Instructions for Use

DxH 500

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BECKMAN COULTER

DxH 500
Instructions for Use
PN B95837AA (January 2018)

Find us on the World Wide Web at:
www.beckmancoulter.com

Original Instructions

Rx Only in the U.S.A.

Revision History

This document applies to the latest software listed and higher versions. When a subsequent software version affects the information in this document, a new issue will be released to the Beckman Coulter Web site. For labeling updates, go to www.beckmancoulter.com and download the latest version of the manual or system help for your instrument.

Initial Issue AA, 1/2018
Software version 2.0

NOTE: This Instructions for Use Manual is an update of B23922AB. It contains information related to software version 2.0

Safety Notice

Read all product manuals and consult with Beckman Coulter-trained personnel before attempting to operate instrument. Do not attempt to perform any procedure before carefully reading all instructions. Always follow product labeling and manufacturer's recommendations. If in doubt as to how to proceed in any situation, contact your Beckman Coulter Representative.

Beckman Coulter, Inc. urges its customers to comply with all national health and safety standards such as the use of barrier protection. This may include, but is not limited to, protective eyewear, gloves, and suitable laboratory attire when operating or maintaining this or any other automated laboratory analyzer.

Alerts for Warning and Caution

Throughout this manual, you will see the appearance of these alerts for Warning and Caution conditions:

⚠ WARNING

WARNING indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury. May be used to indicate the possibility of erroneous data that could result in an incorrect diagnosis.

⚠ CAUTION

CAUTION indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices. May be used to indicate the possibility of erroneous data that could result in an incorrect diagnosis.

Safety Precautions

⚠ WARNING

Risk of operator injury and/or biohazardous contamination if:

- **All doors, covers, and panels are not closed and secured in place prior to and during instrument operation.**
- **The integrity of safety interlocks and sensors is compromised.**
- **Instrument alarms and error messages are not acknowledged and acted upon.**
- **You contact moving parts.**
- **You mishandle broken parts.**
- **Doors, covers, and panels are not opened, closed, removed, and/or replaced with care.**
- **Improper tools are used for troubleshooting.**

To avoid injury:

- **Keep doors, covers, and panels closed and secured in place while the instrument is in use.**
- **Take full advantage of the safety features of the instrument.**
- **Acknowledge and act upon instrument alarms and error messages.**
- **Keep away from moving parts.**
- **Report any broken parts to your Beckman Coulter Representative.**
- **Open/remove and close/replace doors, covers, and panels with care.**
- **Use the proper tools when troubleshooting.**

⚠ CAUTION

System integrity could be compromised and operational failures could occur if:

- **This equipment is used in a manner other than specified. Operate the instrument as instructed in the product manuals.**
- **You introduce software that is not authorized by Beckman Coulter into your computer. Only operate your system's computer with software authorized by Beckman Coulter.**
- **You install software that is not an original copyrighted version. Only use software that is an original copyrighted version to prevent virus contamination.**
- **You do not scan removable media (USB flash drive) before connecting it to a computer. Always scan removable media.**

⚠ CAUTION

If you purchased this product from anyone other than Beckman Coulter or an authorized Beckman Coulter distributor, and, it is not presently under a Beckman Coulter service maintenance agreement, Beckman Coulter cannot guarantee that the product is fitted with the most current mandatory engineering revisions or that you will receive the most current information bulletins concerning the

product. If you purchased this product from a third party and would like further information concerning this topic, call your Beckman Coulter Representative.

Electronic Precautions

⚠ WARNING

Risk of injury from electronic shock. Electronic components can shock and injure you. To prevent possible injury and/or shock, do not tamper with the instrument. Do not remove any components (covers, doors, panels, and so forth) unless otherwise instructed in this document. If conditions that cause static charge exist in your laboratory, be sure to be properly discharged before touching the instrument.

Electromagnetic Compatibility (EMC) Information

⚠ CAUTION

This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment, it could cause radio interference, in which case, you may need to take measures to mitigate the interference. It is advised that prior to operation of the device, the electromagnetic environment should be evaluated. Do not use this device in close proximity to sources of strong electromagnetic radiation (for example, unshielded intentional RF sources), as these could interfere with the proper operation.

This in vitro diagnostic (IVD) equipment complies with the emission and immunity requirement described in IEC 61326-2-6.

Biological Hazards

⚠ WARNING

Risk of injury and/or biological contamination. Failure to properly shield yourself while using or servicing the instrument can result in injury and/or contamination. To prevent possible injury and/or biological contamination, you must wear proper laboratory attire, including gloves, a laboratory coat, and eye protection.

Use universal precautions when working with pathogenic materials. Means must be available for decontaminating the instrument and disposing of biohazardous waste.

Moving Parts

⚠ WARNING

Risk of injury and/or biohazardous contamination. Operating the instrument with open covers and doors can cause injury. When you operate the instrument, ensure that all covers and doors are closed. Operating the instrument with a loose or bent probe can cause injury. If the probe is loose or bent, do not run the instrument.

Biohazardous Contamination

⚠ WARNING

Risk of injury and/or biohazardous contamination. The aspiration probe and the associated tubing contain residual biohazardous material. Clean up any blood spill as quickly as possible. Handle with care. Avoid skin contact. Clean up spills immediately and dispose of all contaminated disposable cleaning materials in accordance with your local regulations and good laboratory practices.

Operational Hazards

Safety symbols alert you to potentially dangerous conditions.

The symbol applies to specific procedures and appears as needed throughout this manual.

Symbol	Warning Condition	Action
	Biohazard	Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.
	Caution or Warning	See Alerts for Warning and Caution for more information.
	Hot Surface	Hot surfaces in this area. Avoid contact with any surface in this area until you are sure that it has cooled down first.
	Pinch Point	Potential pinch or pierce point in this area. Be aware of the moving probe and carefully present the test sample to avoid injury.

Hazard Labels

Carefully read the hazard warning labels on the instrument. The hazard labels are located on the instrument as indicated Instrument Views in CHAPTER 1, System Overview.

NOTE If the labels are unclear, call your Beckman Coulter Representative.

Disposal of Electrical Instrumentation

It is very important that customers understand and follow all laws regarding the safe and proper disposal of electrical instrumentation.

The symbol of a crossed-out wheeled bin on the product is required in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union. The presence of this marking on the product indicates:

1. The device was put on the European Market after August 13, 2005 and
2. The device is not to be disposed of via the municipal waste collection system of any member state of the European Union.

For products under the requirement of the WEEE directive, please contact your dealer or local Beckman Coulter office for the proper decontamination information and take back program which will facilitate the proper collection, treatment, recovery, recycling and safe disposal of device.

Waste Disposal Warning

⚠ WARNING

Risk of biohazardous contamination. Biohazardous contamination could occur from contact with the waste container and its associated tube if not handled with care. Check the tubing connection and container location periodically. Wear personal protective equipment. Avoid skin contact. Clean up spills immediately. Dispose of the contents of the waste container in accordance with your local regulations and good laboratory practices.

Be sure to dispose of waste in accordance with local environmental protection regulations.

The maximum waste line length is 1.50 m (5 ft.). The waste drain tube supplied with the system can be connected to either:

- An open drain, suitable for biohazardous waste less than 76 cm (30 in.) above the floor
- A waste container with a minimum capacity of 2,000 mL (0.53 gal). Discard the old container in accordance with your laboratory's standards for biohazardous material.

⚠ WARNING

Risk of biohazardous contamination. Use caution when draining the waste directly into an open drain. Ensure that the waste line is mechanically secured into the drain so the tubing cannot accidentally come out. If you are using this method of waste removal, Beckman Coulter recommends that you schedule routine maintenance of the laboratory drain pipes. The waste tubing length must not exceed 1.50 m (5 ft.).

CE Mark

CE

A "CE"mark indicates that a product has been assessed before being placed on the market, and has been found to meet European Union safety, health, and/or environmental protection requirements.

RoHS Notice

These labels and materials declaration table (the Table of Hazardous Substance's Name and Concentration) are to meet People's Republic of China Electronic Industry Standard SJ/T11364-2006 "Marking for Control of Pollution Caused by Electronic Information Products" requirements.

China RoHS Caution Label

This label indicates that the electronic information product contains certain toxic or hazardous substances. The center number is the Environmentally Friendly Use Period (EFUP) date, and indicates the number of calendar years the product can be in operation. Upon the expiration of the EFUP, the product must be immediately recycled. The circling arrows indicate the product is recyclable. The date code on the label or product indicates the date of manufacture.

China RoHS Environmental Label

This label indicates that the electronic information does not contain any toxic or hazardous substances. The center “e” indicates the product is environmentally safe and does not have an Environmentally Friendly Use Period (EFUP) date. Therefore, it can safely be used indefinitely. The circling arrows indicate the product is recyclable. The date code on the label or product indicates the date of manufacture.

California Proposition 65

WARNING

This product may contain chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

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Beckman Coulter, Inc.
Customer End User License Agreement

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Introduction

How to Use Your Manuals

Use this Instructions for Use manual for the day-to-day operation of your system.

This manual contains:

- Safety information
- Specifications and characteristics
- Principles of operation
- Detailed information for daily operation
- Maintenance and troubleshooting information
- Training checklist
- Performance verification checklist

Use the Host Transmission Manual to find the information for programming the transmission interface between the system and your laboratory's host computer.

To determine which manual to read for the information you need, see Related Documents.

About This Manual

NOTE Screens and hardware depicted in this manual may differ slightly from the screens and hardware in your system configuration.

