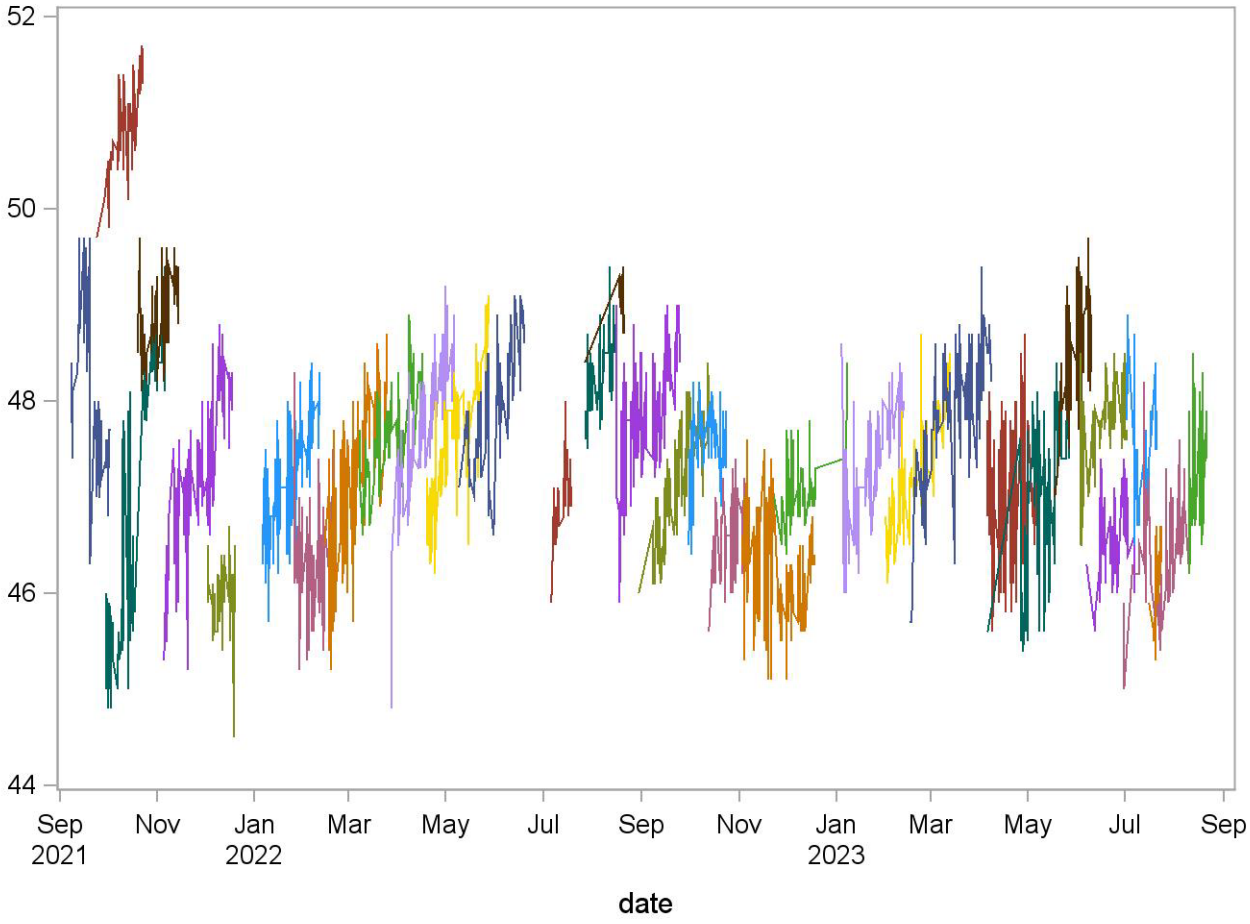
August 2021 – August 2023 Summary Statistics and QC Chart
LBCHCT3 (Hematocrit (%) (Lvl 3))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
14319388	50	08SEP21	03OCT21	48.0880	0.8705	1.8
14319389	53	24SEP21	23OCT21	50.7792	0.4781	0.9
14319393	109	30SEP21	06NOV21	46.8486	1.3533	2.9
14319395	56	20OCT21	14NOV21	48.9071	0.4208	0.9
14319399	141	05NOV21	18DEC21	47.1163	0.6683	1.4
14319402	41	03DEC21	20DEC21	45.9732	0.3969	0.9
14319408	128	06JAN22	11FEB22	47.0883	0.5598	1.2
14319412	53	26JAN22	19FEB22	46.2943	0.6392	1.4
14319416	131	14FEB22	25MAR22	46.9969	0.8097	1.7
14319418	85	08MAR22	16APR22	47.6341	0.4750	1.0
14319423	77	28MAR22	06MAY22	47.6922	0.7084	1.5
14319426	87	19APR22	28MAY22	47.6069	0.6673	1.4
14319430	78	09MAY22	19JUN22	47.9846	0.5689	1.2
14319435	32	06JUL22	19JUL22	46.9469	0.3698	0.8
14319440	12	27JUL22	21AUG22	48.9833	0.3010	0.6
14319439	45	28JUL22	15AUG22	48.3222	0.4084	0.8
14319445	133	16AUG22	25SEP22	47.8203	0.5657	1.2
14319448	116	30AUG22	13OCT22	47.1466	0.5497	1.2
14319451	70	30SEP22	24OCT22	47.4929	0.3861	0.8
14319457	67	13OCT22	06NOV22	46.5597	0.3730	0.8
14319460	144	03NOV22	18DEC22	46.1910	0.5067	1.1
14319463	54	23NOV22	08JAN23	47.1370	0.3636	0.8
14319468	130	04JAN23	12FEB23	47.1931	0.5292	1.1
14319472	87	01FEB23	13MAR23	47.3724	0.5311	1.1
14319475	136	16FEB23	08APR23	47.9566	0.6133	1.3
14319480	121	06APR23	07MAY23	47.0041	0.6627	1.4
14319483	110	06APR23	27MAY23	46.8400	0.8381	1.8
14319485	89	18MAY23	10JUN23	48.4697	0.5186	1.1
14319490	66	03JUN23	02JUL23	47.6939	0.4781	1.0
14319489	51	07JUN23	07JUL23	46.5941	0.4159	0.9
14319494	70	30JUN23	11AUG23	46.4143	0.5779	1.2
14319491	57	02JUL23	21JUL23	47.4439	0.5816	1.2
14319495	28	16JUL23	24JUL23	46.0250	0.4518	1.0
14319499	46	10AUG23	21AUG23	47.0783	0.5955	1.3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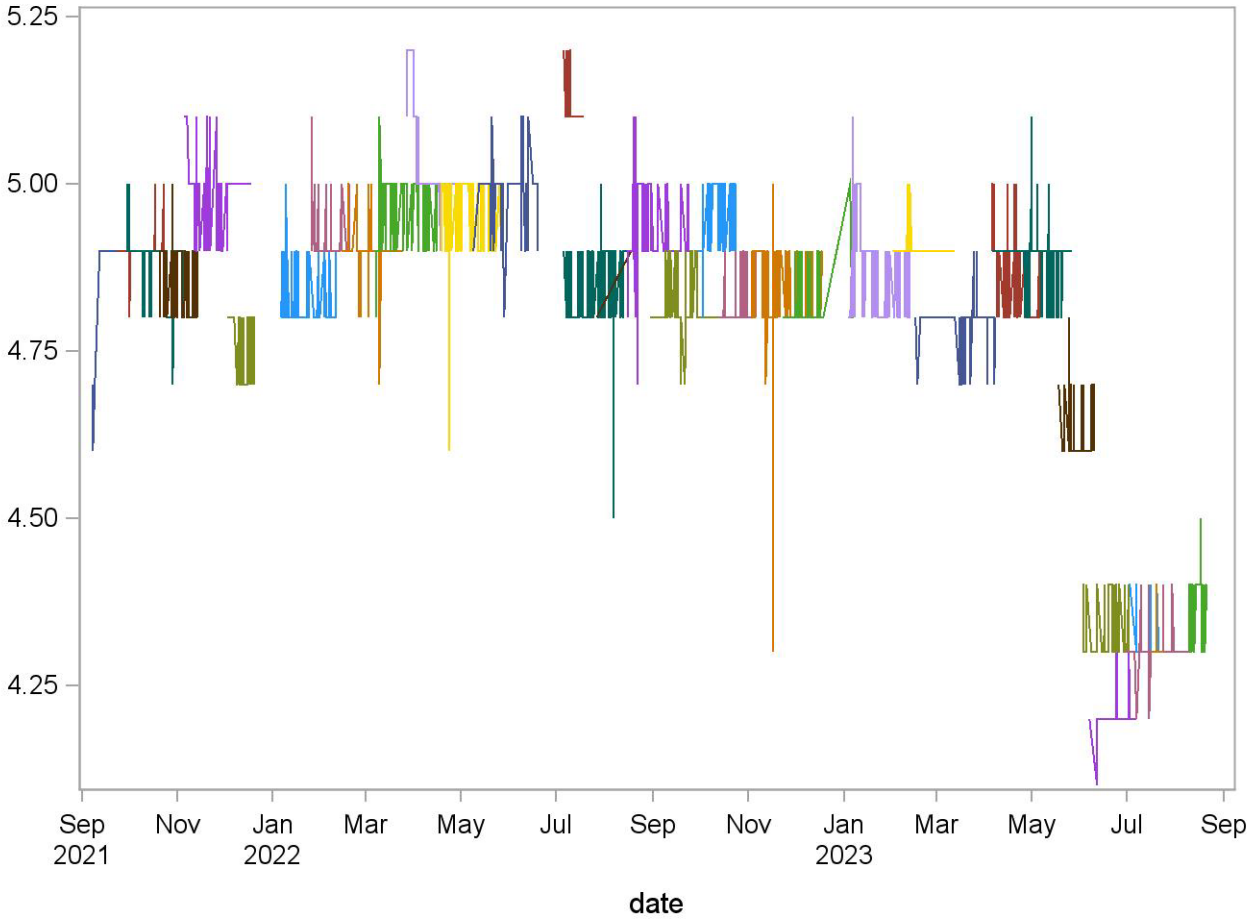
August 2021 – August 2023 Summary Statistics and QC Chart
LBCHGB1 (Hemoglobin (g/dL) (Lvl 1))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
12317388	48	08SEP21	03OCT21	4.8813	0.0641	1.3
12317389	54	24SEP21	23OCT21	4.9019	0.0237	0.5
12317393	107	30SEP21	06NOV21	4.8850	0.0430	0.9
12317395	56	20OCT21	14NOV21	4.8500	0.0539	1.1
12317399	142	05NOV21	18DEC21	4.9887	0.0520	1.0
12317402	41	03DEC21	20DEC21	4.7610	0.0494	1.0
12317408	127	06JAN22	11FEB22	4.8173	0.0400	0.8
12317412	52	26JAN22	19FEB22	4.9173	0.0430	0.9
12317416	131	14FEB22	25MAR22	4.9008	0.0316	0.6
12317418	85	08MAR22	16APR22	4.9624	0.0556	1.1
12317423	77	28MAR22	06MAY22	5.0143	0.0531	1.1
12317426	89	19APR22	28MAY22	4.9539	0.0623	1.3
12317431	78	09MAY22	19JUN22	4.9872	0.0493	1.0
12317435	32	06JUL22	19JUL22	5.1156	0.0369	0.7
12317439	126	06JUL22	18AUG22	4.8492	0.0616	1.3
12317440	12	27JUL22	21AUG22	4.9167	0.0577	1.2
12317444	133	16AUG22	25SEP22	4.9271	0.0552	1.1
12317448	116	30AUG22	13OCT22	4.8241	0.0468	1.0
12317451	66	30SEP22	24OCT22	4.9424	0.0528	1.1
12317457	67	13OCT22	06NOV22	4.8269	0.0447	0.9
12317460	146	03NOV22	18DEC22	4.8452	0.0725	1.5
12317463	54	23NOV22	08JAN23	4.8241	0.0473	1.0
12317468	132	04JAN23	12FEB23	4.8720	0.0597	1.2
12317472	87	01FEB23	13MAR23	4.9023	0.0151	0.3
12317475	137	16FEB23	08APR23	4.7927	0.0312	0.7
12317480	122	06APR23	07MAY23	4.8590	0.0586	1.2
12317483	108	06APR23	27MAY23	4.8722	0.0561	1.2
12317485	87	18MAY23	10JUN23	4.6230	0.0450	1.0
12317490	65	03JUN23	02JUL23	4.3246	0.0434	1.0
12317489	51	07JUN23	07JUL23	4.2039	0.0280	0.7
12317494	73	30JUN23	11AUG23	4.3041	0.0309	0.7
12317491	57	02JUL23	21JUL23	4.3228	0.0423	1.0
12317495	28	16JUL23	24JUL23	4.3179	0.0390	0.9
12317499	44	10AUG23	21AUG23	4.3636	0.0532	1.2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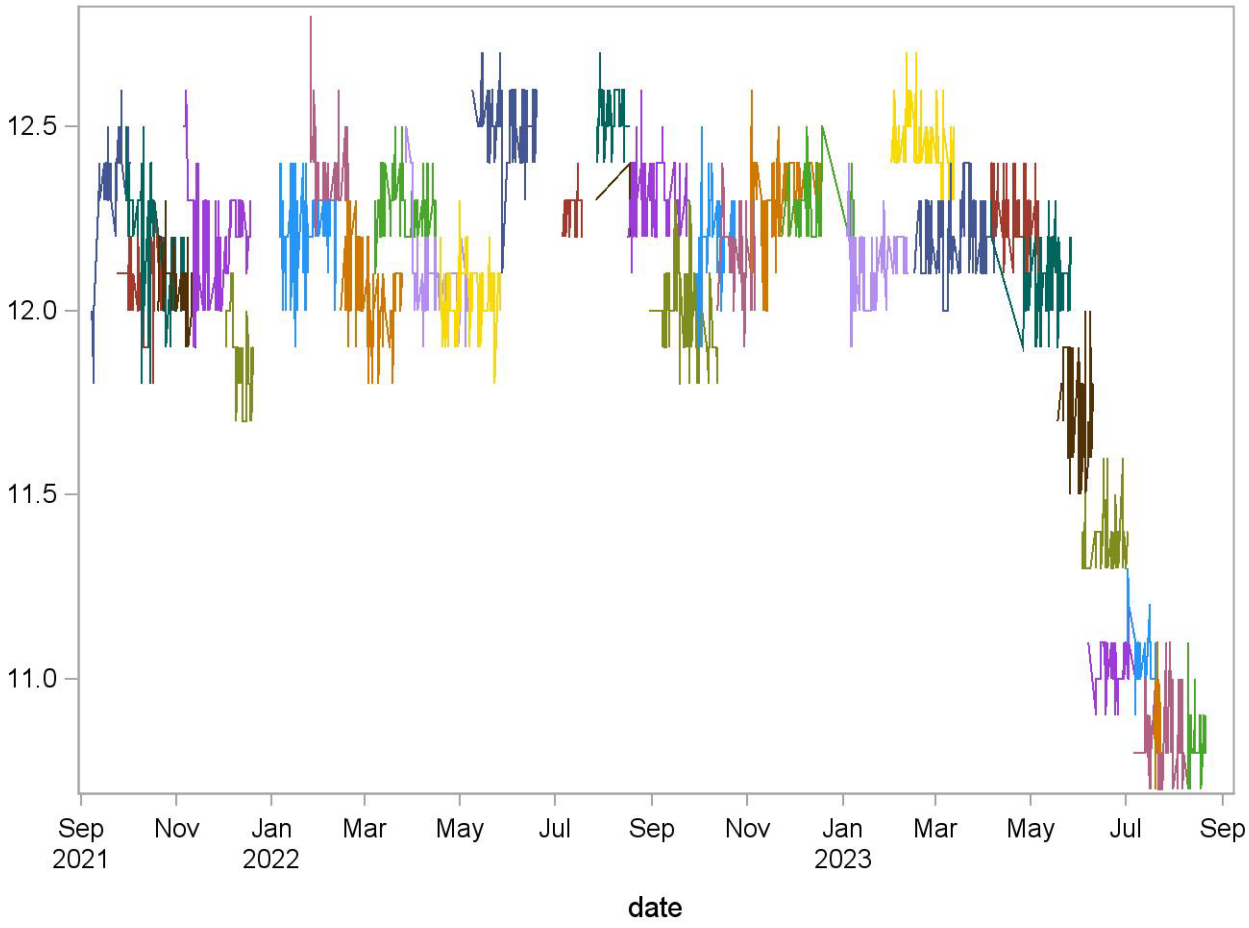
August 2021 – August 2023 Summary Statistics and QC Chart
LBCHGB2 (Hemoglobin (g/dL) (Lvl 2))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
13318388	49	08SEP21	03OCT21	12.3510	0.1340	1.1
13318389	53	24SEP21	23OCT21	12.0755	0.0979	0.8
13318393	109	30SEP21	06NOV21	12.1697	0.1566	1.3
13318395	57	20OCT21	14NOV21	12.0684	0.0805	0.7
13318399	143	05NOV21	18DEC21	12.1727	0.1375	1.1
13318402	40	03DEC21	20DEC21	11.8900	0.1128	0.9
13318408	128	06JAN22	11FEB22	12.2141	0.1085	0.9
13318412	53	26JAN22	19FEB22	12.3717	0.1133	0.9
13318415	130	14FEB22	25MAR22	12.0738	0.1185	1.0
13318418	85	08MAR22	16APR22	12.2871	0.0799	0.6
13318423	81	28MAR22	06MAY22	12.0802	0.1089	0.9
13318426	89	19APR22	28MAY22	12.0449	0.0853	0.7
13318430	78	09MAY22	19JUN22	12.5090	0.1022	0.8
13318435	32	06JUL22	19JUL22	12.2688	0.0535	0.4
13318440	12	27JUL22	21AUG22	12.3333	0.0651	0.5
13318439	47	28JUL22	18AUG22	12.5362	0.0673	0.5
13318444	131	16AUG22	25SEP22	12.3038	0.0798	0.6
13318448	119	30AUG22	13OCT22	12.0185	0.1207	1.0
13318451	67	30SEP22	24OCT22	12.1746	0.1146	0.9
13318458	67	13OCT22	06NOV22	12.1507	0.0990	0.8
13318460	142	03NOV22	18DEC22	12.3070	0.1083	0.9
13318463	55	23NOV22	08JAN23	12.2909	0.0845	0.7
13318468	131	04JAN23	12FEB23	12.1153	0.0789	0.7
13318472	89	01FEB23	13MAR23	12.4427	0.0796	0.6
13318475	141	16FEB23	08APR23	12.2071	0.0907	0.7
13318480	127	06APR23	07MAY23	12.2638	0.0773	0.6
13318483	110	06APR23	27MAY23	12.0745	0.0923	0.8
13318485	86	18MAY23	10JUN23	11.7291	0.1371	1.2
13318490	66	03JUN23	02JUL23	11.3742	0.0771	0.7
13318489	52	07JUN23	07JUL23	11.0404	0.0721	0.7
13318491	57	02JUL23	21JUL23	11.0667	0.0764	0.7
13318494	66	06JUL23	11AUG23	10.8288	0.1049	1.0
13318495	28	19JUL23	24JUL23	10.9000	0.0981	0.9
13318499	45	10AUG23	21AUG23	10.8356	0.0830	0.8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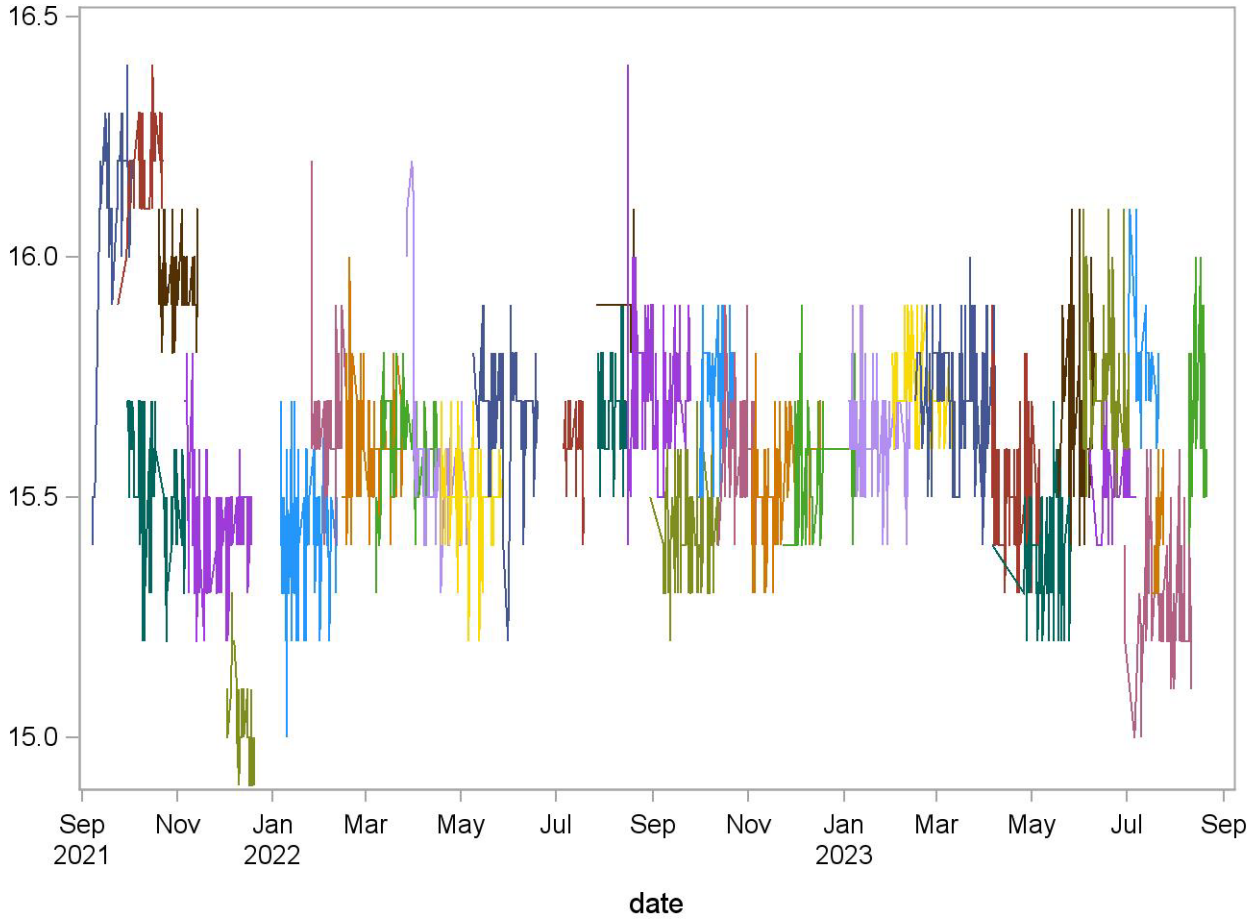
August 2021 – August 2023 Summary Statistics and QC Chart
LBCHGB3 (Hemoglobin (g/dL) (Lvl 3))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
14319388	50	08SEP21	03OCT21	16.0920	0.2078	1.3
14319389	53	24SEP21	23OCT21	16.1962	0.0940	0.6
14319393	109	30SEP21	06NOV21	15.5156	0.1355	0.9
14319395	56	20OCT21	14NOV21	15.9482	0.0831	0.5
14319399	141	05NOV21	18DEC21	15.4220	0.1159	0.8
14319402	41	03DEC21	20DEC21	15.0366	0.1067	0.7
14319408	128	06JAN22	11FEB22	15.4031	0.1310	0.9
14319412	53	26JAN22	19FEB22	15.6566	0.1352	0.9
14319416	131	14FEB22	25MAR22	15.6115	0.1028	0.7
14319418	85	08MAR22	16APR22	15.5953	0.1022	0.7
14319423	77	28MAR22	06MAY22	15.5649	0.1502	1.0
14319426	87	19APR22	28MAY22	15.5046	0.0901	0.6
14319430	78	09MAY22	19JUN22	15.6885	0.1173	0.7
14319435	32	06JUL22	19JUL22	15.6094	0.0734	0.5
14319440	12	27JUL22	21AUG22	15.9083	0.0793	0.5
14319439	45	28JUL22	15AUG22	15.6778	0.0951	0.6
14319445	133	16AUG22	25SEP22	15.7451	0.1305	0.8
14319448	116	30AUG22	13OCT22	15.4276	0.0919	0.6
14319451	70	30SEP22	24OCT22	15.6843	0.1137	0.7
14319457	67	13OCT22	06NOV22	15.5970	0.1058	0.7
14319460	144	03NOV22	18DEC22	15.5347	0.0992	0.6
14319463	54	23NOV22	08JAN23	15.5463	0.1255	0.8
14319468	130	04JAN23	12FEB23	15.6462	0.0908	0.6
14319472	87	01FEB23	13MAR23	15.7276	0.0831	0.5
14319475	136	16FEB23	08APR23	15.7132	0.1114	0.7
14319480	121	06APR23	07MAY23	15.5058	0.1192	0.8
14319483	110	06APR23	27MAY23	15.3782	0.0971	0.6
14319485	89	18MAY23	10JUN23	15.6899	0.1679	1.1
14319490	66	03JUN23	02JUL23	15.7394	0.1456	0.9
14319489	51	07JUN23	07JUL23	15.5235	0.0764	0.5
14319494	70	30JUN23	11AUG23	15.2829	0.1372	0.9
14319491	57	02JUL23	21JUL23	15.7982	0.1094	0.7
14319495	28	16JUL23	24JUL23	15.4000	0.0981	0.6
14319499	46	10AUG23	21AUG23	15.6587	0.1499	1.0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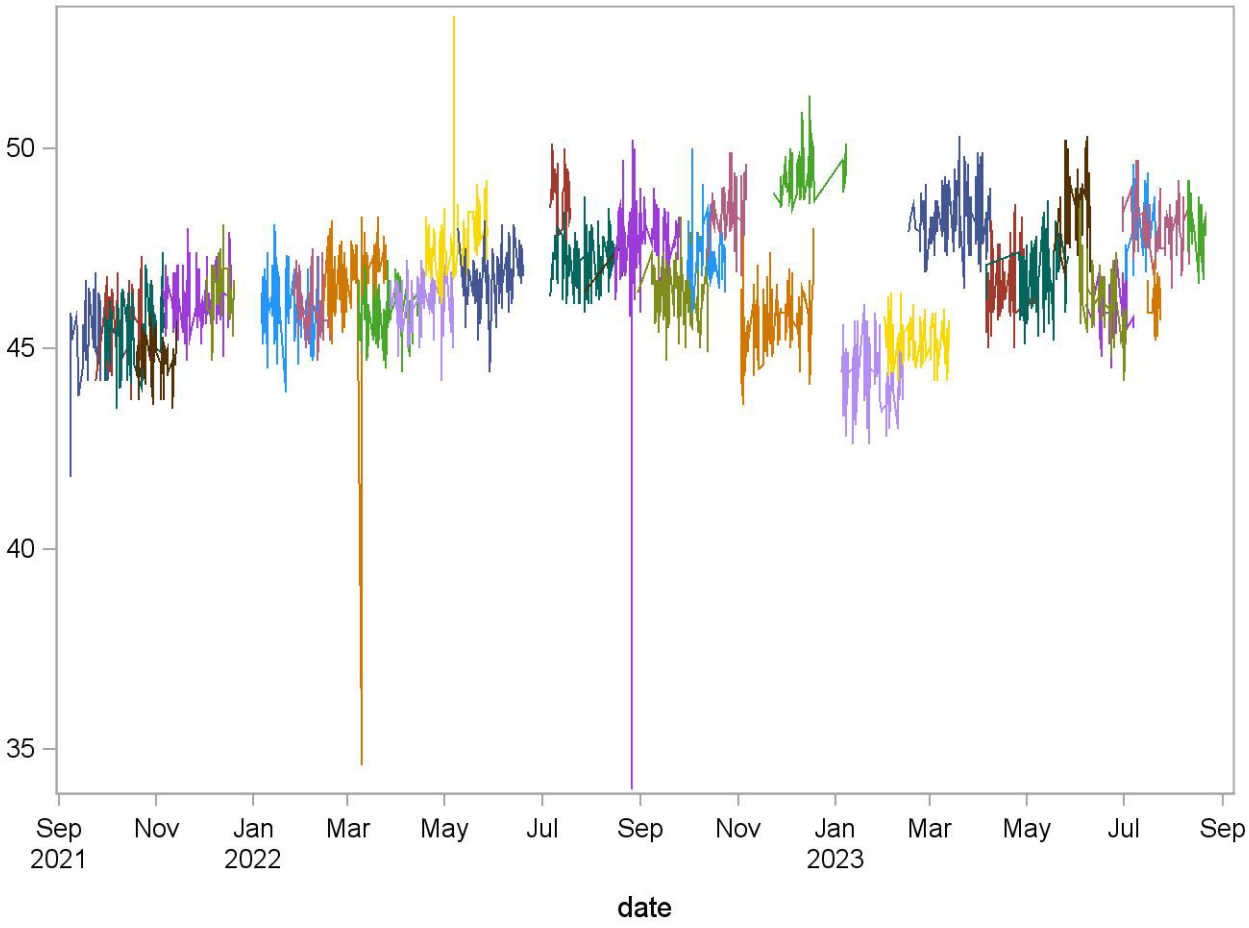
August 2021 – August 2023 Summary Statistics and QC Chart
LBCLYP1 (Lymphocyte (%) (Lvl 1))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
12317388	48	08SEP21	03OCT21	45.2542	0.9216	2.0
12317389	54	24SEP21	23OCT21	45.6611	0.7411	1.6
12317393	107	30SEP21	06NOV21	45.4477	0.6972	1.5
12317395	56	20OCT21	14NOV21	44.7946	0.6274	1.4
12317399	142	05NOV21	18DEC21	46.2275	0.6014	1.3
12317402	41	03DEC21	20DEC21	46.4341	0.6211	1.3
12317408	127	06JAN22	11FEB22	46.0882	0.7086	1.5
12317412	52	26JAN22	19FEB22	46.0635	0.6911	1.5
12317416	131	14FEB22	25MAR22	46.7527	1.2824	2.7
12317418	85	08MAR22	16APR22	45.9200	0.5902	1.3
12317423	77	28MAR22	06MAY22	46.1506	0.6698	1.5
12317426	90	19APR22	28MAY22	47.6456	0.8810	1.8
12317431	78	09MAY22	19JUN22	46.7423	0.6731	1.4
12317435	32	06JUL22	19JUL22	48.8125	0.7219	1.5
12317439	126	06JUL22	18AUG22	47.1413	0.6016	1.3
12317440	12	27JUL22	21AUG22	47.4500	0.5697	1.2
12317444	130	16AUG22	25SEP22	47.6123	1.3945	2.9
12317448	116	30AUG22	13OCT22	46.3440	0.6792	1.5
12317451	66	30SEP22	24OCT22	47.3561	0.6540	1.4
12317457	67	13OCT22	06NOV22	48.4239	0.6843	1.4
12317460	146	03NOV22	18DEC22	45.6630	0.7249	1.6
12317463	54	23NOV22	08JAN23	49.3685	0.6158	1.2
12317468	132	04JAN23	12FEB23	44.2902	0.7214	1.6
12317472	87	01FEB23	13MAR23	45.1943	0.5286	1.2
12317475	136	16FEB23	08APR23	48.3309	0.7002	1.4
12317480	122	06APR23	07MAY23	46.6508	0.6937	1.5
12317483	108	06APR23	27MAY23	46.8463	0.7742	1.7
12317485	87	18MAY23	10JUN23	48.6908	0.8007	1.6
12317490	65	03JUN23	02JUL23	46.3292	0.8605	1.9
12317489	51	07JUN23	07JUL23	46.1000	0.6714	1.5
12317494	73	30JUN23	11AUG23	48.0493	0.6135	1.3
12317491	57	02JUL23	21JUL23	48.1719	0.8200	1.7
12317495	28	16JUL23	24JUL23	46.1107	0.5336	1.2
12317499	44	10AUG23	21AUG23	48.1227	0.6671	1.4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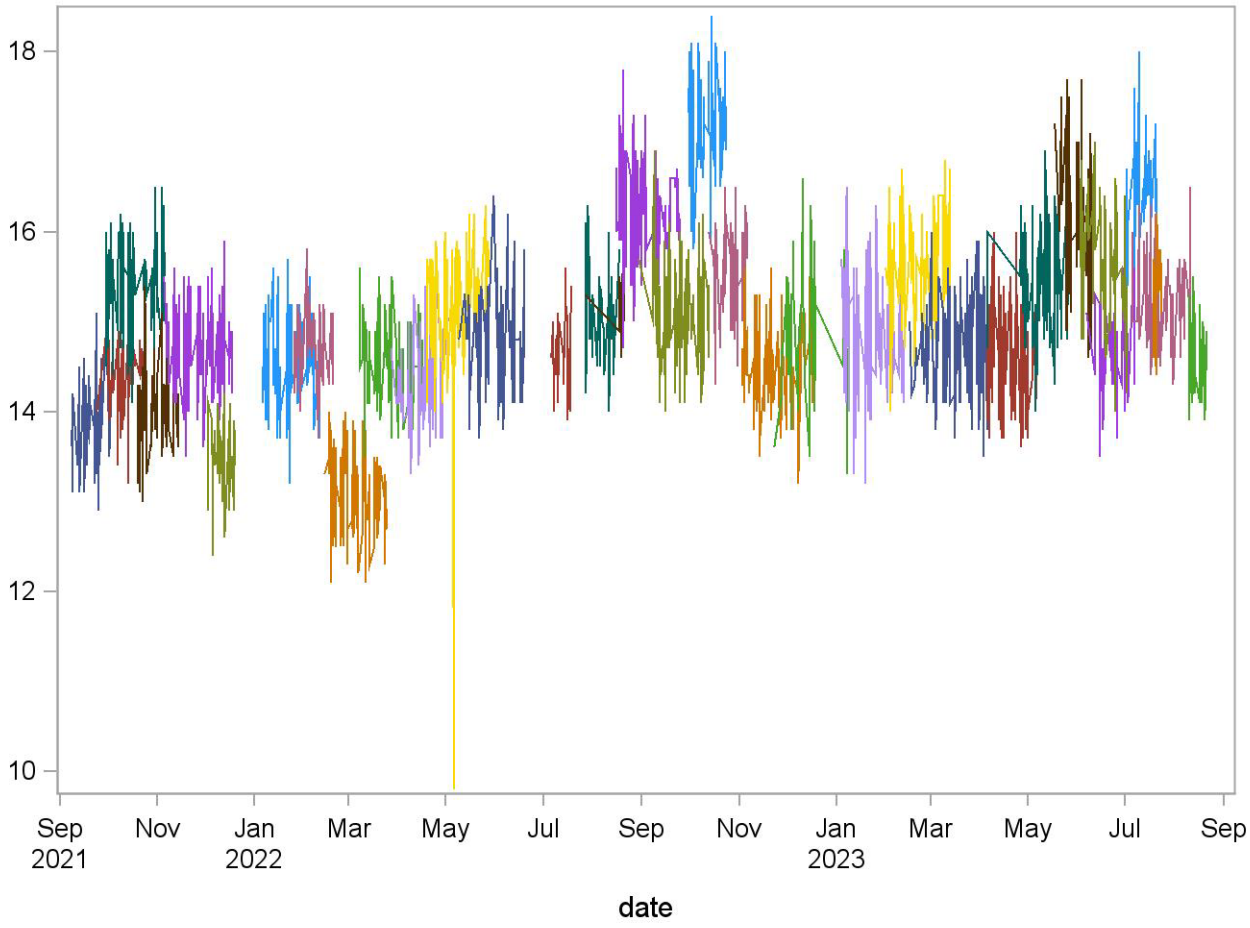
August 2021 – August 2023 Summary Statistics and QC Chart
LBCLYP2 (Lymphocyte (%) (Lvl 2))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
13318388	49	08SEP21	03OCT21	13.9918	0.5578	4.0
13318389	53	24SEP21	23OCT21	14.4377	0.4516	3.1
13318393	109	30SEP21	06NOV21	15.4330	0.4665	3.0
13318395	57	20OCT21	14NOV21	14.0667	0.4517	3.2
13318399	143	05NOV21	18DEC21	14.7573	0.4597	3.1
13318402	40	03DEC21	20DEC21	13.4775	0.4111	3.0
13318408	128	06JAN22	11FEB22	14.5148	0.4558	3.1
13318412	53	26JAN22	19FEB22	14.7509	0.4277	2.9
13318415	130	14FEB22	25MAR22	13.1208	0.4334	3.3
13318418	85	08MAR22	16APR22	14.5412	0.4661	3.2
13318423	80	28MAR22	06MAY22	14.4713	0.4855	3.4
13318426	89	19APR22	28MAY22	15.1292	0.7740	5.1
13318430	78	09MAY22	19JUN22	14.8192	0.5323	3.6
13318435	32	06JUL22	19JUL22	14.6531	0.4593	3.1
13318440	12	27JUL22	21AUG22	15.2417	0.4295	2.8
13318439	47	28JUL22	18AUG22	15.0426	0.4831	3.2
13318444	131	16AUG22	25SEP22	16.1847	0.5265	3.3
13318448	119	30AUG22	13OCT22	15.0933	0.5075	3.4
13318451	67	30SEP22	24OCT22	17.1463	0.5738	3.3
13318458	67	13OCT22	06NOV22	15.5567	0.4557	2.9
13318460	142	03NOV22	18DEC22	14.5676	0.4449	3.1
13318463	55	23NOV22	08JAN23	14.8600	0.6548	4.4
13318468	131	04JAN23	12FEB23	14.8947	0.6057	4.1
13318472	89	01FEB23	13MAR23	15.6404	0.5439	3.5
13318475	141	16FEB23	08APR23	14.7035	0.4866	3.3
13318480	127	06APR23	07MAY23	14.5976	0.5439	3.7
13318483	110	06APR23	27MAY23	15.3873	0.5281	3.4
13318485	86	18MAY23	10JUN23	16.1058	0.6523	4.1
13318490	66	03JUN23	02JUL23	15.7167	0.6211	4.0
13318489	52	07JUN23	07JUL23	14.6596	0.4832	3.3
13318491	57	02JUL23	21JUL23	16.5281	0.5294	3.2
13318494	66	06JUL23	11AUG23	15.2652	0.4799	3.1
13318495	28	19JUL23	24JUL23	15.2536	0.4290	2.8
13318499	45	10AUG23	21AUG23	14.5933	0.3858	2.6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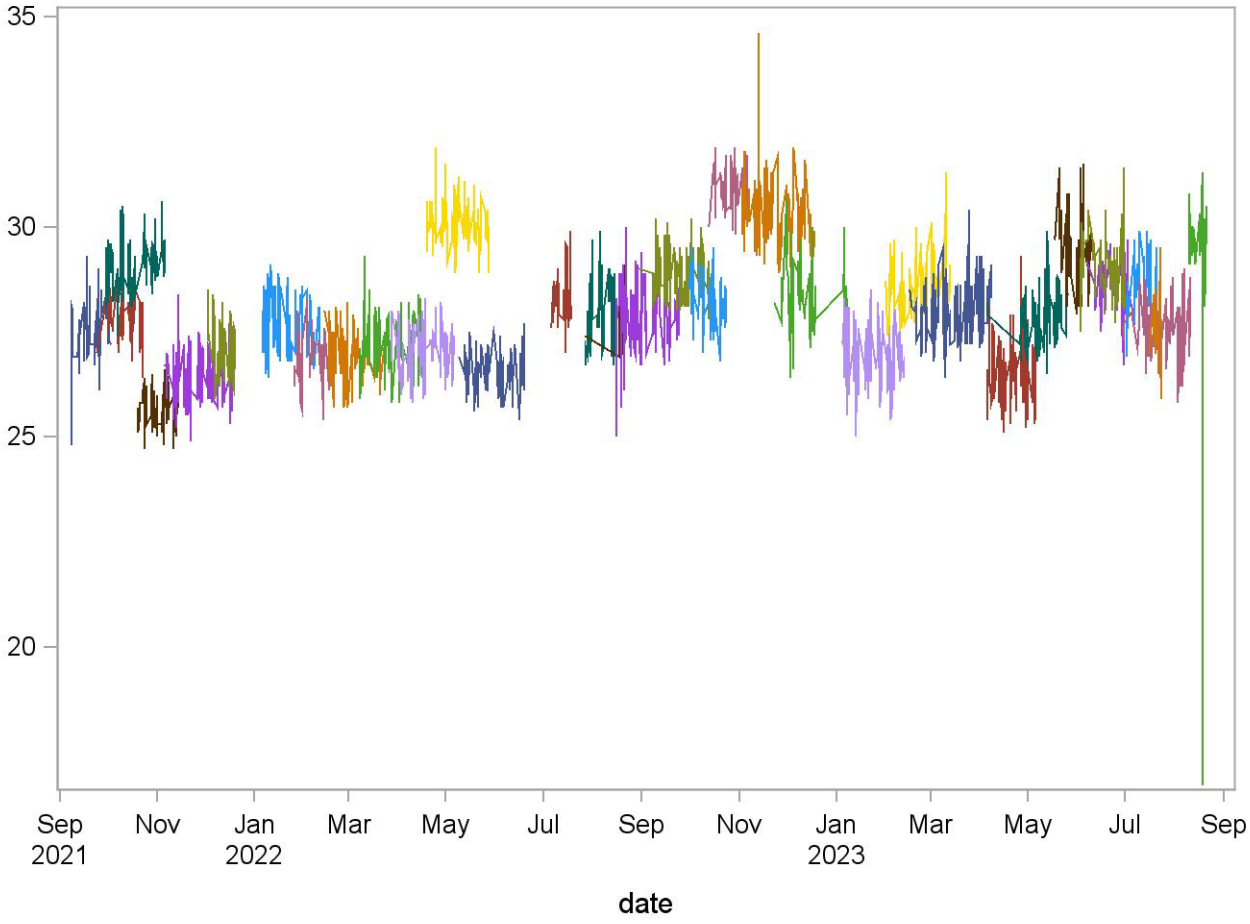
August 2021 – August 2023 Summary Statistics and QC Chart
LBCLYP3 (Lymphocyte (%) (Lvl 3))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
14319388	50	08SEP21	03OCT21	27.5520	0.7546	2.7