The information in your Instructions for Use manual is organized as follows:

CHAPTER 1, System Overview
States the instrument's intended use, the controls and indicators to be used, information on performance, and information on using the system's software.

CHAPTER 2, Operation Principles
Contains a description of the Coulter Method, the normal sample flow, counting and sizing.

CHAPTER 3, Startup and Daily Checks
Provides information about logging in, logging out, and how to perform and review Daily Checks.

CHAPTER 4, Quality Control
Provides information on how to run quality control material.

CHAPTER 5, Sample Analysis
Provides information on specimen collection, the proper method for affixing a bar-code label to a tube, and running a specimen.

CHAPTER 6, Data Review
Provides information on reviewing and interpreting sample results including flagged results.

CHAPTER 7, Worklist
Provides information for pending test orders, unmatched orders, and sample run results.

CHAPTER 8, Shutdown
Provides information on shutdown.

CHAPTER 9, Setup
Provides information on setting up your system including supplies, operators and roles, flagging, reporting, patient demographics, and quality control.

CHAPTER 10, Troubleshooting
Describes safety precautions, operational hazards, troubleshooting information, and system messages.

CHAPTER 11, Quality Assurance
Provides the instructions for when to verify and adjust calibration, and procedures for repeatability, carryover, and calibration.

CHAPTER 12, Cleaning Procedures
Describes why, how, and when to perform cleaning procedures.

CHAPTER 13, Replacement/Adjustment Procedures
Describes why, how, and when to perform replacement procedures.

APPENDIX A, Access Levels and Reports
Contains a table with security access levels and examples of reports.

APPENDIX B, Bar Codes
Contains the printing parameter specifications for the handheld bar-code scanner.

APPENDIX C, Training Checklist
Contains a training checklist for you to follow. Ensure that you have read this manual and understand how to operate the DxH 500 before attempting to use the instrument.

APPENDIX D, Implementation Checklist
Contains a performance verification checklist for you to follow to verify that your instrument is set to run properly.

This manual also includes a list of references, a list of abbreviations and acronyms, a glossary, and warranty information.

Conventions

This manual uses the following conventions:

- **Bold** font indicates selections on the screens.
- *Italics* font indicates screen text displayed by the system.
- The term *Select* is used to indicate tapping or touching the screen with your finger.

IMPORTANT IMPORTANT is used for comments that add value to the step or procedure being performed. Following the advice in the IMPORTANT adds benefit to the performance of a piece of equipment or to a process.

NOTE NOTE is used to call attention to notable information that should be followed during use or maintenance of this equipment.

Graphics

All graphics, including screens and printouts, are for illustration purposes only and must not be used for any other purpose.

CHAPTER 1

System Overview

Intended Use

The DxH 500 is a quantitative, multi-parameter, automated hematology analyzer for in vitro diagnostic use in clinical laboratories; including hospital, reference, and physician's office laboratories. It is used to identify the normal patient with normal system-generated parameters from patients with abnormal parameters and/or flags that require additional studies.

The DxH 500 identifies and enumerates the following parameters: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV, LY%, LY#, MO%, MO#, NE%, NE#, EO%, EO#, BA%, BA# in whole-blood samples (venous and capillary) collected in K_2EDTA and K_3EDTA anticoagulants, and prediluted whole blood.

CBC/Diff Parameters

Table 1.1 Parameters

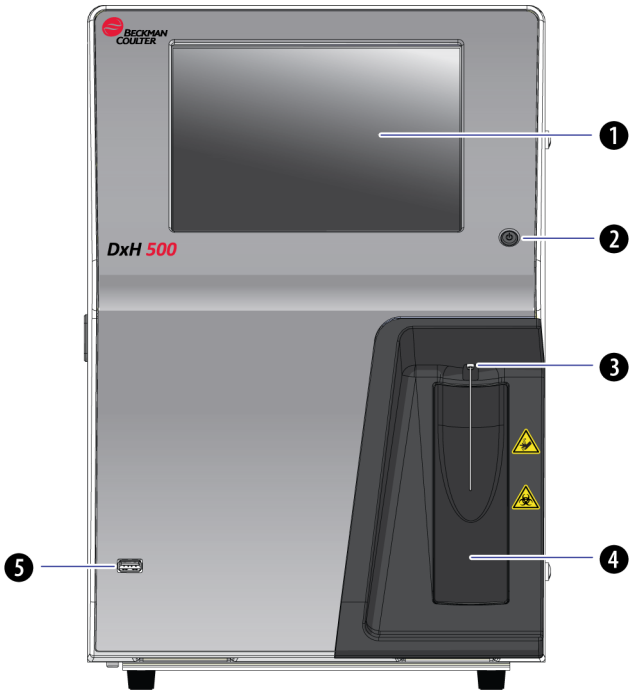
Parameter	Analyte
White Blood Cell	WBC
Red Blood Cell	RBC
Hemoglobin	HGB
Hematocrit	HCT
Mean Cell Volume	MCV
Mean Corpuscular Hemoglobin	MCH
Mean Corpuscular Hemoglobin Concentration	MCHC
Red Cell Distribution Width	RDW
Red Cell Distribution Width - SD	RDW-SD
Platelet	PLT
Mean Platelet Volume	MPV
Lymphocyte Percentage	LY
Lymphocyte Absolute Number	LY#
Monocyte Percentage	MO
Monocyte Absolute Number	MO#
Neutrophil Percentage	NE
Neutrophil Absolute Number	NE#
Eosinophil Percentage	EO

Table 1.1 Parameters *(Continued)*

Parameter	Analyte
Eosinophil Absolute Number	EO#
Basophil Percentage	BA
Basophil Absolute Number	BA#

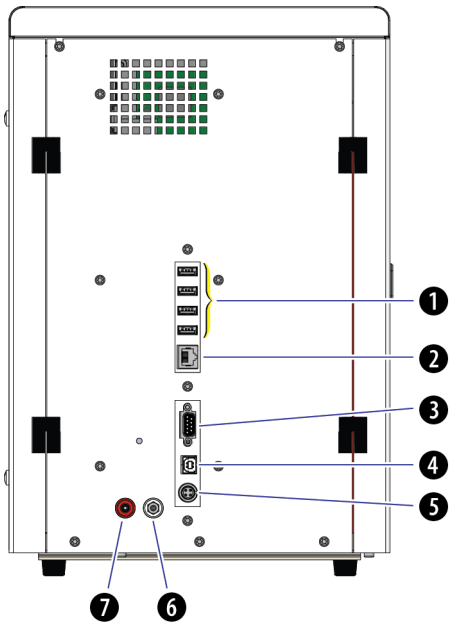
Instrument Views

Figure 1.1 DxH 500 Front View



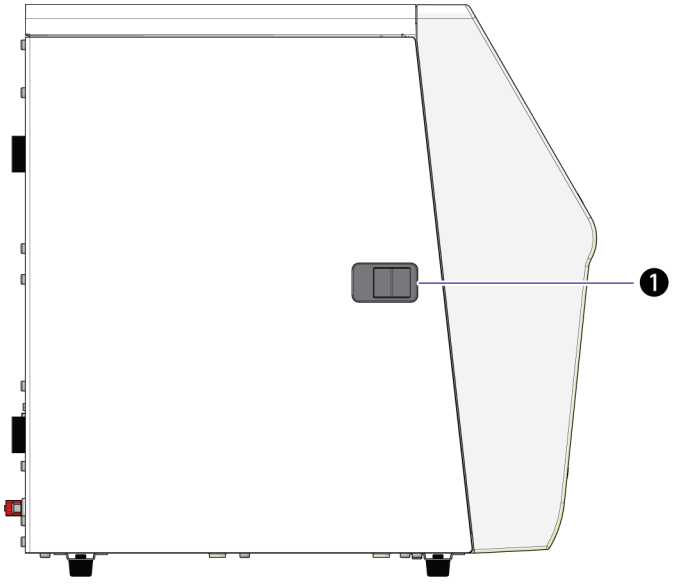
Number	Description	Number	Description
1	Touch Screen Display	4	Aspiration Plate
2	Power Button and Status LED Indicator	5	Front USB Port
3	Aspiration Probe		

Figure 1.2 DxH 500 Back View



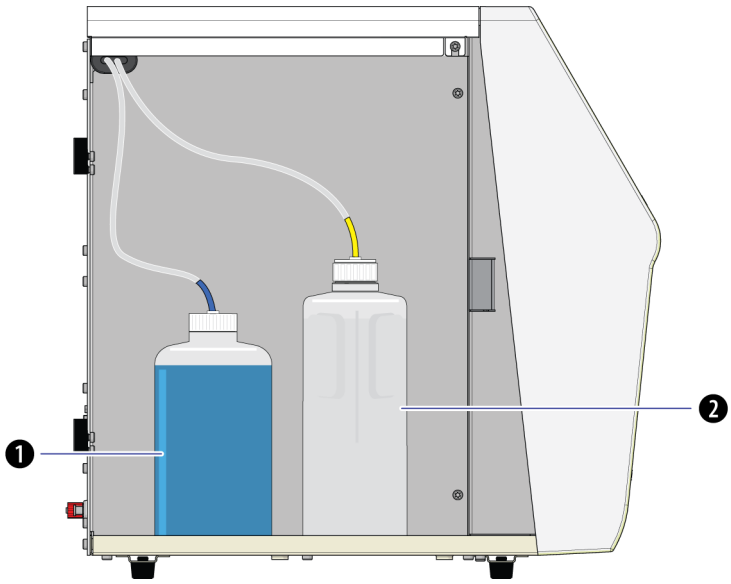
Number	Description	Number	Description
1	Rear USB Ports	5	Power Supply Connector
2	Ethernet Port	6	Diluent Line Connector
3	EIA-232 D Connector	7	Waste Line Connector
4	USB D Port		

Figure 1.3 DxH 500 Left Side View



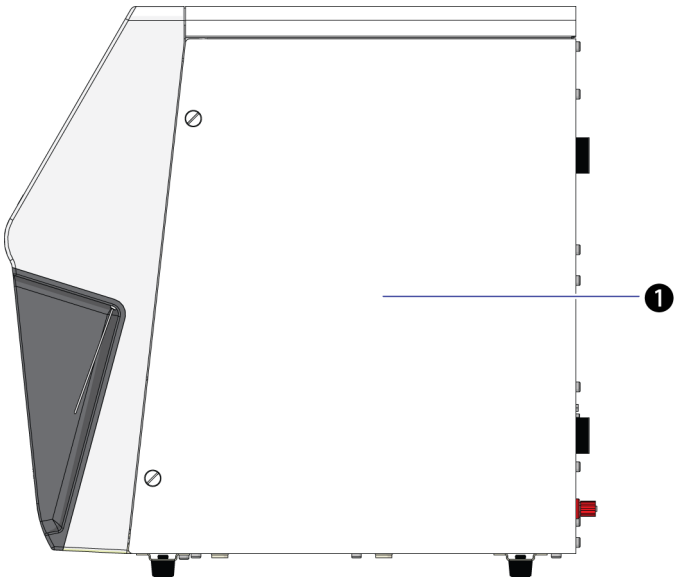
Number	Description
1	Reagent Compartment Door Latch

Figure 1.4 DxH 500 Left Side View Behind Reagent Compartment Door



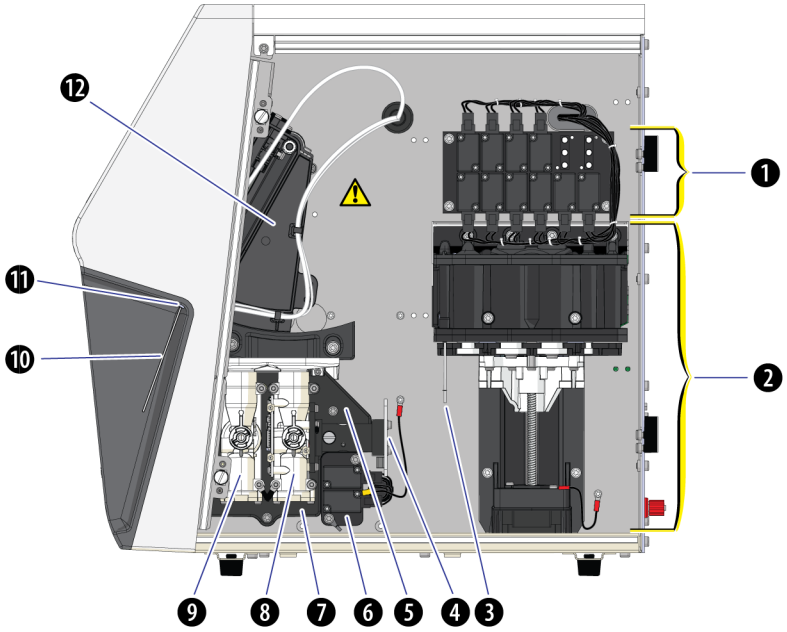
Number	Description
1	Cleaner
2	Lyse

Figure 1.5 DxH 500 Right Side View



Number	Description
1	Diluter Door

Figure 1.6 DxH 500 Right Side View Behind Diluter Door



Number	Description	Number	Description
1	Solenoid Manifold (2-Way and 3-Way Solenoid Valves)	7	Counting Area
2	Syringe Drive Assembly	8	WBC/Diff Bath
3	Sample Syringe Piston	9	RBC Bath
4	Optical Bench	10	Aspiration Probe
5	Count Manifold	11	Rocker Assembly
6	Drain/Mix Solenoid Valves	12	Rinsing Head (in this area)

Hardware

This section contains information on the instrument hardware and its requirements.

Instrument Dimensions, Weight, and Clearance Space

⚠ CAUTION

This device is intended for indoor use only. Safety protection may be impaired if used in a manner not specified by the manufacturer.

Table 1.2 Instrument Dimensions, Weight, and Clearance Space

DxH 500	Dimension/Weight/Clearance Space
Depth	43.0 cm (16.9 in.)
Width	27.0 cm (10.6 in.)
Height	40.6 cm (16.0 in.)
Weight	11.4 kg (25.1 lbs.)
Clearance Behind Instrument for Connections	10.1 cm (4.0 in.)
Clearance on Left Side for Loading Reagents	22.9 cm (9.0 in.)
Clearance on Right Side for Troubleshooting	30.5 cm (12 in.)

Power Requirements

⚠ CAUTION

Risk of erroneous results. Do not use an extension cord to connect the instrument to a power outlet. Using an extension cord can increase electrical interference that could affect the instrument's results. Place the instrument close enough to a power outlet so that an extension cord is not necessary.

This instrument requires the following:

- 100-240 Vac
- 50-60 Hz
- Single phase with ground
- The ground is a confirmed third-wire earth ground that can carry the full current of the circuit
- The circuit is independent and protected
- External power supply (supplied with the instrument) as:
  - Output Voltage: 24 V
  - Current: 6.25A
- To reduce the risk of electrical shock, this device uses a three-wire electrical cable and plug to connect (ground) the equipment to earth. When replacing the cord, use equivalent ratings as follows:
  - U.S.A. cord:
    - Plug Type: 498G, 15A, 125V

- Connector Type: C13, 10A, 250V
- Cord Set Rating: 10A, 125V

— European cord:

- Plug Type: VIIG, 16A, 250V
- Connector Type: C13, 10A, 250V
- Cord Set Rating: 10A, 250V

DO NOT use a three-to-two wire plug adapter.

Power Consumption

Less than 120W

Acoustic Noise

The instrument produces a maximum sound pressure level of less than 80 dBa.

Operational Temperature

The instrument configured with DxH 500 Series consumables meets performance specifications when operated at a temperature of +18 to 32°C (64.4 to 89.6°F).

If the average room temperature changes more than 10°F or 6°C at which the instrument CBC was calibrated, verify the calibration and recalibrate, if necessary, to ensure optimum performance.

⚠ CAUTION

Risk of erroneous results for the differential. Erroneous differential results are possible when the temperature changes more than 9°C (16°F). Perform a repeatability test to determine if the differential is stable. Contact your local Beckman Coulter Representative if a failure occurs.

Storage Temperature

The instrument without reagents can be stored at a temperature range of -10 to +50° C (14 to 122° F).

Humidity

The instrument meets performance claims when operated at a maximum of 80% relative humidity (non-condensing) at 32° C (89.6° F).

Transport

The instrument packaging complies with shipping standards ISTA 2A.

Altitude

The instrument can operate at two different altitude ranges:

- Normal - Up to 1,500 m (4,921 ft)
- High - 1,501 to 3,000 m (4,925 to 9,843 ft)

The proper altitude range is set up during the installation process.

External Storage - USB

The instrument:

- Supports USB 2.0.
- Has one USB port on the front of the instrument for data transfer to and from a USB flash drive.
- The USB flash drive must be formatted as FAT32 prior to use on the instrument. Use the standard disk formatting capabilities available in a Windows-based computer.
- Has four USB ports on the rear of the instrument for data transfer and/or peripherals.

LIS

The instrument supports serial (RS-232) and ethernet communication for data transmission to an LIS. See the Host Transmission Manual listed in Related Documents for more information.

Printer - Optional

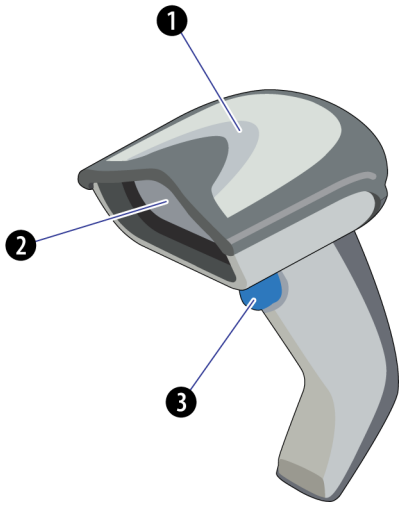
The system has pre-installed drivers for the optional USB printers available with this instrument. Use the driver that applies to your printer, as applicable.

Bar-Code Scanner

A USB-compatible, handheld bar-code scanner is included with the instrument to enter:

- Reagent lot numbers and expiration dates
- Control and calibrator lot numbers, expiration dates, assigned values, and limits
- Specimen IDs

Figure 1.7 Bar-Code Scanner



Number	Description
1	LED
2	Scan Window
3	Trigger

The following bar-code symbologies are supported:

- Code 128
- Codabar
- Code 39
- Interleaved 2 of 5
- ISBT 128 (Donor ID only)
- NW 7

See Bar-Code Label Specifications in APPENDIX B, Bar Codes for more information.

Consumables

The recommended consumables are listed in this section.

Reagents

DxH 500 Series Diluent

DxH 500 Series Diluent is an enhanced low formaldehyde-producing isotonic-buffered solution. DxH 500 Series Diluent dilutes the specimen and is used for rinsing module components between sample analyses.