14319389	53	24SEP21	23OCT21	27.8509	0.5951	2.1
14319393	109	30SEP21	06NOV21	29.0661	0.5772	2.0
14319395	56	20OCT21	14NOV21	25.6857	0.5118	2.0
14319399	141	05NOV21	18DEC21	26.4312	0.5760	2.2
14319402	41	03DEC21	20DEC21	27.0122	0.6911	2.6
14319408	128	06JAN22	11FEB22	27.6977	0.6274	2.3
14319412	53	26JAN22	19FEB22	26.9208	0.5943	2.2
14319416	131	14FEB22	25MAR22	27.0359	0.5546	2.1
14319418	85	08MAR22	16APR22	27.1941	0.6445	2.4
14319423	77	28MAR22	06MAY22	27.0688	0.5809	2.1
14319426	87	19APR22	28MAY22	30.0678	0.5442	1.8
14319430	78	09MAY22	19JUN22	26.5359	0.5001	1.9
14319435	32	06JUL22	19JUL22	28.3031	0.6592	2.3
14319440	12	27JUL22	21AUG22	27.7667	0.7114	2.6
14319439	45	28JUL22	15AUG22	28.0800	0.8140	2.9
14319445	133	16AUG22	25SEP22	27.8722	0.7176	2.6
14319448	116	30AUG22	13OCT22	28.8905	0.5298	1.8
14319451	70	30SEP22	24OCT22	28.2329	0.6040	2.1
14319457	67	13OCT22	06NOV22	30.8731	0.5465	1.8
14319460	144	03NOV22	18DEC22	30.2146	0.7666	2.5
14319463	54	23NOV22	08JAN23	28.3981	0.8466	3.0
14319468	130	04JAN23	12FEB23	26.9823	0.7148	2.6
14319472	87	01FEB23	13MAR23	28.5069	0.7105	2.5
14319475	136	16FEB23	08APR23	28.0243	0.6633	2.4
14319480	121	06APR23	07MAY23	26.5314	0.6945	2.6
14319483	110	06APR23	27MAY23	27.9027	0.6125	2.2
14319485	89	18MAY23	10JUN23	29.3640	0.7740	2.6
14319490	66	03JUN23	02JUL23	29.0348	0.7255	2.5
14319489	51	07JUN23	07JUL23	28.5882	0.6045	2.1
14319494	70	30JUN23	11AUG23	27.5786	0.7132	2.6
14319491	57	02JUL23	21JUL23	28.6351	0.6594	2.3
14319495	28	16JUL23	24JUL23	27.6143	0.6803	2.5
14319499	46	10AUG23	21AUG23	29.4370	1.9958	6.8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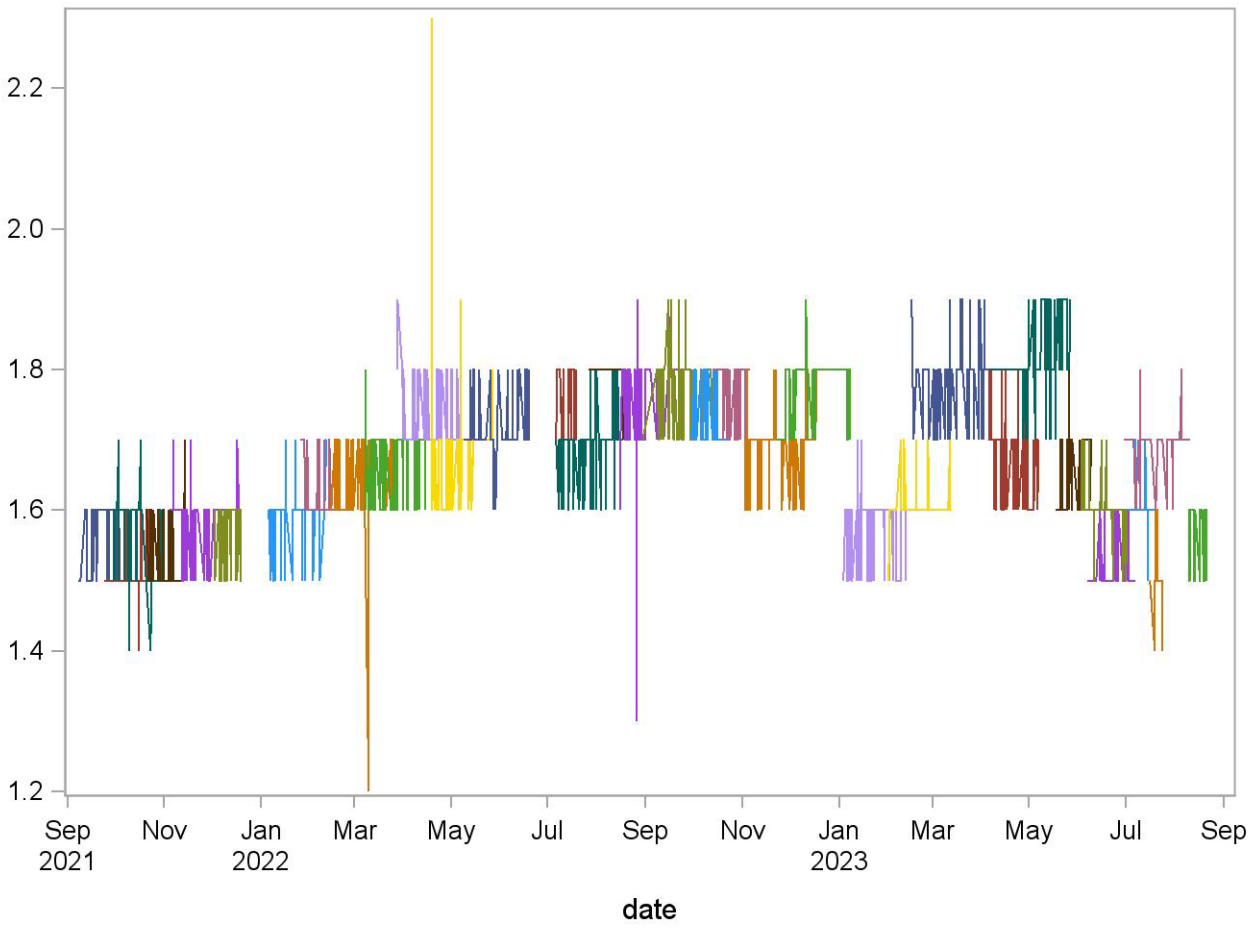
August 2021 – August 2023 Summary Statistics and QC Chart
LBCLYN1 (Lymphocyte No.(10^3 cells/uL) (Lvl 1))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
12317388	48	08SEP21	03OCT21	1.5708	0.0459	2.9
12317389	54	24SEP21	23OCT21	1.5130	0.0391	2.6
12317393	107	30SEP21	06NOV21	1.5579	0.0567	3.6
12317395	56	20OCT21	14NOV21	1.5375	0.0524	3.4
12317399	142	05NOV21	18DEC21	1.5831	0.0429	2.7
12317402	41	03DEC21	20DEC21	1.5659	0.0480	3.1
12317408	127	06JAN22	11FEB22	1.5929	0.0382	2.4
12317412	52	26JAN22	19FEB22	1.6288	0.0457	2.8
12317416	131	14FEB22	25MAR22	1.6412	0.0631	3.8
12317418	85	08MAR22	16APR22	1.6600	0.0516	3.1
12317423	77	28MAR22	06MAY22	1.7364	0.0511	2.9
12317426	90	19APR22	28MAY22	1.6811	0.0847	5.0
12317431	78	09MAY22	19JUN22	1.7192	0.0457	2.7
12317435	32	06JUL22	19JUL22	1.7688	0.0471	2.7
12317439	126	06JUL22	18AUG22	1.6905	0.0464	2.7
12317440	12	27JUL22	21AUG22	1.7333	0.0492	2.8
12317444	130	16AUG22	25SEP22	1.7500	0.0673	3.8
12317448	116	30AUG22	13OCT22	1.7655	0.0561	3.2
12317451	66	30SEP22	24OCT22	1.7288	0.0456	2.6
12317457	67	13OCT22	06NOV22	1.7687	0.0467	2.6
12317460	146	03NOV22	18DEC22	1.6870	0.0459	2.7
12317463	54	23NOV22	08JAN23	1.7667	0.0514	2.9
12317468	132	04JAN23	12FEB23	1.5705	0.0506	3.2
12317472	87	01FEB23	13MAR23	1.6057	0.0279	1.7
12317475	136	16FEB23	08APR23	1.7897	0.0491	2.7
12317480	122	06APR23	07MAY23	1.6787	0.0549	3.3
12317483	108	06APR23	27MAY23	1.8148	0.0544	3.0
12317485	87	18MAY23	10JUN23	1.6609	0.0514	3.1
12317490	65	03JUN23	02JUL23	1.6031	0.0432	2.7
12317489	51	07JUN23	07JUL23	1.5255	0.0440	2.9
12317494	73	30JUN23	11AUG23	1.6973	0.0332	2.0
12317491	57	02JUL23	21JUL23	1.6088	0.0342	2.1
12317495	28	16JUL23	24JUL23	1.5071	0.0466	3.1
12317499	44	10AUG23	21AUG23	1.5705	0.0462	2.9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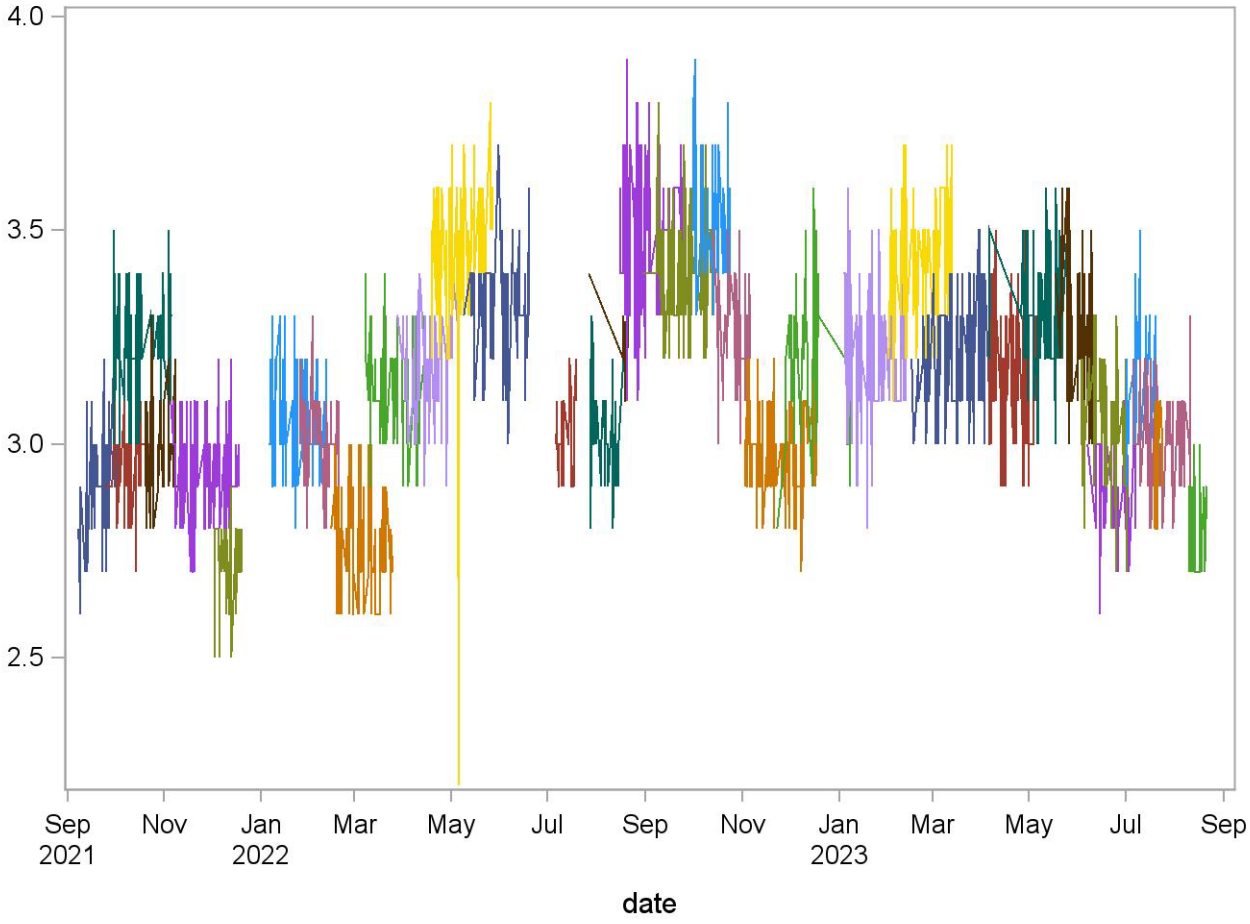
August 2021 – August 2023 Summary Statistics and QC Chart
LBCLYN2 (Lymphocyte No.(10^3 cells/uL) (Lvl 2))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
13318388	49	08SEP21	03OCT21	2.9204	0.1399	4.8
13318389	53	24SEP21	23OCT21	2.9604	0.0987	3.3
13318393	109	30SEP21	06NOV21	3.2404	0.1148	3.5
13318395	57	20OCT21	14NOV21	2.9877	0.1001	3.4
13318399	143	05NOV21	18DEC21	2.9441	0.1046	3.6
13318402	40	03DEC21	20DEC21	2.7100	0.0928	3.4
13318408	128	06JAN22	11FEB22	3.0539	0.1079	3.5
13318412	53	26JAN22	19FEB22	3.0151	0.1063	3.5
13318415	130	14FEB22	25MAR22	2.7754	0.1004	3.6
13318418	85	08MAR22	16APR22	3.1329	0.1117	3.6
13318423	80	28MAR22	06MAY22	3.1900	0.1154	3.6
13318426	89	19APR22	28MAY22	3.4416	0.1894	5.5
13318430	78	09MAY22	19JUN22	3.3128	0.1242	3.7
13318435	32	06JUL22	19JUL22	3.0188	0.1030	3.4
13318440	12	27JUL22	21AUG22	3.2500	0.1000	3.1
13318439	47	28JUL22	18AUG22	3.0340	0.1048	3.5
13318444	131	16AUG22	25SEP22	3.4672	0.1459	4.2
13318448	119	30AUG22	13OCT22	3.4101	0.1160	3.4
13318451	67	30SEP22	24OCT22	3.5358	0.1400	4.0
13318458	67	13OCT22	06NOV22	3.2746	0.1035	3.2
13318460	142	03NOV22	18DEC22	2.9958	0.1058	3.5
13318463	55	23NOV22	08JAN23	3.2000	0.1587	5.0
13318468	131	04JAN23	12FEB23	3.2122	0.1376	4.3
13318472	89	01FEB23	13MAR23	3.4270	0.1321	3.9
13318475	141	16FEB23	08APR23	3.2078	0.1213	3.8
13318480	127	06APR23	07MAY23	3.1591	0.1335	4.2
13318483	110	06APR23	27MAY23	3.3055	0.1248	3.8
13318485	86	18MAY23	10JUN23	3.2535	0.1403	4.3
13318490	66	03JUN23	02JUL23	3.0576	0.1302	4.3
13318489	52	07JUN23	07JUL23	2.8923	0.1064	3.7
13318491	57	02JUL23	21JUL23	3.1754	0.1123	3.5
13318494	66	06JUL23	11AUG23	3.0212	0.1117	3.7
13318495	28	19JUL23	24JUL23	2.9500	0.1000	3.4
13318499	45	10AUG23	21AUG23	2.8089	0.0848	3.0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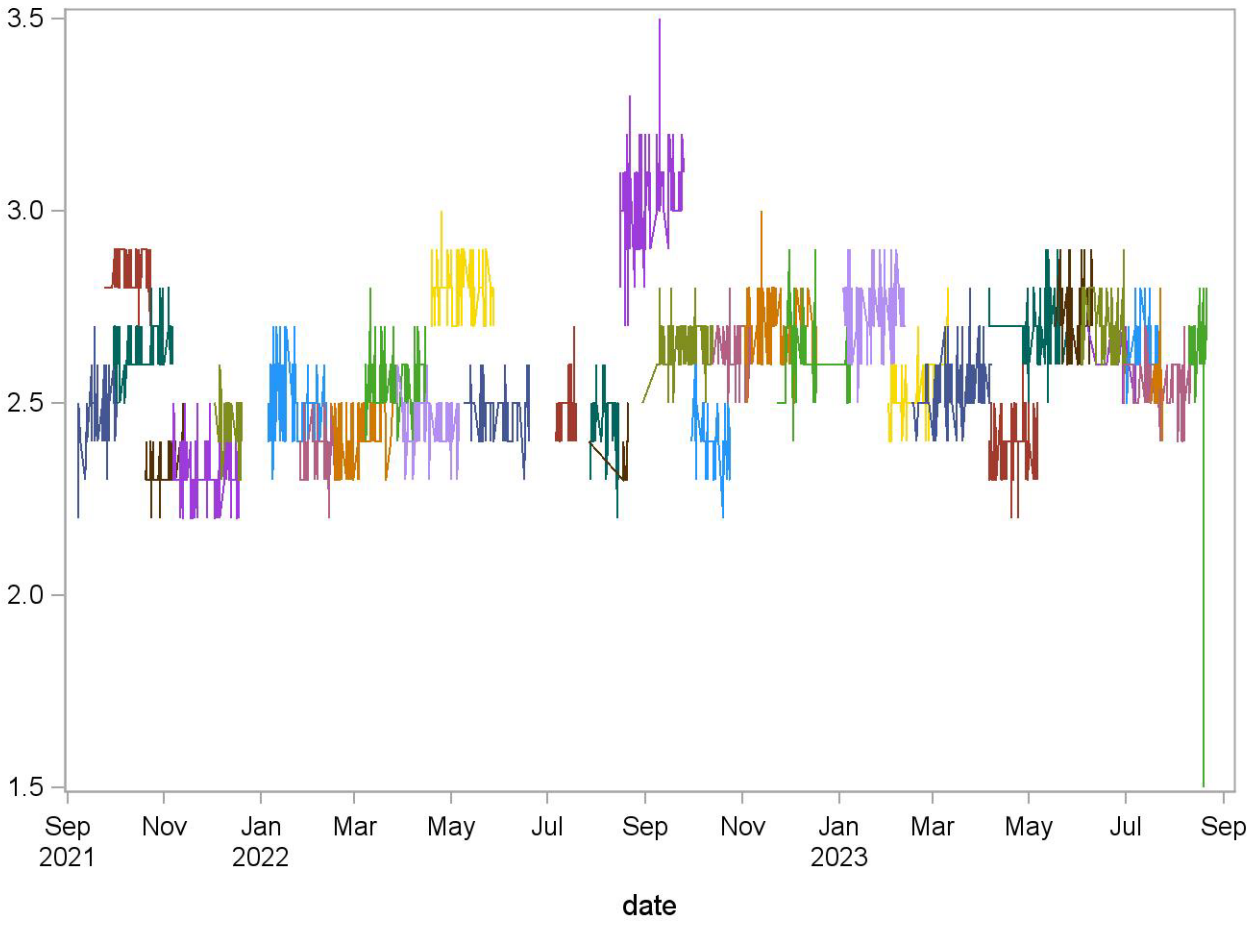
August 2021 – August 2023 Summary Statistics and QC Chart
LBCLYN3 (Lymphocyte No.(10^3 cells/uL) (Lvl 3))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
14319388	50	08SEP21	03OCT21	2.4780	0.0887	3.6
14319389	53	24SEP21	23OCT21	2.8377	0.0562	2.0
14319393	109	30SEP21	06NOV21	2.6385	0.0637	2.4
14319395	56	20OCT21	14NOV21	2.3250	0.0580	2.5
14319399	141	05NOV21	18DEC21	2.3163	0.0723	3.1
14319402	41	03DEC21	20DEC21	2.4390	0.0666	2.7
14319408	128	06JAN22	11FEB22	2.5094	0.0873	3.5
14319412	53	26JAN22	19FEB22	2.3736	0.0655	2.8
14319416	131	14FEB22	25MAR22	2.4122	0.0723	3.0
14319418	85	08MAR22	16APR22	2.5635	0.0769	3.0
14319423	77	28MAR22	06MAY22	2.4403	0.0654	2.7
14319426	87	19APR22	28MAY22	2.7966	0.0690	2.5
14319430	78	09MAY22	19JUN22	2.4808	0.0582	2.3
14319435	32	06JUL22	19JUL22	2.4813	0.0780	3.1
14319440	12	27JUL22	21AUG22	2.3750	0.0754	3.2
14319439	45	28JUL22	15AUG22	2.4556	0.0813	3.3
14319445	133	16AUG22	25SEP22	3.0203	0.1166	3.9
14319448	116	30AUG22	13OCT22	2.6483	0.0611	2.3
14319451	70	30SEP22	24OCT22	2.4229	0.0854	3.5
14319457	67	13OCT22	06NOV22	2.6433	0.0657	2.5
14319460	144	03NOV22	18DEC22	2.6819	0.0726	2.7
14319463	54	23NOV22	08JAN23	2.6352	0.1012	3.8
14319468	130	04JAN23	12FEB23	2.7315	0.0836	3.1
14319472	87	01FEB23	13MAR23	2.5287	0.0730	2.9
14319475	136	16FEB23	08APR23	2.5493	0.0740	2.9
14319480	121	06APR23	07MAY23	2.3901	0.0746	3.1
14319483	110	06APR23	27MAY23	2.7045	0.0783	2.9
14319485	89	18MAY23	10JUN23	2.7124	0.0850	3.1
14319490	66	03JUN23	02JUL23	2.6939	0.0857	3.2
14319489	51	07JUN23	07JUL23	2.6118	0.0516	2.0
14319494	70	30JUN23	11AUG23	2.5443	0.0735	2.9
14319491	57	02JUL23	21JUL23	2.6561	0.0756	2.8
14319495	28	16JUL23	24JUL23	2.5679	0.0723	2.8
14319499	46	10AUG23	21AUG23	2.6239	0.1828	7.0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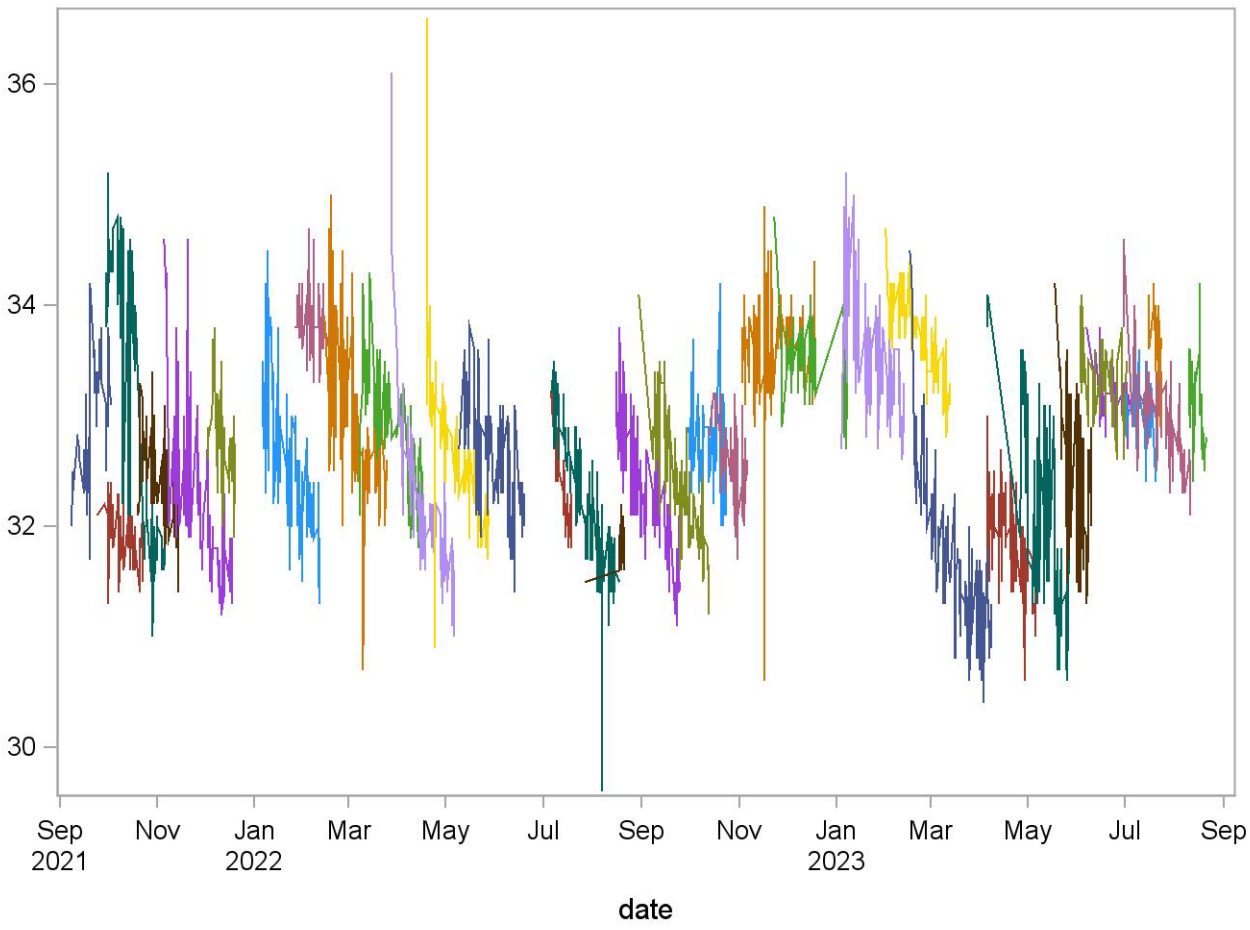
August 2021 – August 2023 Summary Statistics and QC Chart
LBCMCHC1 (MCHC (g/dL) (Lvl 1))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
12317388	48	08SEP21	03OCT21	32.9854	0.5581	1.7
12317389	54	24SEP21	23OCT21	31.9167	0.2704	0.8
12317393	107	30SEP21	06NOV21	33.1486	1.2008	3.6
12317395	56	20OCT21	14NOV21	32.4589	0.4080	1.3
12317399	142	05NOV21	18DEC21	32.3592	0.6677	2.1
12317402	41	03DEC21	20DEC21	32.7561	0.4184	1.3
12317408	127	06JAN22	11FEB22	32.6165	0.5327	1.6
12317412	52	26JAN22	19FEB22	33.8308	0.3013	0.9
12317416	131	14FEB22	25MAR22	33.1481	0.7316	2.2
12317418	85	08MAR22	16APR22	32.8929	0.5026	1.5
12317423	77	28MAR22	06MAY22	32.2727	0.7421	2.3
12317426	90	19APR22	28MAY22	32.7122	0.6579	2.0
12317431	78	09MAY22	19JUN22	32.6128	0.5280	1.6
12317435	32	06JUL22	19JUL22	32.4594	0.4613	1.4
12317439	126	06JUL22	18AUG22	32.0873	0.5984	1.9
12317440	12	27JUL22	21AUG22	31.8333	0.2462	0.8
12317444	133	16AUG22	25SEP22	32.4707	0.5257	1.6
12317448	116	30AUG22	13OCT22	32.4474	0.5616	1.7
12317451	66	30SEP22	24OCT22	32.7591	0.3922	1.2
12317457	67	13OCT22	06NOV22	32.5836	0.3347	1.0
12317460	146	03NOV22	18DEC22	33.6199	0.4422	1.3
12317463	54	23NOV22	08JAN23	33.5074	0.3507	1.0
12317468	132	04JAN23	12FEB23	33.6417	0.5016	1.5
12317472	87	01FEB23	13MAR23	33.7126	0.3608	1.1
12317475	137	16FEB23	08APR23	31.5745	0.6873	2.2
12317480	122	06APR23	07MAY23	31.9025	0.4003	1.3
12317483	108	06APR23	27MAY23	32.2944	0.8273	2.6
12317485	87	18MAY23	10JUN23	32.4126	0.6107	1.9
12317490	65	03JUN23	02JUL23	33.2985	0.3305	1.0
12317489	51	07JUN23	07JUL23	33.1529	0.2327	0.7
12317494	73	30JUN23	11AUG23	33.0329	0.4992	1.5
12317491	57	02JUL23	21JUL23	33.0930	0.2981	0.9
12317495	28	16JUL23	24JUL23	33.7036	0.2701	0.8
12317499	44	10AUG23	21AUG23	33.1295	0.3645	1.1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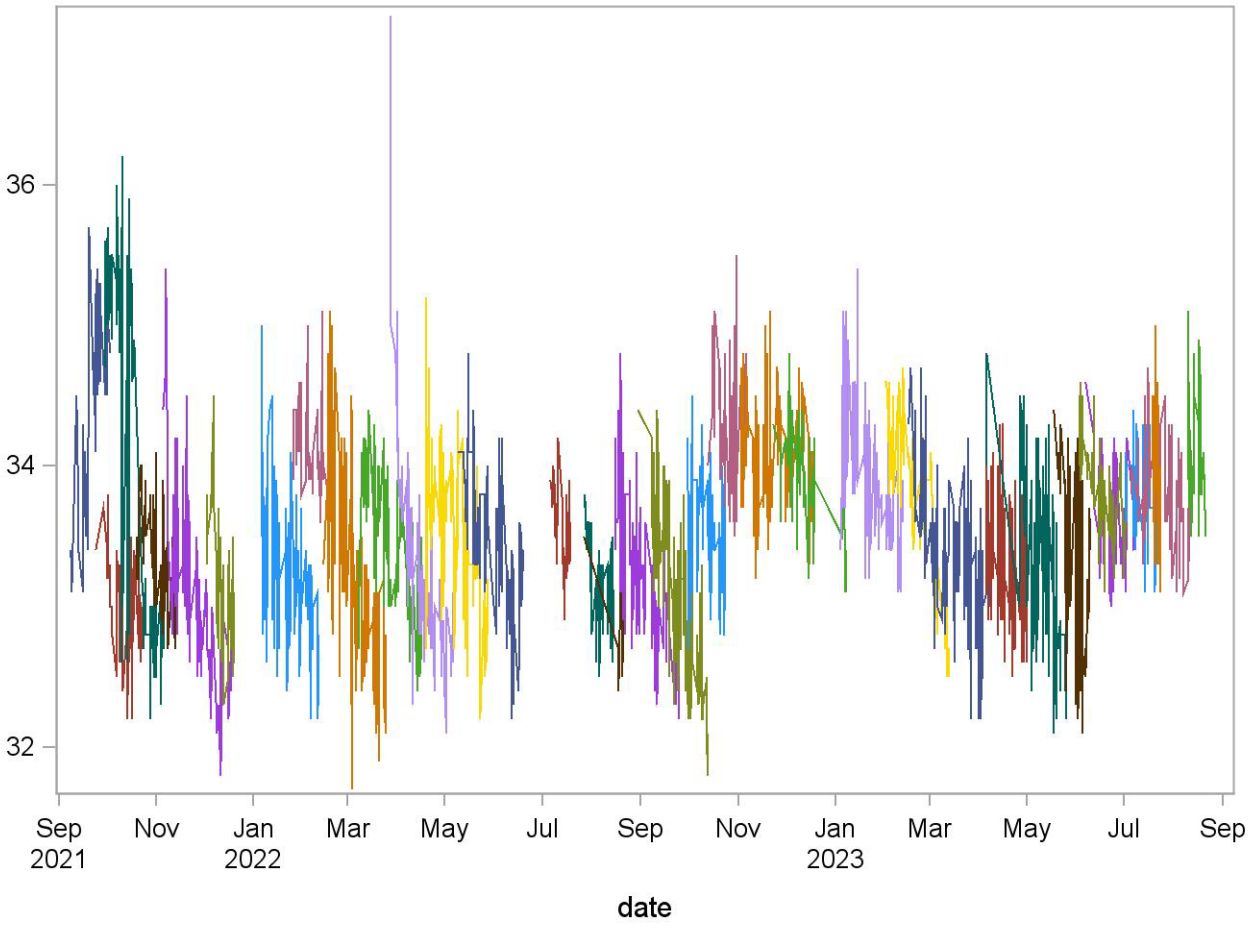
August 2021 – August 2023 Summary Statistics and QC Chart
LBCMCHC2 (MCHC (g/dL) (Lvl 2))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
13318388	49	08SEP21	03OCT21	34.3816	0.6927	2.0
13318389	53	24SEP21	23OCT21	33.0453	0.4003	1.2
13318393	109	30SEP21	06NOV21	34.0908	1.1777	3.5
13318395	57	20OCT21	14NOV21	33.4105	0.3395	1.0
13318399	143	05NOV21	18DEC21	33.1552	0.6206	1.9
13318402	40	03DEC21	20DEC21	33.2325	0.4741	1.4
13318408	128	06JAN22	11FEB22	33.2773	0.4726	1.4
13318412	53	26JAN22	19FEB22	34.1113	0.3297	1.0
13318415	130	14FEB22	25MAR22	33.4292	0.7383	2.2
13318418	85	08MAR22	16APR22	33.4412	0.4586	1.4
13318423	81	28MAR22	06MAY22	33.2765	0.7675	2.3
13318426	89	19APR22	28MAY22	33.5371	0.5113	1.5
13318430	78	09MAY22	19JUN22	33.4731	0.4717	1.4
13318435	32	06JUL22	19JUL22	33.5938	0.2929	0.9
13318440	12	27JUL22	21AUG22	32.8917	0.3088	0.9
13318439	47	28JUL22	18AUG22	33.1638	0.3319	1.0
13318444	131	16AUG22	25SEP22	33.2412	0.4197	1.3
13318448	119	30AUG22	13OCT22	33.1067	0.5798	1.8
13318451	67	30SEP22	24OCT22	33.4970	0.3927	1.2
13318458	67	13OCT22	06NOV22	34.2597	0.3935	1.1
13318460	142	03NOV22	18DEC22	34.1021	0.3582	1.1
13318463	55	23NOV22	08JAN23	33.9055	0.3699	1.1
13318468	131	04JAN23	12FEB23	34.0458	0.4618	1.4
13318472	89	01FEB23	13MAR23	33.7348	0.5419	1.6
13318475	141	16FEB23	08APR23	33.2957	0.4928	1.5
13318480	127	06APR23	07MAY23	33.3102	0.3986	1.2
13318483	110	06APR23	27MAY23	33.3991	0.6092	1.8
13318485	86	18MAY23	10JUN23	33.3430	0.5470	1.6
13318490	66	03JUN23	02JUL23	33.8470	0.3540	1.0
13318489	52	07JUN23	07JUL23	33.6231	0.3590	1.1
13318491	57	02JUL23	21JUL23	33.8088	0.3025	0.9
13318494	66	06JUL23	11AUG23	33.8030	0.3419	1.0
13318495	28	19JUL23	24JUL23	33.9821	0.4579	1.3
13318499	45	10AUG23	21AUG23	34.1622	0.3904	1.1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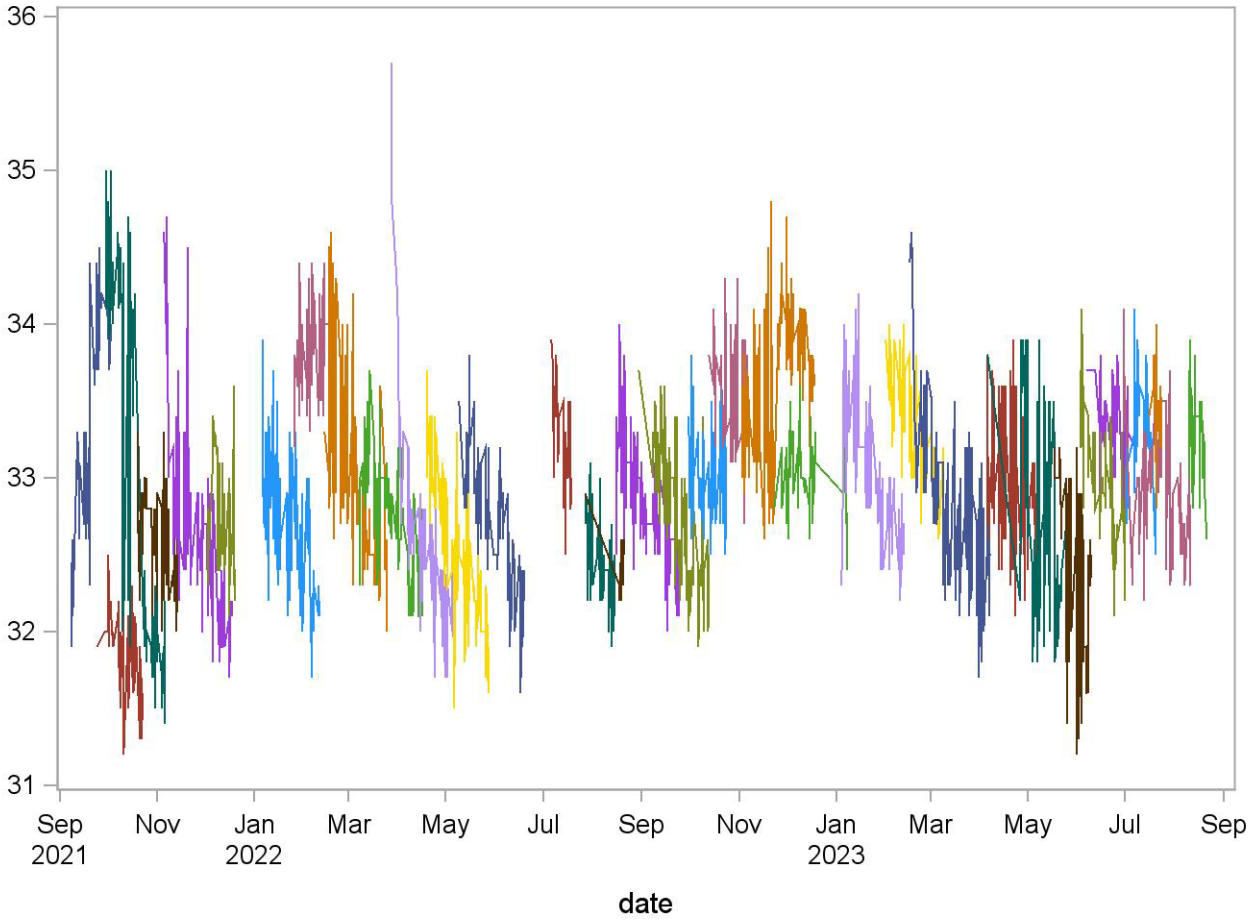
August 2021 – August 2023 Summary Statistics and QC Chart
LBCMCHC3 (MCHC (g/dL) (Lvl 3))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
14319388	50	08SEP21	03OCT21	33.4760	0.7035	2.1
14319389	53	24SEP21	23OCT21	31.8943	0.2790	0.9
14319393	109	30SEP21	06NOV21	33.1450	1.1464	3.5
14319395	56	20OCT21	14NOV21	32.6125	0.3157	1.0
14319399	141	05NOV21	18DEC21	32.7404	0.5452	1.7
14319402	41	03DEC21	20DEC21	32.7098	0.3774	1.2
14319408	128	06JAN22	11FEB22	32.7109	0.3691	1.1