DxH 500 Series Lyse

DxH 500 Series Lyse is a cyanide-free lytic reagent that lyses red blood cells for:

- White blood cell count (WBC)
- Classification of WBC subpopulations
- Hemoglobin measurement (HGB)

DxH 500 Series Cleaner

DxH 500 Series Cleaner is an azide-free, formaldehyde-free, biodegradable cleaner that contains a proteolytic enzyme that aids in the removal of protein buildup.

Controls and Calibrators

DxH 500 Series Control

DxH 500 Series Control is a tri-level integrated control that enables monitoring of the system's performance and calibration status for all CBC and Diff parameters.

DxH 500 Series Calibrator

DxH 500 Series Calibrator is traceable to reference methods and recommended for determining the adjustment of the directly measured CBC parameters. Calibration status should be monitored with Beckman Coulter controls.

Bar-Code Labels

See APPENDIX B, Bar Codes for information on bar codes.

Safety Data Sheets (SDS)

To obtain an SDS for Beckman Coulter reagents used on the instrument:

- On the Internet, go to www.beckmancoulter.com
  - Select Safety Data Sheets (SDS/MSDS) from the Support menu.
  - Follow the instructions on the screen.
- Alternately, contact your Beckman Coulter Representative.

Data Storage

The instrument stores patient data (results, flags, and demographics), QC controls and graphs, daily checks information, event logs, and calibration results.

The instrument software stores a maximum of 30,000 patient results including graphics, flags, codes, and messages. When the patient results database is full, the software automatically deletes the oldest results first.

The software can also store up to 12 control files, each with a maximum capacity of 150 individual runs.

Software

The system software displays system icons, navigation icons, and warning indicators, and contains an on-screen keyboard.

Main Menu Icons

The main menu icons are displayed on the left side and on the top right side of the screen as shown in Figure 1.8, Main Menu.

Figure 1.8 Main Menu

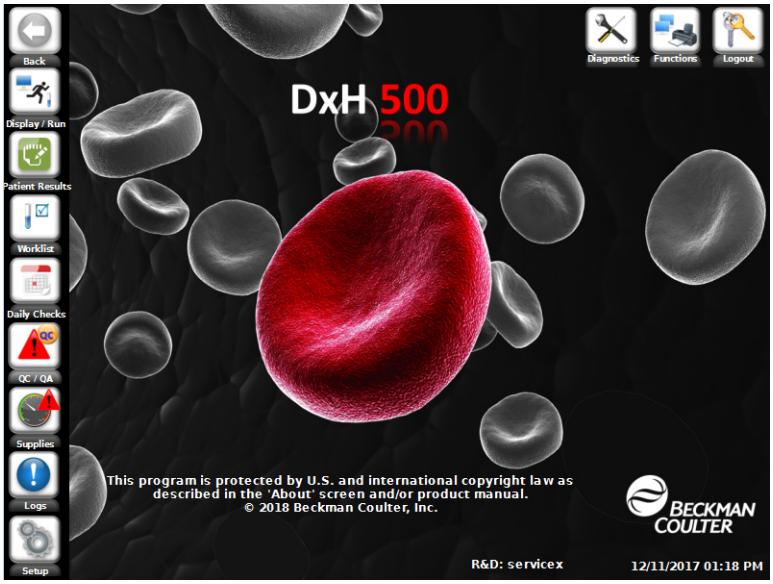


Table 1.3 Main Menu Icons

Icon	Name	Description
	Back Arrow	Goes back to the previous screen or the main screen.
	Display/Run	Displays the Sample Analysis - Patient Results screen where you can run specimens and controls.
	Patient Results	Displays the Patient Results screen where you can search for, display, rerun, edit, match, and delete results for processed specimens.
	Worklist	Displays the Worklist screen where you can view a list of test orders, create orders, and delete orders.
	Daily Checks	Displays the Daily Checks screen where you can run Daily Checks, run a Background Count, or perform a Shutdown.
	QC/QA	Displays the Quality Control (Data View) screen where you can access QA, XB, and XM screens. You can also download IQAP information, view graphs, view individual QC runs, make comments, and delete files from this screen.
	Supplies	Displays the Supplies screen related to loading and priming supplies, managing waste, viewing the supplies log, and viewing the cycle counter.
	Logs	Displays the Event Logs screen for viewing event logs and exporting event logs.
	Setup	Displays the Setup screen for setting up the system including quality assurance, quality controls, reporting, printers, and other system options.
	Diagnostics	Displays the Diagnostics menu for performing cleaning procedures and troubleshooting the instrument.
	Functions	Provides print, transmit, and export functions for the screen displayed. See Functions Menu for more information.
	Logout	Logs you out of the system.

Functions Menu

Select  to access the options in the following table.

NOTE The options on the Functions menu may vary depending on the screen displayed and are not accessible on the Main menu.

Table 1.4 Functions Menu

Icon	Name	Description
	Transmit	Transmits a selected result or all results
	Print	Prints a selected result or all results
	Export	Exports a selected result or all results
	Exit	Exits the Functions menu

Global and Navigation Icons

Table 1.5 Global Icons

Icon	Name	Description
	OK	Accepts the information you have entered or modified, or acknowledges a message.
	Exit	Exits the screen without accepting any new or modified information.
	Search	Searches for information based on the criteria you enter.

Table 1.6 Navigation Icons

Icon	Name	Description
	Enter System	Goes to the next screen after logging in (available on the log-in screen only).
	Back Arrow	Goes back to the previous screen or the main screen.
	Scroll to Top	Goes to the top of a table.
	Scroll Up	Goes one page up.
	Scroll Down	Goes one page down.
	Scroll to Bottom	Goes to the bottom of a table.
	Scroll to Beginning	Goes to the beginning (left-most) of a table.
	Scroll Left	Goes one page to the left.
	Scroll Right	Goes one page to the right.
	Scroll to End	Goes to the end (right-most) of a table.

Error and Warning Indicators

Table 1.7 Error and Warning Indicators

Icon	Name	Description
	Warning	Displayed on top of an icon affected by a warning event.

Table 1.7 Error and Warning Indicators *(Continued)*

Icon	Name	Description
	Error	Displayed on top of an icon affected by an error event.
	QC/QA	Is displayed with an icon, as applicable, to indicate the source or sources of a QC or QA out condition.  - QC out  - XB out  - XM out  - Extended QC (EQC) out

Screen View

For an enlarged view of an item, select it (graph, histogram, demographics, scatter plot, flag, or message) to zoom in. To exit the screen, select  .

Keyboard

The system displays an on-screen keyboard, similar to the example in Figure 1.9, On-Screen Keyboard.

Figure 1.9 On-Screen Keyboard

Most of the keys function much like a standard keyboard. Functions include:

Table 1.8 System Keyboard Keys

Icon	Name	Description
	Tab	Moves the cursor from field to field.
	Backspace	Moves the cursor back one space and deletes the entered character.
	Plus	Enters + as a character. **NOTE** This key is displayed and active on the Supplies entry screen only.
	Dash	Enters - as a character.
	Point	Enters . as a character.
	Language Keyboard Selection	Lets you select an on-screen keyboard for the language you choose.

A numeric-only keyboard is available.

An optional USB keyboard is also available for use with the instrument.

NOTE Alpha characters entered by using the on-screen keyboard are displayed in uppercase only. Alpha characters entered by using the optional keyboard are displayed in uppercase or lowercase depending on the entry. The system is not case-sensitive. For example, Specimen ID *abcd* will match a test order with Specimen ID *ABCD*.

Performance

Anticoagulants

NOTE All performance claims in this manual are based on data from specimens collected into the anticoagulants indicated below.

The recommended anticoagulants are K_2 or K_3 EDTA.

Aspiration

The volume of whole blood aspirated is 12 µL.

Prediluted sample analysis requires a dilution of 20 µL whole blood in 300 µL of diluent solution. The aspiration volume of a prediluted sample mixture is 180 µL.

Method Comparison - Whole Blood

Accuracy was assessed using a minimum of 40 morphologically normal samples collected into K_2 or K_3 EDTA stored at the operational temperature (see Operational Temperature) and analyzed within 8 hours of collection on the DxH 500 and a comparator. Results with system messages were excluded. The mean difference was calculated according to *CLSI EP09-A3*[23]. Mean difference results should be within the limits defined below.

Table 1.9 Method Comparison Specifications - Whole Blood

Whole Blood Parameter	Units	Measuring Range	Difference or % Difference (whichever is greater)
WBC	x 10^3 cells/µL	0.20 to 100.00	± 0.30 or ± 5.00%
RBC	x 10^6 cells/µL	0.20 to 8.00	± 0.07 or ± 3.00%
HGB	g/dL	0.20 to 25.00	± 0.30 or ± 3.00%
HCT	%	0.0 to 85.0	± 1.0 or ± 4.0%
MCV	fL	50.0 to 150.0	± 2.5 or ± 3.0%
MCH	pg	0.0 to 99.9	± 5.0%
MCHC	g/dL	0.0 to 99.9	± 5.0%
RDW	%	10.0 to 40.0	± 2.0 or ± 10.0%
RDW-SD	fL	15.0 to 150.0	± 7.5 or ± 10.0%
PLT	x 10^3 cells/µL	7.0 to 2000.0	± 10.0 or ± 10.0%
MPV	fL	5.00 to 25.00	± 1.00 or ± 10.00%
LY	%	0.00 to 100.00	± 3.00 or ± 10.00%
MO	%	0.00 to 100.00	± 2.00 or ± 10.00%
NE	%	0.00 to 100.00	± 3.00 or ± 10.00%
EO	%	0.00 to 100.00	± 1.50 or ± 10.00%
BA	%	0.00 to 100.00	± 1.00 or ± 10.00%
LY#	x 10^3 cells/µL	0.00 to 100.00	± 0.20 or ± 10.00%
MO#	x 10^3 cells/µL	0.00 to 100.00	± 0.20 or ± 10.00%
NE#	x 10^3 cells/µL	0.00 to 100.00	± 0.30 or ± 10.00%
EO#	x 10^3 cells/µL	0.00 to 100.00	± 0.15 or ± 10.00%
BA#	x 10^3 cells/µL	0.00 to 100.00	± 0.10 or ± 10.00%

Method Comparison Specifications - Diff - Whole Blood - DxH 500 Versus Manual Differential

Accuracy was assessed by comparing DxH 500 versus Comparator Instrument results to those obtained by a 400-cell manual differential according to *CLSI H20-A2*[30]. Results with system messages were excluded.

Table 1.10 Method Comparison Specifications - Diff - Whole Blood - DxH 520 versus Manual Differential

Whole Blood Parameter	Units	Measuring Range	Bias or % Bias
LY	%	0.00 to 100.00	± 3.00 or ± 10.00%
MO	%	0.00 to 100.00	± 3.00 or ± 10.00%
NE	%	0.00 to 100.00	± 3.00 or ± 10.00%
EO	%	0.00 to 100.00	± 1.50 or ± 10.00%
BA	%	0.00 to 100.00	± 1.00 or ± 10.00%

Method Comparison Specifications - Prediluted Versus Whole Blood

Diluted samples must be analyzed within 15 minutes of preparation. Results with system messages should be excluded. Results compared between whole-blood specimens and their prediluted sample on the DxH 500 should agree within the limits defined in Table 1.11, Method Comparison Specifications - Prediluted Versus Whole Blood.

Table 1.11 Method Comparison Specifications - Prediluted Versus Whole Blood

Whole Blood Parameter	Units	Measuring Range	Difference or % Difference (whichever is greater)
WBC	$x10^3$ cells/µL	0.20 to 100.00	± 0.60 or ± 10.00%
RBC	$x10^6$ cells/µL	0.20 to 8.00	± 0.10 or ± 10.00%
HGB	g/dL	0.20 to 25.00	± 0.40 or ± 6.00%
HCT	%	0.0 to 85.0	± 1.0 or ± 5.0%
MCV	fL	50.0 to 150.0	± 4.0%
MCH	p/g	0.0 to 99.9	± 5.0%
MCHC	g/dL	0.0 to 99.9	± 5.0%
RDW	%	10.0 to 40.0	± 2.0 or ± 5.0%
RDW-SD	fL	15.0 to 150.0	± 7.5 or ± 10.0%
PLT	$x10^3$ cells/µL	7.0 to 2000.0	± 20.0 or ± 15.0%
MPV	fL	5.00 to 25.00	± 1.50 or ± 8.00%
LY	%	0.00 to 100.00	± 3.00 or ± 10.00%
MO	%	0.00 to 100.00	± 3.00 or ± 10.00%
NE	%	0.00 to 100.00	± 3.00 or ± 10.00%
EO	%	0.00 to 100.00	± 1.50 or ± 10.00%

Table 1.11 Method Comparison Specifications - Prediluted Versus Whole Blood *(Continued)*

Whole Blood Parameter	Units	Measuring Range	Difference or % Difference (whichever is greater)
BA	%	0.00 to 100.00	± 1.50 or ± 10.00%
LY#	$x10^3$ cells/µL	0.00 to 100.00	± 0.30 or ± 10.00%
MO#	$x10^3$ cells/µL	0.00 to 100.00	± 0.30 or ± 10.00%
NE#	$x10^3$ cells/µL	0.00 to 100.00	± 0.30 or ± 10.00%
EO#	$x10^3$ cells/µL	0.00 to 100.00	± 0.20 or ± 10.00%
BA#	$x10^3$ cells/µL	0.00 to 100.00	± 0.10 or ± 10.00%

Repeatability

Repeatability results (N = 10, within-run precision) should agree within the limits and ranges shown in Table 1.12, Repeatability Limits for samples free of flags, codes, or messages that indicate a need for review.[31]

Table 1.12 Repeatability Limits

Parameter	Units	Range*	Repeatability Limits: Whole Blood	Repeatability Limits: Prediluted Whole Blood
WBC	$x10^3$ cells/µL	0.20 to < 1.00	≤ 0.15 SD	≤ 0.17 SD
		1.00 to < 3.00	≤ 0.17 SD	≤ 0.17 SD
		3.00 to 5.00	≤ 5.00% CV	≤ 7.00% CV
		> 5.00 to 7.00	≤ 4.00% CV	≤ 6.00% CV
		> 7.00 to 100.00	≤ 3.00% CV	≤ 5.00% CV
RBC	$x10^6$ cells/µL	1.00 to < 3.50	≤ 3.00% CV	≤ 5.00% CV
		3.50 to 8.00	≤ 2.00% CV	≤ 4.00% CV
HGB	g/dL	3.00 to < 5.00	≤ 4.00% CV	≤ 5.00% CV
		5.00 to < 11.00	≤ 2.00% CV	≤ 3.00% CV
		≥ 11.00	≤ 1.50% CV	≤ 3.00% CV
HCT	%	10.0 to 85.0	≤ 3.00% CV	≤ 4.00% CV
MCV	fL	50.0 to 150.0	≤ 1.00% CV	≤ 2.00% CV
MCH	p/g	10.0 to 45.0	≤ 3.00% CV	≤ 4.00% CV
MCHC	g/dL	26.0 to 38.0	≤ 4.00% CV	≤ 5.00% CV
RDW	%	10.0 to 40.0	≤ 3.50% CV	≤ 5.00% CV
RDW-SD	fL	15.0 to 50.0	≤ 3.50% CV	≤ 5.00% CV

Table 1.12 Repeatability Limits *(Continued)*

Parameter	Units	Range*	Repeatability Limits: Whole Blood	Repeatability Limits: Prediluted Whole Blood
PLT	x10^3 cells/µL	7.0 to < 25.0	≤ 20.00% CV	≤ 25.00% CV
		25.0 to 50.0	≤ 15.00% CV	≤ 20.00% CV
		> 50.0 to < 100.0	≤ 10.00% CV	≤ 15.00% CV
		100.0 to 200.0	≤ 7.50% CV	≤ 12.00% CV
		> 200.00 to 2000.0	≤ 5.00% CV	≤ 12.00% CV
MPV	fL	5.00 to < 8.00	≤ 2.00% CV	≤ 7.00% CV
		≥ 8.00	≤ 3.00% CV	≤ 5.00% CV
LY	%	1.00 to < 5.00	≤ 0.50 SD	≤ 0.70 SD
		5.00 to < 15.00	≤ 12.00% CV	≤ 15.00% CV
		15.00 to < 25.00	≤ 10.00% CV	≤ 12.00% CV
		25.00 to 50.00	≤ 7.00% CV	≤ 10.00% CV
		> 50.00	≤ 5.00% CV	≤ 7.00% CV
MO	%	1.00 to < 5.00	≤ 1.00 SD	≤ 1.20 SD
		5.00 to 10.00	≤ 15.00% CV	≤ 17.00% CV
		> 10.00	≤ 10.00% CV	≤ 12.00% CV
NE	%	5.00 to < 10.00	≤ 20.00% CV	≤ 20.00% CV
		10.00 to < 15.00	≤ 12.00% CV	≤ 15.00% CV
		15.00 to 50.00	≤ 7.00% CV	≤ 10.00% CV
		> 50.00	≤ 5.00% CV	≤ 7.00% CV
EO	%	1.00 to ≤ 4.99	≤ 0.75 SD	≤ 1.00 SD
		5.00 to 10.00	≤ 15.00% CV	≤ 17.00% CV
		> 10.00	≤ 12.00% CV	≤ 15.00% CV
BA	%	≥ 0.01	≤ 1.00 SD	≤ 1.50 SD
LY#	x10^3 cells/µL	0.20 to < 5.00	≤ 0.50 SD	≤ 0.70 SD
		5.00 to < 10.00	≤ 10.00% CV	≤ 12.00% CV
		10.00 to 100.00	≤ 7.00% CV	≤ 10.00% CV
MO#	x10^3 cells/µL	0.30 to 3.00	≤ 0.20 SD	≤ 0.30 SD
		> 3.00	≤ 7.00% CV	≤ 10.00% CV
NE#	x10^3 cells/µL	0.20 to < 3.00	≤ 0.17 SD	≤ 0.20 SD
		3.00 to 7.00	≤ 4.00% CV	≤ 6.00% CV
		> 7.00 to 100.00	≤ 3.00% CV	≤ 5.00% CV
EO#	x10^3 cells/µL	0.10 to 5.00	≤ 0.75 SD	≤ 1.00 SD
		> 5.00	≤ 1.00 SD	≤ 1.50 SD
BA#	x10^3 cells/µL	≥ 0.01	≤ 1.00 SD	≤ 1.50 SD

*MPV parameters all apply at PLT > 100.0 x 10^3 cells/µL. Differential parameters all apply at WBC > 4.00 x 10^3 cells/µL.