14319412	53	26JAN22	19FEB22	33.8113	0.3417	1.0
14319416	131	14FEB22	25MAR22	33.2237	0.6393	1.9
14319418	85	08MAR22	16APR22	32.7541	0.3862	1.2
14319423	77	28MAR22	06MAY22	32.6494	0.6690	2.0
14319426	87	19APR22	28MAY22	32.5816	0.4957	1.5
14319430	78	09MAY22	19JUN22	32.7038	0.4069	1.2
14319435	32	06JUL22	19JUL22	33.2438	0.3151	0.9
14319440	12	27JUL22	21AUG22	32.4833	0.2290	0.7
14319439	45	28JUL22	15AUG22	32.4667	0.2852	0.9
14319445	133	16AUG22	25SEP22	32.9256	0.3603	1.1
14319448	116	30AUG22	13OCT22	32.7293	0.4078	1.2
14319451	70	30SEP22	24OCT22	33.0243	0.2810	0.9
14319457	67	13OCT22	06NOV22	33.5164	0.3198	1.0
14319460	144	03NOV22	18DEC22	33.6319	0.4252	1.3
14319463	54	23NOV22	08JAN23	33.0019	0.2343	0.7
14319468	130	04JAN23	12FEB23	33.1546	0.4060	1.2
14319472	87	01FEB23	13MAR23	33.1966	0.4048	1.2
14319475	136	16FEB23	08APR23	32.7699	0.4643	1.4
14319480	121	06APR23	07MAY23	32.9950	0.3958	1.2
14319483	110	06APR23	27MAY23	32.8418	0.6404	2.0
14319485	89	18MAY23	10JUN23	32.3764	0.4975	1.5
14319490	66	03JUN23	02JUL23	33.0106	0.3697	1.1
14319489	51	07JUN23	07JUL23	33.3373	0.2630	0.8
14319494	70	30JUN23	11AUG23	32.9300	0.3987	1.2
14319491	57	02JUL23	21JUL23	33.2982	0.3265	1.0
14319495	28	16JUL23	24JUL23	33.4500	0.2925	0.9
14319499	46	10AUG23	21AUG23	33.2891	0.3121	0.9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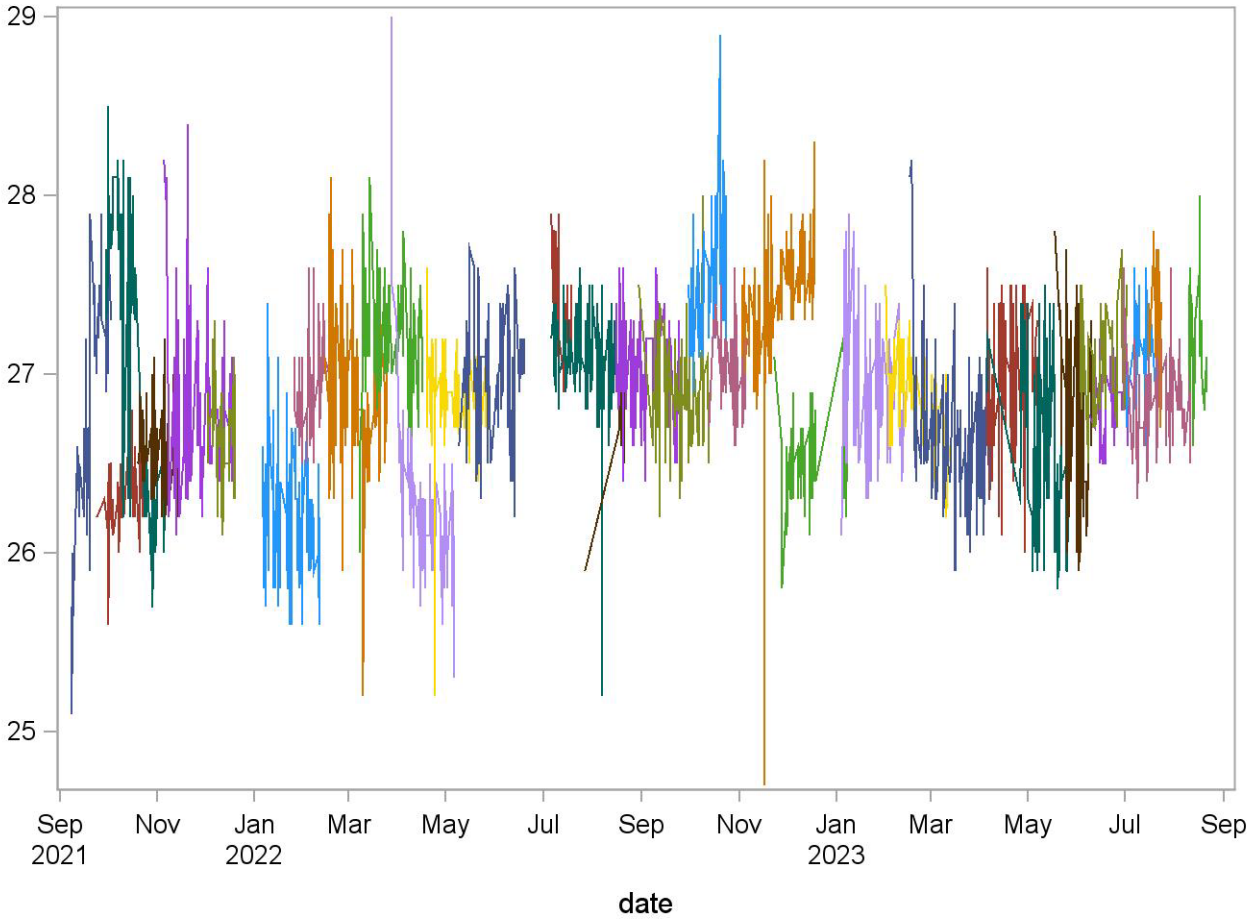
August 2021 – August 2023 Summary Statistics and QC Chart
LBCMCH1 (Mean cell hemoglobin (pg) (Lvl 1))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
12317388	48	08SEP21	03OCT21	26.9188	0.6447	2.4
12317389	54	24SEP21	23OCT21	26.3426	0.2160	0.8
12317393	107	30SEP21	06NOV21	27.0393	0.7677	2.8
12317395	56	20OCT21	14NOV21	26.6125	0.2552	1.0
12317399	142	05NOV21	18DEC21	26.8113	0.4334	1.6
12317402	41	03DEC21	20DEC21	26.6707	0.2741	1.0
12317408	127	06JAN22	11FEB22	26.1906	0.2991	1.1
12317412	52	26JAN22	19FEB22	26.9558	0.2675	1.0
12317416	131	14FEB22	25MAR22	26.9237	0.3988	1.5
12317418	85	08MAR22	16APR22	27.1659	0.3459	1.3
12317423	77	28MAR22	06MAY22	26.2922	0.4754	1.8
12317426	90	19APR22	28MAY22	26.8833	0.2598	1.0
12317431	78	09MAY22	19JUN22	26.9705	0.3404	1.3
12317435	32	06JUL22	19JUL22	27.3875	0.2709	1.0
12317439	126	06JUL22	18AUG22	27.0722	0.2679	1.0
12317440	12	27JUL22	21AUG22	26.7917	0.3605	1.3
12317444	133	16AUG22	25SEP22	27.0173	0.2347	0.9
12317448	116	30AUG22	13OCT22	26.9000	0.2687	1.0
12317451	66	30SEP22	24OCT22	27.4833	0.3377	1.2
12317457	67	13OCT22	06NOV22	27.0627	0.2080	0.8
12317460	146	03NOV22	18DEC22	27.3801	0.3562	1.3
12317463	54	23NOV22	08JAN23	26.5222	0.2853	1.1
12317468	132	04JAN23	12FEB23	26.9182	0.3361	1.2
12317472	87	01FEB23	13MAR23	26.8322	0.2213	0.8
12317475	137	16FEB23	08APR23	26.5942	0.3595	1.4
12317480	122	06APR23	07MAY23	26.9926	0.3313	1.2
12317483	108	06APR23	27MAY23	26.7148	0.4575	1.7
12317485	87	18MAY23	10JUN23	26.7759	0.4393	1.6
12317490	65	03JUN23	02JUL23	27.0600	0.2461	0.9
12317489	51	07JUN23	07JUL23	26.8353	0.2134	0.8
12317494	73	30JUN23	11AUG23	26.8795	0.2603	1.0
12317491	57	02JUL23	21JUL23	27.1246	0.2214	0.8
12317495	28	16JUL23	24JUL23	27.3429	0.2395	0.9
12317499	44	10AUG23	21AUG23	27.1682	0.2726	1.0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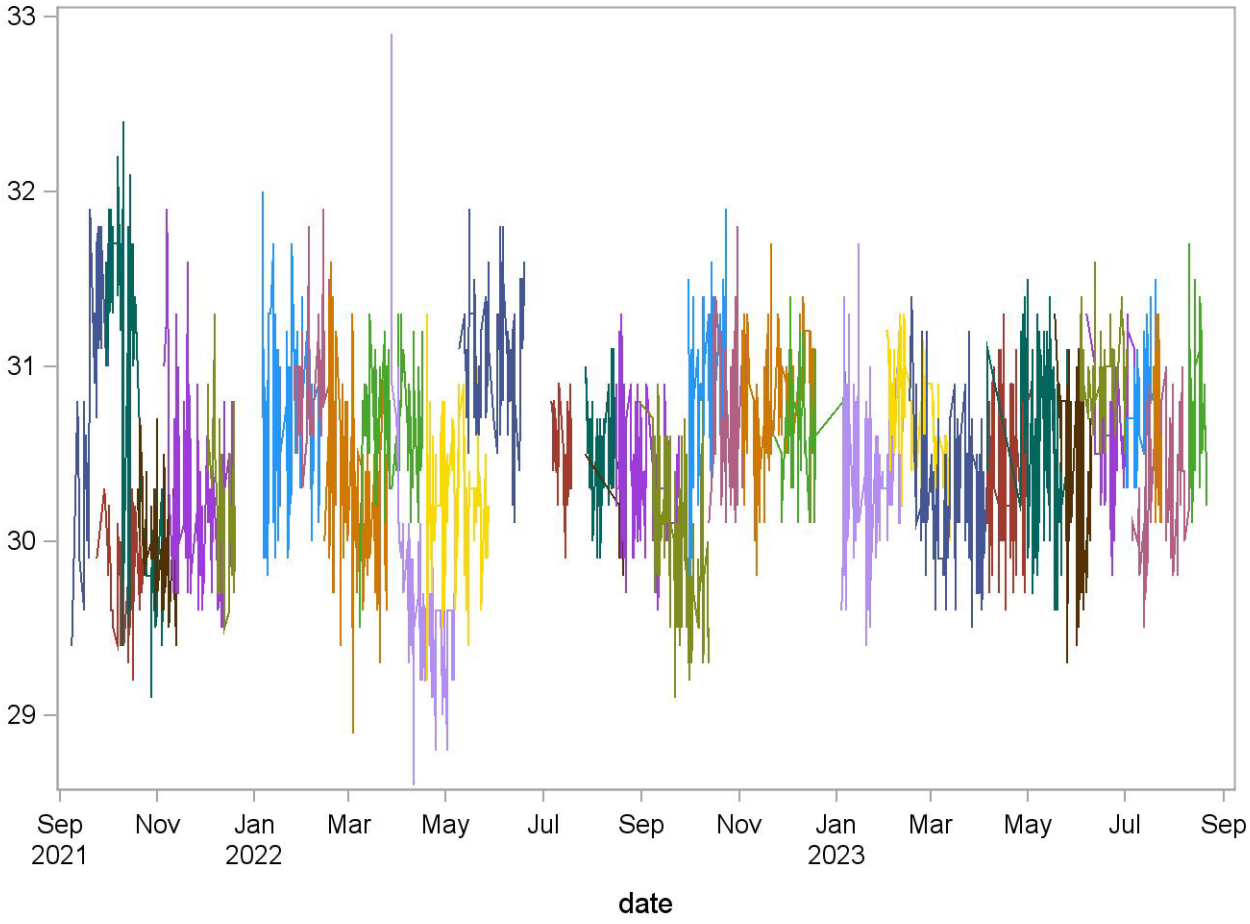
August 2021 – August 2023 Summary Statistics and QC Chart
LBCMCH2 (Mean cell hemoglobin (pg) (Lvl 2))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
13318388	49	08SEP21	03OCT21	30.8592	0.6961	2.3
13318389	53	24SEP21	23OCT21	29.8434	0.3243	1.1
13318393	109	30SEP21	06NOV21	30.6624	0.8638	2.8
13318395	57	20OCT21	14NOV21	30.0404	0.2840	0.9
13318399	143	05NOV21	18DEC21	30.2664	0.4654	1.5
13318402	40	03DEC21	20DEC21	30.2425	0.4044	1.3
13318408	128	06JAN22	11FEB22	30.6625	0.4049	1.3
13318412	53	26JAN22	19FEB22	30.8887	0.2991	1.0
13318415	130	14FEB22	25MAR22	30.3523	0.4824	1.6
13318418	85	08MAR22	16APR22	30.6518	0.3631	1.2
13318423	81	28MAR22	06MAY22	29.6235	0.5786	2.0
13318426	89	19APR22	28MAY22	30.2483	0.3529	1.2
13318430	78	09MAY22	19JUN22	31.0628	0.3561	1.1
13318435	32	06JUL22	19JUL22	30.5156	0.2451	0.8
13318440	12	27JUL22	21AUG22	30.2750	0.2864	0.9
13318439	47	28JUL22	18AUG22	30.5191	0.2909	1.0
13318444	131	16AUG22	25SEP22	30.3191	0.2928	1.0
13318448	119	30AUG22	13OCT22	29.9958	0.3977	1.3
13318451	67	30SEP22	24OCT22	30.7746	0.4325	1.4
13318458	67	13OCT22	06NOV22	30.7209	0.3637	1.2
13318460	142	03NOV22	18DEC22	30.7789	0.3222	1.0
13318463	55	23NOV22	08JAN23	30.6509	0.2892	0.9
13318468	131	04JAN23	12FEB23	30.3985	0.3825	1.3
13318472	89	01FEB23	13MAR23	30.6663	0.3034	1.0
13318475	141	16FEB23	08APR23	30.2312	0.3598	1.2
13318480	127	06APR23	07MAY23	30.4291	0.3767	1.2
13318483	110	06APR23	27MAY23	30.5827	0.4553	1.5
13318485	86	18MAY23	10JUN23	30.3616	0.4315	1.4
13318490	66	03JUN23	02JUL23	30.9500	0.2400	0.8
13318489	52	07JUN23	07JUL23	30.6173	0.3240	1.1
13318491	57	02JUL23	21JUL23	30.6789	0.2914	0.9
13318494	66	06JUL23	11AUG23	30.3500	0.3536	1.2
13318495	28	19JUL23	24JUL23	30.6857	0.3556	1.2
13318499	45	10AUG23	21AUG23	30.7911	0.3573	1.2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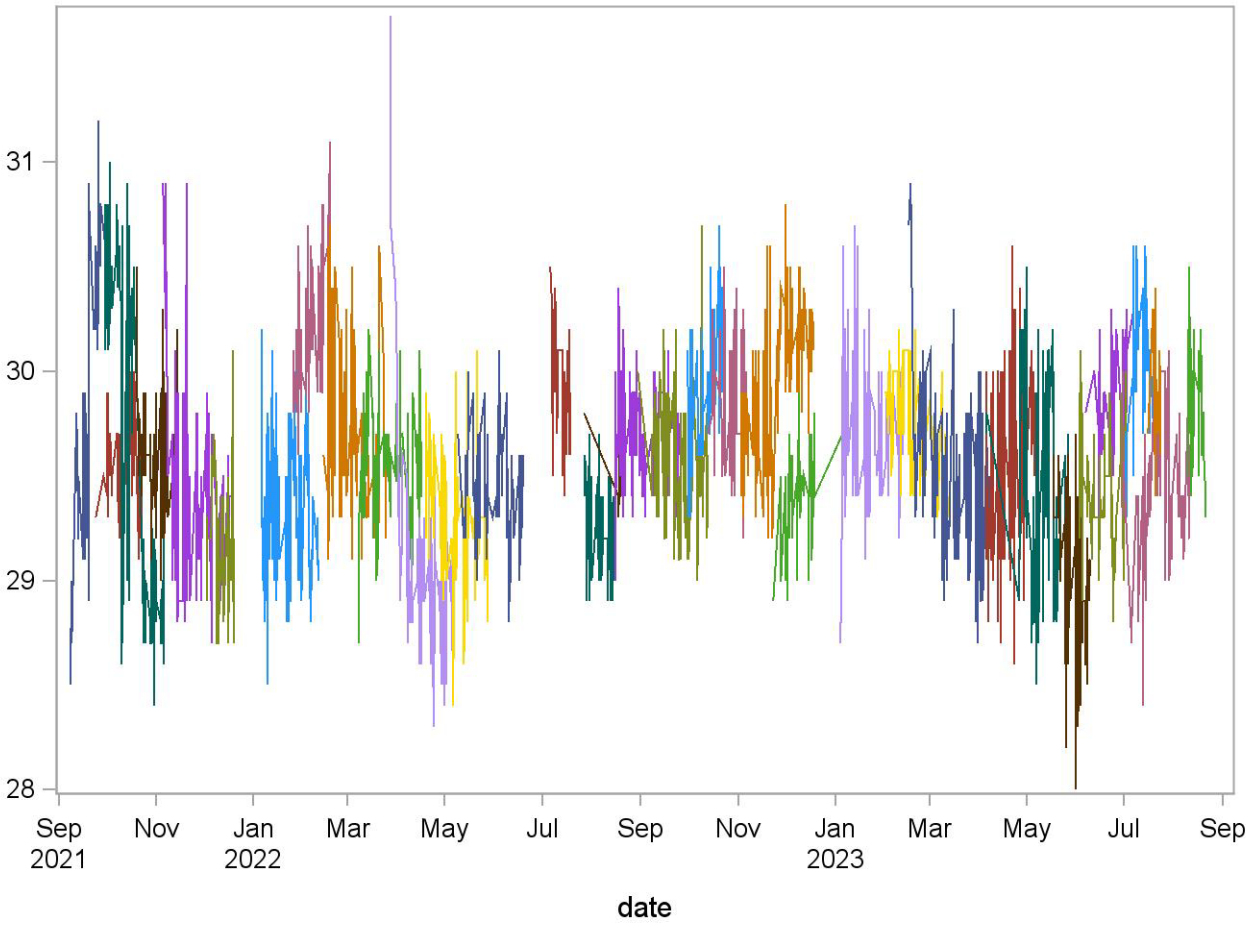
August 2021 – August 2023 Summary Statistics and QC Chart
LBCMCH3 (Mean cell hemoglobin (pg) (Lvl 3))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
14319388	50	08SEP21	03OCT21	29.9920	0.6998	2.3
14319389	53	24SEP21	23OCT21	29.5698	0.2198	0.7
14319393	109	30SEP21	06NOV21	29.6670	0.7879	2.7
14319395	56	20OCT21	14NOV21	29.5893	0.2946	1.0
14319399	141	05NOV21	18DEC21	29.4028	0.4132	1.4
14319402	41	03DEC21	20DEC21	29.1439	0.3083	1.1
14319408	128	06JAN22	11FEB22	29.2734	0.2989	1.0
14319412	53	26JAN22	19FEB22	30.1981	0.3273	1.1
14319416	131	14FEB22	25MAR22	29.7481	0.3838	1.3
14319418	85	08MAR22	16APR22	29.5224	0.2921	1.0
14319423	77	28MAR22	06MAY22	29.0805	0.5086	1.7
14319426	87	19APR22	28MAY22	29.3207	0.2866	1.0
14319430	78	09MAY22	19JUN22	29.4372	0.2589	0.9
14319435	32	06JUL22	19JUL22	29.9344	0.2719	0.9
14319440	12	27JUL22	21AUG22	29.6167	0.2250	0.8
14319439	45	28JUL22	15AUG22	29.2378	0.2208	0.8
14319445	133	16AUG22	25SEP22	29.6872	0.2347	0.8
14319448	116	30AUG22	13OCT22	29.5310	0.2726	0.9
14319451	70	30SEP22	24OCT22	29.8600	0.3268	1.1
14319457	67	13OCT22	06NOV22	29.8254	0.2642	0.9
14319460	144	03NOV22	18DEC22	29.8958	0.3315	1.1
14319463	54	23NOV22	08JAN23	29.4111	0.2640	0.9
14319468	130	04JAN23	12FEB23	29.7462	0.3007	1.0
14319472	87	01FEB23	13MAR23	29.6874	0.2366	0.8
14319475	136	16FEB23	08APR23	29.5029	0.3468	1.2
14319480	121	06APR23	07MAY23	29.5554	0.4052	1.4
14319483	110	06APR23	27MAY23	29.5100	0.4603	1.6
14319485	89	18MAY23	10JUN23	29.0258	0.3694	1.3
14319490	66	03JUN23	02JUL23	29.4121	0.2490	0.8
14319489	51	07JUN23	07JUL23	29.8941	0.2387	0.8
14319494	70	30JUN23	11AUG23	29.4143	0.3385	1.2
14319491	57	02JUL23	21JUL23	30.0123	0.3140	1.0
14319495	28	16JUL23	24JUL23	29.9214	0.2794	0.9
14319499	46	10AUG23	21AUG23	29.8543	0.2697	0.9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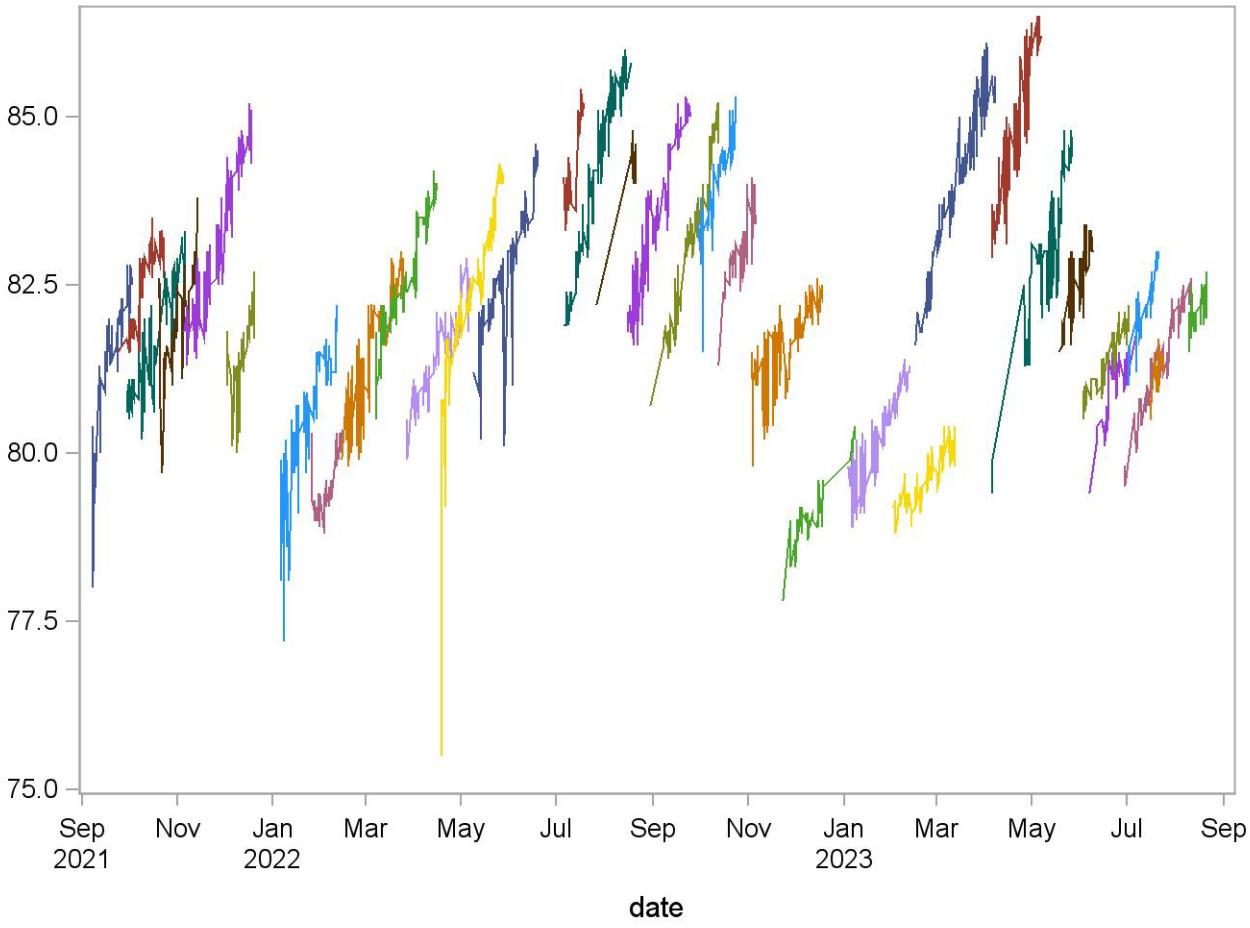
August 2021 – August 2023 Summary Statistics and QC Chart
LBCMCV1 (Mean cell volume (fL) (Lvl 1))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
12317388	48	08SEP21	03OCT21	81.5854	0.8745	1.1
12317389	54	24SEP21	23OCT21	82.5093	0.6150	0.7
12317393	107	30SEP21	06NOV21	81.6037	0.7522	0.9
12317395	56	20OCT21	14NOV21	81.9946	0.7237	0.9
12317399	142	05NOV21	18DEC21	82.8563	0.9839	1.2
12317402	41	03DEC21	20DEC21	81.4244	0.6276	0.8
12317408	127	06JAN22	11FEB22	80.2992	0.8701	1.1
12317412	52	26JAN22	19FEB22	79.6846	0.5100	0.6
12317416	131	14FEB22	25MAR22	81.2389	0.8840	1.1
12317418	85	08MAR22	16APR22	82.6118	0.8445	1.0
12317423	77	28MAR22	06MAY22	81.4844	0.6440	0.8
12317426	90	19APR22	28MAY22	82.2156	1.2573	1.5
12317431	78	09MAY22	19JUN22	82.7308	0.9215	1.1
12317435	32	06JUL22	19JUL22	84.3594	0.6839	0.8
12317439	126	06JUL22	18AUG22	84.3881	1.1434	1.4
12317440	12	27JUL22	21AUG22	84.1083	0.6459	0.8
12317444	133	16AUG22	25SEP22	83.2105	1.0167	1.2
12317448	116	30AUG22	13OCT22	82.9267	1.0621	1.3
12317451	66	30SEP22	24OCT22	83.9030	0.7634	0.9
12317457	67	13OCT22	06NOV22	83.0642	0.4978	0.6
12317460	146	03NOV22	18DEC22	81.4466	0.5737	0.7
12317463	54	23NOV22	08JAN23	79.1463	0.5168	0.7
12317468	132	04JAN23	12FEB23	80.0114	0.6517	0.8
12317472	87	01FEB23	13MAR23	79.5908	0.3967	0.5
12317475	137	16FEB23	08APR23	84.2504	1.1117	1.3
12317480	122	06APR23	07MAY23	84.6172	0.9785	1.2
12317483	108	06APR23	27MAY23	82.7676	0.9996	1.2
12317485	87	18MAY23	10JUN23	82.6069	0.4617	0.6
12317490	65	03JUN23	02JUL23	81.2769	0.4629	0.6
12317489	51	07JUN23	07JUL23	80.9686	0.4921	0.6
12317494	73	30JUN23	11AUG23	81.3918	0.7963	1.0
12317491	57	02JUL23	21JUL23	81.9684	0.4755	0.6
12317495	28	16JUL23	24JUL23	81.1429	0.2873	0.4
12317499	44	10AUG23	21AUG23	82.0159	0.2761	0.3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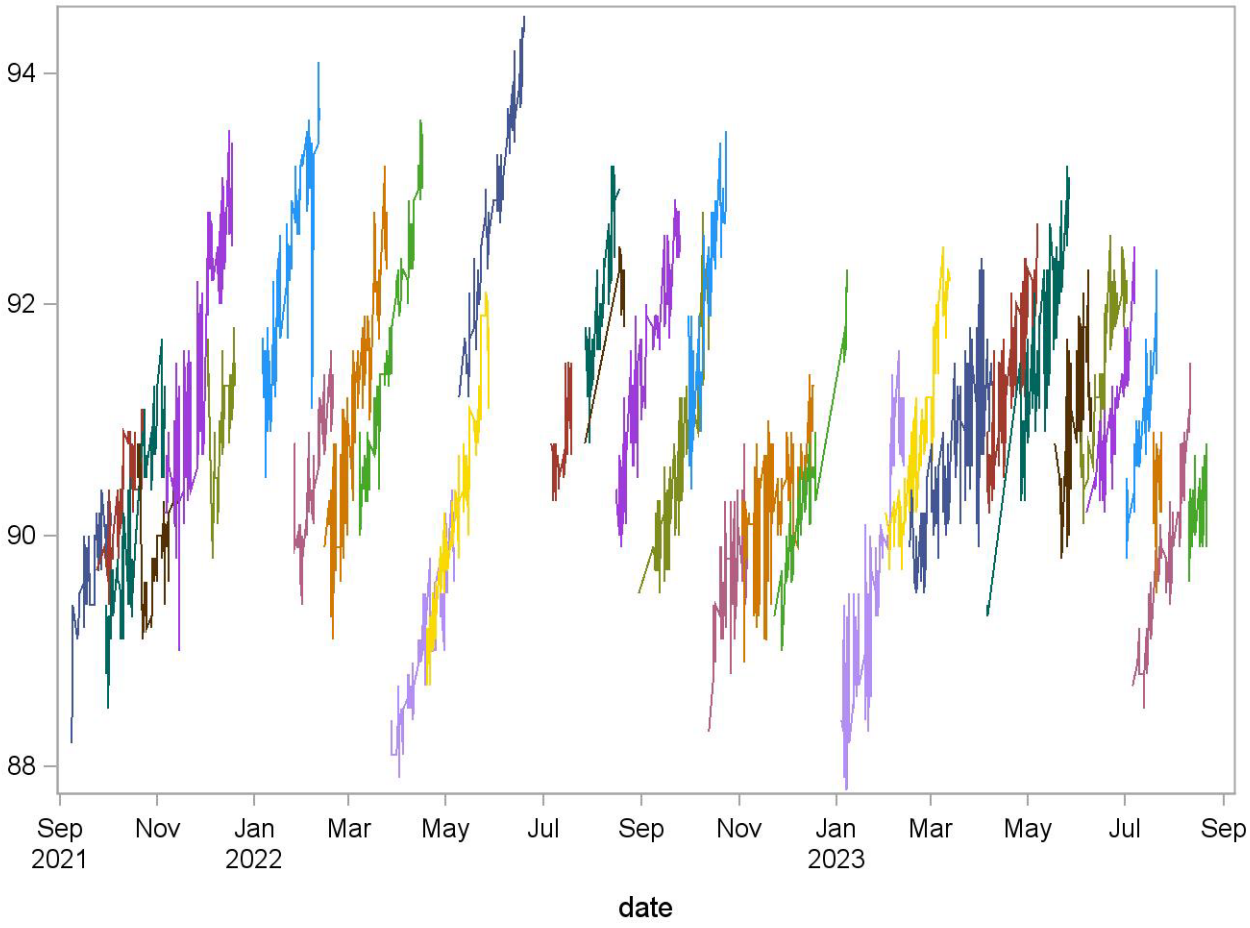
August 2021 – August 2023 Summary Statistics and QC Chart
LBCMCV2 (Mean cell volume (fL) (Lvl 2))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
13318388	49	08SEP21	03OCT21	89.7449	0.3814	0.4
13318389	53	24SEP21	23OCT21	90.3340	0.4345	0.5
13318393	109	30SEP21	06NOV21	89.9670	0.7259	0.8
13318395	57	20OCT21	14NOV21	89.9246	0.4584	0.5
13318399	143	05NOV21	18DEC21	91.2860	0.9525	1.0
13318402	40	03DEC21	20DEC21	91.0050	0.4899	0.5
13318408	128	06JAN22	11FEB22	92.1438	0.7924	0.9
13318412	53	26JAN22	19FEB22	90.5623	0.5530	0.6
13318415	130	14FEB22	25MAR22	90.7985	0.9324	1.0
13318418	85	08MAR22	16APR22	91.6388	0.9304	1.0
13318423	81	28MAR22	06MAY22	89.0296	0.5629	0.6
13318426	89	19APR22	28MAY22	90.1899	0.8507	0.9
13318430	78	09MAY22	19JUN22	92.8064	0.8700	0.9
13318435	32	06JUL22	19JUL22	90.8375	0.3554	0.4
13318440	12	27JUL22	21AUG22	92.0667	0.4479	0.5
13318439	47	28JUL22	18AUG22	92.0234	0.5865	0.6
13318444	131	16AUG22	25SEP22	91.2115	0.7225	0.8
13318448	119	30AUG22	13OCT22	90.5941	0.7182	0.8
13318451	67	30SEP22	24OCT22	91.8776	0.8166	0.9
13318458	67	13OCT22	06NOV22	89.6731	0.4581	0.5
13318460	142	03NOV22	18DEC22	90.2479	0.5119	0.6
13318463	55	23NOV22	08JAN23	90.3836	0.7525	0.8
13318468	131	04JAN23	12FEB23	89.2771	0.9140	1.0
13318472	89	01FEB23	13MAR23	90.9101	0.7831	0.9
13318475	141	16FEB23	08APR23	90.8071	0.6646	0.7
13318480	127	06APR23	07MAY23	91.3362	0.5641	0.6
13318483	110	06APR23	27MAY23	91.5818	0.7182	0.8
13318485	86	18MAY23	10JUN23	91.0628	0.5303	0.6
13318490	66	03JUN23	02JUL23	91.4000	0.6610	0.7
13318489	52	07JUN23	07JUL23	91.0673	0.5098	0.6
13318491	57	02JUL23	21JUL23	90.7649	0.5276	0.6
13318494	66	06JUL23	11AUG23	89.7955	0.6900	0.8
13318495	28	19JUL23	24JUL23	90.3107	0.3436	0.4
13318499	45	10AUG23	21AUG23	90.1600	0.2799	0.3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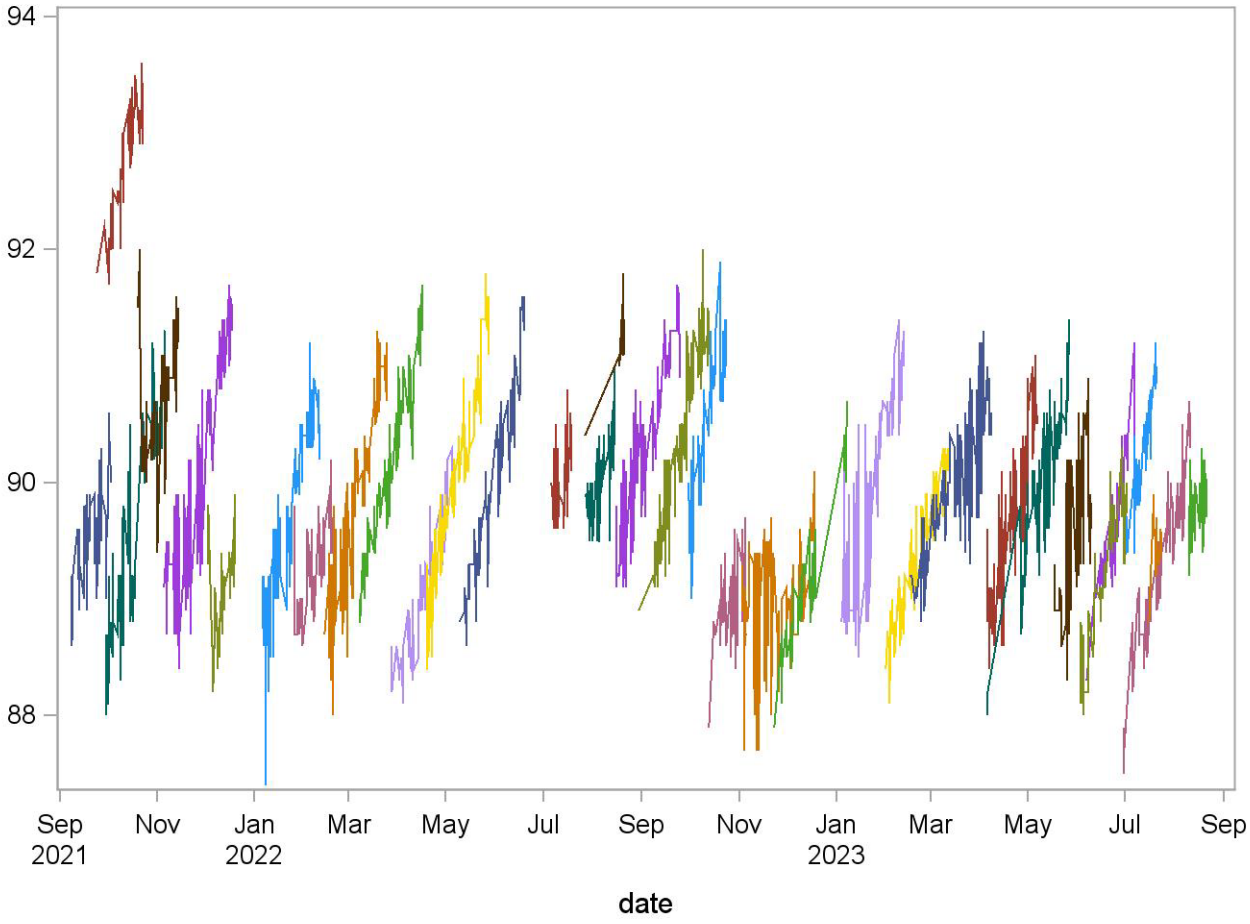
August 2021 – August 2023 Summary Statistics and QC Chart
LBCMCV3 (Mean cell volume (fL) (Lvl 3))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
14319388	50	08SEP21	03OCT21	89.5800	0.4180	0.5
14319389	53	24SEP21	23OCT21	92.6943	0.5063	0.5
14319393	109	30SEP21	06NOV21	89.5367	0.8621	1.0
14319395	56	20OCT21	14NOV21	90.7357	0.4992	0.6
14319399	141	05NOV21	18DEC21	89.8121	0.8107	0.9
14319402	41	03DEC21	20DEC21	89.0756	0.4140	0.5
14319408	128	06JAN22	11FEB22	89.4852	0.7035	0.8
14319412	53	26JAN22	19FEB22	89.2717	0.3602	0.4
14319416	131	14FEB22	25MAR22	89.5351	0.8040	0.9
14319418	85	08MAR22	16APR22	90.1353	0.7230	0.8
14319423	77	28MAR22	06MAY22	89.0831	0.5550	0.6