Reproducibility

The results for reproducibility should agree with the stated limits when three levels of controls are analyzed in triplicate by replicate analysis, twice per day, for five days. Control values with system messages and/or suspect messages should be excluded. Specimens with flags, codes, or messages indicating a need for review should not be used for reproducibility testing.[38]

Table 1.13 Imprecision (Reproducibility) Limits

Parameter	Units	Range*	Reproducibility Limits Whole Blood
WBC	$x10^3$ cells/µL	0.20 to < 3.00	≤ 0.20 SD
		≥ 3.00	≤ 6.00% CV
RBC	$x10^6$ cells/µL	1.00 to < 3.50	≤ 5.00% CV
		3.50 to 8.00	≤ 3.00% CV
HGB	g/dL	3.00 to < 11.00	≤ 4.00% CV
		11.00 to 25.00	≤ 2.00% CV
HCT	%	10.0 to 85.0	≤ 3.00% CV
MCV	fL	50.0 to 150.0	≤ 2.00% CV
MCH	p/g	10.0 to 45.0	≤ 3.00% CV
MCHC	g/dL	26.0 to 38.0	≤ 4.00% CV
RDW	%	10.0 to 40.0	≤ 4.00% CV
RDW-SD	fL	15.0 to 50.0	≤ 8.00% CV
PLT	$x10^3$ cells/µL	7.0 to < 100.0	≤ 20.00% CV
		100.0 to 2000.0	≤ 10.00% CV
MPV	fL	8.00 to 25.00	≤ 5.00% CV
LY	%	5.00 to < 25.00	≤ 12.00% CV
		≥ 25.00	≤ 10.00% CV
MO	%	0.10 to 10.00	≤ 1.00 SD
NE	%	5.00 to < 25.00	≤ 12.00% CV
		25.00 to 50.00	≤ 10.00% CV
		> 50.00	≤ 7.00% CV
EO	%	1.00 to 10.00	≤ 1.00 SD
		> 10.00	≤ 1.50 SD
BA	%	≥ 0.01	≤ 1.50 SD
LY#	$x10^3$ cells/µL	0.20 to 3.00	≤ 0.50 SD
MO#	$x10^3$ cells/µL	≥ 0.01	≤ 0.20 SD
NE#	$x10^3$ cells/µL	0.20 to 3.00	≤ 0.20 SD
		> 3.00 to 7.00	≤ 6.00% CV
		> 7.00 to 100.00	≤ 5.00% CV
EO#	$x10^3$ cells/µL	0.10 to 3.00	≤ 0.75 SD

Table 1.13 Imprecision (Reproducibility) Limits *(Continued)*

Parameter	Units	Range*	Reproducibility Limits Whole Blood
BA#	x10^3 cells/µL	≥ 0.01	≤ 1.00 SD
*MPV parameters all apply at PLT > 100.0 x 10^3 cells/µL. Differential parameters all apply at WBC > 4.00 x 10^3 cells/µL.			

Measuring and Operating Ranges, and Linearity

Measuring range is the set of values of quantities of the same kind that can be measured by a given measuring instrument or system with specified instrument measurement uncertainty under defined conditions. The measuring ranges are shown in Table 1.14, Whole Blood Measuring and Operating Ranges, and Linearity Limits.

Operating range is the range over which the system, including the predilute functionality, reports, displays, prints, exports, and/or transmits results. Values that are between the measuring range and operating range are flagged.

Linearity is the ability to provide results that are directly proportional to the concentration of the analyte in the test sample. Linearity can be assessed by testing levels of an analyte known by formulation, by using commercially available materials qualified for use on the DxH 500, or according to *CLSI EP06-A*[22].

The measuring and operating ranges apply to both whole blood and prediluted samples. Linearity limits apply to whole blood only.

Table 1.14 Whole Blood Measuring and Operating Ranges, and Linearity Limits

Whole Blood Parameter	Units	Measuring Range	Operating Range	Linearity Limits (r^2)
WBC	x10^3 cells/µL	0.20 to 100.00	0.00 to 150.00	$r^2 > 0.95$
RBC	x10^6 cells/µL	0.20 to 8.00	0.00 to 12.00	$r^2 > 0.95$
HGB	g/dL	0.20 to 25.00	0.00 to 25.00	$r^2 > 0.95$
HCT	%	0.0 to 85.0	0.0 to 85.0	N/A
MCV	fL	50.0 to 150.0	50.0 to 150.0	N/A
MCH	pg	0.0 to 99.9	0.0 to 99.9	N/A
MCHC	g/dL	0.0 to 99.9	0.0 to 99.9	N/A
RDW	%	10.0 to 40.0	0.0 to 70.0	N/A
RDW-SD	fL	15.0 to 150.0	0.0 to 220.0	N/A
PLT	x10^3 cells/µL	7.0 to 2000.0	0.0 to 4000.0	$r^2 > 0.95$
MPV	fL	5.00 to 25.00	0.00 to 25.00	N/A
LY	%	0.00 to 100.00	0.00 to 100.00	N/A
MO	%	0.00 to 100.00	0.00 to 100.00	N/A
NE	%	0.00 to 100.00	0.00 to 100.00	N/A
EO	%	0.00 to 100.00	0.00 to 100.00	N/A

Table 1.14 Whole Blood Measuring and Operating Ranges, and Linearity Limits *(Continued)*

Whole Blood Parameter	Units	Measuring Range	Operating Range	Linearity Limits (r^2)
BA	%	0.00 to 100.00	0.00 to 100.00	N/A
LY#	$x10^3$ cells/µL	0.00 to 100.00	0.00 to 150.00	N/A
MO#	$x10^3$ cells/µL	0.00 to 100.00	0.00 to 150.00	N/A
NE#	$x10^3$ cells/µL	0.00 to 100.00	0.00 to 150.00	N/A
EO#	$x10^3$ cells/µL	0.00 to 100.00	0.00 to 150.00	N/A
BA#	$x10^3$ cells/µL	0.00 to 100.00	0.00 to 150.00	N/A

Carryover

Carryover may be assessed using the carryover mode on the instrument following *CLSI H26-A2*[31]. Three replicates of blood with high test values are followed by three replicates of Diluent. Carryover less than or equal to 1.00% for WBC, RBC, HGB, PLT, and the differential, when the WBC carryover is within the defined limit, are considered acceptable. See Running Carryover in CHAPTER 11, Quality Assurance.

Background Limits

NOTE Due to the technology used, the DIFF background is assessed by the WBC background. If the WBC background is within the defined limit, the DIFF measurement is considered acceptable.

Table 1.15 Background Limits

Parameter	Units	Background Limits
WBC and Diff	$x10^3$ cells/µL	≤ 0.20
RBC	$x10^6$ cells/µL	≤ 0.03
HGB	g/dL	≤ 0.10
PLT	$x10^3$ cells/µL	≤ 7.0

Throughput

Throughput is 60 specimens per hour.

Reference Interval

A reference interval study was conducted to assess the reference intervals for the DxH 500. Whole-blood samples were collected at least 240 healthy adult donors aged 21 to 65 years (males and females). Donors were selected according to *CLSI EP28-A3c*[24]. These intervals are used as default adult reference interval limits. Your laboratory's patient population intervals may be different.

These reference intervals are referred to as *reference ranges* on the instrument screens.

Table 1.16 Whole-Blood Reference Intervals - All Samples

Parameter	Units	All Samples		
		Mean	**95% Confidence Interval**	**95% Confidence Interval**
WBC	$x10^3$ cells/µL	6.53	3.71	10.67
RBC	$x10^6$ cells/µL	4.65	3.87	5.68
HGB	g/dL	14.09	12.00	16.75
HCT	%	41.3	35.1	48.7
MCV	fL	88.9	78.4	97.6
MCH	pg	30.4	26.5	33.5
MCHC	g/dL	34.1	32.9	35.4
RDW	%	13.9	12.7	15.6
RDW-SD	fL	43.9	38.9	49.0
PLT	$x10^3$ cells/µL	250.1	150.5	366.8
MPV	fL	8.86	7.42	10.77
LY	%	31.98	18.94	46.71
MO	%	7.87	4.88	12.81
NE	%	57.06	40.62	71.65
EO	%	2.83	0.74	6.73
BA	%	0.25	0.05	0.48
LY#	$x10^3$ cells/µL	2.05	1.15	3.52
MO#	$x10^3$ cells/µL	0.51	0.25	0.99
NE#	$x10^3$ cells/µL	3.77	1.85	6.72
EO#	$x10^3$ cells/µL	0.18	0.04	0.48
BA#	$x10^3$ cells/µL	0.02	0.00	0.03

Table 1.17 Whole-Blood Reference Intervals - Male

Parameter	Units	Male		
		Mean	**95% Confidence Interval**	**95% Confidence Interval**
WBC	$x10^3$ cells/µL	6.29	3.53	9.52
RBC	$x10^6$ cells/µL	4.98	4.33	5.72
HGB	g/dL	14.99	12.55	16.99
HCT	%	43.7	38.3	49.3
MCV	fL	88.0	78.3	95.5
MCH	pg	30.2	25.9	33.2