14319426	87	19APR22	28MAY22	90.0103	0.8131	0.9
14319430	78	09MAY22	19JUN22	90.0077	0.7661	0.9
14319435	32	06JUL22	19JUL22	90.0719	0.3285	0.4
14319440	12	27JUL22	21AUG22	91.1667	0.3257	0.4
14319439	45	28JUL22	15AUG22	90.0600	0.3602	0.4
14319445	133	16AUG22	25SEP22	90.1594	0.6457	0.7
14319448	116	30AUG22	13OCT22	90.2250	0.7182	0.8
14319451	70	30SEP22	24OCT22	90.3957	0.7047	0.8
14319457	67	13OCT22	06NOV22	88.9985	0.3310	0.4
14319460	144	03NOV22	18DEC22	88.8986	0.4833	0.5
14319463	54	23NOV22	08JAN23	89.1352	0.6470	0.7
14319468	130	04JAN23	12FEB23	89.7277	0.7634	0.9
14319472	87	01FEB23	13MAR23	89.4172	0.5465	0.6
14319475	136	16FEB23	08APR23	90.0301	0.5731	0.6
14319480	121	06APR23	07MAY23	89.5893	0.5928	0.7
14319483	110	06APR23	27MAY23	89.8727	0.6076	0.7
14319485	89	18MAY23	10JUN23	89.6607	0.5297	0.6
14319490	66	03JUN23	02JUL23	89.1106	0.5897	0.7
14319489	51	07JUN23	07JUL23	89.6725	0.5717	0.6
14319494	70	30JUN23	11AUG23	89.3243	0.6944	0.8
14319491	57	02JUL23	21JUL23	90.1316	0.4404	0.5
14319495	28	16JUL23	24JUL23	89.4643	0.2181	0.2
14319499	46	10AUG23	21AUG23	89.6870	0.2849	0.3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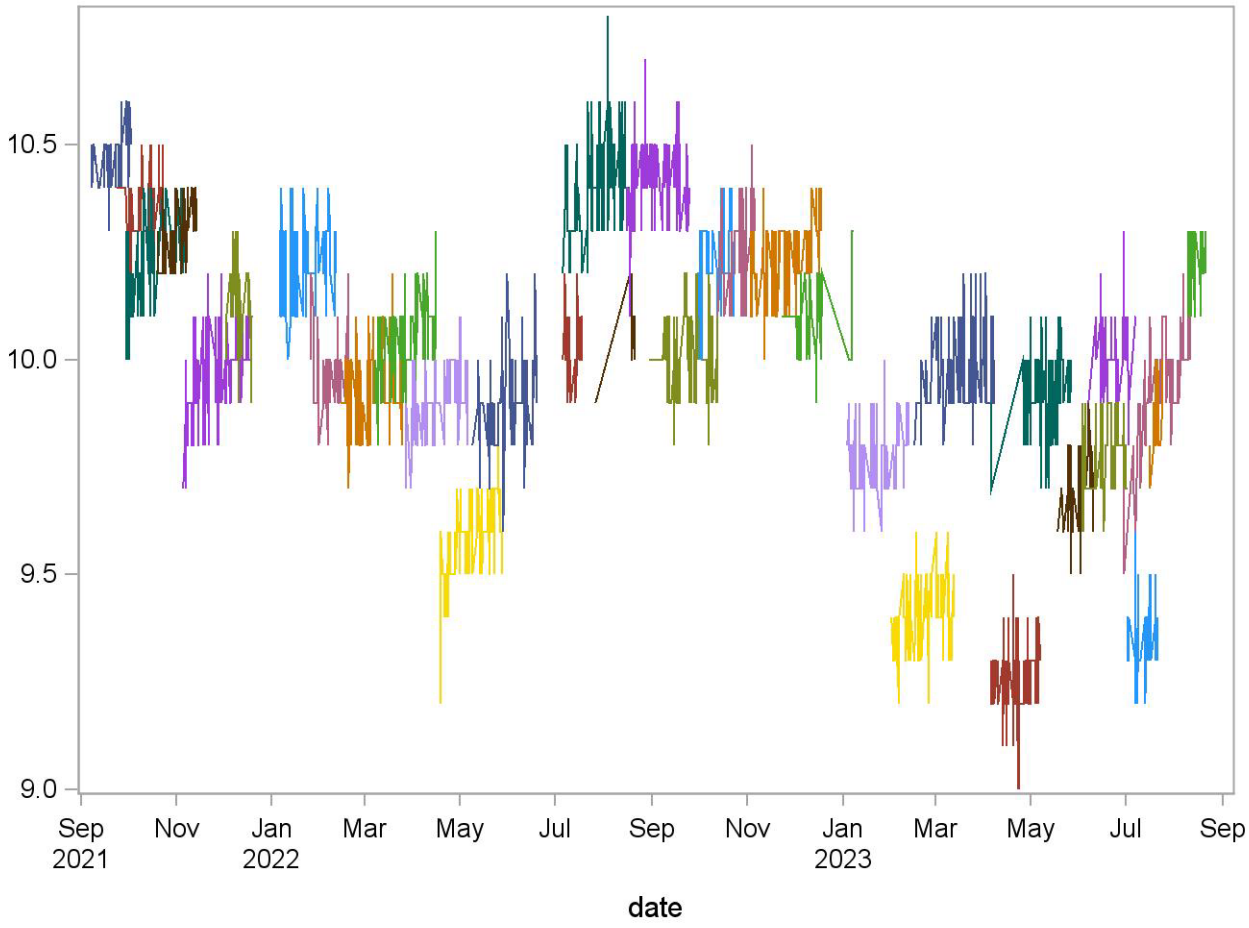
August 2021 – August 2023 Summary Statistics and QC Chart
LBCMPV1 (Mean platelet volume (fL) (Lvl 1))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
12317388	48	08SEP21	03OCT21	10.4729	0.0676	0.6
12317389	54	24SEP21	23OCT21	10.3407	0.0836	0.8
12317393	107	30SEP21	06NOV21	10.2243	0.0889	0.9
12317395	56	20OCT21	14NOV21	10.2893	0.0755	0.7
12317399	142	05NOV21	18DEC21	9.9528	0.0951	1.0
12317402	41	03DEC21	20DEC21	10.1171	0.0919	0.9
12317408	127	06JAN22	11FEB22	10.2150	0.0855	0.8
12317412	52	26JAN22	19FEB22	9.9712	0.0848	0.9
12317416	131	14FEB22	25MAR22	9.9191	0.0954	1.0
12317418	85	08MAR22	16APR22	10.0424	0.0943	0.9
12317423	77	28MAR22	06MAY22	9.9013	0.0786	0.8
12317426	90	19APR22	28MAY22	9.5767	0.0960	1.0
12317431	78	09MAY22	19JUN22	9.8974	0.1044	1.1
12317435	32	06JUL22	19JUL22	10.0281	0.0772	0.8
12317439	126	06JUL22	18AUG22	10.4175	0.1051	1.0
12317440	12	27JUL22	21AUG22	10.0750	0.0866	0.9
12317444	133	16AUG22	25SEP22	10.4195	0.0883	0.8
12317448	116	30AUG22	13OCT22	10.0138	0.0864	0.9
12317451	66	30SEP22	24OCT22	10.2288	0.0890	0.9
12317457	67	13OCT22	06NOV22	10.2537	0.0927	0.9
12317460	146	03NOV22	18DEC22	10.2219	0.0783	0.8
12317463	54	23NOV22	08JAN23	10.1000	0.0890	0.9
12317468	132	04JAN23	12FEB23	9.7727	0.0721	0.7
12317472	87	01FEB23	13MAR23	9.4057	0.0840	0.9
12317475	137	16FEB23	08APR23	9.9847	0.0882	0.9
12317480	122	06APR23	07MAY23	9.2492	0.0774	0.8
12317483	108	06APR23	27MAY23	9.9111	0.0921	0.9
12317485	87	18MAY23	10JUN23	9.7126	0.0790	0.8
12317490	65	03JUN23	02JUL23	9.7646	0.0874	0.9
12317489	51	07JUN23	07JUL23	10.0118	0.0887	0.9
12317494	73	30JUN23	11AUG23	9.9205	0.1343	1.4
12317491	57	02JUL23	21JUL23	9.3632	0.0837	0.9
12317495	28	16JUL23	24JUL23	9.8536	0.0793	0.8
12317499	44	10AUG23	21AUG23	10.2114	0.0655	0.6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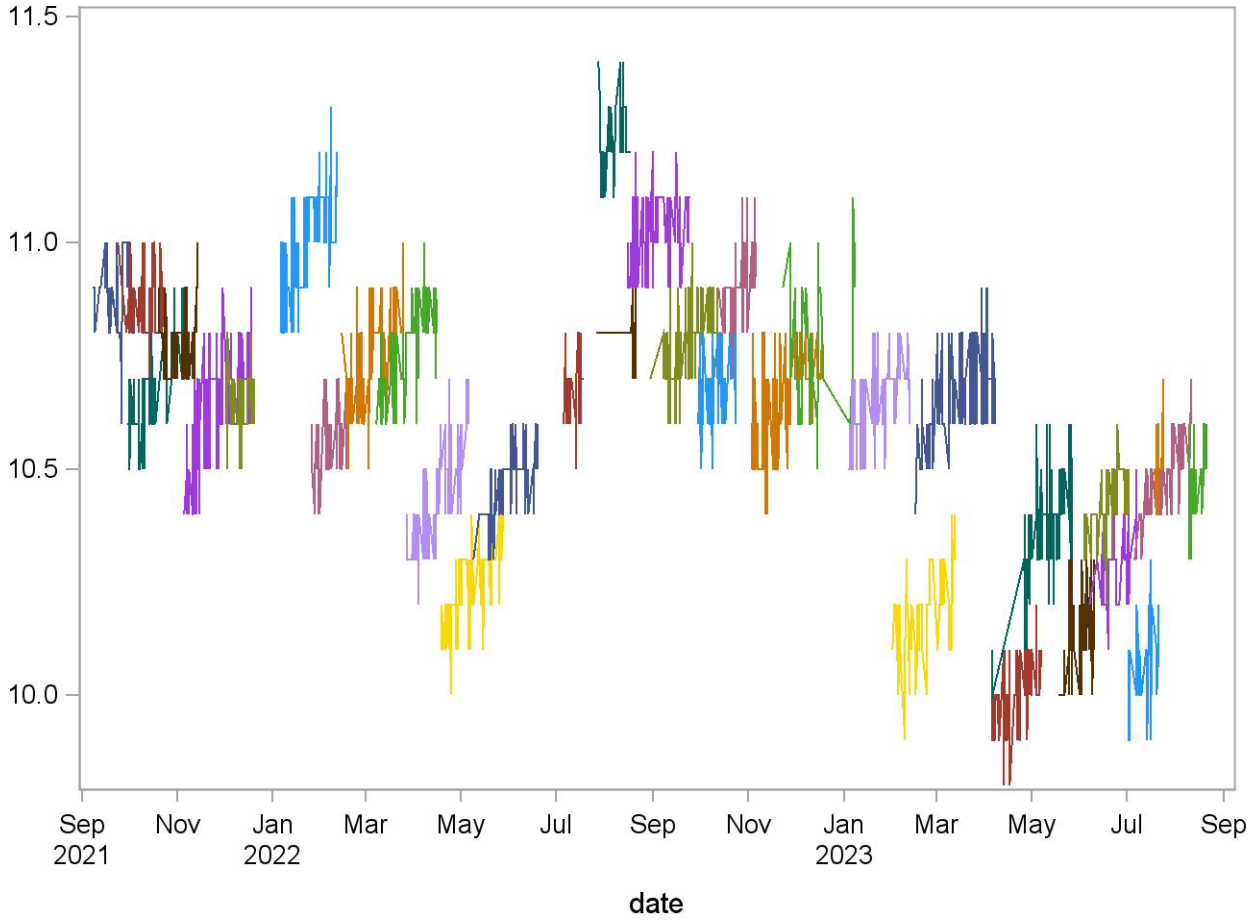
August 2021 – August 2023 Summary Statistics and QC Chart
LBCMPV2 (Mean platelet volume (fL) (Lvl 2))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
13318388	49	08SEP21	03OCT21	10.8755	0.0830	0.8
13318389	53	24SEP21	23OCT21	10.8660	0.0783	0.7
13318393	109	30SEP21	06NOV21	10.6789	0.0991	0.9
13318395	57	20OCT21	14NOV21	10.7789	0.0750	0.7
13318399	143	05NOV21	18DEC21	10.6245	0.1102	1.0
13318402	40	03DEC21	20DEC21	10.6550	0.0749	0.7
13318408	128	06JAN22	11FEB22	10.9750	0.1087	1.0
13318412	53	26JAN22	19FEB22	10.5679	0.0872	0.8
13318415	130	14FEB22	25MAR22	10.7285	0.0982	0.9
13318418	85	08MAR22	16APR22	10.7541	0.1007	0.9
13318423	81	28MAR22	06MAY22	10.4444	0.1072	1.0
13318426	89	19APR22	28MAY22	10.2393	0.0887	0.9
13318430	78	09MAY22	19JUN22	10.4603	0.0827	0.8
13318435	32	06JUL22	19JUL22	10.6906	0.0734	0.7
13318440	12	27JUL22	21AUG22	10.8083	0.0793	0.7
13318439	47	28JUL22	18AUG22	11.2383	0.0822	0.7
13318444	131	16AUG22	25SEP22	11.0221	0.0787	0.7
13318448	119	30AUG22	13OCT22	10.7798	0.0839	0.8
13318451	67	30SEP22	24OCT22	10.6761	0.0939	0.9
13318458	67	13OCT22	06NOV22	10.9149	0.0803	0.7
13318460	142	03NOV22	18DEC22	10.6451	0.0986	0.9
13318463	55	23NOV22	08JAN23	10.7509	0.1373	1.3
13318468	131	04JAN23	12FEB23	10.6374	0.0844	0.8
13318472	89	01FEB23	13MAR23	10.1865	0.0968	0.9
13318475	141	16FEB23	08APR23	10.6794	0.0945	0.9
13318480	127	06APR23	07MAY23	9.9898	0.0688	0.7
13318483	110	06APR23	27MAY23	10.3600	0.1068	1.0
13318485	86	18MAY23	10JUN23	10.1314	0.0858	0.8
13318490	66	03JUN23	02JUL23	10.4000	0.0784	0.8
13318489	52	07JUN23	07JUL23	10.2788	0.0825	0.8
13318491	57	02JUL23	21JUL23	10.0667	0.0852	0.8
13318494	66	06JUL23	11AUG23	10.4773	0.0873	0.8
13318495	28	19JUL23	24JUL23	10.5107	0.0685	0.7
13318499	45	10AUG23	21AUG23	10.4733	0.0720	0.7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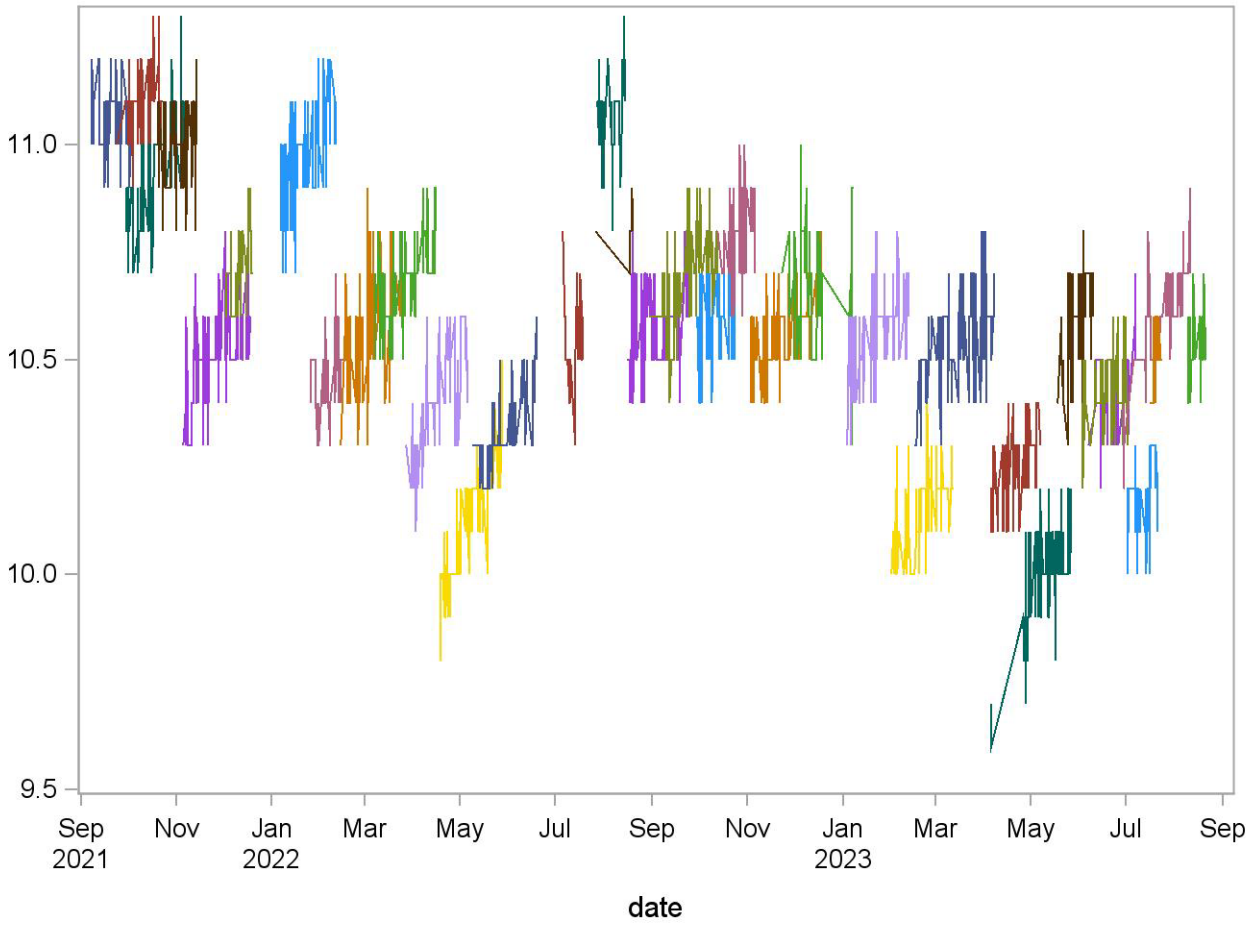
August 2021 – August 2023 Summary Statistics and QC Chart
LBCMPV3 (Mean platelet volume (fL) (Lvl 3))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
14319388	50	08SEP21	03OCT21	11.0660	0.0823	0.7
14319389	53	24SEP21	23OCT21	11.1019	0.0843	0.8
14319393	109	30SEP21	06NOV21	10.9174	0.1153	1.1
14319395	56	20OCT21	14NOV21	10.9964	0.0990	0.9
14319399	141	05NOV21	18DEC21	10.5156	0.0980	0.9
14319402	41	03DEC21	20DEC21	10.7146	0.0853	0.8
14319408	128	06JAN22	11FEB22	10.9656	0.1083	1.0
14319412	53	26JAN22	19FEB22	10.4642	0.0901	0.9
14319416	131	14FEB22	25MAR22	10.5603	0.1238	1.2
14319418	85	08MAR22	16APR22	10.6929	0.1009	0.9
14319423	77	28MAR22	06MAY22	10.3961	0.1175	1.1
14319426	87	19APR22	28MAY22	10.1195	0.1354	1.3
14319430	78	09MAY22	19JUN22	10.3513	0.0894	0.9
14319435	32	06JUL22	19JUL22	10.5406	0.1043	1.0
14319440	12	27JUL22	21AUG22	10.7500	0.0798	0.7
14319439	45	28JUL22	15AUG22	11.0689	0.0996	0.9
14319445	133	16AUG22	25SEP22	10.5707	0.0903	0.9
14319448	116	30AUG22	13OCT22	10.6914	0.0983	0.9
14319451	70	30SEP22	24OCT22	10.5771	0.0904	0.9
14319457	67	13OCT22	06NOV22	10.7881	0.0879	0.8
14319460	144	03NOV22	18DEC22	10.5625	0.0852	0.8
14319463	54	23NOV22	08JAN23	10.6648	0.1348	1.3
14319468	130	04JAN23	12FEB23	10.5492	0.0942	0.9
14319472	87	01FEB23	13MAR23	10.1391	0.0907	0.9
14319475	136	16FEB23	08APR23	10.5478	0.1075	1.0
14319480	121	06APR23	07MAY23	10.2421	0.0824	0.8
14319483	110	06APR23	27MAY23	9.9909	0.1193	1.2
14319485	89	18MAY23	10JUN23	10.5944	0.0958	0.9
14319490	66	03JUN23	02JUL23	10.4182	0.0910	0.9
14319489	51	07JUN23	07JUL23	10.4294	0.0944	0.9
14319494	70	30JUN23	11AUG23	10.5943	0.1226	1.2
14319491	57	02JUL23	21JUL23	10.1649	0.0834	0.8
14319495	28	16JUL23	24JUL23	10.5286	0.0659	0.6
14319499	46	10AUG23	21AUG23	10.5174	0.0769	0.7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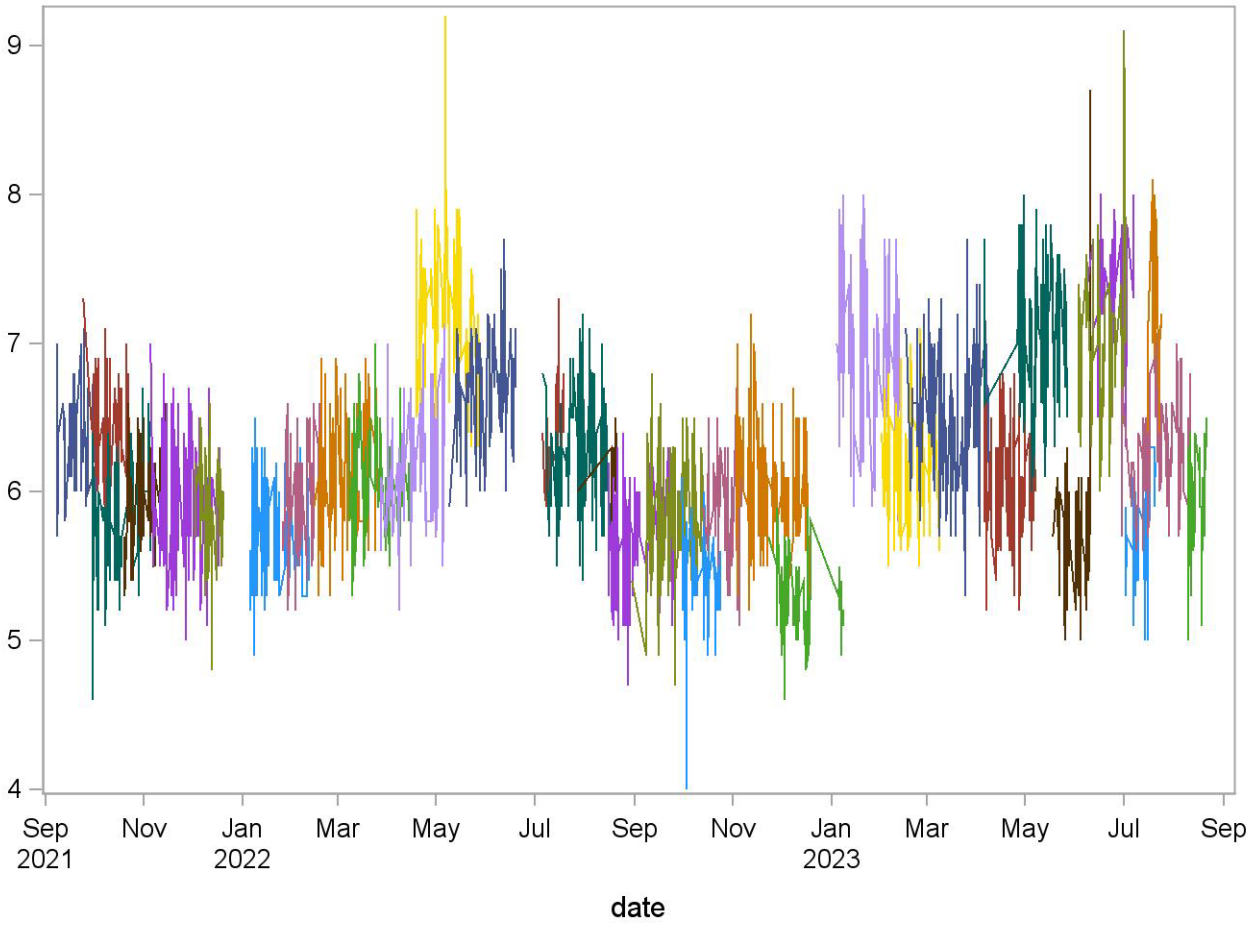
August 2021 – August 2023 Summary Statistics and QC Chart
LBCMOP1 (Monocyte (%) (Lvl 1))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
12317388	48	08SEP21	03OCT21	6.3667	0.3277	5.1
12317389	54	24SEP21	23OCT21	6.4556	0.3396	5.3
12317393	107	30SEP21	06NOV21	5.8673	0.3461	5.9
12317395	56	20OCT21	14NOV21	5.9321	0.3265	5.5
12317399	142	05NOV21	18DEC21	5.9415	0.3772	6.3
12317402	41	03DEC21	20DEC21	5.8927	0.3394	5.8
12317408	127	06JAN22	11FEB22	5.7236	0.2942	5.1
12317412	52	26JAN22	19FEB22	6.0192	0.3619	6.0
12317416	130	14FEB22	25MAR22	6.0462	0.3544	5.9
12317418	85	08MAR22	16APR22	6.1235	0.3287	5.4
12317423	77	28MAR22	06MAY22	6.1701	0.3994	6.5
12317426	90	19APR22	28MAY22	7.1833	0.4518	6.3
12317431	78	09MAY22	19JUN22	6.6885	0.3696	5.5
12317435	32	06JUL22	19JUL22	6.3250	0.3152	5.0
12317439	126	06JUL22	18AUG22	6.3079	0.3726	5.9
12317440	12	27JUL22	21AUG22	6.1333	0.2270	3.7
12317444	129	16AUG22	25SEP22	5.6442	0.3165	5.6
12317448	116	30AUG22	13OCT22	5.8302	0.3944	6.8
12317451	66	30SEP22	24OCT22	5.4076	0.3075	5.7
12317457	67	13OCT22	06NOV22	5.8433	0.3564	6.1
12317460	146	03NOV22	18DEC22	6.0342	0.3577	5.9
12317463	54	23NOV22	08JAN23	5.2630	0.2790	5.3
12317468	132	04JAN23	12FEB23	6.9545	0.4796	6.9
12317472	87	01FEB23	13MAR23	6.1920	0.3495	5.6
12317475	136	16FEB23	08APR23	6.5015	0.4277	6.6
12317480	122	06APR23	07MAY23	5.9992	0.3344	5.6
12317483	108	06APR23	27MAY23	7.1046	0.4643	6.5
12317485	87	18MAY23	10JUN23	5.6598	0.4515	8.0
12317490	65	03JUN23	02JUL23	6.9646	0.4900	7.0
12317489	51	07JUN23	07JUL23	7.4078	0.3709	5.0
12317494	73	30JUN23	11AUG23	6.2877	0.3346	5.3
12317491	57	02JUL23	21JUL23	5.7123	0.3163	5.5
12317495	28	16JUL23	24JUL23	7.2214	0.4013	5.6
12317499	44	10AUG23	21AUG23	5.9409	0.3643	6.1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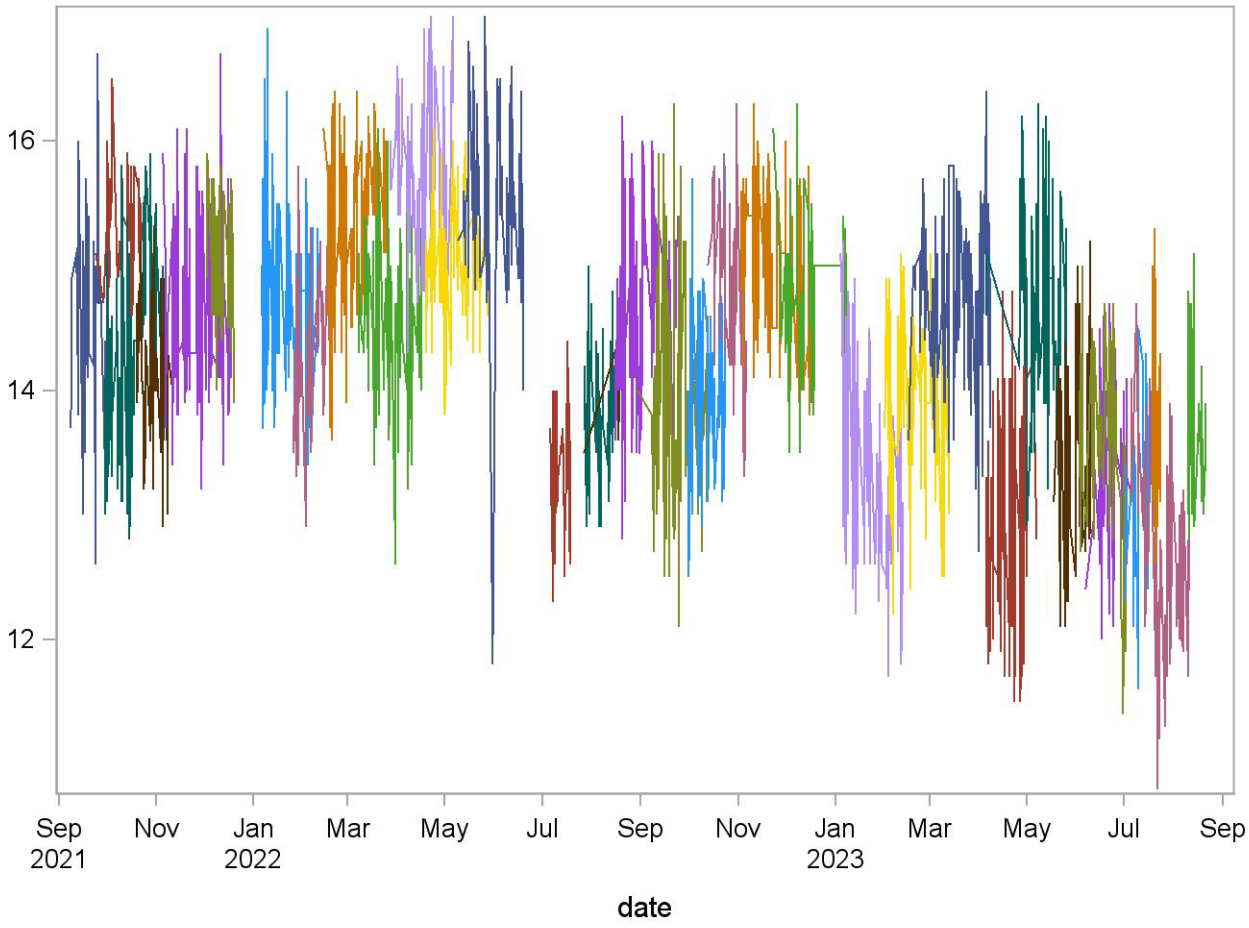
August 2021 – August 2023 Summary Statistics and QC Chart
LBCMOP2 (Monocyte (%) (Lvl 2))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
13318388	49	08SEP21	03OCT21	14.6449	0.7329	5.0
13318389	53	24SEP21	23OCT21	15.2717	0.4097	2.7
13318393	109	30SEP21	06NOV21	14.3697	0.7382	5.1
13318395	57	20OCT21	14NOV21	14.2789	0.5502	3.9
13318399	143	05NOV21	18DEC21	14.6650	0.6083	4.1
13318402	40	03DEC21	20DEC21	14.9150	0.4980	3.3
13318408	128	06JAN22	11FEB22	14.7906	0.6320	4.3
13318412	53	26JAN22	19FEB22	14.3660	0.5697	4.0
13318415	130	14FEB22	25MAR22	15.3015	0.5650	3.7
13318418	85	08MAR22	16APR22	14.5518	0.6248	4.3
13318423	80	28MAR22	06MAY22	15.7663	0.5833	3.7
13318426	88	19APR22	28MAY22	15.0716	0.4705	3.1
13318430	78	09MAY22	19JUN22	15.5231	0.7137	4.6
13318435	32	06JUL22	19JUL22	13.2781	0.5369	4.0
13318440	12	27JUL22	21AUG22	14.1750	0.4048	2.9
13318439	47	28JUL22	18AUG22	13.7915	0.5124	3.7
13318444	131	16AUG22	25SEP22	14.6656	0.6705	4.6
13318448	119	30AUG22	13OCT22	14.0689	0.8778	6.2
13318451	67	30SEP22	24OCT22	14.0388	0.6279	4.5
13318458	67	13OCT22	06NOV22	14.8239	0.5983	4.0
13318460	142	03NOV22	18DEC22	15.0289	0.5373	3.6
13318463	55	23NOV22	08JAN23	14.7364	0.5867	4.0
13318468	131	04JAN23	12FEB23	13.4527	0.6696	5.0
13318472	89	01FEB23	13MAR23	13.9303	0.5970	4.3
13318475	141	16FEB23	08APR23	14.6085	0.5766	3.9
13318480	127	06APR23	07MAY23	13.0323	0.8420	6.5
13318483	110	06APR23	27MAY23	14.7291	0.6756	4.6
13318485	86	18MAY23	10JUN23	13.5372	0.6756	5.0
13318490	66	03JUN23	02JUL23	13.5045	0.7834	5.8
13318489	52	07JUN23	07JUL23	13.2731	0.6374	4.8
13318491	57	02JUL23	21JUL23	13.2912	0.7137	5.4
13318494	66	06JUL23	11AUG23	12.7121	0.7580	6.0
13318495	28	19JUL23	24JUL23	13.8000	0.7149	5.2
13318499	45	10AUG23	21AUG23	13.7911	0.5732	4.2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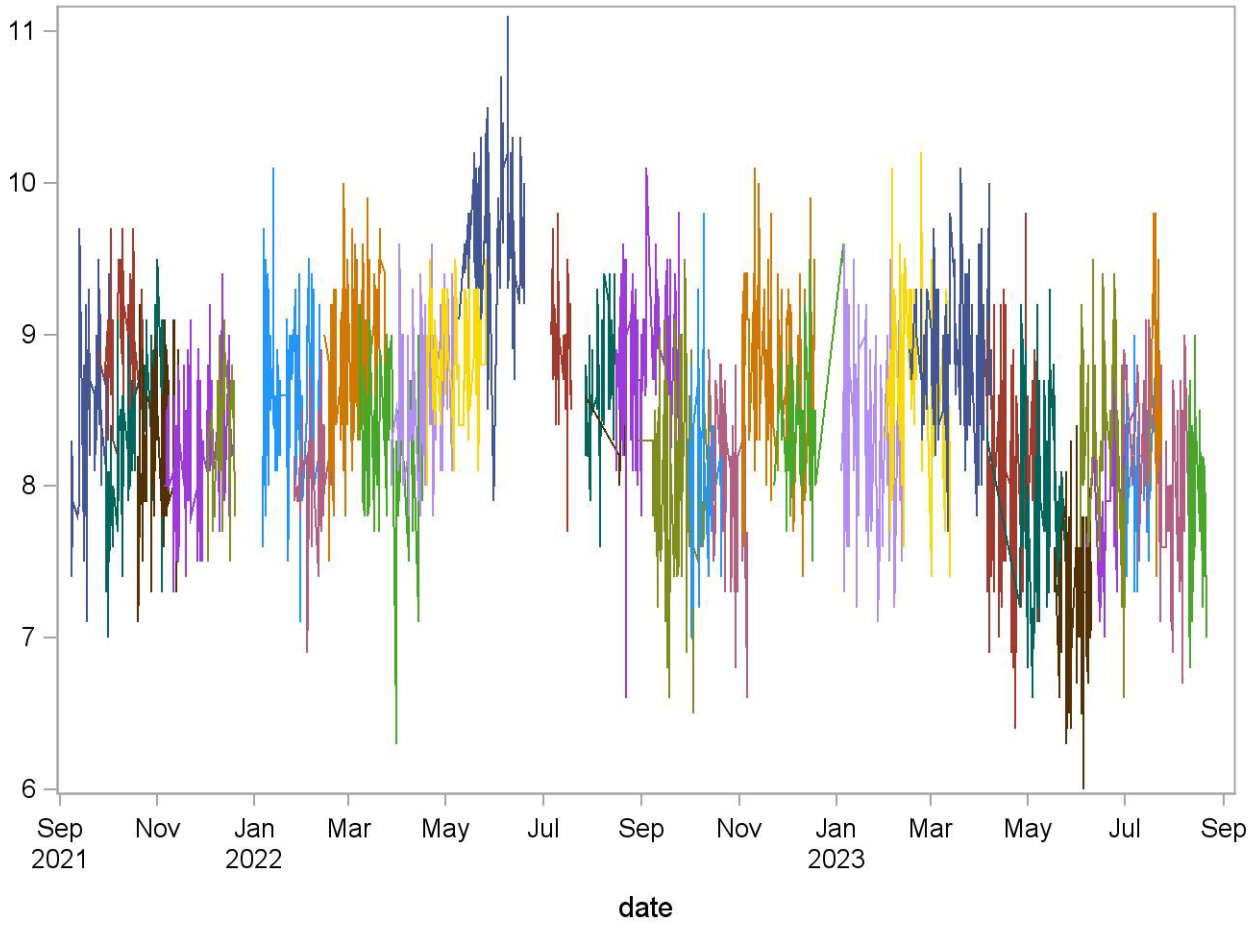
August 2021 – August 2023 Summary Statistics and QC Chart
LBCMOP3 (Monocyte (%) (Lvl 3))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
14319388	50	08SEP21	03OCT21	8.5160	0.5475	6.4
14319389	53	24SEP21	23OCT21	8.9679	0.3663	4.1
14319393	109	30SEP21	06NOV21	8.2706	0.4865	5.9
14319395	56	20OCT21	14NOV21	8.2625	0.5058	6.1
14319399	141	05NOV21	18DEC21	8.2617	0.3916	4.7
14319402	41	03DEC21	20DEC21	8.3000	0.3962	4.8
14319408	128	06JAN22	11FEB22	8.5891	0.4776	5.6
14319412	53	26JAN22	19FEB22	8.1094	0.3471	4.3
14319416	131	14FEB22	25MAR22	8.8260	0.4662	5.3
14319418	85	08MAR22	16APR22	8.3506	0.4695	5.6
14319423	77	28MAR22	06MAY22	8.5948	0.4662	5.4
14319426	87	19APR22	28MAY22	8.8839	0.3480	3.9
14319430	78	09MAY22	19JUN22	9.6756	0.4798	5.0
14319435	32	06JUL22	19JUL22	8.9250	0.4158	4.7
14319440	12	27JUL22	21AUG22	8.4333	0.3025	3.6
14319439	45	28JUL22	15AUG22	8.6267	0.4418	5.1