Table 1.17 Whole-Blood Reference Intervals - Male *(Continued)*

Parameter	Units	Male		
		Mean	95% Confidence Interval	95% Confidence Interval
MCHC	g/dL	34.3	33.0	35.3
RDW	%	13.9	12.9	15.5
RDW-SD	fL	43.4	39.0	48.3
PLT	$x10^3$ cells/µL	232.1	146.5	351.5
MPV	fL	8.76	7.42	10.65
LY	%	31.63	20.23	43.53
MO	%	8.37	5.23	13.22
NE	%	56.39	40.62	70.51
EO	%	3.34	0.84	7.67
BA	%	0.26	0.11	0.53
LY#	$x10^3$ cells/µL	1.95	1.15	3.13
MO#	$x10^3$ cells/µL	0.53	0.25	1.06
NE#	$x10^3$ cells/µL	3.59	1.85	5.94
EO#	$x10^3$ cells/µL	0.21	0.05	0.50
BA#	$x10^3$ cells/µL	0.02	0.01	0.04

Table 1.18 Whole-Blood Reference Intervals - Female

Parameter	Units	Female		
		Mean	95% Confidence Interval	95% Confidence Interval
WBC	$x10^3$ cells/µL	6.73	3.77	11.03
RBC	$x10^6$ cells/µL	4.39	3.83	5.06
HGB	g/dL	13.35	11.59	15.11
HCT	%	39.3	34.6	44.1
MCV	fL	89.7	80.0	98.0
MCH	pg	30.5	26.6	33.5
MCHC	g/dL	34.0	32.9	35.4
RDW	%	13.9	12.6	15.6
RDW-SD	fL	44.3	38.9	50.6
PLT	$x10^3$ cells/µL	264.8	169.1	368.3
MPV	fL	8.93	7.45	10.84
LY	%	32.27	18.51	48.98
MO	%	7.46	4.72	11.35
NE	%	57.62	41.35	72.27

Table 1.18 Whole-Blood Reference Intervals - Female *(Continued)*

Parameter	Units	Female		
		Mean	95% Confidence Interval	95% Confidence Interval
EO	%	2.42	0.71	6.09
BA	%	0.24	0.05	0.47
LY#	$x10^3$ cells/µL	2.14	1.16	3.78
MO#	$x10^3$ cells/µL	0.49	0.28	0.83
NE#	$x10^3$ cells/µL	3.92	2.03	7.67
EO#	$x10^3$ cells/µL	0.16	0.04	0.42
BA#	$x10^3$ cells/µL	0.02	0.00	0.03

Sample Stability and Storage - Whole Blood

Samples stored at ≤ 19°C (66°F) for longer than two hours may exhibit increased cellular interference messages.

Sample stability may be measured by comparing the mean of multiple samples analyzed within two hours and at 24 hours at 18 to 26°C (64 to 79°F). For a refrigerated temperature of 2 to 8°C (35.6 to 46.4°F), samples may be analyzed at 8 hours for WBC and differential parameters, and at 24 hours for the remainder of the parameters. Mean results should be within the difference or percent difference, whichever is greater. See Table 1.19, Sample Stability and Storage.

Samples stored at refrigerated temperatures are removed from storage, mixed by inversion 20 times, allowed to remain at ambient room temperature for 30 minutes, and remixed by inversion 20 times prior to analysis.

IMPORTANT Beckman Coulter recommends analyzing refrigerated and non-refrigerated whole-blood samples within eight hours.

Table 1.19 Sample Stability and Storage

Parameter	Limits	Controlled Room Temperature 18 to 26°C (64 to 79°F)	Refrigerated Temperature 2 to 8°C (35.6 to 46.4°F)
		Hours	Hours
WBC ($x10^3$ cells/µL)	± 0.50 or ± 10.00%	24	8
RBC ($x10^6$ cells/µL)	± 0.07 or ± 3.00%	24	24
HGB (g/dL)	± 0.30 or ± 2.00%	24	24
HCT (%)	± 1.1 or ± 5.0%	24	24
MCV (fL)	± 2.5 or ± 3.0%	24	24
MCH (pg)	± 0.5 or ± 6.0%	24	24
MCHC (g/dL)	± 0.6 or ± 6.0%	24	24
RDW (%)	± 1.5 or ± 10.0%	24	24

Table 1.19 Sample Stability and Storage *(Continued)*

Parameter	Limits	Controlled Room Temperature 18 to 26°C (64 to 79°F)	Refrigerated Temperature 2 to 8°C (35.6 to 46.4°F)
		Hours	Hours
RDW-SD (fL)	± 6.0 or ± 15.0%	24	24
PLT (x10^3 cells/µL)	± 10.0 or ± 7.0%	24	24
MPV (fL)	± 1.00 or ± 10.00%	24	24
LY (%)	± 5.00 or ± 15.00%	24	8
MO (%)	± 3.00 or ± 10.00%	24	8
NE (%)	± 5.00 or ± 12.00%	24	8
EO (%)	± 1.50 or ± 10.00%	24	8
BA (%)	± 1.00	24	8
LY# (x10^3 cells/µL)	± 0.35 or ± 25.00%	24	8
MO# (x10^3 cells/µL)	± 0.20 or ± 10.00%	24	8
NE# (x10^3 cells/µL)	± 0.35 or ± 20.00%	24	8
EO# (x10^3 cells/µL)	± 0.50 or ± 10.00%	24	8
BA# (x10^3 cells/µL)	± 1.00	24	8

Sample Stability and Storage - Prediluted Whole Blood

Prediluted samples must be analyzed within 15 minutes of preparation. Whole blood and diluent should be at room temperature before the dilution is prepared. Prediluted results should agree with whole-blood results as shown in Table 1.11, Method Comparison Specifications - Prediluted Versus Whole Blood.

Clinical Sensitivity and Specificity

Clinical sensitivity and specificity of WBC differential flagging performance can be influenced by a number of factors related to instrument technology, cellular frequency, uncertainty in the reference determination of a positive, and the sample population evaluated.

Beckman Coulter recommends performing sensitivity and specificity studies using your sample population and laboratory settings. See *CLSI H20-A2*[30].

Limitations

⚠ CAUTION

Risk of erroneous results. The presence of a rare event cell can fail to trigger a suspect message. Beckman Coulter recommends a review in accordance with your laboratory protocol.

An interfering substance is described as a component of the sample, other than the analyte, that causes a bias in the measured analyte concentration.[33]

Table 1.20 Limitations

Parameter	Limitation
All Specimens	Erroneous results can occur: • If the specimen is not properly collected, stored, or transported. Beckman Coulter recommends following *CLSI GP 44-A4*[27] or equivalent procedures to ensure proper specimen collection, storage, and transport. Always follow the manufacturer's recommendations when using microcollection devices for capillary specimen collection. • If the specimen contains clots. Always use good laboratory practices for inspecting specimens for clots and verifying results. • If the specimen is not properly mixed. Always use good laboratory practices to ensure specimens are appropriately mixed. • System algorithms identify population overlaps where result review is recommended and indicated by specific flags and messages. See Table 6.2, Codes in CHAPTER 6, Data Review. • This table represents information obtained during validation testing. Other limitations may exist.[36, 37]
WBC	Unlysed RBCs, NRBCs, cryoglobulin, cryofibrinogen, PLT clumps, giant PLTs, and agglutinated white cells[37]
Diff #	See WBC
RBC	Agglutinated red cells, unlysed RBCs, and elevated WBCs 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.[37]
HGB	Lipids > 62.5 mg/dL (lipemia)[37]
HCT	See MCV
MCV	See RBC[37]
MCH	See HGB and RBC[37]
MCHC	See HGB and MCV[37]
RDW, RDW-SD	See RBC[37]

Table 1.20 Limitations *(Continued)*

Parameter	Limitation
PLT	Giant PLTs, platelet clumps, microcytic RBCs, cryoglobulin, and white or red cell fragments [36]
MPV	See PLT

CHAPTER 2

Operation Principles

Method History

This chapter includes information on the history of the Coulter Principle, the Coulter Method, and how they relate to this instrument.

History of the Coulter Principle

W.H. Coulter (1956) described the Coulter Principle[1] as:

"A suspension of blood cells is passed thru [sic] 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. 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 to reduce the statistical error by a factor of approximately 10 times."

This substantial improvement in precision over previous methods helped to establish the erythrocyte count as a sensitive index of erythropoietic dyscrasia, particularly when considered together with HCT and HGB measurements.[2]

The COULTER COUNTER Model S analyzer was the first instrument that automated simultaneous multiparameter measurements on blood. Brittin et al., Gottmann, and Hamilton and Davidson, reviewed the performance and clinical value of the Model S.[3, 4, 5]

Refinements of the COULTER COUNTER analyzer to provide accurate size (volume) distribution data led to a reawakening of interest in pathological erythrocyte size distribution, first sparked by Price-Jones.[6, 7]

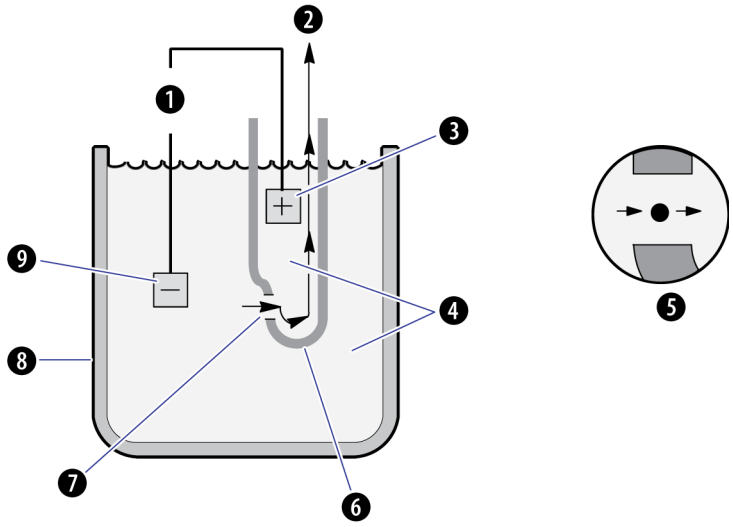
Among the advantages offered by the Coulter method of counting and sizing was the ability to derive an accurate HCT measurement by summing the electronic volume of erythrocytes. England et al. speculated that electronic HCT measurements did not contain the trapped plasma error of centrifugal HCT measurements.[8]

Bull et al. described the use of a COULTER COUNTER analyzer for counting thrombocytes.[9] This method, useful as it was, depended on preparing thrombocyte-rich plasma to avoid counting erythrocytes as thrombocytes. Mundschenk et al. and Schulz and Thom discussed the possibility of counting thrombocytes in the presence of erythrocytes and classifying them by size.[10, 11] Electronic refinements in the Model S-PLUS enhanced the accuracy of the hydrodynamic method.
Von Behrens and Paulus have also cited the feasibility of counting thrombocytes by the Coulter method.[12, 13]

Coulter Principle

The Coulter Principle accurately counts and sizes cells by detecting and measuring changes in electrical resistance when a particle (such as a cell) in a conductive liquid passes through a small aperture as shown in the following figure.