14319445	133	16AUG22	25SEP22	8.8391	0.4746	5.4
14319448	116	30AUG22	13OCT22	8.0698	0.5508	6.8
14319451	70	30SEP22	24OCT22	8.0757	0.4695	5.8
14319457	67	13OCT22	06NOV22	8.0328	0.4781	6.0
14319460	143	03NOV22	18DEC22	8.8056	0.4768	5.4
14319463	54	23NOV22	08JAN23	8.4185	0.4683	5.6
14319468	130	04JAN23	12FEB23	8.3723	0.5420	6.5
14319472	87	01FEB23	13MAR23	8.7368	0.5199	6.0
14319475	136	16FEB23	08APR23	8.8199	0.4268	4.8
14319480	121	06APR23	07MAY23	7.9826	0.6095	7.6
14319483	110	06APR23	27MAY23	8.0418	0.6345	7.9
14319485	89	18MAY23	10JUN23	7.2551	0.5074	7.0
14319490	66	03JUN23	02JUL23	8.3273	0.6009	7.2
14319489	51	07JUN23	07JUL23	7.9235	0.4264	5.4
14319494	70	30JUN23	11AUG23	8.0371	0.5504	6.8
14319491	57	02JUL23	21JUL23	8.1386	0.4337	5.3
14319495	28	16JUL23	24JUL23	8.6893	0.6321	7.3
14319499	45	10AUG23	21AUG23	7.8778	0.4889	6.2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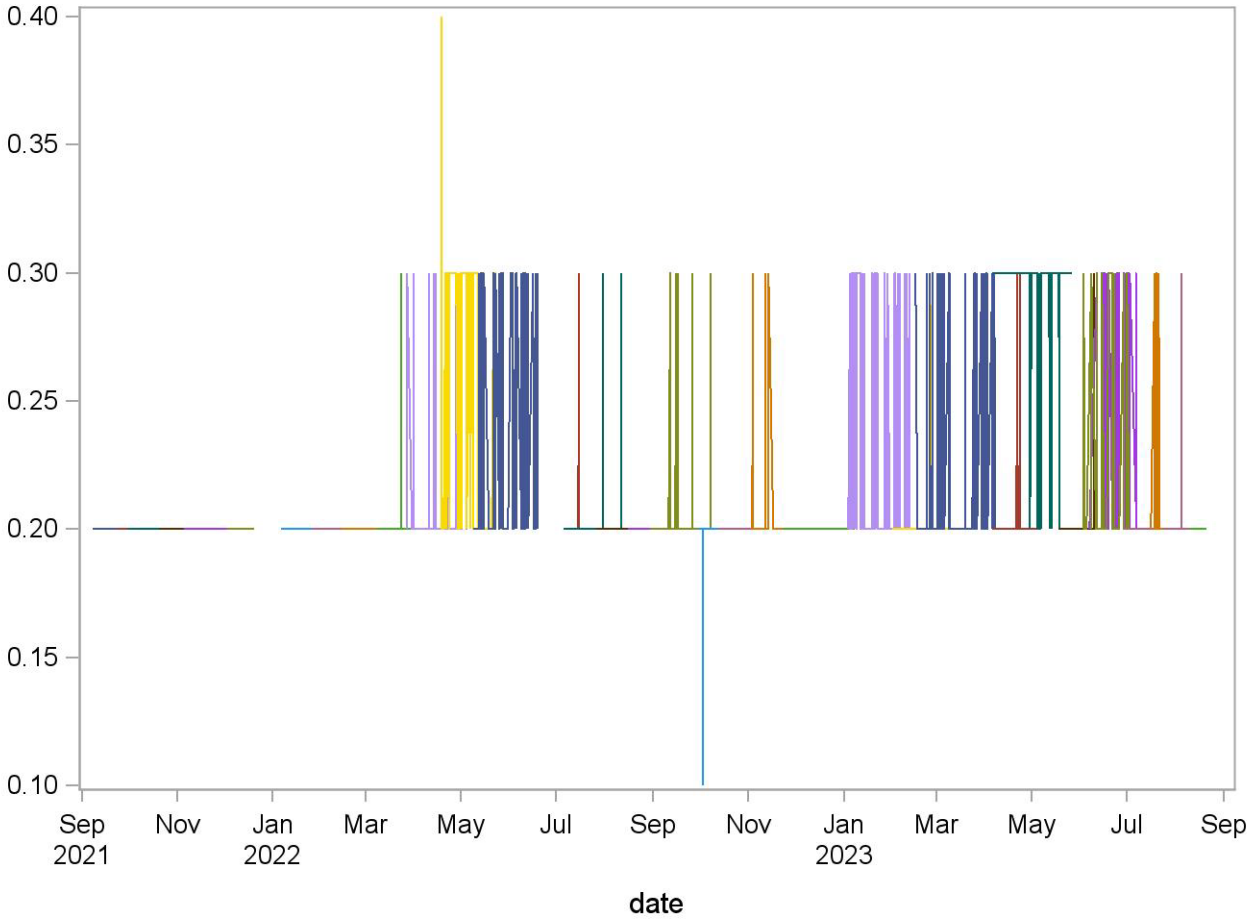
August 2021 – August 2023 Summary Statistics and QC Chart
LBCMON1 (Monocyte No.(10^3 cells/uL) (Lvl 1))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
12317388	48	08SEP21	03OCT21	0.2000	0.0000	0.0
12317389	54	24SEP21	23OCT21	0.2000	0.0000	0.0
12317393	107	30SEP21	06NOV21	0.2000	0.0000	0.0
12317395	56	20OCT21	14NOV21	0.2000	0.0000	0.0
12317399	142	05NOV21	18DEC21	0.2000	0.0000	0.0
12317402	41	03DEC21	20DEC21	0.2000	0.0000	0.0
12317408	127	06JAN22	11FEB22	0.2000	0.0000	0.0
12317412	52	26JAN22	19FEB22	0.2000	0.0000	0.0
12317416	130	14FEB22	25MAR22	0.2000	0.0000	0.0
12317418	85	08MAR22	16APR22	0.2012	0.0108	5.4
12317423	77	28MAR22	06MAY22	0.2182	0.0388	17.8
12317426	90	19APR22	28MAY22	0.2578	0.0519	20.1
12317431	78	09MAY22	19JUN22	0.2372	0.0486	20.5
12317435	32	06JUL22	19JUL22	0.2031	0.0177	8.7
12317439	126	06JUL22	18AUG22	0.2024	0.0153	7.6
12317440	12	27JUL22	21AUG22	0.2000	0.0000	0.0
12317444	129	16AUG22	25SEP22	0.2000	0.0000	0.0
12317448	116	30AUG22	13OCT22	0.2052	0.0222	10.8
12317451	66	30SEP22	24OCT22	0.1985	0.0123	6.2
12317457	67	13OCT22	06NOV22	0.2000	0.0000	0.0
12317460	146	03NOV22	18DEC22	0.2021	0.0142	7.0
12317463	54	23NOV22	08JAN23	0.2000	0.0000	0.0
12317468	132	04JAN23	12FEB23	0.2409	0.0494	20.5
12317472	87	01FEB23	13MAR23	0.2011	0.0107	5.3
12317475	136	16FEB23	08APR23	0.2243	0.0430	19.2
12317480	122	06APR23	07MAY23	0.2016	0.0128	6.3
12317483	108	06APR23	27MAY23	0.2917	0.0278	9.5
12317485	87	18MAY23	10JUN23	0.2011	0.0107	5.3
12317490	65	03JUN23	02JUL23	0.2246	0.0434	19.3
12317489	51	07JUN23	07JUL23	0.2392	0.0493	20.6
12317494	73	30JUN23	11AUG23	0.2027	0.0164	8.1
12317491	57	02JUL23	21JUL23	0.2000	0.0000	0.0
12317495	28	16JUL23	24JUL23	0.2179	0.0390	17.9
12317499	44	10AUG23	21AUG23	0.2000	0.0000	0.0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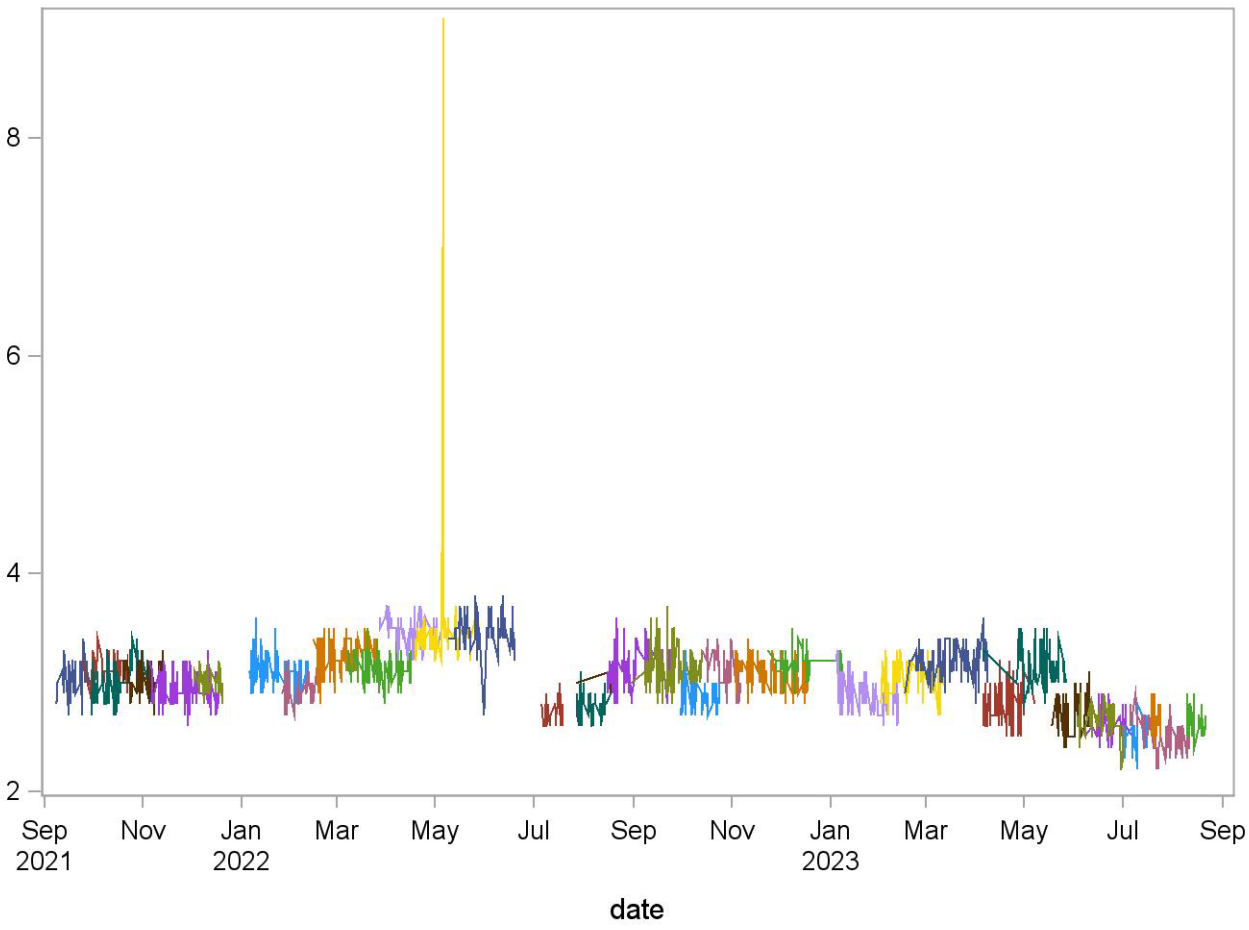
August 2021 – August 2023 Summary Statistics and QC Chart
LBCMON2 (Monocyte No.(10^3 cells/uL) (Lvl 2))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
13318388	49	08SEP21	03OCT21	3.0510	0.1431	4.7
13318389	53	24SEP21	23OCT21	3.1340	0.1055	3.4
13318393	109	30SEP21	06NOV21	3.0202	0.1550	5.1
13318395	57	20OCT21	14NOV21	3.0368	0.1304	4.3
13318399	143	05NOV21	18DEC21	2.9308	0.1312	4.5
13318402	40	03DEC21	20DEC21	3.0050	0.0986	3.3
13318408	128	06JAN22	11FEB22	3.1125	0.1436	4.6
13318412	53	26JAN22	19FEB22	2.9358	0.1178	4.0
13318415	130	14FEB22	25MAR22	3.2385	0.1400	4.3
13318418	85	08MAR22	16APR22	3.1306	0.1345	4.3
13318423	80	28MAR22	06MAY22	3.4763	0.1398	4.0
13318426	89	19APR22	28MAY22	3.4843	0.6138	17.6
13318430	78	09MAY22	19JUN22	3.4692	0.1614	4.7
13318435	32	06JUL22	19JUL22	2.7313	0.1148	4.2
13318440	12	27JUL22	21AUG22	3.0250	0.0622	2.1
13318439	47	28JUL22	18AUG22	2.7809	0.1173	4.2
13318444	131	16AUG22	25SEP22	3.1382	0.1707	5.4
13318448	119	30AUG22	13OCT22	3.1697	0.2073	6.5
13318451	67	30SEP22	24OCT22	2.8925	0.1295	4.5
13318458	67	13OCT22	06NOV22	3.1239	0.1488	4.8
13318460	142	03NOV22	18DEC22	3.0852	0.1288	4.2
13318463	55	23NOV22	08JAN23	3.1709	0.1212	3.8
13318468	131	04JAN23	12FEB23	2.9046	0.1430	4.9
13318472	89	01FEB23	13MAR23	3.0551	0.1446	4.7
13318475	141	16FEB23	08APR23	3.1837	0.1318	4.1
13318480	127	06APR23	07MAY23	2.8213	0.1749	6.2
13318483	110	06APR23	27MAY23	3.1645	0.1583	5.0
13318485	86	18MAY23	10JUN23	2.7267	0.1451	5.3
13318490	66	03JUN23	02JUL23	2.6242	0.1646	6.3
13318489	52	07JUN23	07JUL23	2.6269	0.1285	4.9
13318491	57	02JUL23	21JUL23	2.5509	0.1325	5.2
13318494	66	06JUL23	11AUG23	2.5106	0.1510	6.0
13318495	28	19JUL23	24JUL23	2.6643	0.1393	5.2
13318499	45	10AUG23	21AUG23	2.6511	0.1180	4.5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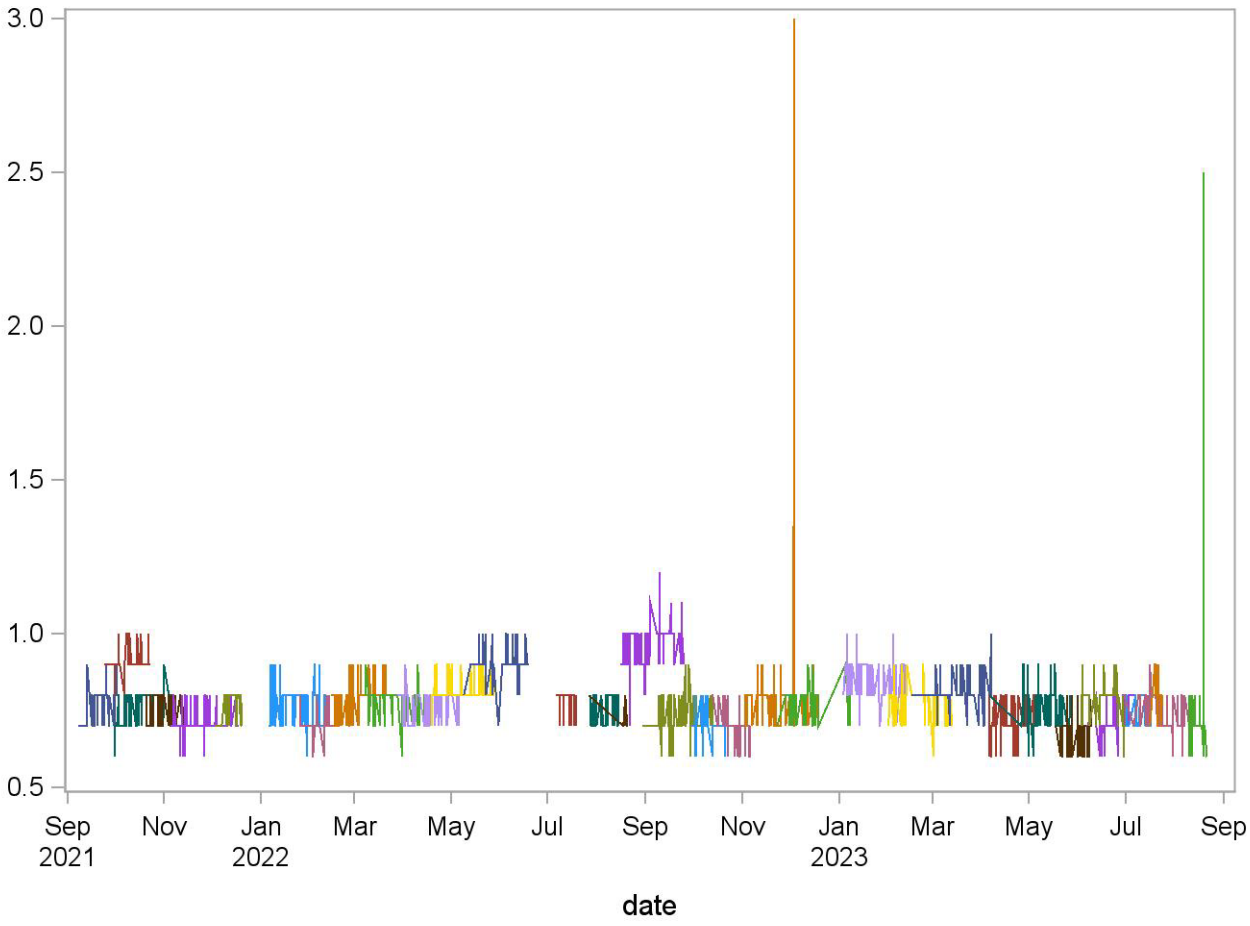
August 2021 – August 2023 Summary Statistics and QC Chart
LBCMON3 (Monocyte No.(10^3 cells/uL) (Lvl 3))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
14319388	50	08SEP21	03OCT21	0.7680	0.0587	7.6
14319389	53	24SEP21	23OCT21	0.9170	0.0470	5.1
14319393	109	30SEP21	06NOV21	0.7514	0.0538	7.2
14319395	56	20OCT21	14NOV21	0.7482	0.0504	6.7
14319399	141	05NOV21	18DEC21	0.7184	0.0457	6.4
14319402	41	03DEC21	20DEC21	0.7537	0.0505	6.7
14319408	128	06JAN22	11FEB22	0.7773	0.0578	7.4
14319412	53	26JAN22	19FEB22	0.7075	0.0432	6.1
14319416	131	14FEB22	25MAR22	0.7893	0.0515	6.5
14319418	85	08MAR22	16APR22	0.7812	0.0475	6.1
14319423	77	28MAR22	06MAY22	0.7701	0.0540	7.0
14319426	87	19APR22	28MAY22	0.8218	0.0443	5.4
14319430	78	09MAY22	19JUN22	0.9051	0.0507	5.6
14319435	32	06JUL22	19JUL22	0.7813	0.0397	5.1
14319440	12	27JUL22	21AUG22	0.7250	0.0452	6.2
14319439	45	28JUL22	15AUG22	0.7511	0.0506	6.7
14319445	133	16AUG22	25SEP22	0.9609	0.0661	6.9
14319448	116	30AUG22	13OCT22	0.7371	0.0612	8.3
14319451	70	30SEP22	24OCT22	0.6986	0.0434	6.2
14319457	67	13OCT22	06NOV22	0.6940	0.0489	7.0
14319460	144	03NOV22	18DEC22	0.7986	0.1907	23.9
14319463	54	23NOV22	08JAN23	0.7833	0.0575	7.3
14319468	130	04JAN23	12FEB23	0.8469	0.0600	7.1
14319472	87	01FEB23	13MAR23	0.7793	0.0553	7.1
14319475	136	16FEB23	08APR23	0.8074	0.0466	5.8
14319480	121	06APR23	07MAY23	0.7165	0.0624	8.7
14319483	110	06APR23	27MAY23	0.7745	0.0683	8.8
14319485	89	18MAY23	10JUN23	0.6742	0.0554	8.2
14319490	66	03JUN23	02JUL23	0.7773	0.0627	8.1
14319489	51	07JUN23	07JUL23	0.7196	0.0566	7.9
14319494	70	30JUN23	11AUG23	0.7414	0.0602	8.1
14319491	57	02JUL23	21JUL23	0.7509	0.0504	6.7
14319495	28	16JUL23	24JUL23	0.8071	0.0663	8.2
14319499	46	10AUG23	21AUG23	0.7348	0.2710	36.9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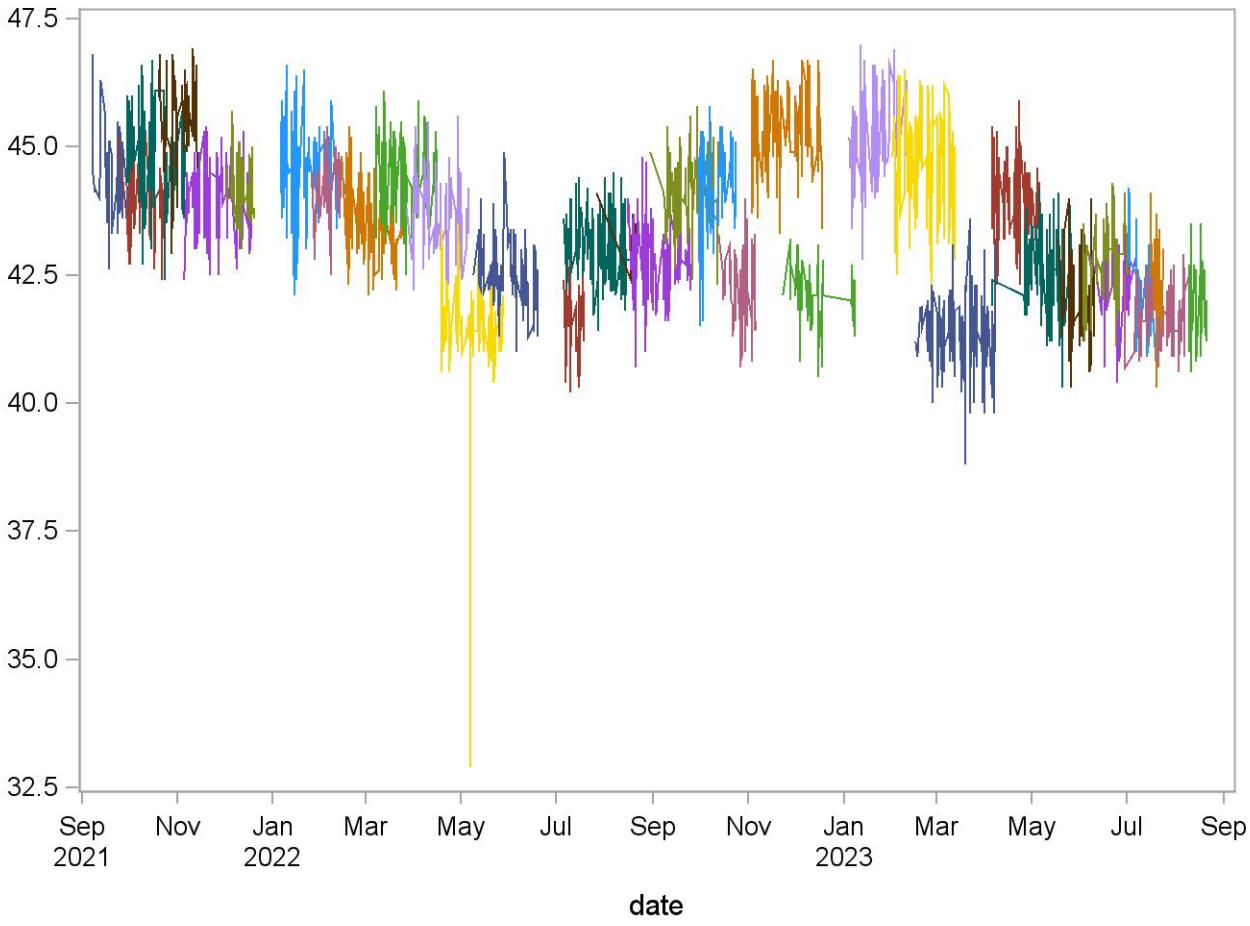
August 2021 – August 2023 Summary Statistics and QC Chart
LBCNEP1 (Neutrophil (%) (Lvl 1))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
12317388	48	08SEP21	03OCT21	44.4646	0.8284	1.9
12317389	54	24SEP21	23OCT21	43.9852	0.6597	1.5
12317393	107	30SEP21	06NOV21	44.8364	0.8207	1.8
12317395	56	20OCT21	14NOV21	45.5536	0.8018	1.8
12317399	142	05NOV21	18DEC21	44.0035	0.6037	1.4
12317402	41	03DEC21	20DEC21	44.1951	0.6115	1.4
12317408	127	06JAN22	11FEB22	44.5433	0.7811	1.8
12317412	52	26JAN22	19FEB22	44.1635	0.6281	1.4
12317416	130	14FEB22	25MAR22	43.6200	0.6891	1.6
12317418	85	08MAR22	16APR22	44.3576	0.7065	1.6
12317423	77	28MAR22	06MAY22	43.7065	0.7743	1.8
12317426	90	19APR22	28MAY22	41.4611	1.0766	2.6
12317431	78	09MAY22	19JUN22	42.4936	0.6527	1.5
12317435	32	06JUL22	19JUL22	41.5938	0.7286	1.8
12317439	126	06JUL22	18AUG22	43.0373	0.6393	1.5
12317440	12	27JUL22	21AUG22	42.9167	0.6860	1.6
12317444	129	16AUG22	25SEP22	42.8566	0.6617	1.5
12317448	116	30AUG22	13OCT22	44.1586	0.6602	1.5
12317451	66	30SEP22	24OCT22	44.2439	0.8931	2.0
12317457	67	13OCT22	06NOV22	42.3179	0.7290	1.7
12317460	146	03NOV22	18DEC22	45.2863	0.7199	1.6
12317463	54	23NOV22	08JAN23	42.0944	0.6073	1.4
12317468	132	04JAN23	12FEB23	45.0970	0.7596	1.7
12317472	87	01FEB23	13MAR23	44.6793	1.0625	2.4
12317475	136	16FEB23	08APR23	41.3243	0.7460	1.8
12317480	122	06APR23	07MAY23	43.9303	0.7100	1.6
12317483	108	06APR23	27MAY23	42.5963	0.7517	1.8
12317485	87	18MAY23	10JUN23	41.9977	0.7522	1.8
12317490	65	03JUN23	02JUL23	42.7277	0.7158	1.7
12317489	51	07JUN23	07JUL23	42.4196	0.6856	1.6
12317494	73	30JUN23	11AUG23	41.7315	0.5862	1.4
12317491	57	02JUL23	21JUL23	42.1386	0.8639	2.1
12317495	28	16JUL23	24JUL23	42.5179	0.8201	1.9
12317499	44	10AUG23	21AUG23	42.0295	0.6812	1.6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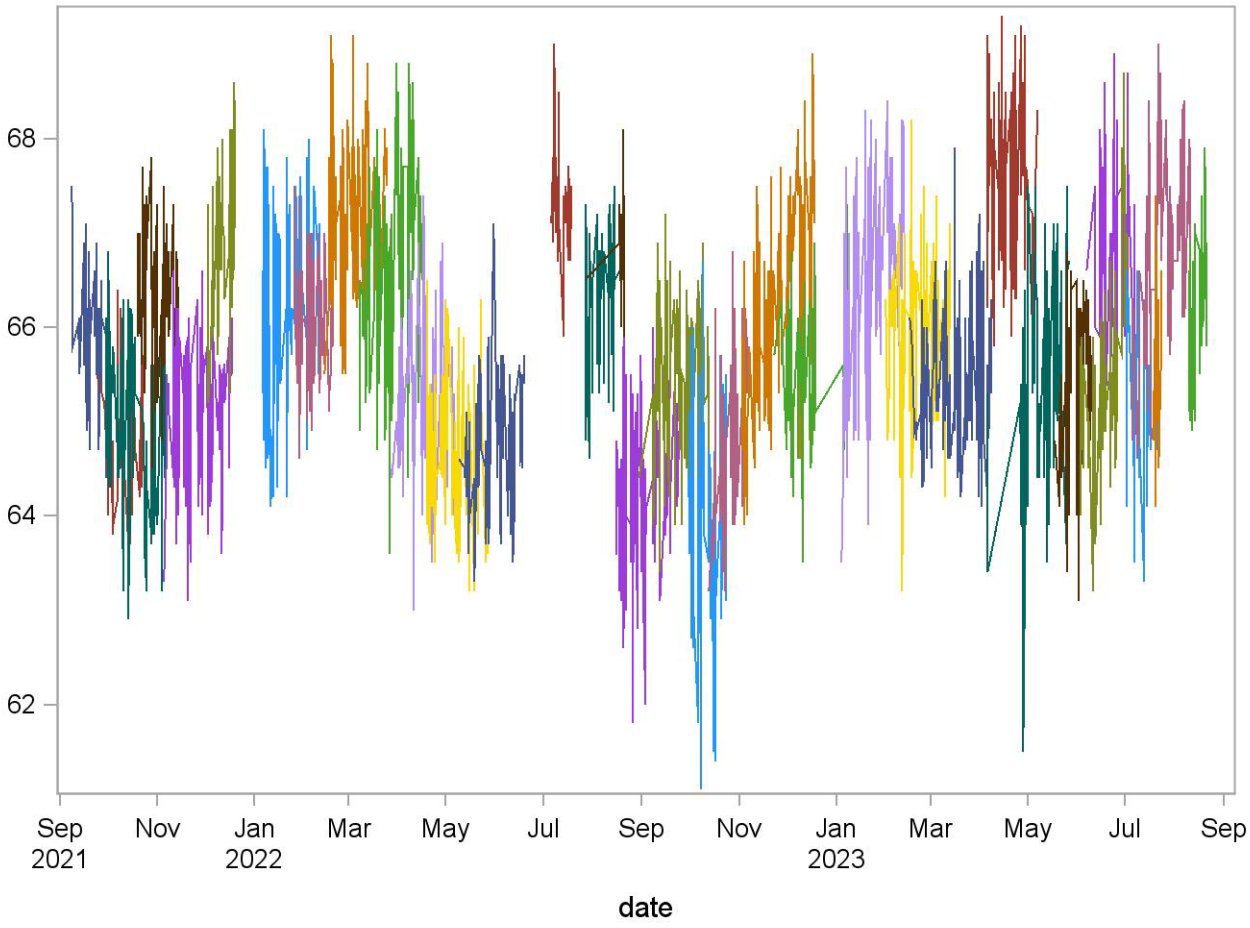
August 2021 – August 2023 Summary Statistics and QC Chart
LBCNEP2 (Neutrophil (%) (Lvl 2))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
13318388	49	08SEP21	03OCT21	65.8918	0.6611	1.0
13318389	53	24SEP21	23OCT21	64.7660	0.5847	0.9
13318393	109	30SEP21	06NOV21	64.9147	0.8356	1.3
13318395	57	20OCT21	14NOV21	66.3070	0.8069	1.2
13318399	143	05NOV21	18DEC21	65.0797	0.6841	1.1
13318402	40	03DEC21	20DEC21	66.9375	0.7970	1.2
13318408	128	06JAN22	11FEB22	66.0852	0.9088	1.4
13318412	53	26JAN22	19FEB22	66.0472	0.6542	1.0
13318415	130	14FEB22	25MAR22	67.1531	0.7801	1.2
13318418	85	08MAR22	16APR22	66.6176	1.0480	1.6
13318423	80	28MAR22	06MAY22	65.2513	0.8342	1.3
13318426	88	19APR22	28MAY22	64.7091	0.7296	1.1
13318430	78	09MAY22	19JUN22	64.7449	0.6761	1.0
13318435	32	06JUL22	19JUL22	67.3094	0.6103	0.9
13318440	12	27JUL22	21AUG22	66.8667	0.7139	1.1
13318439	47	28JUL22	18AUG22	66.3170	0.7458	1.1
13318444	131	16AUG22	25SEP22	64.2702	0.7595	1.2
13318448	119	30AUG22	13OCT22	65.3597	0.7777	1.2
13318451	67	30SEP22	24OCT22	64.1164	1.1832	1.8
13318458	67	13OCT22	06NOV22	64.8418	0.7785	1.2
13318460	142	03NOV22	18DEC22	66.0415	0.9681	1.5
13318463	55	23NOV22	08JAN23	65.4982	0.7104	1.1
13318468	131	04JAN23	12FEB23	66.4198	0.9669	1.5
13318472	89	01FEB23	13MAR23	65.9169	0.8198	1.2
13318475	141	16FEB23	08APR23	65.5674	0.6988	1.1
13318480	127	06APR23	07MAY23	67.6087	0.7896	1.2
13318483	110	06APR23	27MAY23	65.3427	1.0735	1.6
13318485	86	18MAY23	10JUN23	65.3651	0.7872	1.2
13318490	66	03JUN23	02JUL23	65.4970	1.0413	1.6
13318489	52	07JUN23	07JUL23	66.8596	0.8965	1.3
13318491	57	02JUL23	21JUL23	65.1211	0.7803	1.2
13318494	66	06JUL23	11AUG23	66.8773	0.9543	1.4
13318495	28	19JUL23	24JUL23	65.7679	0.7818	1.2
13318499	45	10AUG23	21AUG23	66.0311	0.7064	1.1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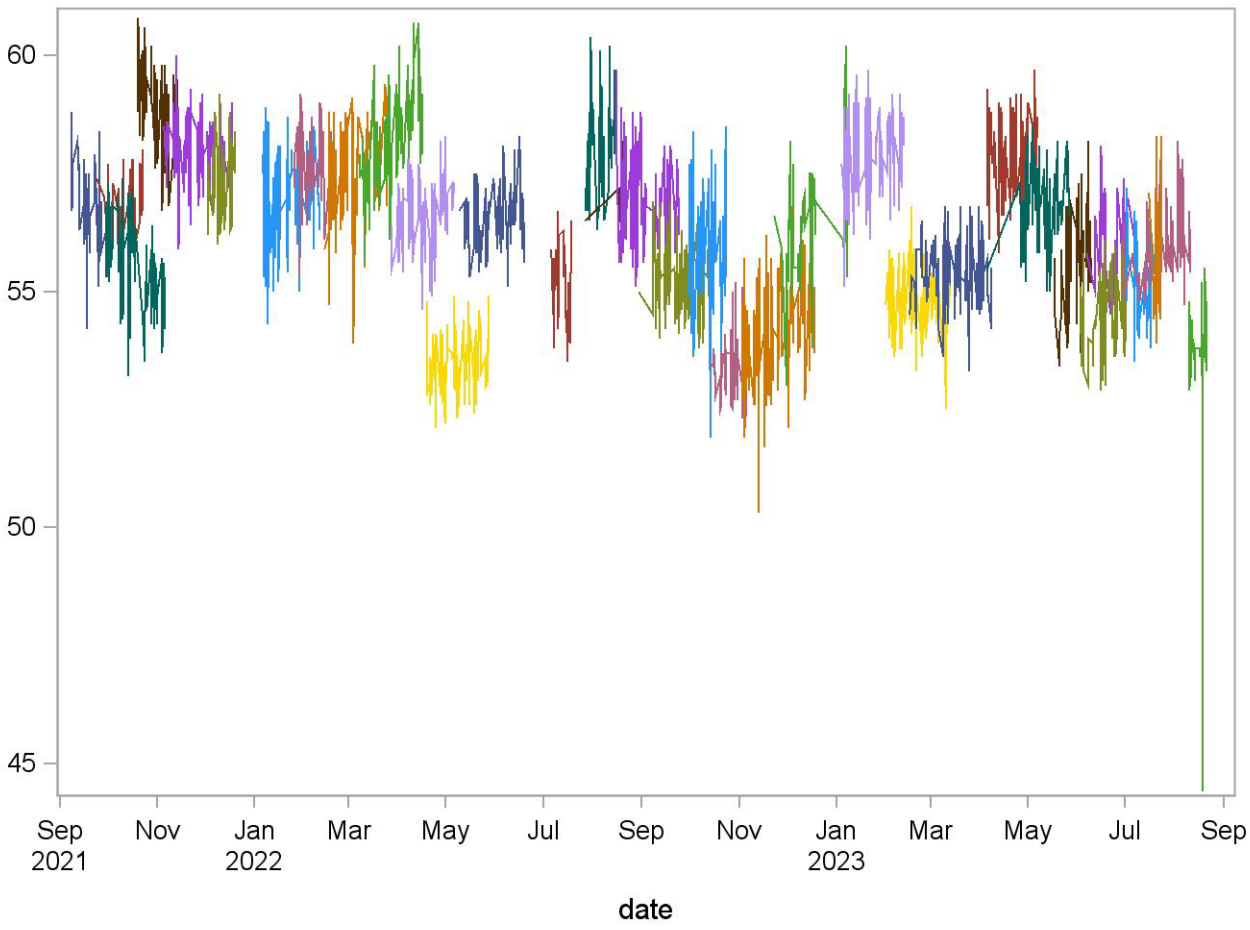
August 2021 – August 2023 Summary Statistics and QC Chart
LBCNEP3 (Neutrophil (%) (Lvl 3))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
14319388	50	08SEP21	03OCT21	56.7120	0.8628	1.5
14319389	53	24SEP21	23OCT21	56.7642	0.6310	1.1
14319393	109	30SEP21	06NOV21	55.5927	0.9175	1.7
14319395	56	20OCT21	14NOV21	58.8661	0.9040	1.5
14319399	141	05NOV21	18DEC21	57.9433	0.6473	1.1
14319402	41	03DEC21	20DEC21	57.3585	0.8237	1.4
14319408	128	06JAN22	11FEB22	56.9461	0.8846	1.6
14319412	53	26JAN22	19FEB22	57.6264	0.7776	1.3
14319416	131	14FEB22	25MAR22	57.4656	0.9194	1.6
14319418	85	08MAR22	16APR22	58.1588	1.0241	1.8
14319423	77	28MAR22	06MAY22	56.6273	0.7739	1.4
14319426	87	19APR22	28MAY22	53.4931	0.6633	1.2
14319430	78	09MAY22	19JUN22	56.5103	0.6768	1.2
14319435	32	06JUL22	19JUL22	55.1969	0.8656	1.6
14319440	12	27JUL22	21AUG22	56.9083	0.5551	1.0
14319439	45	28JUL22	15AUG22	58.0800	1.0708	1.8
14319445	133	16AUG22	25SEP22	56.9105	0.8236	1.4
14319448	116	30AUG22	13OCT22	55.2940	0.6862	1.2
14319451	70	30SEP22	24OCT22	56.1200	1.3154	2.3
14319457	67	13OCT22	06NOV22	53.4045	0.6696	1.3
14319460	143	03NOV22	18DEC22	54.2538	1.0731	2.0
14319463	54	23NOV22	08JAN23	56.3407	1.2176	2.2
14319468	130	04JAN23	12FEB23	57.8277	0.8463	1.5
14319472	87	01FEB23	13MAR23	54.7793	0.8029	1.5
14319475	136	16FEB23	08APR23	55.3500	0.6661	1.2
14319480	121	06APR23	07MAY23	57.9000	0.7713	1.3
14319483	110	06APR23	27MAY23	56.6736	0.7812	1.4
14319485	89	18MAY23	10JUN23	55.6607	0.8970	1.6
14319490	66	03JUN23	02JUL23	54.5682	0.9252	1.7
14319489	51	07JUN23	07JUL23	55.9941	0.8191	1.5
14319494	70	30JUN23	11AUG23	55.9400	0.7734	1.4
14319491	57	02JUL23	21JUL23	55.2947	0.8376	1.5
14319495	28	16JUL23	24JUL23	55.8857	1.1613	2.1
14319499	46	10AUG23	21AUG23	53.6478	1.5095	2.8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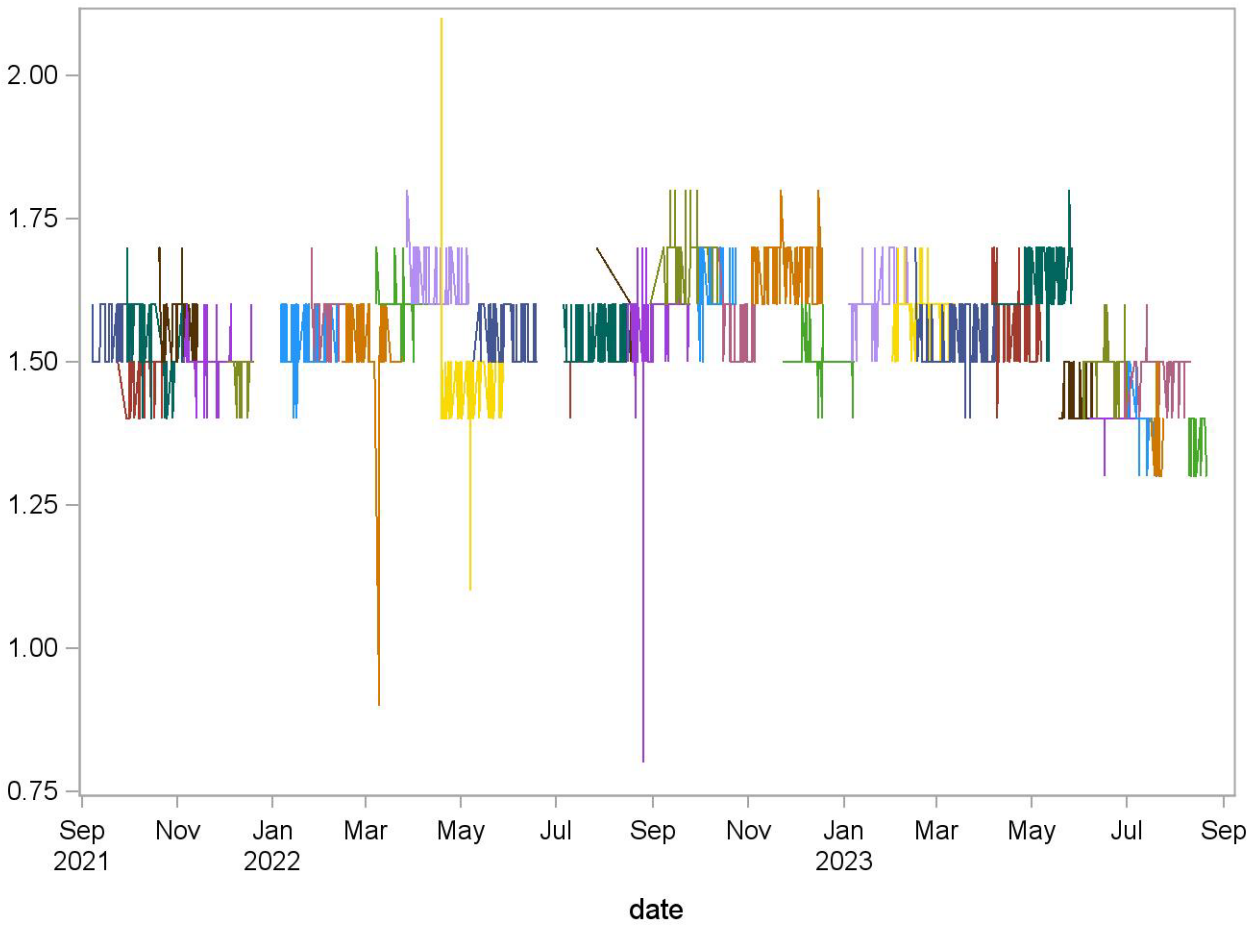
August 2021 – August 2023 Summary Statistics and QC Chart
LBCNEN1 (Neutrophil No.(10^3 cells/uL) (Lvl 1))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
12317388	48	08SEP21	03OCT21	1.5458	0.0504	3.3
12317389	54	24SEP21	23OCT21	1.4778	0.0420	2.8
12317393	107	30SEP21	06NOV21	1.5383	0.0624	4.1
12317395	56	20OCT21	14NOV21	1.5714	0.0594	3.8
12317399	142	05NOV21	18DEC21	1.5028	0.0314	2.1
12317402	41	03DEC21	20DEC21	1.4902	0.0300	2.0
12317408	127	06JAN22	11FEB22	1.5339	0.0507	3.3
12317412	52	26JAN22	19FEB22	1.5865	0.0397	2.5
12317416	131	14FEB22	25MAR22	1.5260	0.0719	4.7
12317418	85	08MAR22	16APR22	1.6035	0.0360	2.2
12317423	77	28MAR22	06MAY22	1.6455	0.0527	3.2
12317426	90	19APR22	28MAY22	1.4622	0.0919	6.3
12317431	78	09MAY22	19JUN22	1.5513	0.0503	3.2
12317435	32	06JUL22	19JUL22	1.5000	0.0254	1.7
12317439	126	06JUL22	18AUG22	1.5381	0.0488	3.2
12317440	12	27JUL22	21AUG22	1.5583	0.0669	4.3
12317444	130	16AUG22	25SEP22	1.5654	0.0869	5.6
12317448	116	30AUG22	13OCT22	1.6819	0.0486	2.9
12317451	66	30SEP22	24OCT22	1.6212	0.0512	3.2
12317457	67	13OCT22	06NOV22	1.5403	0.0524	3.4
12317460	146	03NOV22	18DEC22	1.6747	0.0467	2.8
12317463	54	23NOV22	08JAN23	1.5056	0.0408	2.7
12317468	132	04JAN23	12FEB23	1.6038	0.0358	2.2
12317472	87	01FEB23	13MAR23	1.5862	0.0486	3.1
12317475	136	16FEB23	08APR23	1.5294	0.0518	3.4
12317480	122	06APR23	07MAY23	1.5795	0.0602	3.8
12317483	108	06APR23	27MAY23	1.6500	0.0555	3.4
12317485	87	18MAY23	10JUN23	1.4264	0.0444	3.1
12317490	65	03JUN23	02JUL23	1.4892	0.0437	2.9
12317489	51	07JUN23	07JUL23	1.4000	0.0200	1.4
12317494	73	30JUN23	11AUG23	1.4836	0.0409	2.8
12317491	57	02JUL23	21JUL23	1.4053	0.0440	3.1
12317495	28	16JUL23	24JUL23	1.3821	0.0548	4.0
12317499	44	10AUG23	21AUG23	1.3750	0.0438	3.2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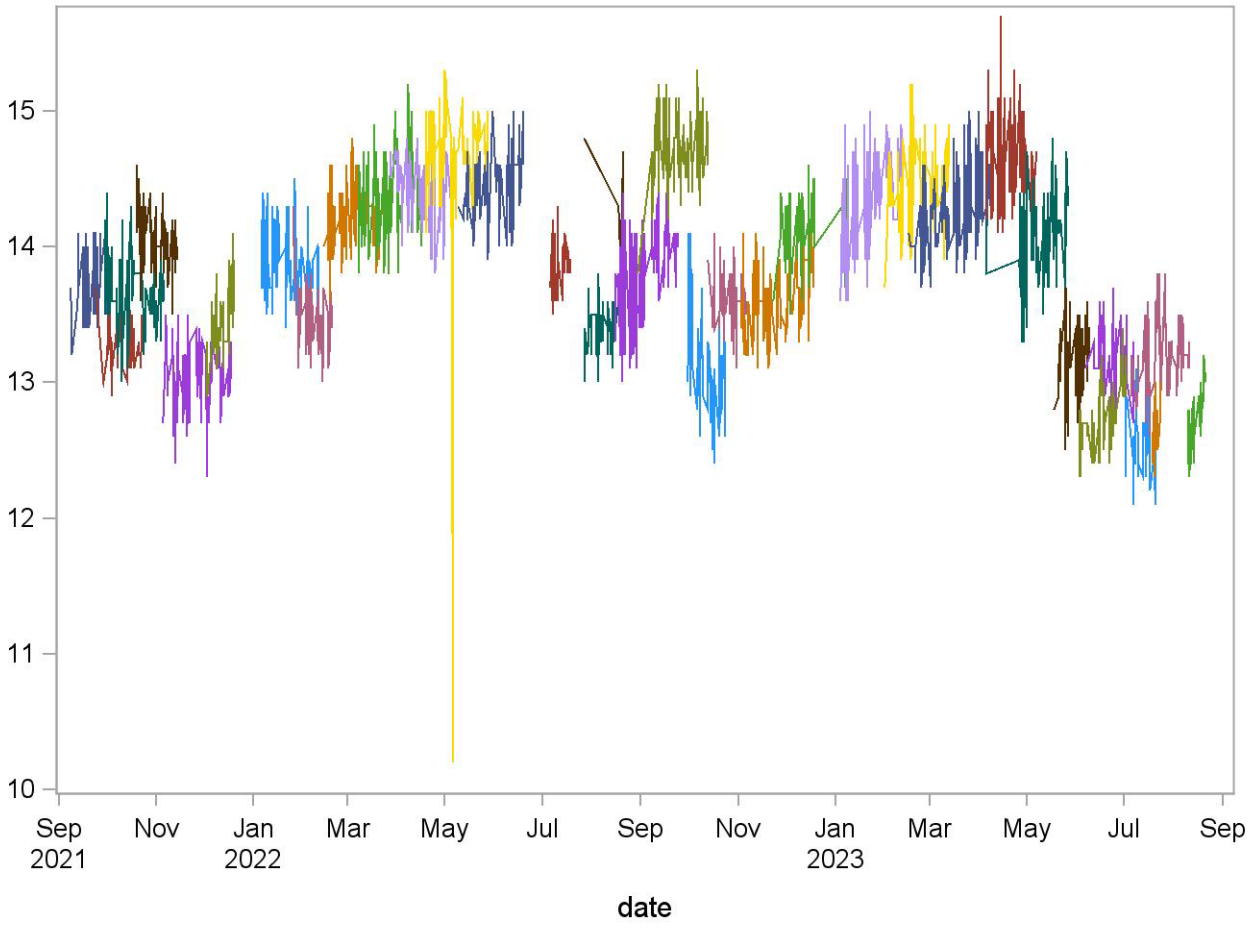
August 2021 – August 2023 Summary Statistics and QC Chart
LBCNEN2 (Neutrophil No.(10^3 cells/uL) (Lvl 2))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
13318388	49	08SEP21	03OCT21	13.7143	0.2533	1.8
13318389	53	24SEP21	23OCT21	13.2943	0.1802	1.4
13318393	109	30SEP21	06NOV21	13.6385	0.2775	2.0
13318395	57	20OCT21	14NOV21	14.0561	0.2204	1.6
13318399	143	05NOV21	18DEC21	13.0063	0.2290	1.8
13318402	40	03DEC21	20DEC21	13.4475	0.2631	2.0
13318408	128	06JAN22	11FEB22	13.8938	0.2268	1.6
13318412	53	26JAN22	19FEB22	13.4849	0.2545	1.9
13318415	130	14FEB22	25MAR22	14.2238	0.2134	1.5
13318418	85	08MAR22	16APR22	14.3518	0.3030	2.1
13318423	80	28MAR22	06MAY22	14.4025	0.2250	1.6
13318426	89	19APR22	28MAY22	14.6539	0.5317	3.6
13318430	78	09MAY22	19JUN22	14.4551	0.2394	1.7
13318435	32	06JUL22	19JUL22	13.8719	0.1955	1.4
13318440	12	27JUL22	21AUG22	14.2583	0.2778	1.9
13318439	47	28JUL22	18AUG22	13.3766	0.1697	1.3
13318444	131	16AUG22	25SEP22	13.7557	0.3324	2.4
13318448	119	30AUG22	13OCT22	14.7361	0.2382	1.6
13318451	67	30SEP22	24OCT22	13.2090	0.3911	3.0
13318458	67	13OCT22	06NOV22	13.6418	0.1947	1.4
13318460	142	03NOV22	18DEC22	13.5775	0.2332	1.7
13318463	55	23NOV22	08JAN23	14.1073	0.2523	1.8
13318468	131	04JAN23	12FEB23	14.3267	0.3236	2.3
13318472	89	01FEB23	13MAR23	14.4393	0.2704	1.9
13318475	141	16FEB23	08APR23	14.3028	0.2637	1.8
13318480	127	06APR23	07MAY23	14.6465	0.2960	2.0
13318483	110	06APR23	27MAY23	14.0400	0.2934	2.1
13318485	86	18MAY23	10JUN23	13.1849	0.2632	2.0
13318490	66	03JUN23	02JUL23	12.7394	0.2306	1.8
13318489	52	07JUN23	07JUL23	13.1712	0.2172	1.6
13318491	57	02JUL23	21JUL23	12.5263	0.2040	1.6
13318494	66	06JUL23	11AUG23	13.2106	0.2567	1.9
13318495	28	19JUL23	24JUL23	12.7000	0.1721	1.4
13318499	45	10AUG23	21AUG23	12.7022	0.2017	1.6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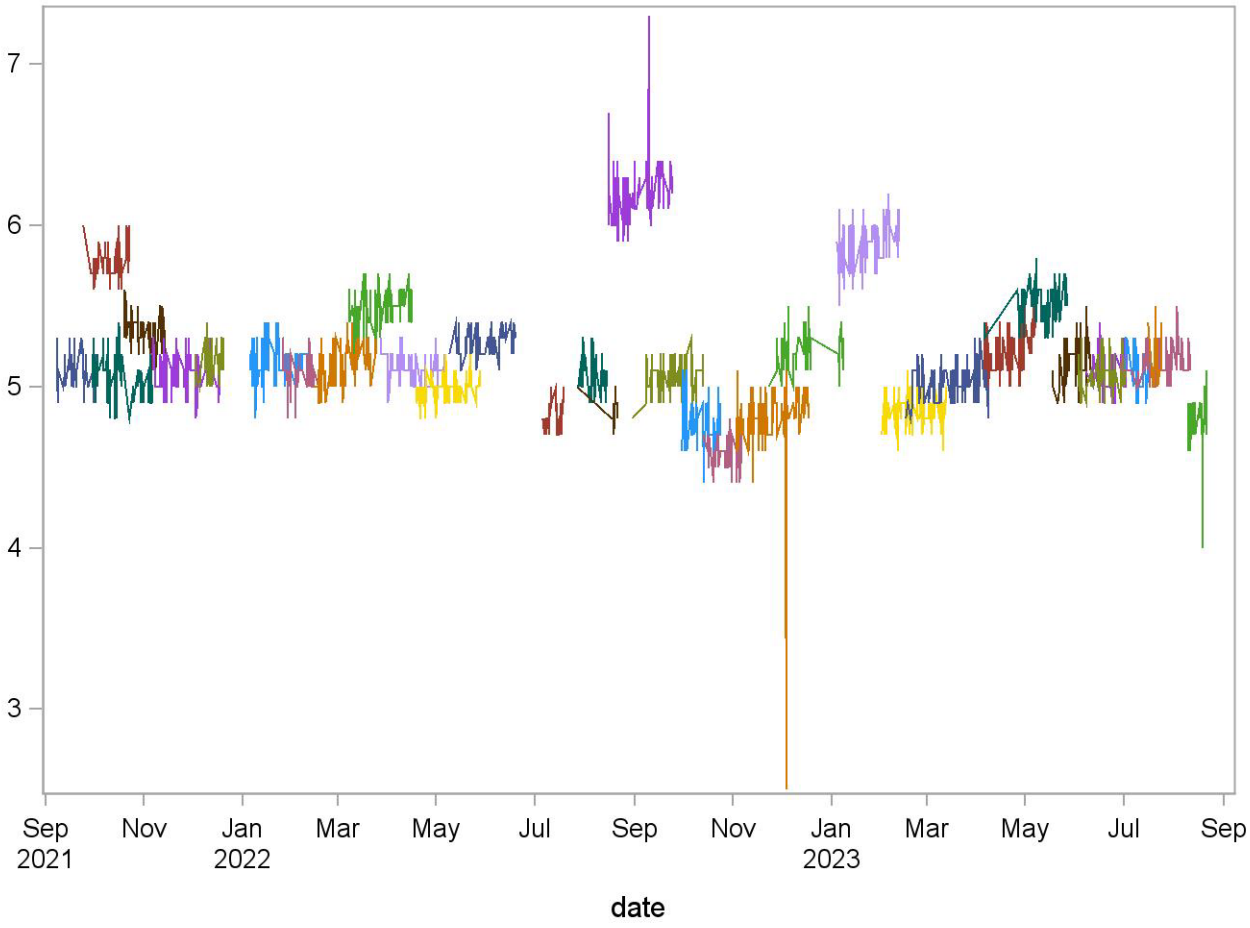
August 2021 – August 2023 Summary Statistics and QC Chart
LBCNEN3 (Neutrophil No.(10^3 cells/uL) (Lvl 3))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
14319388	50	08SEP21	03OCT21	5.0940	0.1058	2.1
14319389	53	24SEP21	23OCT21	5.7792	0.1044	1.8
14319393	109	30SEP21	06NOV21	5.0468	0.1244	2.5
14319395	56	20OCT21	14NOV21	5.3393	0.1090	2.0
14319399	141	05NOV21	18DEC21	5.0773	0.1085	2.1
14319402	41	03DEC21	20DEC21	5.1610	0.1046	2.0
14319408	128	06JAN22	11FEB22	5.1547	0.1034	2.0
14319412	53	26JAN22	19FEB22	5.0849	0.1063	2.1
14319416	131	14FEB22	25MAR22	5.1260	0.1225	2.4
14319418	85	08MAR22	16APR22	5.4859	0.1114	2.0
14319423	77	28MAR22	06MAY22	5.1078	0.0929	1.8
14319426	87	19APR22	28MAY22	4.9724	0.0817	1.6
14319430	78	09MAY22	19JUN22	5.2808	0.0823	1.6
14319435	32	06JUL22	19JUL22	4.8156	0.0954	2.0
14319440	12	27JUL22	21AUG22	4.8750	0.0965	2.0
14319439	45	28JUL22	15AUG22	5.0733	0.1116	2.2
14319445	133	16AUG22	25SEP22	6.1782	0.1648	2.7
14319448	116	30AUG22	13OCT22	5.0638	0.0908	1.8
14319451	70	30SEP22	24OCT22	4.8100	0.1543	3.2
14319457	67	13OCT22	06NOV22	4.5836	0.0898	2.0
14319460	144	03NOV22	18DEC22	4.8014	0.2275	4.7
14319463	54	23NOV22	08JAN23	5.2315	0.1256	2.4
14319468	130	04JAN23	12FEB23	5.8638	0.1341	2.3
14319472	87	01FEB23	13MAR23	4.8563	0.1031	2.1
14319475	136	16FEB23	08APR23	5.0375	0.0988	2.0
14319480	121	06APR23	07MAY23	5.2140	0.1105	2.1
14319483	110	06APR23	27MAY23	5.4964	0.1125	2.0
14319485	89	18MAY23	10JUN23	5.1539	0.1178	2.3
14319490	66	03JUN23	02JUL23	5.0621	0.1147	2.3
14319489	51	07JUN23	07JUL23	5.1059	0.1121	2.2
14319494	70	30JUN23	11AUG23	5.1514	0.1032	2.0
14319491	57	02JUL23	21JUL23	5.1211	0.1114	2.2
14319495	28	16JUL23	24JUL23	5.2000	0.1440	2.8
14319499	46	10AUG23	21AUG23	4.7783	0.1576	3.3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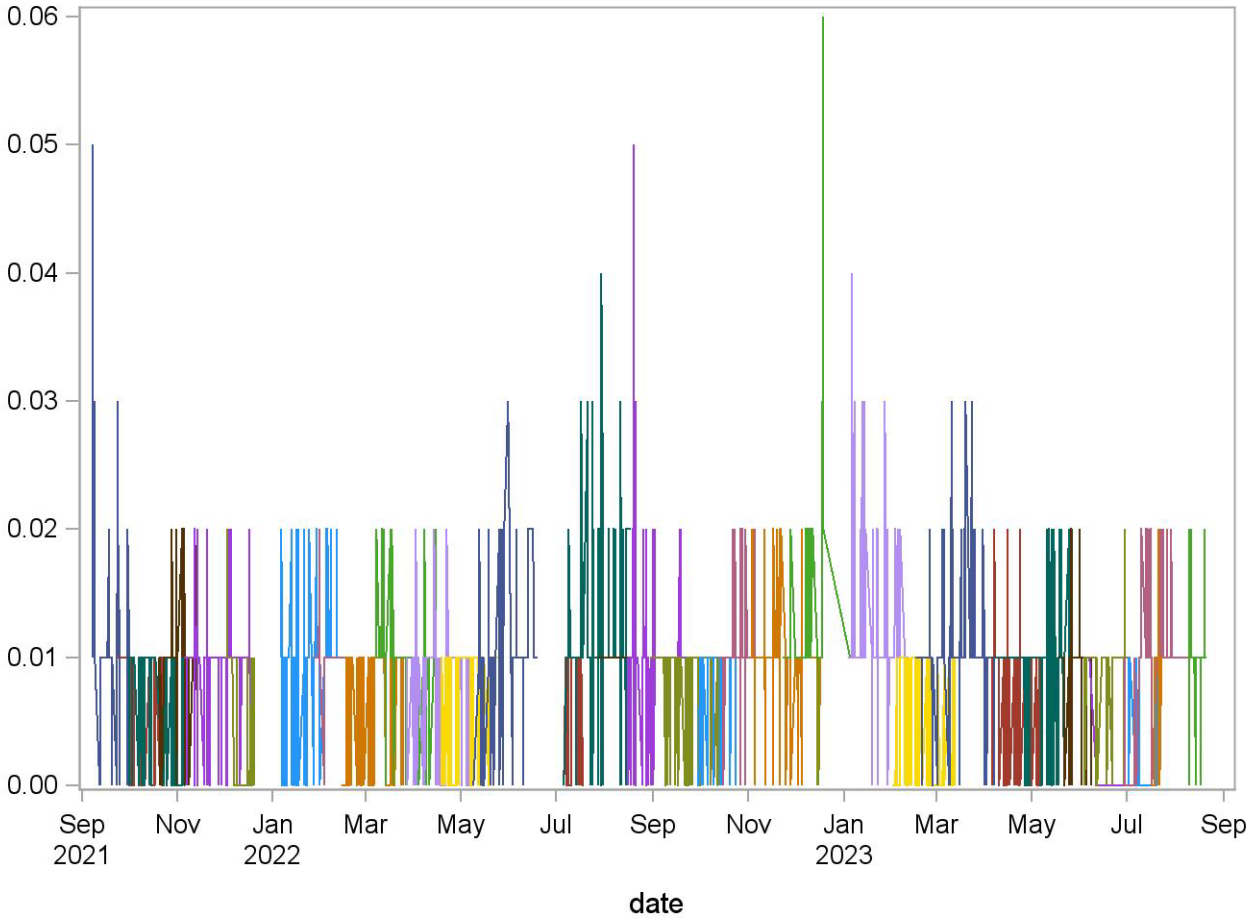
August 2021 – August 2023 Summary Statistics and QC Chart
LBCNRBC1 (Nucleated red blood cells (Lvl 1))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
12317388	48	08SEP21	03OCT21	0.0108	0.0085	78.1
12317389	54	24SEP21	23OCT21	0.0044	0.0050	112.9
12317393	107	30SEP21	06NOV21	0.0064	0.0048	74.6
12317395	56	20OCT21	14NOV21	0.0104	0.0050	48.6
12317399	142	05NOV21	18DEC21	0.0092	0.0043	46.7
12317402	41	03DEC21	20DEC21	0.0039	0.0054	138.9
12317408	127	06JAN22	11FEB22	0.0080	0.0064	80.0
12317412	52	26JAN22	19FEB22	0.0096	0.0028	28.8
12317416	131	14FEB22	25MAR22	0.0066	0.0049	73.8
12317418	85	08MAR22	16APR22	0.0102	0.0046	45.2
12317423	77	28MAR22	06MAY22	0.0074	0.0052	70.7
12317426	89	19APR22	28MAY22	0.0072	0.0048	66.3
12317431	78	09MAY22	19JUN22	0.0100	0.0056	55.8
12317435	32	06JUL22	19JUL22	0.0050	0.0051	101.6
12317439	126	06JUL22	18AUG22	0.0115	0.0066	57.2
12317440	12	27JUL22	21AUG22	0.0133	0.0049	36.9
12317444	133	16AUG22	25SEP22	0.0102	0.0060	58.3
12317448	116	30AUG22	13OCT22	0.0077	0.0042	55.3
12317451	66	30SEP22	24OCT22	0.0086	0.0035	40.0
12317457	67	13OCT22	06NOV22	0.0107	0.0040	37.3
12317460	146	03NOV22	18DEC22	0.0101	0.0041	40.1
12317463	54	23NOV22	08JAN23	0.0128	0.0079	61.6
12317468	132	04JAN23	12FEB23	0.0130	0.0065	50.2
12317472	87	01FEB23	13MAR23	0.0034	0.0048	138.6
12317475	137	16FEB23	08APR23	0.0104	0.0048	46.3
12317480	122	06APR23	07MAY23	0.0065	0.0053	81.7
12317483	108	06APR23	27MAY23	0.0080	0.0061	76.3
12317485	87	18MAY23	10JUN23	0.0097	0.0042	43.1
12317490	65	03JUN23	02JUL23	0.0091	0.0034	37.6
12317489	51	07JUN23	07JUL23	0.0002	0.0014	714.1
12317494	73	30JUN23	11AUG23	0.0108	0.0049	45.6
12317491	57	02JUL23	21JUL23	0.0023	0.0042	185.6
12317495	28	16JUL23	24JUL23	0.0079	0.0050	63.5
12317499	44	10AUG23	21AUG23	0.0102	0.0040	39.4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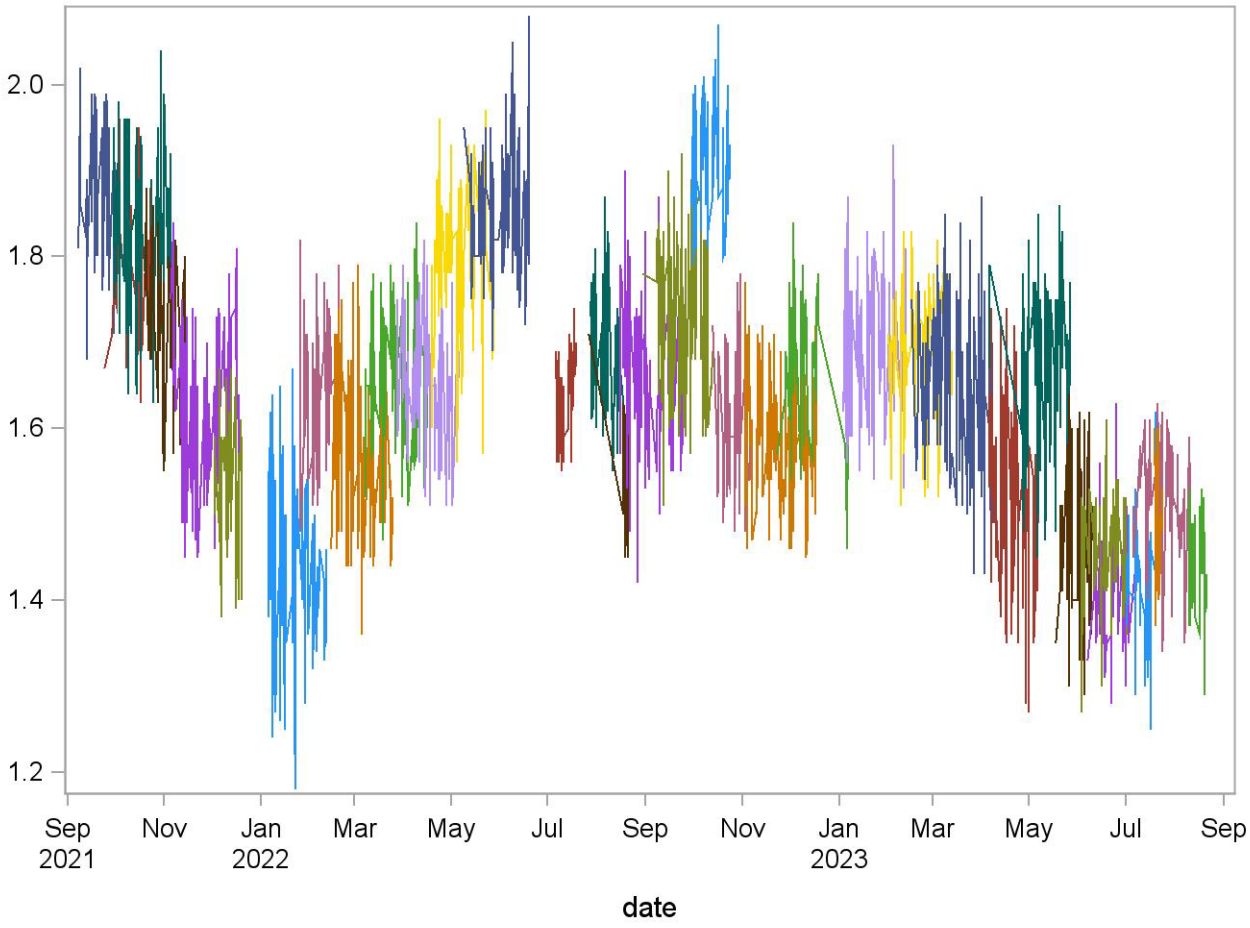
August 2021 – August 2023 Summary Statistics and QC Chart
LBCNRBC2 (Nucleated red blood cells (Lvl 2))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
13318388	49	08SEP21	03OCT21	1.8790	0.0793	4.2
13318389	53	24SEP21	23OCT21	1.7821	0.0698	3.9
13318393	109	30SEP21	06NOV21	1.8139	0.0879	4.8
13318395	57	20OCT21	14NOV21	1.7316	0.0748	4.3
13318399	143	05NOV21	18DEC21	1.6190	0.0790	4.9
13318402	40	03DEC21	20DEC21	1.5465	0.0751	4.9
13318408	128	06JAN22	11FEB22	1.4375	0.0970	6.7
13318412	53	26JAN22	19FEB22	1.6449	0.0775	4.7
13318415	130	14FEB22	25MAR22	1.5821	0.0815	5.1
13318418	85	08MAR22	16APR22	1.6576	0.0760	4.6
13318423	81	28MAR22	06MAY22	1.6477	0.0703	4.3
13318426	89	19APR22	28MAY22	1.8028	0.0807	4.5
13318430	78	09MAY22	19JUN22	1.8505	0.0726	3.9
13318435	32	06JUL22	19JUL22	1.6409	0.0550	3.4
13318440	12	27JUL22	21AUG22	1.5658	0.0762	4.9
13318439	47	28JUL22	18AUG22	1.6955	0.0766	4.5
13318444	130	16AUG22	25SEP22	1.6700	0.0766	4.6
13318448	119	30AUG22	13OCT22	1.7242	0.0826	4.8
13318451	67	30SEP22	24OCT22	1.9104	0.0658	3.4
13318458	67	13OCT22	06NOV22	1.5985	0.0663	4.1
13318460	142	03NOV22	18DEC22	1.5980	0.0680	4.3
13318463	54	23NOV22	08JAN23	1.6683	0.0753	4.5
13318468	131	04JAN23	12FEB23	1.6978	0.0716	4.2
13318472	89	01FEB23	13MAR23	1.6938	0.0700	4.1
13318475	141	16FEB23	08APR23	1.6432	0.0873	5.3
13318480	127	06APR23	07MAY23	1.5320	0.0944	6.2
13318483	110	06APR23	27MAY23	1.6638	0.0893	5.4
13318485	86	18MAY23	10JUN23	1.4771	0.0823	5.6
13318490	66	03JUN23	02JUL23	1.4533	0.0634	4.4
13318489	52	07JUN23	07JUL23	1.4119	0.0689	4.9
13318491	57	02JUL23	21JUL23	1.4028	0.0611	4.4
13318494	66	06JUL23	11AUG23	1.5183	0.0603	4.0
13318495	28	19JUL23	24JUL23	1.4986	0.0649	4.3
13318499	45	10AUG23	21AUG23	1.4400	0.0539	3.7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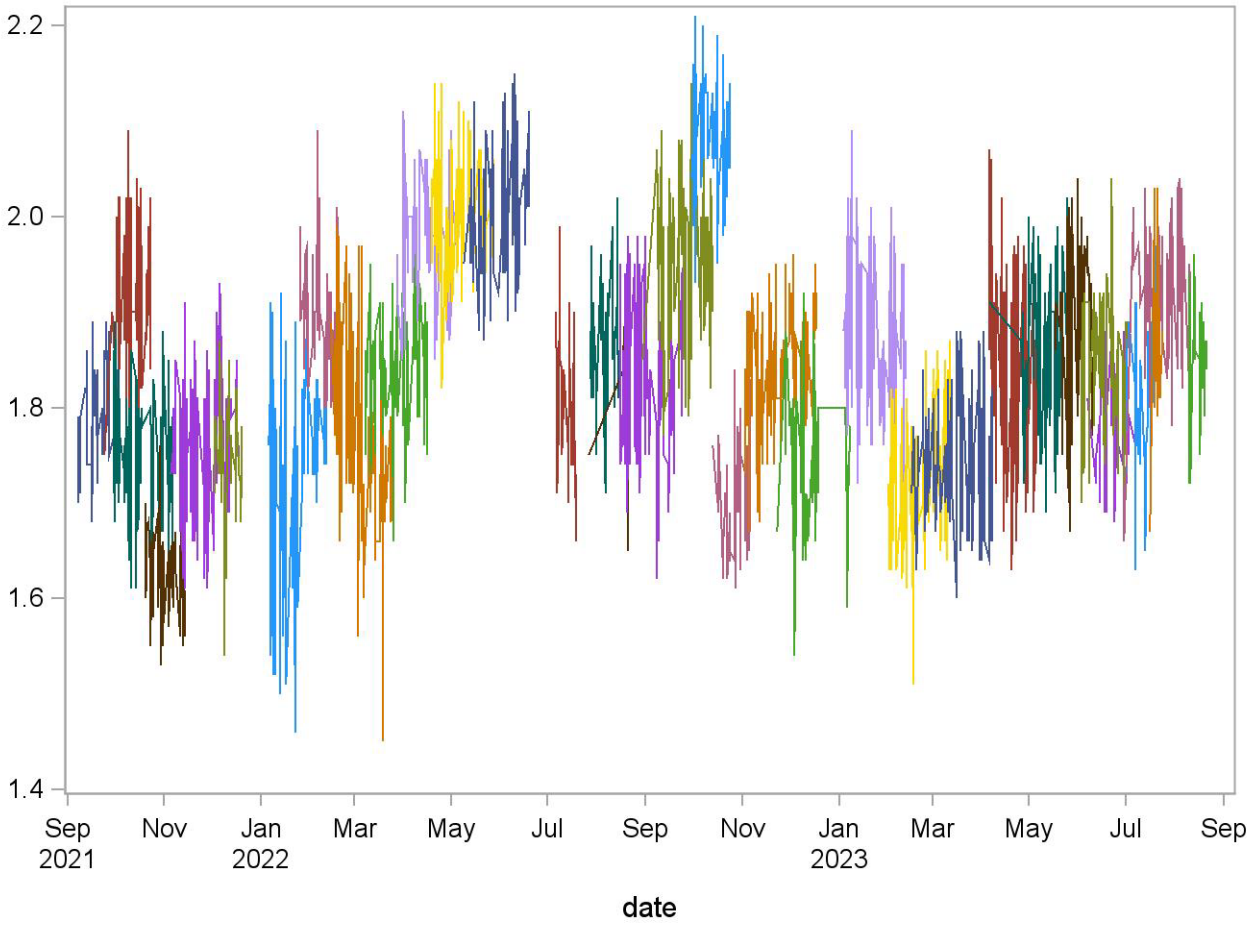
August 2021 – August 2023 Summary Statistics and QC Chart
LBCNRBC3 (Nucleated red blood cells (Lvl 3))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
14319388	50	08SEP21	03OCT21	1.7998	0.0512	2.8
14319389	53	24SEP21	23OCT21	1.9174	0.0864	4.5
14319393	109	30SEP21	06NOV21	1.7461	0.0618	3.5
14319395	56	20OCT21	14NOV21	1.6316	0.0493	3.0
14319399	141	05NOV21	18DEC21	1.7486	0.0626	3.6
14319402	41	03DEC21	20DEC21	1.7434	0.0624	3.6
14319408	128	06JAN22	11FEB22	1.7176	0.1018	5.9
14319412	53	26JAN22	19FEB22	1.8930	0.0605	3.2
14319416	131	14FEB22	25MAR22	1.7847	0.0902	5.1
14319418	85	08MAR22	16APR22	1.8371	0.0602	3.3
14319423	77	28MAR22	06MAY22	1.9752	0.0597	3.0
14319426	87	19APR22	28MAY22	2.0010	0.0594	3.0
14319430	78	09MAY22	19JUN22	2.0056	0.0652	3.3
14319435	32	06JUL22	19JUL22	1.8072	0.0709	3.9
14319440	12	27JUL22	21AUG22	1.8158	0.0807	4.4
14319439	45	28JUL22	15AUG22	1.8664	0.0624	3.3
14319445	132	16AUG22	25SEP22	1.8375	0.0748	4.1
14319448	116	30AUG22	13OCT22	1.9486	0.0735	3.8
14319451	70	30SEP22	24OCT22	2.0870	0.0603	2.9
14319457	67	13OCT22	06NOV22	1.7106	0.0547	3.2
14319460	144	03NOV22	18DEC22	1.8351	0.0572	3.1
14319463	54	23NOV22	08JAN23	1.7419	0.0772	4.4
14319468	130	04JAN23	12FEB23	1.8804	0.0737	3.9
14319472	87	01FEB23	13MAR23	1.7356	0.0713	4.1
14319475	136	16FEB23	08APR23	1.7441	0.0610	3.5
14319480	121	06APR23	07MAY23	1.8571	0.0886	4.8
14319483	110	06APR23	27MAY23	1.8470	0.0732	4.0
14319485	89	18MAY23	10JUN23	1.8961	0.0773	4.1
14319490	66	03JUN23	02JUL23	1.8270	0.0700	3.8
14319489	51	07JUN23	07JUL23	1.7898	0.0490	2.7
14319494	70	30JUN23	11AUG23	1.9089	0.0828	4.3
14319491	57	02JUL23	21JUL23	1.7923	0.0727	4.1
14319495	28	16JUL23	24JUL23	1.8796	0.0731	3.9
14319499	46	10AUG23	21AUG23	1.8330	0.0615	3.4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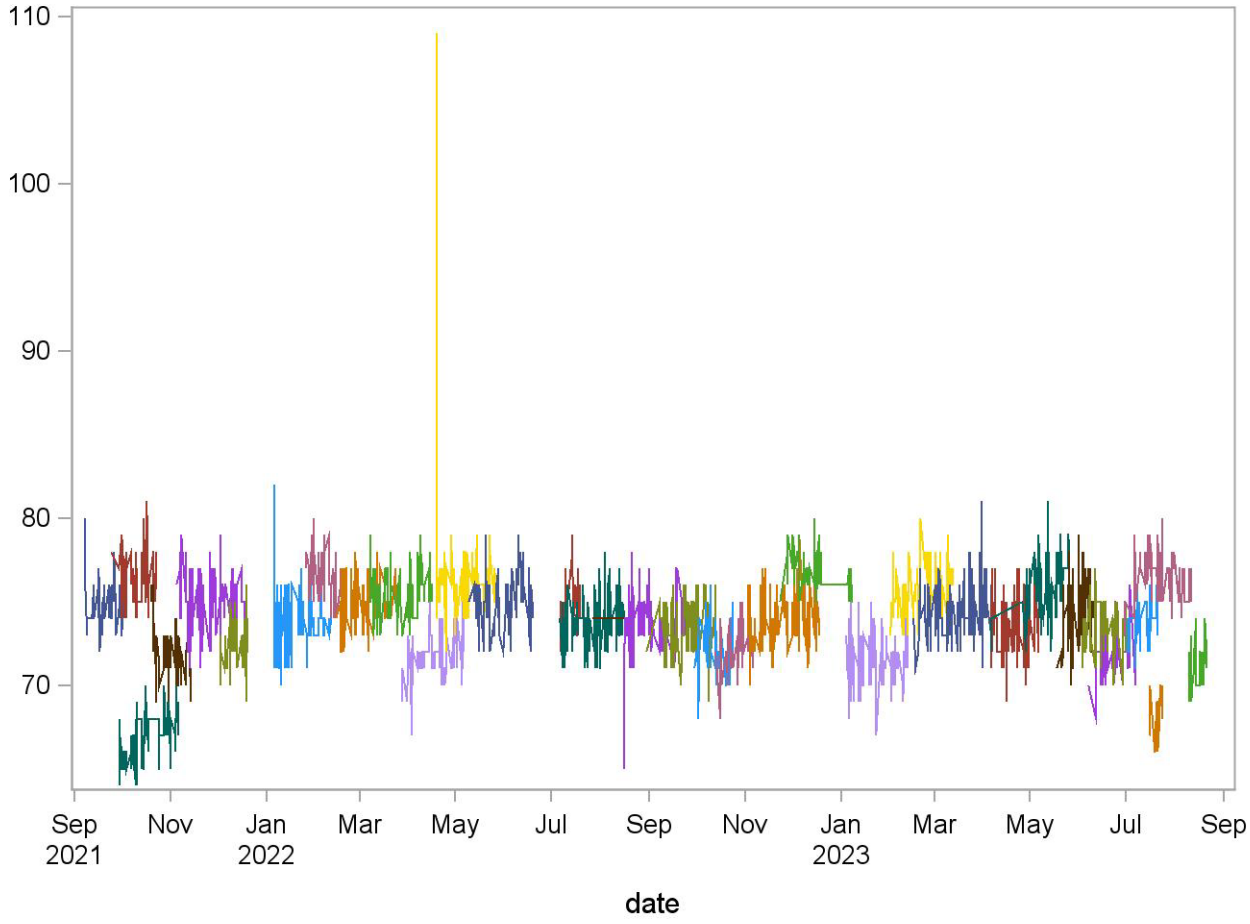
August 2021 – August 2023 Summary Statistics and QC Chart
LBCPLT1 (Platelet count (10^3 cells/uL) (Lvl 1))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
12317388	48	08SEP21	03OCT21	74.8333	1.4780	2.0
12317389	54	24SEP21	23OCT21	76.4259	1.6090	2.1
12317393	107	30SEP21	06NOV21	66.6355	1.4034	2.1
12317395	56	20OCT21	14NOV21	71.8929	1.5803	2.2
12317399	142	05NOV21	18DEC21	74.8099	1.6284	2.2
12317402	41	03DEC21	20DEC21	72.4146	1.4659	2.0
12317408	127	06JAN22	11FEB22	73.8110	1.5823	2.1
12317412	52	26JAN22	19FEB22	76.5000	1.4349	1.9
12317416	131	14FEB22	25MAR22	74.7939	1.3515	1.8
12317418	85	08MAR22	16APR22	75.5059	1.3855	1.8
12317423	77	28MAR22	06MAY22	71.8312	1.5509	2.2
12317426	90	19APR22	28MAY22	76.5333	3.7151	4.9
12317431	78	09MAY22	19JUN22	75.0897	1.6371	2.2
12317435	32	06JUL22	19JUL22	74.6875	1.6740	2.2
12317439	126	06JUL22	18AUG22	73.7381	1.4039	1.9
12317440	12	27JUL22	21AUG22	74.3333	1.0731	1.4
12317444	133	16AUG22	25SEP22	73.9098	1.6165	2.2
12317448	116	30AUG22	13OCT22	73.4655	1.4472	2.0
12317451	66	30SEP22	24OCT22	71.9394	1.6161	2.2
12317457	67	13OCT22	06NOV22	72.4478	1.3627	1.9
12317460	146	03NOV22	18DEC22	73.8219	1.4701	2.0
12317463	54	23NOV22	08JAN23	76.9259	1.2108	1.6
12317468	132	04JAN23	12FEB23	71.5379	1.4378	2.0
12317472	87	01FEB23	13MAR23	75.8506	1.5137	2.0
12317475	137	16FEB23	08APR23	74.6423	1.5565	2.1
12317480	122	06APR23	07MAY23	73.4508	1.5540	2.1
12317483	108	06APR23	27MAY23	75.6389	1.7479	2.3
12317485	87	18MAY23	10JUN23	74.2069	1.9774	2.7
12317490	65	03JUN23	02JUL23	73.1385	1.4018	1.9
12317489	51	07JUN23	07JUL23	72.1373	1.6002	2.2
12317494	73	30JUN23	11AUG23	76.3151	1.4708	1.9
12317491	57	02JUL23	21JUL23	73.1579	1.3731	1.9
12317495	28	16JUL23	24JUL23	67.8929	1.3968	2.1
12317499	44	10AUG23	21AUG23	71.0682	1.1493	1.6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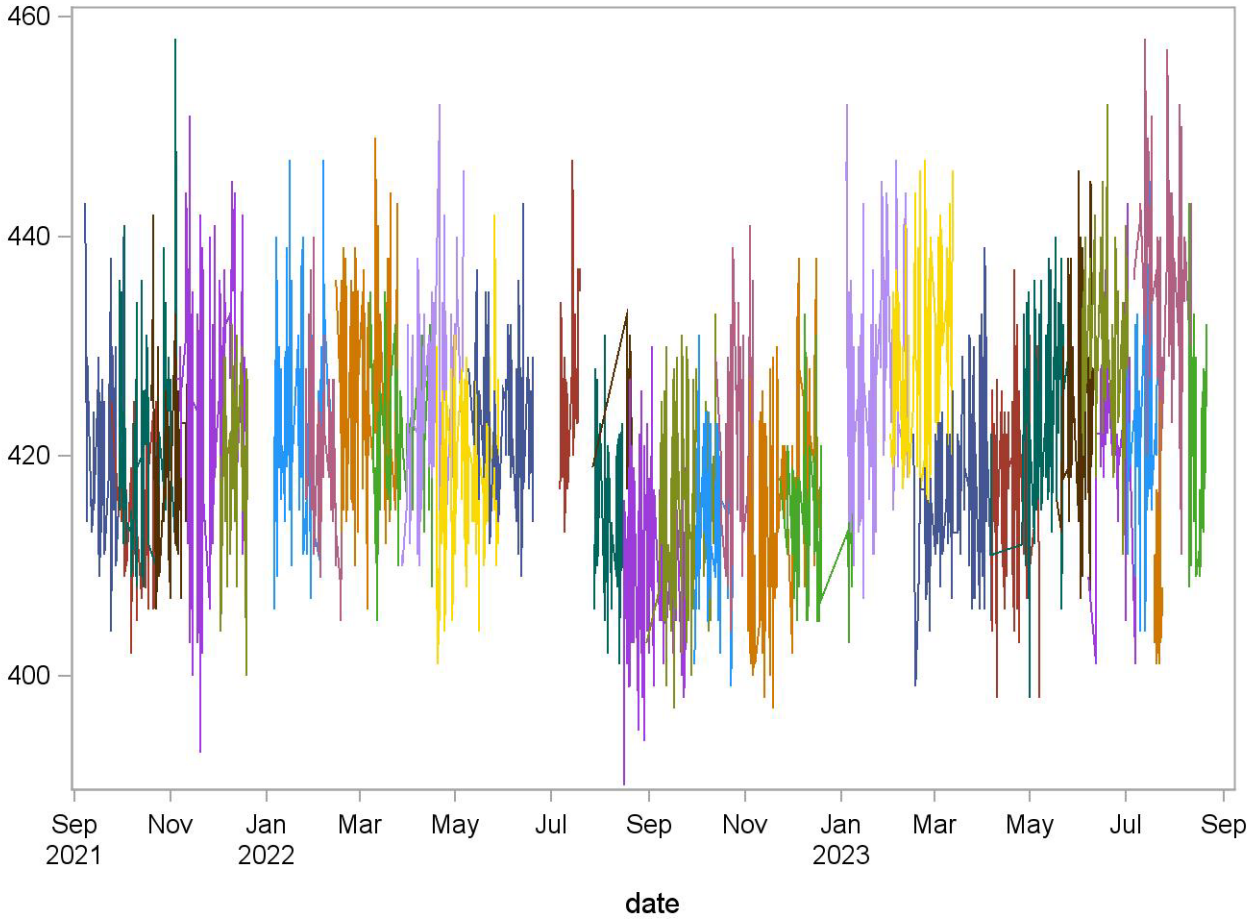
August 2021 – August 2023 Summary Statistics and QC Chart
LBCPLT2 (Platelet count (10^3 cells/uL) (Lvl 2))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
13318388	49	08SEP21	03OCT21	422.0204	8.3703	2.0
13318389	53	24SEP21	23OCT21	414.5283	6.2929	1.5
13318393	109	30SEP21	06NOV21	420.7890	7.9011	1.9
13318395	57	20OCT21	14NOV21	419.0877	8.0938	1.9
13318399	143	05NOV21	18DEC21	423.7902	10.2873	2.4
13318402	40	03DEC21	20DEC21	419.3500	7.7841	1.9
13318408	128	06JAN22	11FEB22	423.0078	7.6380	1.8
13318412	53	26JAN22	19FEB22	420.3396	7.3300	1.7
13318415	130	14FEB22	25MAR22	426.0154	7.8335	1.8
13318418	85	08MAR22	16APR22	422.4824	6.3163	1.5
13318423	81	28MAR22	06MAY22	425.4074	8.4923	2.0
13318426	89	19APR22	28MAY22	418.4494	7.3097	1.7
13318430	78	09MAY22	19JUN22	424.2949	6.4003	1.5
13318435	32	06JUL22	19JUL22	426.5313	7.8164	1.8
13318440	12	27JUL22	21AUG22	421.9167	6.0221	1.4
13318439	47	28JUL22	18AUG22	416.0638	6.8315	1.6
13318444	131	16AUG22	25SEP22	410.8473	7.3017	1.8
13318448	119	30AUG22	13OCT22	415.3109	7.6610	1.8
13318451	67	30SEP22	24OCT22	414.7313	6.9163	1.7
13318458	67	13OCT22	06NOV22	420.3582	7.8888	1.9
13318460	142	03NOV22	18DEC22	414.8169	7.9650	1.9
13318463	55	23NOV22	08JAN23	413.8727	6.1284	1.5
13318468	131	04JAN23	12FEB23	425.6947	8.4379	2.0
13318472	89	01FEB23	13MAR23	429.5056	8.3803	2.0
13318475	141	16FEB23	08APR23	417.3050	6.7049	1.6
13318480	127	06APR23	07MAY23	417.8898	7.0105	1.7
13318483	110	06APR23	27MAY23	424.3091	7.3544	1.7
13318485	86	18MAY23	10JUN23	425.8372	8.1006	1.9
13318490	66	03JUN23	02JUL23	429.9697	6.9724	1.6
13318489	52	07JUN23	07JUL23	423.1538	8.2732	2.0
13318491	57	02JUL23	21JUL23	422.4737	8.1703	1.9
13318494	66	06JUL23	11AUG23	435.5303	9.6671	2.2
13318495	28	19JUL23	24JUL23	409.3929	5.8837	1.4
13318499	45	10AUG23	21AUG23	420.8222	7.7086	1.8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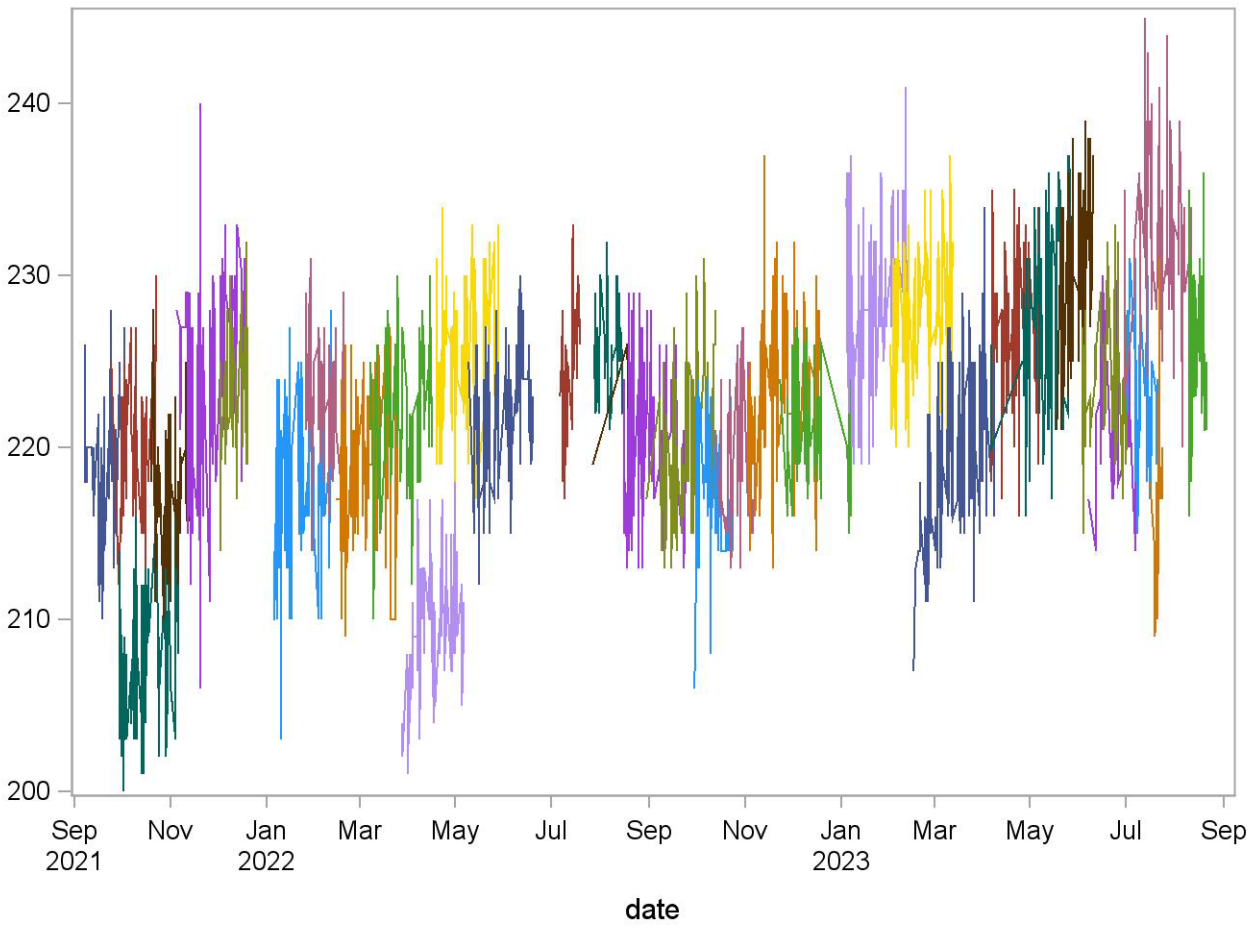
August 2021 – August 2023 Summary Statistics and QC Chart
LBCPLT3 (Platelet count (10^3 cells/uL) (Lvl 3))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
14319388	50	08SEP21	03OCT21	218.4000	4.0958	1.9
14319389	53	24SEP21	23OCT21	220.0189	4.0072	1.8
14319393	109	30SEP21	06NOV21	207.6514	3.8112	1.8
14319395	56	20OCT21	14NOV21	217.5714	3.9306	1.8
14319399	141	05NOV21	18DEC21	223.5461	4.8690	2.2
14319402	41	03DEC21	20DEC21	223.7561	3.8130	1.7
14319408	128	06JAN22	11FEB22	217.4609	4.0526	1.9
14319412	53	26JAN22	19FEB22	222.6604	3.8025	1.7
14319416	131	14FEB22	25MAR22	218.7405	3.8222	1.7
14319418	85	08MAR22	16APR22	221.8000	3.7378	1.7
14319423	77	28MAR22	06MAY22	209.4545	3.7224	1.8
14319426	87	19APR22	28MAY22	225.1724	3.9213	1.7
14319430	78	09MAY22	19JUN22	222.2564	3.8458	1.7
14319435	32	06JUL22	19JUL22	225.1250	3.6961	1.6
14319440	12	27JUL22	21AUG22	221.4167	3.4234	1.5
14319439	45	28JUL22	15AUG22	225.7556	2.7564	1.2
14319445	133	16AUG22	25SEP22	220.7368	3.8414	1.7
14319448	116	30AUG22	13OCT22	220.0086	3.7312	1.7
14319451	70	30SEP22	24OCT22	217.0000	3.4599	1.6
14319457	67	13OCT22	06NOV22	220.1343	3.4461	1.6
14319460	144	03NOV22	18DEC22	223.0139	3.9631	1.8
14319463	54	23NOV22	08JAN23	221.6111	3.3501	1.5
14319468	130	04JAN23	12FEB23	228.0231	4.2563	1.9
14319472	87	01FEB23	13MAR23	227.7586	3.7602	1.7
14319475	136	16FEB23	08APR23	219.9779	4.5485	2.1
14319480	121	06APR23	07MAY23	226.7190	3.9733	1.8
14319483	110	06APR23	27MAY23	227.5364	4.6188	2.0
14319485	89	18MAY23	10JUN23	230.0899	4.3081	1.9
14319490	66	03JUN23	02JUL23	223.7121	3.6067	1.6
14319489	51	07JUN23	07JUL23	222.8824	4.0132	1.8
14319494	70	30JUN23	11AUG23	232.4429	5.0552	2.2
14319491	57	02JUL23	21JUL23	223.2807	3.4731	1.6
14319495	28	16JUL23	24JUL23	215.4286	4.3413	2.0
14319499	46	10AUG23	21AUG23	224.8696	4.2823	1.9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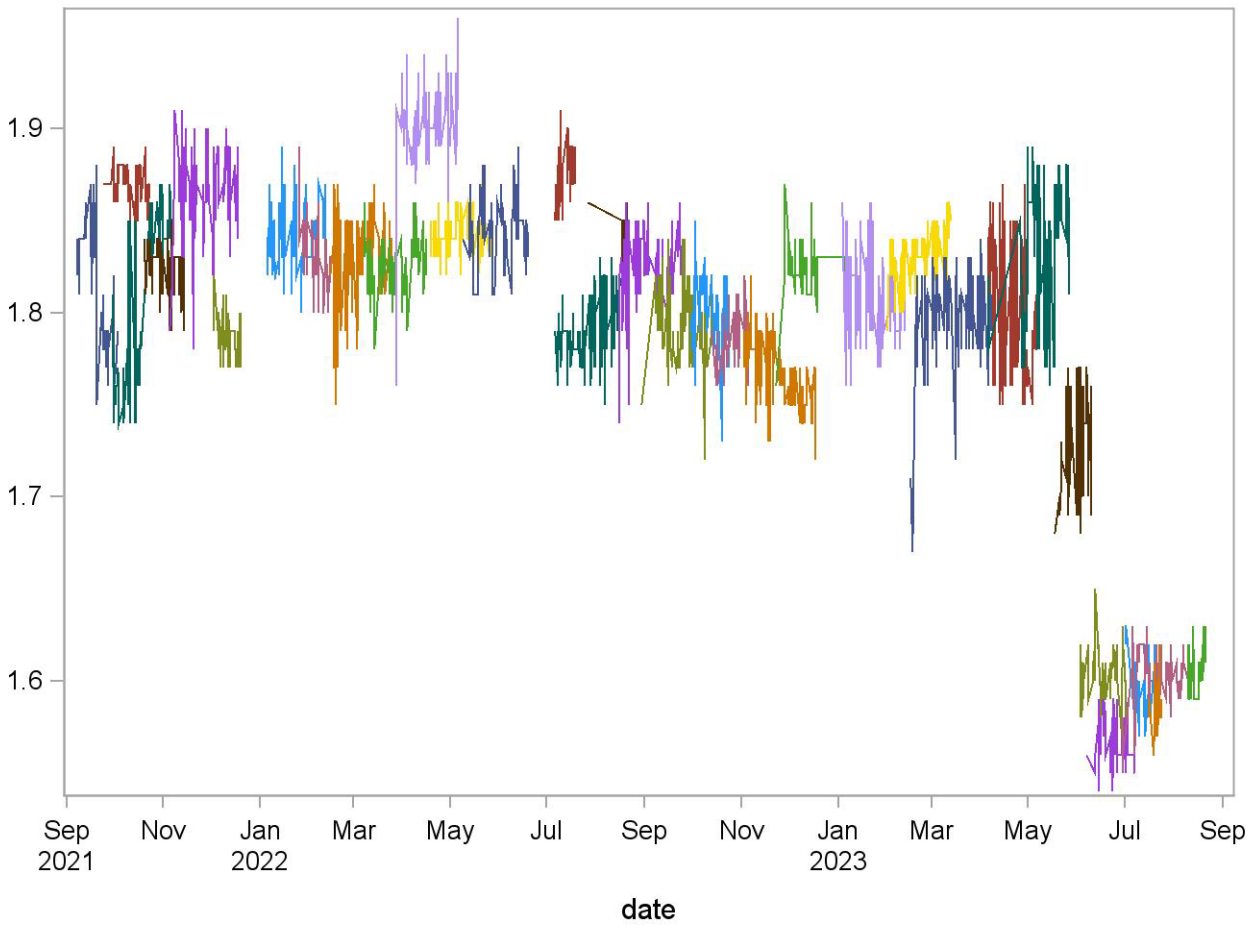
August 2021 – August 2023 Summary Statistics and QC Chart
LBCRBC1 (Red Cell Count (10^6 cells/uL) (Lvl 1))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
12317388	48	08SEP21	03OCT21	1.8094	0.0335	1.9
12317389	54	24SEP21	23OCT21	1.8687	0.0106	0.6
12317393	107	30SEP21	06NOV21	1.8053	0.0425	2.4
12317395	56	20OCT21	14NOV21	1.8234	0.0140	0.8
12317399	142	05NOV21	18DEC21	1.8620	0.0223	1.2
12317402	41	03DEC21	20DEC21	1.7888	0.0140	0.8
12317408	127	06JAN22	11FEB22	1.8426	0.0150	0.8
12317412	52	26JAN22	19FEB22	1.8304	0.0184	1.0
12317416	131	14FEB22	25MAR22	1.8255	0.0247	1.4
12317418	85	08MAR22	16APR22	1.8248	0.0148	0.8
12317423	77	28MAR22	06MAY22	1.9026	0.0246	1.3
12317426	89	19APR22	28MAY22	1.8424	0.0109	0.6
12317431	78	09MAY22	19JUN22	1.8458	0.0183	1.0
12317435	32	06JUL22	19JUL22	1.8756	0.0166	0.9
12317439	126	06JUL22	18AUG22	1.7921	0.0169	0.9
12317440	12	27JUL22	21AUG22	1.8425	0.0142	0.8
12317444	133	16AUG22	25SEP22	1.8273	0.0182	1.0
12317448	116	30AUG22	13OCT22	1.7930	0.0190	1.1
12317451	66	30SEP22	24OCT22	1.7988	0.0207	1.2
12317457	67	13OCT22	06NOV22	1.7876	0.0132	0.7
12317460	146	03NOV22	18DEC22	1.7683	0.0170	1.0
12317463	54	23NOV22	08JAN23	1.8235	0.0168	0.9
12317468	132	04JAN23	12FEB23	1.8117	0.0229	1.3
12317472	87	01FEB23	13MAR23	1.8294	0.0145	0.8
12317475	137	16FEB23	08APR23	1.7999	0.0227	1.3
12317480	122	06APR23	07MAY23	1.8021	0.0346	1.9
12317483	108	06APR23	27MAY23	1.8229	0.0373	2.0
12317485	87	18MAY23	10JUN23	1.7310	0.0256	1.5
12317490	65	03JUN23	02JUL23	1.6040	0.0134	0.8
12317489	51	07JUN23	07JUL23	1.5696	0.0147	0.9
12317494	73	30JUN23	11AUG23	1.6008	0.0164	1.0
12317491	57	02JUL23	21JUL23	1.5970	0.0165	1.0
12317495	28	16JUL23	24JUL23	1.5854	0.0150	0.9
12317499	44	10AUG23	21AUG23	1.6059	0.0113	0.7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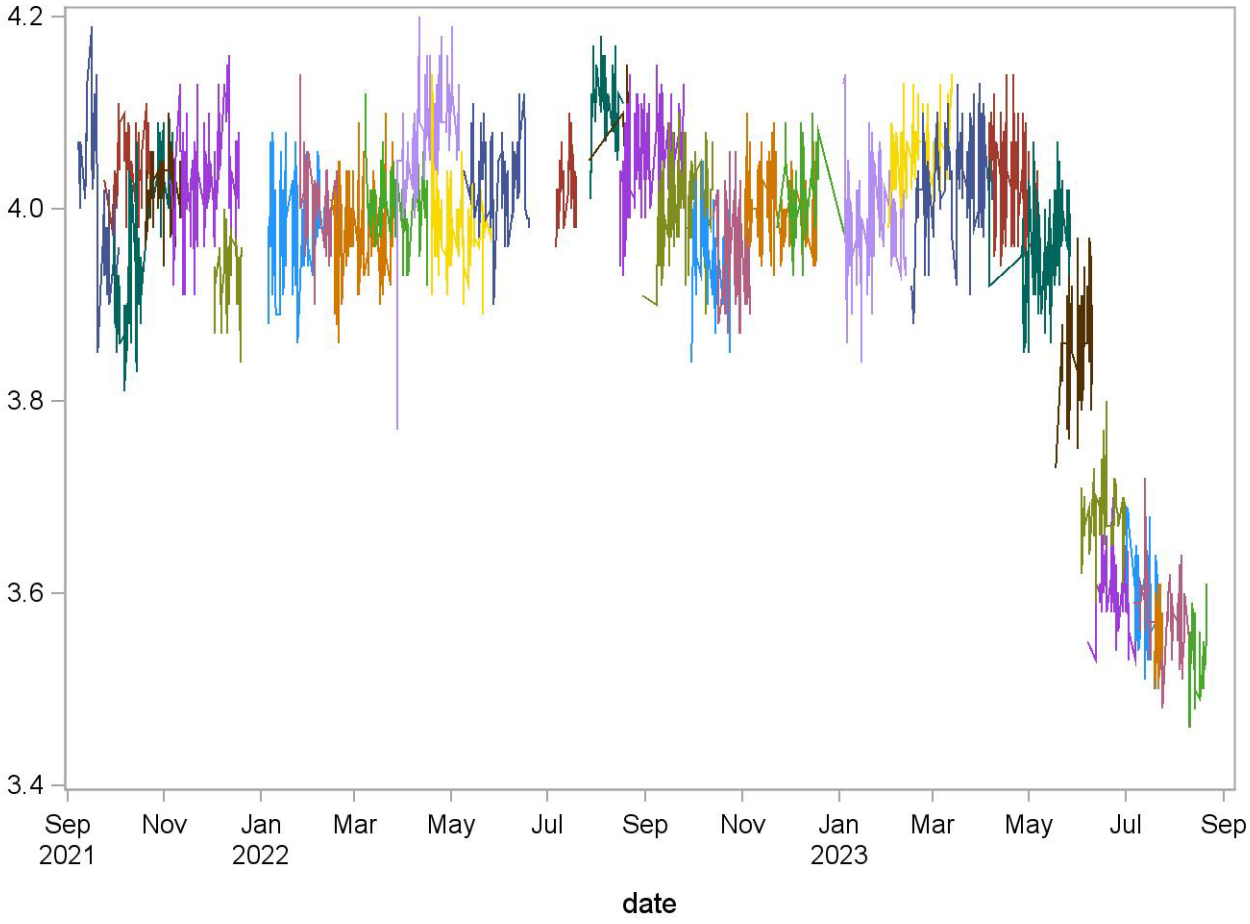
August 2021 – August 2023 Summary Statistics and QC Chart
LBCRBC2 (Red Cell Count (10^6 cells/uL) (Lvl 2))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
13318388	49	08SEP21	03OCT21	4.0061	0.0780	1.9
13318389	53	24SEP21	23OCT21	4.0440	0.0363	0.9
13318393	109	30SEP21	06NOV21	3.9699	0.0712	1.8
13318395	57	20OCT21	14NOV21	4.0172	0.0333	0.8
13318399	143	05NOV21	18DEC21	4.0233	0.0504	1.3
13318402	40	03DEC21	20DEC21	3.9340	0.0355	0.9
13318408	128	06JAN22	11FEB22	3.9827	0.0425	1.1
13318412	53	26JAN22	19FEB22	4.0045	0.0455	1.1
13318415	130	14FEB22	25MAR22	3.9782	0.0462	1.2
13318418	85	08MAR22	16APR22	4.0092	0.0374	0.9
13318423	81	28MAR22	06MAY22	4.0795	0.0583	1.4
13318426	89	19APR22	28MAY22	3.9834	0.0382	1.0
13318430	78	09MAY22	19JUN22	4.0286	0.0419	1.0
13318435	32	06JUL22	19JUL22	4.0241	0.0342	0.8
13318440	12	27JUL22	21AUG22	4.0733	0.0339	0.8
13318439	47	28JUL22	18AUG22	4.1094	0.0366	0.9
13318444	131	16AUG22	25SEP22	4.0582	0.0399	1.0
13318448	119	30AUG22	13OCT22	4.0066	0.0414	1.0
13318451	67	30SEP22	24OCT22	3.9578	0.0421	1.1
13318458	67	13OCT22	06NOV22	3.9567	0.0445	1.1
13318460	142	03NOV22	18DEC22	3.9980	0.0353	0.9
13318463	55	23NOV22	08JAN23	4.0091	0.0395	1.0
13318468	131	04JAN23	12FEB23	3.9856	0.0468	1.2
13318472	89	01FEB23	13MAR23	4.0585	0.0373	0.9
13318475	141	16FEB23	08APR23	4.0386	0.0454	1.1
13318480	127	06APR23	07MAY23	4.0309	0.0460	1.1
13318483	110	06APR23	27MAY23	3.9494	0.0482	1.2
13318485	86	18MAY23	10JUN23	3.8649	0.0462	1.2
13318490	66	03JUN23	02JUL23	3.6764	0.0333	0.9
13318489	52	07JUN23	07JUL23	3.6037	0.0382	1.1
13318491	57	02JUL23	21JUL23	3.6051	0.0444	1.2
13318494	66	06JUL23	11AUG23	3.5680	0.0441	1.2
13318495	28	19JUL23	24JUL23	3.5507	0.0322	0.9
13318499	45	10AUG23	21AUG23	3.5216	0.0337	1.0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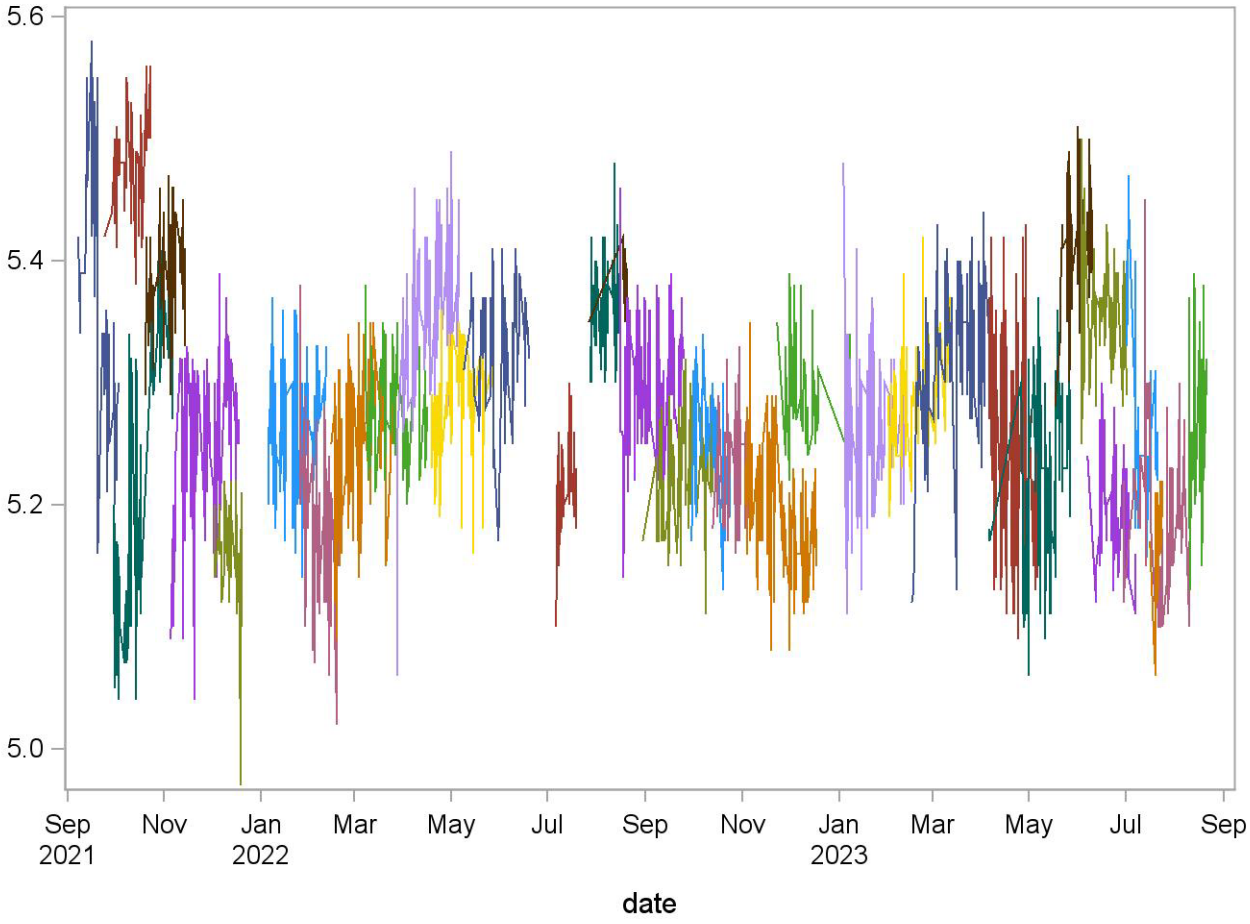
August 2021 – August 2023 Summary Statistics and QC Chart
LBCRBC3 (Red Cell Count (10^6 cells/uL) (Lvl 3))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
14319388	50	08SEP21	03OCT21	5.3678	0.1085	2.0
14319389	53	24SEP21	23OCT21	5.4775	0.0391	0.7
14319393	109	30SEP21	06NOV21	5.2311	0.1086	2.1
14319395	56	20OCT21	14NOV21	5.3891	0.0423	0.8
14319399	141	05NOV21	18DEC21	5.2458	0.0578	1.1
14319402	41	03DEC21	20DEC21	5.1620	0.0445	0.9
14319408	128	06JAN22	11FEB22	5.2626	0.0450	0.9
14319412	53	26JAN22	19FEB22	5.1857	0.0711	1.4
14319416	131	14FEB22	25MAR22	5.2485	0.0570	1.1
14319418	85	08MAR22	16APR22	5.2849	0.0402	0.8
14319423	77	28MAR22	06MAY22	5.3540	0.0651	1.2
14319426	87	19APR22	28MAY22	5.2889	0.0423	0.8
14319430	78	09MAY22	19JUN22	5.3318	0.0454	0.9
14319435	32	06JUL22	19JUL22	5.2116	0.0395	0.8
14319440	12	27JUL22	21AUG22	5.3750	0.0284	0.5
14319439	45	28JUL22	15AUG22	5.3653	0.0408	0.8
14319445	133	16AUG22	25SEP22	5.3047	0.0458	0.9
14319448	116	30AUG22	13OCT22	5.2251	0.0386	0.7
14319451	70	30SEP22	24OCT22	5.2537	0.0443	0.8
14319457	67	13OCT22	06NOV22	5.2315	0.0388	0.7
14319460	144	03NOV22	18DEC22	5.1961	0.0458	0.9
14319463	54	23NOV22	08JAN23	5.2876	0.0430	0.8
14319468	130	04JAN23	12FEB23	5.2603	0.0533	1.0
14319472	87	01FEB23	13MAR23	5.2972	0.0389	0.7
14319475	136	16FEB23	08APR23	5.3269	0.0553	1.0
14319480	121	06APR23	07MAY23	5.2469	0.0866	1.7
14319483	110	06APR23	27MAY23	5.2116	0.0729	1.4
14319485	89	18MAY23	10JUN23	5.4062	0.0519	1.0
14319490	66	03JUN23	02JUL23	5.3517	0.0478	0.9
14319489	51	07JUN23	07JUL23	5.1953	0.0458	0.9
14319494	70	30JUN23	11AUG23	5.1959	0.0627	1.2
14319491	57	02JUL23	21JUL23	5.2632	0.0717	1.4
14319495	28	16JUL23	24JUL23	5.1443	0.0527	1.0
14319499	46	10AUG23	21AUG23	5.2502	0.0645	1.2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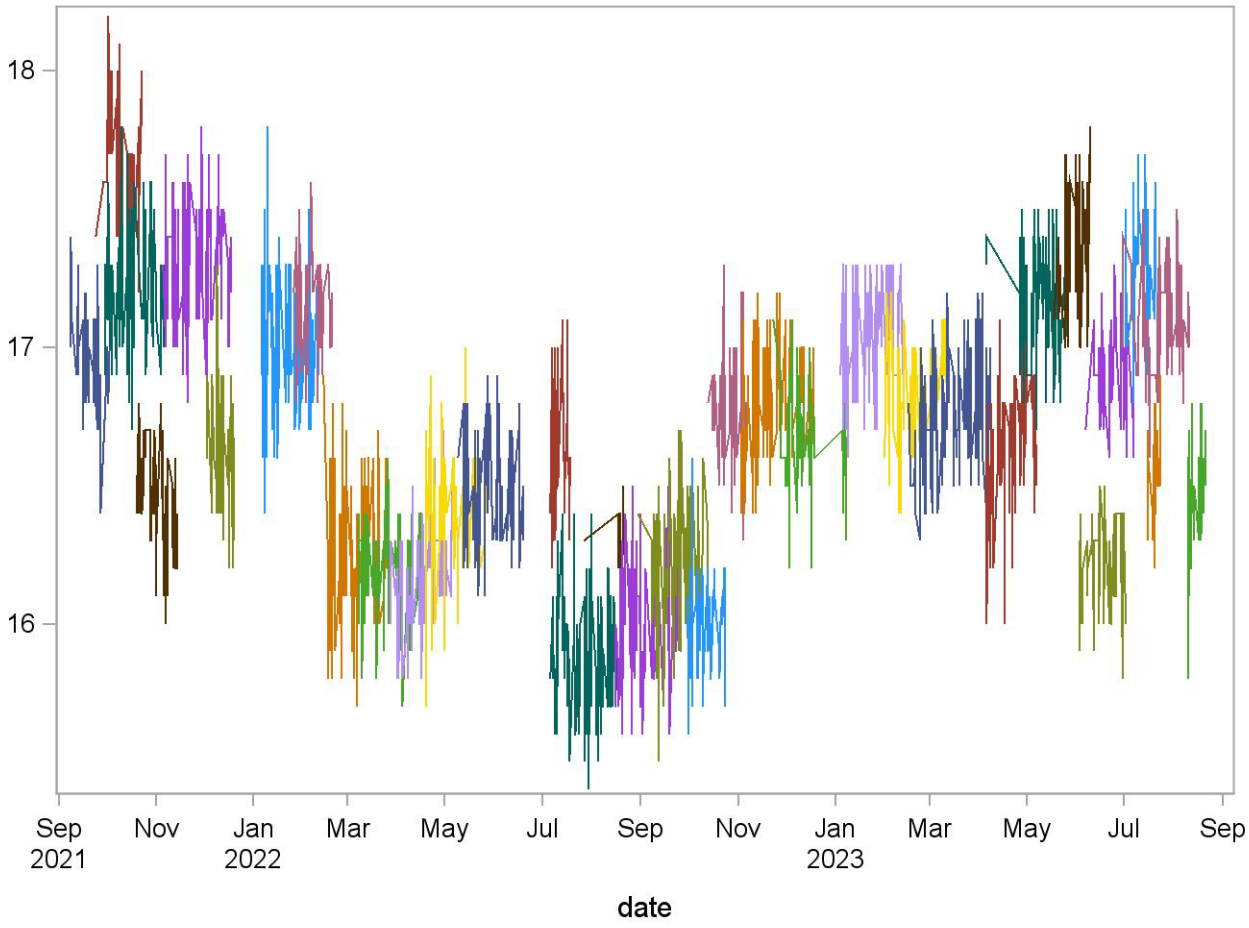
August 2021 – August 2023 Summary Statistics and QC Chart
LBCRDW1 (Red cell distribution width (%) (Lvl 1))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
12317388	48	08SEP21	03OCT21	16.9375	0.1898	1.1
12317389	54	24SEP21	23OCT21	17.6667	0.2137	1.2
12317393	107	30SEP21	06NOV21	17.2178	0.2027	1.2
12317395	56	20OCT21	14NOV21	16.4464	0.1935	1.2
12317399	142	05NOV21	18DEC21	17.2894	0.1999	1.2
12317402	41	03DEC21	20DEC21	16.6220	0.2253	1.4
12317408	127	06JAN22	11FEB22	17.0134	0.2176	1.3
12317412	52	26JAN22	19FEB22	17.1596	0.1729	1.0
12317416	131	14FEB22	25MAR22	16.2649	0.2327	1.4
12317418	85	08MAR22	16APR22	16.1976	0.1603	1.0
12317423	77	28MAR22	06MAY22	16.1649	0.1992	1.2
12317426	90	19APR22	28MAY22	16.4144	0.2037	1.2
12317431	78	09MAY22	19JUN22	16.4782	0.1932	1.2
12317435	32	06JUL22	19JUL22	16.6313	0.2292	1.4
12317439	126	06JUL22	18AUG22	15.8690	0.1990	1.3
12317440	12	27JUL22	21AUG22	16.2833	0.1642	1.0
12317444	133	16AUG22	25SEP22	15.9992	0.1983	1.2
12317448	116	30AUG22	13OCT22	16.1879	0.2139	1.3
12317451	66	30SEP22	24OCT22	15.9833	0.1724	1.1
12317457	67	13OCT22	06NOV22	16.7701	0.1907	1.1
12317460	146	03NOV22	18DEC22	16.7979	0.1844	1.1
12317463	54	23NOV22	08JAN23	16.6759	0.2009	1.2
12317468	132	04JAN23	12FEB23	17.0508	0.1674	1.0
12317472	87	01FEB23	13MAR23	16.8322	0.1762	1.0
12317475	137	16FEB23	08APR23	16.7905	0.2086	1.2
12317480	122	06APR23	07MAY23	16.6443	0.2113	1.3
12317483	108	06APR23	27MAY23	17.1630	0.1868	1.1
12317485	87	18MAY23	10JUN23	17.3655	0.2112	1.2
12317490	65	03JUN23	02JUL23	16.2138	0.1619	1.0
12317489	51	07JUN23	07JUL23	16.9235	0.1668	1.0
12317494	73	30JUN23	11AUG23	17.0904	0.1812	1.1
12317491	57	02JUL23	21JUL23	17.2702	0.2000	1.2
12317495	28	16JUL23	24JUL23	16.5321	0.1867	1.1
12317499	44	10AUG23	21AUG23	16.4386	0.1979	1.2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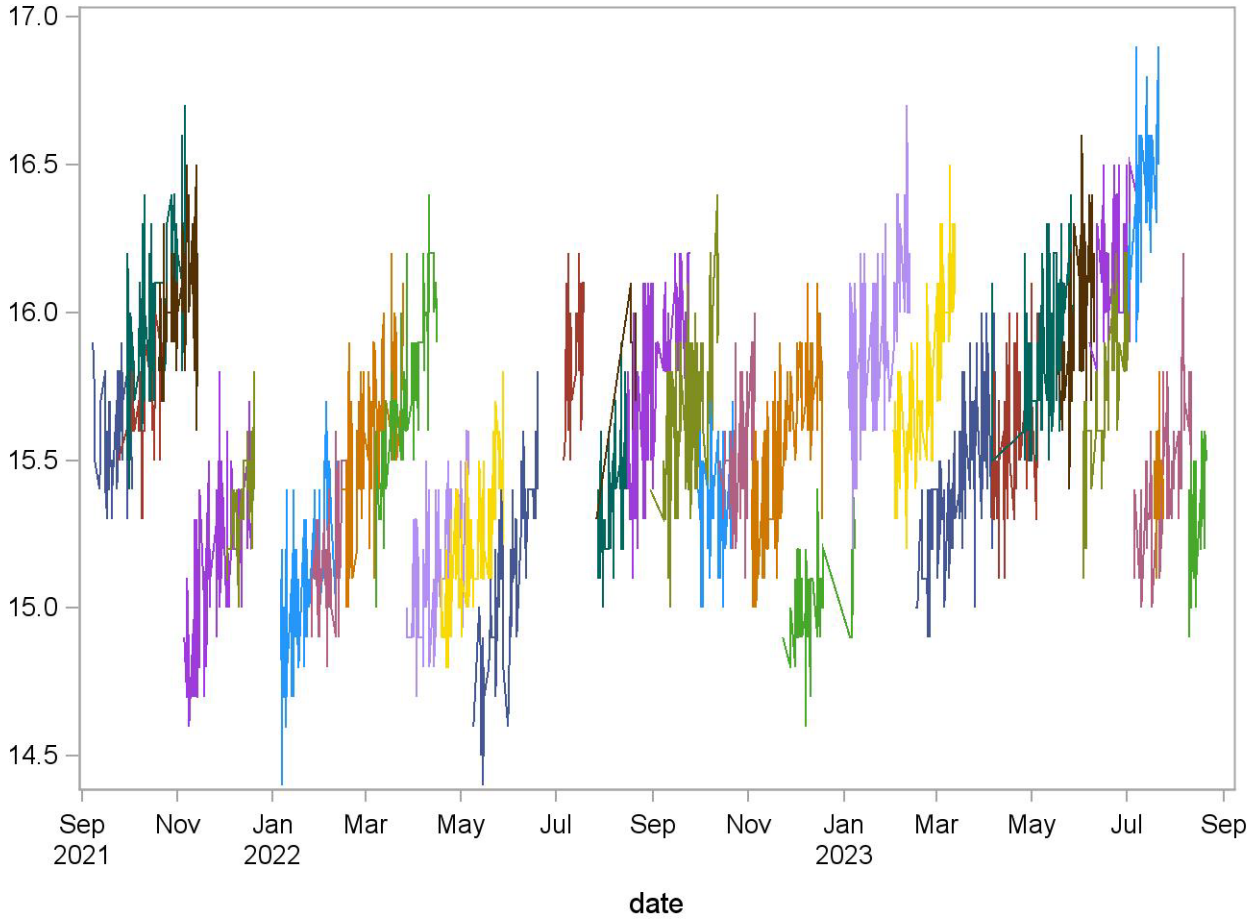
August 2021 – August 2023 Summary Statistics and QC Chart
LBCRDW2 (Red cell distribution width (%) (Lvl 2))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
13318388	49	08SEP21	03OCT21	15.5735	0.1565	1.0
13318389	53	24SEP21	23OCT21	15.6906	0.1548	1.0
13318393	109	30SEP21	06NOV21	15.9881	0.2426	1.5
13318395	57	20OCT21	14NOV21	16.0491	0.2001	1.2
13318399	143	05NOV21	18DEC21	15.1252	0.2278	1.5
13318402	40	03DEC21	20DEC21	15.3425	0.1615	1.1
13318408	128	06JAN22	11FEB22	15.0594	0.2514	1.7
13318412	53	26JAN22	19FEB22	15.1906	0.1983	1.3
13318415	130	14FEB22	25MAR22	15.5385	0.2277	1.5
13318418	85	08MAR22	16APR22	15.7235	0.2776	1.8
13318423	81	28MAR22	06MAY22	15.1951	0.2024	1.3
13318426	89	19APR22	28MAY22	15.1831	0.2085	1.4
13318430	78	09MAY22	19JUN22	15.1038	0.2784	1.8
13318435	32	06JUL22	19JUL22	15.8719	0.1905	1.2
13318440	12	27JUL22	21AUG22	15.7583	0.2275	1.4
13318439	47	28JUL22	18AUG22	15.4000	0.1956	1.3
13318444	131	16AUG22	25SEP22	15.7153	0.2525	1.6
13318448	119	30AUG22	13OCT22	15.6504	0.2594	1.7
13318451	67	30SEP22	24OCT22	15.3448	0.1672	1.1
13318458	67	13OCT22	06NOV22	15.5597	0.1915	1.2
13318460	142	03NOV22	18DEC22	15.5190	0.2617	1.7
13318463	55	23NOV22	08JAN23	15.0382	0.1694	1.1
13318468	131	04JAN23	12FEB23	15.8672	0.2485	1.6
13318472	89	01FEB23	13MAR23	15.7663	0.2759	1.7
13318475	141	16FEB23	08APR23	15.4865	0.2433	1.6
13318480	127	06APR23	07MAY23	15.6102	0.2115	1.4
13318483	110	06APR23	27MAY23	15.8627	0.2128	1.3
13318485	86	18MAY23	10JUN23	15.9523	0.2022	1.3
13318490	66	03JUN23	02JUL23	15.7197	0.2555	1.6
13318489	52	07JUN23	07JUL23	16.1865	0.1930	1.2
13318491	57	02JUL23	21JUL23	16.3491	0.2284	1.4
13318494	66	06JUL23	11AUG23	15.4439	0.2354	1.5
13318495	28	19JUL23	24JUL23	15.4214	0.1449	0.9
13318499	45	10AUG23	21AUG23	15.2778	0.1704	1.1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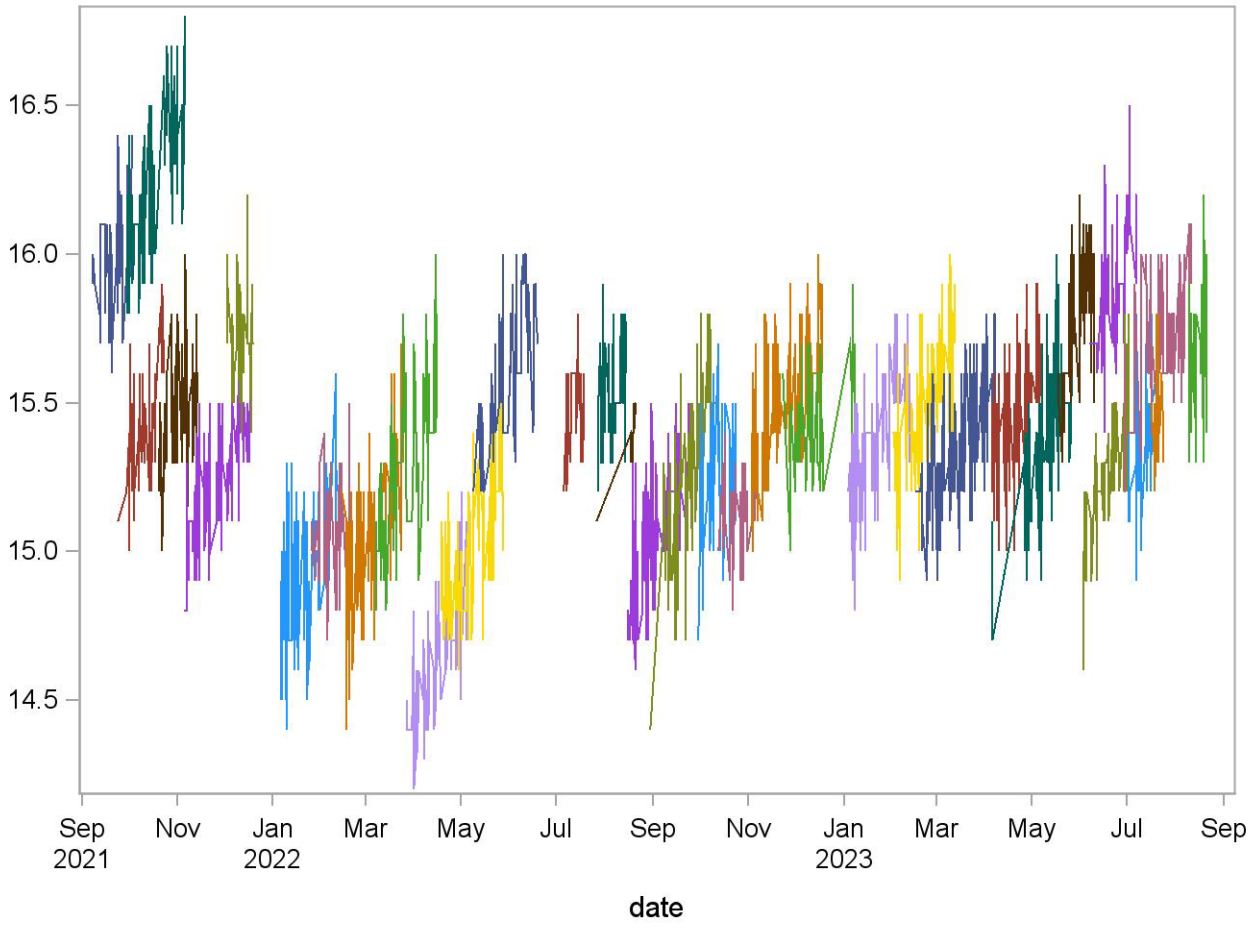
August 2021 – August 2023 Summary Statistics and QC Chart
LBCRDW3 (Red cell distribution width (%) (Lvl 3))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
14319388	50	08SEP21	03OCT21	15.9760	0.1721	1.1
14319389	53	24SEP21	23OCT21	15.4396	0.2022	1.3
14319393	109	30SEP21	06NOV21	16.2064	0.2326	1.4
14319395	56	20OCT21	14NOV21	15.4661	0.1842	1.2
14319399	141	05NOV21	18DEC21	15.2191	0.1816	1.2
14319402	41	03DEC21	20DEC21	15.7341	0.1559	1.0
14319408	128	06JAN22	11FEB22	14.9406	0.2064	1.4
14319412	53	26JAN22	19FEB22	15.0453	0.1671	1.1
14319416	131	14FEB22	25MAR22	15.0366	0.2261	1.5
14319418	85	08MAR22	16APR22	15.3294	0.2604	1.7
14319423	77	28MAR22	06MAY22	14.6714	0.2133	1.5
14319426	87	19APR22	28MAY22	15.0115	0.2175	1.4
14319430	78	09MAY22	19JUN22	15.6013	0.2425	1.6
14319435	32	06JUL22	19JUL22	15.4563	0.1390	0.9
14319440	12	27JUL22	21AUG22	15.3750	0.1422	0.9
14319439	45	28JUL22	15AUG22	15.5511	0.1804	1.2
14319445	133	16AUG22	25SEP22	15.0406	0.2008	1.3
14319448	116	30AUG22	13OCT22	15.2457	0.2626	1.7
14319451	70	30SEP22	24OCT22	15.2257	0.2027	1.3
14319457	67	13OCT22	06NOV22	15.1478	0.1407	0.9
14319460	144	03NOV22	18DEC22	15.4882	0.2182	1.4
14319463	54	23NOV22	08JAN23	15.4426	0.1808	1.2
14319468	130	04JAN23	12FEB23	15.3423	0.1952	1.3
14319472	87	01FEB23	13MAR23	15.5000	0.2157	1.4
14319475	136	16FEB23	08APR23	15.3897	0.2081	1.4
14319480	121	06APR23	07MAY23	15.4463	0.1932	1.3
14319483	110	06APR23	27MAY23	15.3609	0.1996	1.3
14319485	89	18MAY23	10JUN23	15.7910	0.1807	1.1
14319490	66	03JUN23	02JUL23	15.2152	0.2268	1.5
14319489	51	07JUN23	07JUL23	15.8980	0.2140	1.3
14319494	70	30JUN23	11AUG23	15.7271	0.2105	1.3
14319491	57	02JUL23	21JUL23	15.3579	0.2008	1.3
14319495	28	16JUL23	24JUL23	15.4857	0.1604	1.0
14319499	46	10AUG23	21AUG23	15.6674	0.2001	1.3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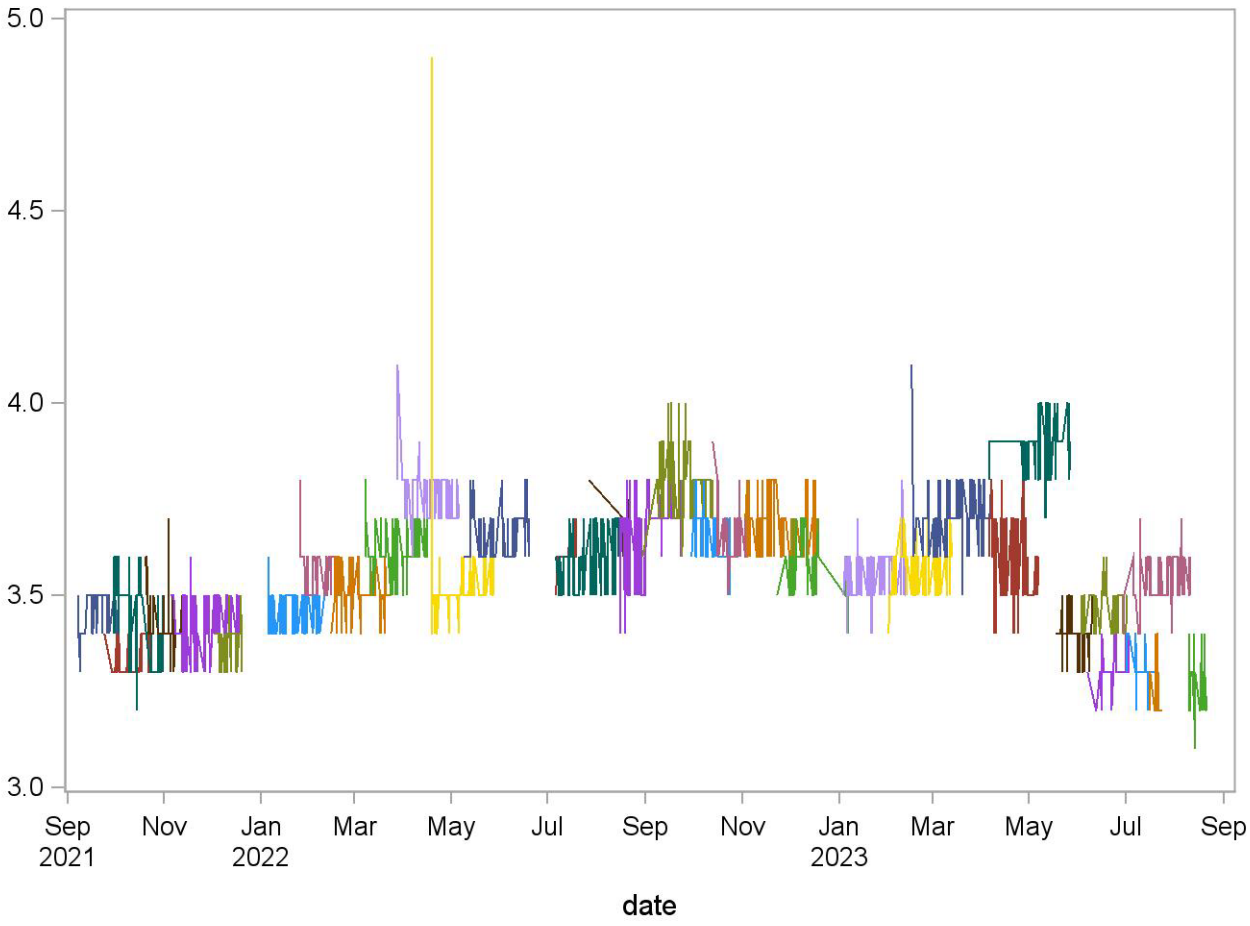
August 2021 – August 2023 Summary Statistics and QC Chart
LBCWBC1 (White Cell Count(10^3 cells/uL) (Lvl 1))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
12317388	48	08SEP21	03OCT21	3.4688	0.0512	1.5
12317389	54	24SEP21	23OCT21	3.3296	0.0500	1.5
12317393	107	30SEP21	06NOV21	3.4308	0.1004	2.9
12317395	56	20OCT21	14NOV21	3.4286	0.0756	2.2
12317399	142	05NOV21	18DEC21	3.4127	0.0651	1.9
12317402	41	03DEC21	20DEC21	3.3707	0.0559	1.7
12317408	127	06JAN22	11FEB22	3.4488	0.0533	1.5
12317412	52	26JAN22	19FEB22	3.5654	0.0590	1.7
12317416	131	14FEB22	25MAR22	3.5130	0.0517	1.5
12317418	85	08MAR22	16APR22	3.6118	0.0625	1.7
12317423	77	28MAR22	06MAY22	3.7649	0.0664	1.8
12317426	90	19APR22	28MAY22	3.5211	0.1547	4.4
12317431	78	09MAY22	19JUN22	3.6628	0.0626	1.7
12317435	32	06JUL22	19JUL22	3.6094	0.0390	1.1
12317439	126	06JUL22	18AUG22	3.5960	0.0674	1.9
12317440	12	27JUL22	21AUG22	3.6500	0.0798	2.2
12317444	133	16AUG22	25SEP22	3.6511	0.0982	2.7
12317448	116	30AUG22	13OCT22	3.8034	0.0874	2.3
12317451	66	30SEP22	24OCT22	3.6621	0.0627	1.7
12317457	67	13OCT22	06NOV22	3.6493	0.0683	1.9
12317460	146	03NOV22	18DEC22	3.6890	0.0655	1.8
12317463	54	23NOV22	08JAN23	3.5778	0.0769	2.1
12317468	132	04JAN23	12FEB23	3.5485	0.0636	1.8
12317472	87	01FEB23	13MAR23	3.5690	0.0616	1.7
12317475	137	16FEB23	08APR23	3.7131	0.0746	2.0
12317480	122	06APR23	07MAY23	3.6066	0.1058	2.9
12317483	108	06APR23	27MAY23	3.8769	0.0718	1.9
12317485	87	18MAY23	10JUN23	3.4011	0.0581	1.7
12317490	65	03JUN23	02JUL23	3.4538	0.0561	1.6
12317489	51	07JUN23	07JUL23	3.3098	0.0500	1.5
12317494	73	30JUN23	11AUG23	3.5384	0.0637	1.8
12317491	57	02JUL23	21JUL23	3.3281	0.0526	1.6
12317495	28	16JUL23	24JUL23	3.2571	0.0690	2.1
12317499	44	10AUG23	21AUG23	3.2636	0.0685	2.1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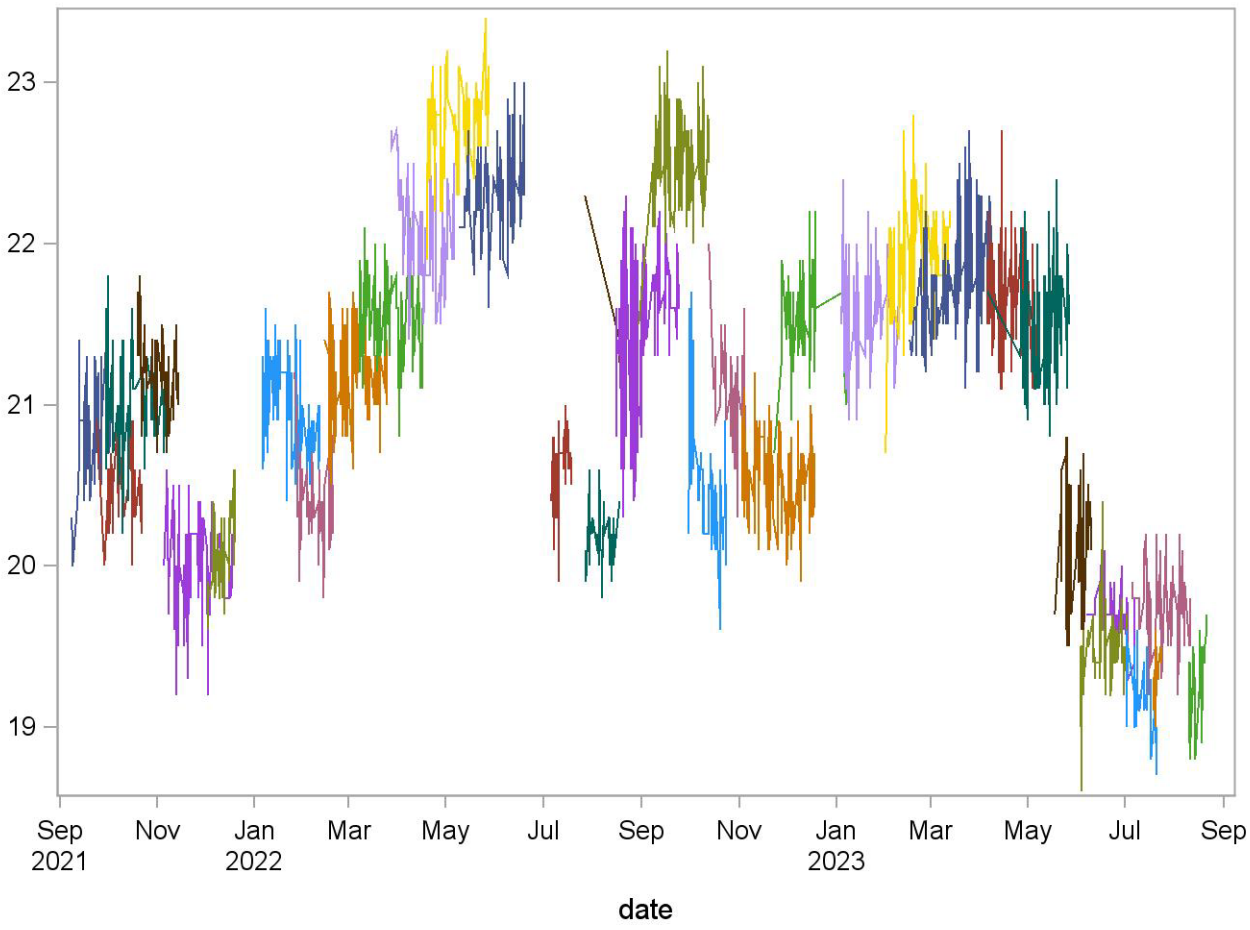
August 2021 – August 2023 Summary Statistics and QC Chart
LBCWBC2 (White Cell Count(10^3 cells/uL) (Lvl 2))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
13318388	49	08SEP21	03OCT21	20.8041	0.3253	1.6
13318389	53	24SEP21	23OCT21	20.5208	0.2265	1.1
13318393	109	30SEP21	06NOV21	21.0018	0.2628	1.3
13318395	57	20OCT21	14NOV21	21.2035	0.2244	1.1
13318399	143	05NOV21	18DEC21	19.9804	0.2720	1.4
13318402	40	03DEC21	20DEC21	20.0825	0.2500	1.2
13318408	128	06JAN22	11FEB22	21.0242	0.2586	1.2
13318412	53	26JAN22	19FEB22	20.4151	0.2931	1.4
13318415	130	14FEB22	25MAR22	21.1692	0.2653	1.3
13318418	85	08MAR22	16APR22	21.5494	0.2767	1.3
13318423	81	28MAR22	06MAY22	22.0679	0.2999	1.4
13318426	89	19APR22	28MAY22	22.7180	0.2720	1.2
13318430	78	09MAY22	19JUN22	22.3308	0.2741	1.2
13318435	32	06JUL22	19JUL22	20.6000	0.2463	1.2
13318440	12	27JUL22	21AUG22	21.3083	0.4100	1.9
13318439	47	28JUL22	18AUG22	20.1809	0.1650	0.8
13318444	131	16AUG22	25SEP22	21.4046	0.4771	2.2
13318448	119	30AUG22	13OCT22	22.5479	0.2655	1.2
13318451	67	30SEP22	24OCT22	20.6134	0.4199	2.0
13318458	67	13OCT22	06NOV22	21.0403	0.2823	1.3
13318460	142	03NOV22	18DEC22	20.5606	0.2438	1.2
13318463	55	23NOV22	08JAN23	21.5309	0.2974	1.4
13318468	131	04JAN23	12FEB23	21.5733	0.2803	1.3
13318472	89	01FEB23	13MAR23	21.9067	0.3179	1.5
13318475	141	16FEB23	08APR23	21.8199	0.3156	1.4
13318480	127	06APR23	07MAY23	21.6543	0.2881	1.3
13318483	110	06APR23	27MAY23	21.4800	0.3159	1.5
13318485	86	18MAY23	10JUN23	20.1651	0.2966	1.5
13318490	66	03JUN23	02JUL23	19.4455	0.2295	1.2
13318489	52	07JUN23	07JUL23	19.7077	0.1824	0.9
13318491	57	02JUL23	21JUL23	19.2316	0.2001	1.0
13318494	66	06JUL23	11AUG23	19.7545	0.2469	1.3
13318495	28	19JUL23	24JUL23	19.3179	0.1467	0.8
13318499	45	10AUG23	21AUG23	19.2311	0.2244	1.2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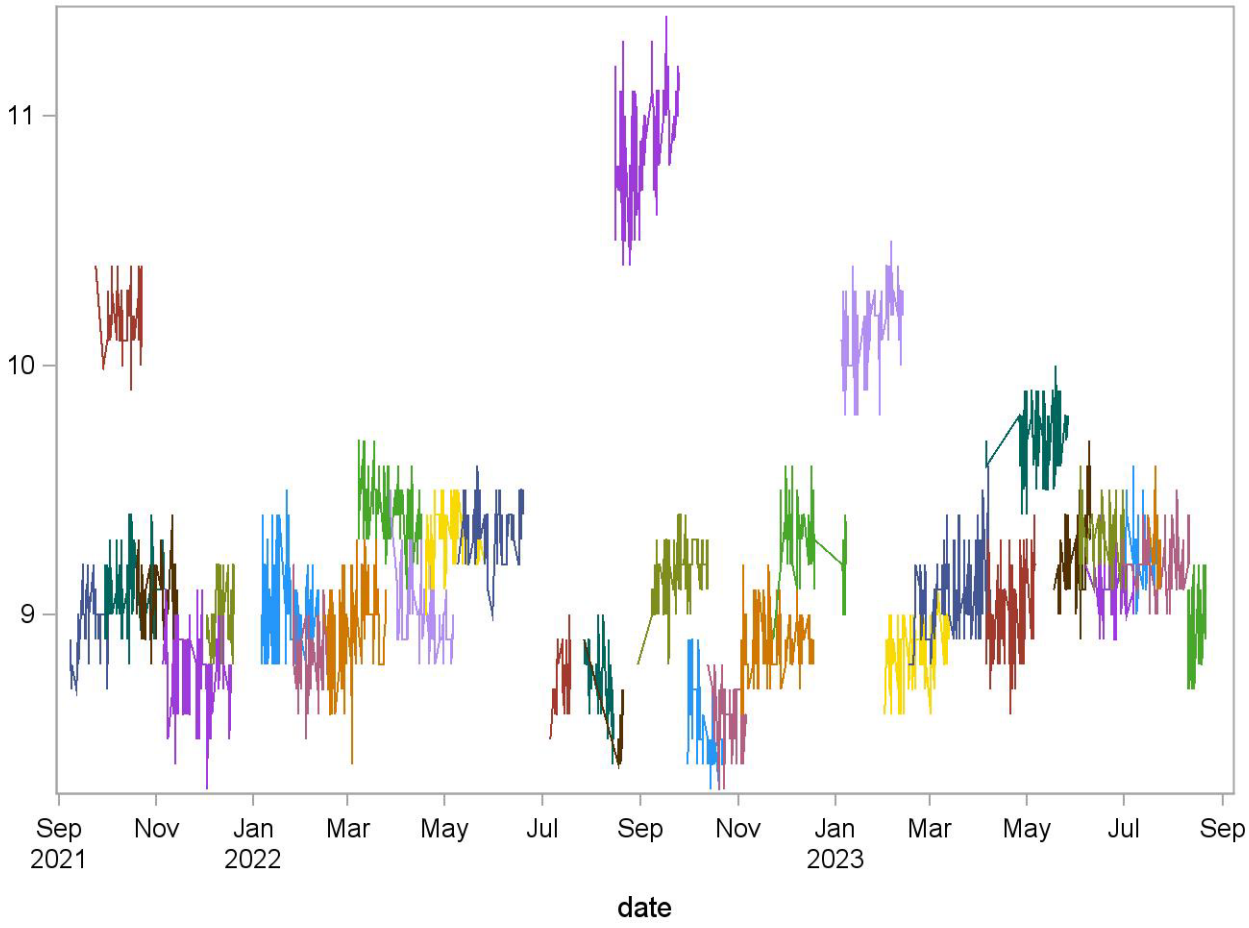
August 2021 – August 2023 Summary Statistics and QC Chart
LBCWBC3 (White Cell Count(10^3 cells/uL) (Lvl 3))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
14319388	50	08SEP21	03OCT21	8.9780	0.1234	1.4
14319389	53	24SEP21	23OCT21	10.1868	0.1241	1.2
14319393	109	30SEP21	06NOV21	9.0798	0.1268	1.4
14319395	56	20OCT21	14NOV21	9.0625	0.1287	1.4
14319399	141	05NOV21	18DEC21	8.7610	0.1625	1.9
14319402	41	03DEC21	20DEC21	9.0171	0.1263	1.4
14319408	128	06JAN22	11FEB22	9.0531	0.1665	1.8
14319412	53	26JAN22	19FEB22	8.8189	0.1468	1.7
14319416	131	14FEB22	25MAR22	8.9282	0.1706	1.9
14319418	85	08MAR22	16APR22	9.4435	0.1277	1.4
14319423	77	28MAR22	06MAY22	9.0169	0.1464	1.6
14319426	87	19APR22	28MAY22	9.2931	0.1159	1.2
14319430	78	09MAY22	19JUN22	9.3513	0.1170	1.3
14319435	32	06JUL22	19JUL22	8.7375	0.1238	1.4
14319440	12	27JUL22	21AUG22	8.5833	0.1403	1.6
14319439	45	28JUL22	15AUG22	8.7333	0.1331	1.5
14319445	132	16AUG22	25SEP22	10.8348	0.2144	2.0
14319448	116	30AUG22	13OCT22	9.1664	0.1164	1.3
14319451	70	30SEP22	24OCT22	8.5686	0.1565	1.8
14319457	67	13OCT22	06NOV22	8.5791	0.1135	1.3
14319460	144	03NOV22	18DEC22	8.8826	0.1173	1.3
14319463	54	23NOV22	08JAN23	9.2981	0.1511	1.6
14319468	130	04JAN23	12FEB23	10.1315	0.1473	1.5
14319472	87	01FEB23	13MAR23	8.8655	0.1228	1.4
14319475	136	16FEB23	08APR23	9.0993	0.1417	1.6
14319480	121	06APR23	07MAY23	9.0099	0.1513	1.7
14319483	110	06APR23	27MAY23	9.6973	0.1230	1.3
14319485	89	18MAY23	10JUN23	9.2506	0.1349	1.5
14319490	66	03JUN23	02JUL23	9.2924	0.1168	1.3
14319489	51	07JUN23	07JUL23	9.1235	0.1210	1.3
14319494	70	30JUN23	11AUG23	9.2029	0.1142	1.2
14319491	57	02JUL23	21JUL23	9.2667	0.1185	1.3
14319495	28	16JUL23	24JUL23	9.3107	0.1133	1.2
14319499	46	10AUG23	21AUG23	8.9217	0.1548	1.7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