Figure 2.1 Coulter Principle



Number	Description	Number	Description
1	Aperture Current	6	Aperture Tube
2	Vacuum	7	Aperture
3	Internal Electrode	8	Sample Beaker
4	Blood Cell Suspension	9	External Electrode
5	Detail of Aperture		

Each cell suspended in a conductive liquid (diluent) acts as an insulator. As each cell goes 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 counting, the vacuum used to pull the diluted suspension of cells through the aperture must be at a regulated volume.[14, 15, 16, 17] While the number of pulses indicates particle count, the size of the electrical pulse is proportional to the cell volume.

CBC Analysis

In hematology, the CBC is the fundamental analytical test that evaluates the three main cellular components: white blood cells, red blood cells, and platelets. The DxH 500 CBC analysis is based on the Coulter Principle.

Specimen Preparation

The aspiration syringe activates and aspirates 12 µL of a well-mixed sample through the probe.

The probe retracts and is externally rinsed with diluent. The waste from the probe rinse is drained by the rinsing head vacuum into the waste syringe. The probe moves to the WBC bath. Diluent is pushed throughout the rinsing head to externally rinse the aspiration probe. The dispensed diluent falls into the WBC bath, rinses the bath, and then drains into the waste. Diluent (1 mL) is then dispensed into the WBC bath. An additional 500 µL of diluent is dispensed through the probe pushing the 12 µL of sample into the bath creating the initial WBC dilution of 1:125 (Blood:Diluent). This dilution is then mixed using mixing bubbles.

From the initial WBC dilution, 25 µL is aspirated into the probe. After aspiration, the probe moves up while diluent is delivered through the rinsing head to externally rinse the probe. The waste from the probe rinse is drained by the rinse head vacuum into the waste syringe. Subsequently, the probe moves to the RBC bath.

As the probe moves to the RBC bath, 0.66 mL of Lyse is dispensed into the WBC bath and mixed creating the final WBC dilution of 1:180. Simultaneously, diluent is pushed through the rinsing head to rinse the aspiration probe over the RBC bath. The diluent falls into the RBC bath which is later drained to waste.

Next, at the RBC bath, 1.5 mL of diluent is dispensed through the outside of the probe. This is followed by 0.5 mL of diluent dispensed through the inside of the probe pushing the 25 µL of sample into the RBC bath for a final dilution of 1:10125. This dilution is mixed and prepared for counting.

Counting/Sizing

The DxH 500 initially counts the CBC (RBC/PLT/WBC) parameters for 3 seconds followed by the second measurement of the CBC + DIFF for 7 seconds. The RBC, WBC, and PLT counts are determined using the Coulter Principle to accurately count and size cells. The WBC differential is determined using a combination of the WBC impedance data and the direct optical measurement data obtained using a blue LED focused through the WBC aperture. This instrument has two count periods (three seconds and seven seconds).

Coincidence Correction

Occasionally, more than one cell passes through the aperture at one time. When cells coincide, only one combined pulse is counted. As the frequency of coincidence is proportional to the actual count, the system automatically corrects results for coincidence.

Scaling

Scaling adjusts for calibration and reportable format.

Voting and Averaging

The system votes on data for WBC, RBC, MCV, RDW, PLT, and MPV to prevent data errors due to statistical outliers, obstructions that may block an aperture, and to verify that data is within a specific statistical range. Voted-in data is averaged for reporting.

Results Calculation and Rounding

Values are sent to the calculation module within the software. The results are rounded based on the number of digits available for display and printing, using traditional mathematical rounding logic.

Hemoglobinometry

Hemoglobin is converted into stable oxyhemoglobin by the Lyse reagent. The absorbance of the pigment of the solution is proportional to the hemoglobin concentration of the sample. Hemoglobin is measured using an LED light source at 545 nm.

Histograms

The histograms show size (X-axis) versus relative cell frequency (Y-axis). Histograms provide information about red cell and platelet frequency and provide a means of comparing the sizes of a patient's cells with normal populations.

IMPORTANT Histograms show only the relative, not actual, number of cells in each size range. Do not estimate the number of cells from the histograms.

Selecting a histogram displays a larger view of the histogram. Each histogram is grey with a white background. Each cell population is shaded as follows: RBC is light red and PLT is light green.

Figure 2.2 RBC Cell Population

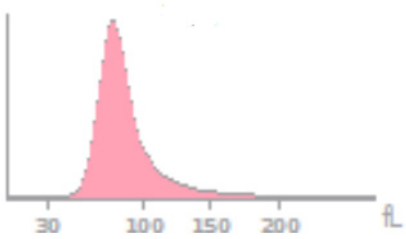
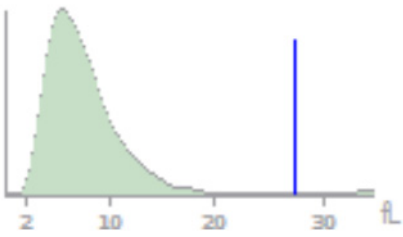


Figure 2.3 PLT Cell Population



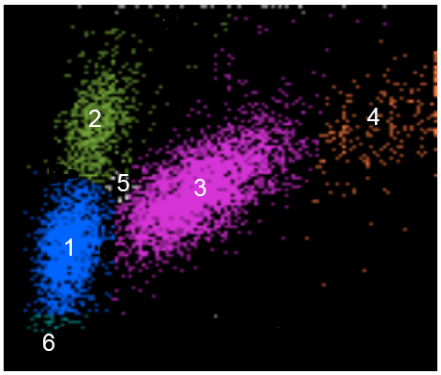
WBC Differential and Differential (Diff) Scatter Plot Development

WBC Differential data is displayed in the diff plot.

The digital information obtained from the WBC analysis is processed through the WBC differential algorithm. This information is represented on a 2D scatter plot according to cell volume plotted on the Y-axis and Axial Light Loss (ALL) plotted on the X-axis. The DxH 500 uses simultaneous

measurements of volume and axial light loss within the WBC aperture to count and size Lymphocytes, Monocytes, Neutrophils, Eosinophils, and Basophils. The LED in the assembly projects blue light through the aperture onto a sensor that detects axial light loss when passing cells interrupt the optical path. The amount of light falling on a sensor varies depending on cell structure. The DxH 500 algorithm generates the WBC differential, flagging, and messaging. A two-dimensional scatter plot is created with volume on the Y-axis and axial light loss on the X-axis. WBC Differential data is displayed in the diff plot.The WBC subpopulations are identified by color and intensity (concentration) within the diff plot as follows:

Figure 2.4 Diff Scatter Plot



Number	WBC Subpopulation	Color
1	Lymphocyte	Blue
2	Monocyte	Green
3	Neutrophil	Purple
4	Eosinophil	Orange
5	Basophil	White
6	Non-White Cell	Blue-Green or Grey

See Differential Scatter Plot Flagging Areas in CHAPTER 6, Data Review.

Parameter Measurement, Derivation, and Calculation

Table 2.1 Parameter Measurement, Derivation, and Calculation

Parameter (US-1 Format)	Method	Description (Using US1 Reporting Units)
WBC	Coulter Principle	White Blood Cell Count or Leukocyte Count Measured directly, multiplied by a calibration factor
RBC	Coulter Principle	Red Blood Cell Count or Erythrocyte Count Measured directly, multiplied by a calibration factor

Table 2.1 Parameter Measurement, Derivation, and Calculation *(Continued)*

Parameter (US-1 Format)	Method	Description (Using US1 Reporting Units)
HGB	Photometric Measurement	Hemoglobin or Hemoglobin Concentration • Transmittance of light at 545 nm through a lysed WBC solution in the WBC bath, 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
HCT	Calculated	Hematocrit • The relative volume of packed erythrocytes to whole blood • The HCT is calculated using RBC and MCV • HCT (%) = (RBC X MCV)/10
MCV	Derived from RBC Histogram	Mean Corpuscular Volume • The average volume of individual erythrocytes derived from the RBC histogram, multiplied by a calibration factor • Expressed in fL
MCH	Calculated	Mean Corpuscular Hemoglobin • The weight of HGB in the average erythrocyte • MCH (pg) = (HGB/RBC) x 10
MCHC	Calculated	Mean Corpuscular Hemoglobin Concentration • The average weight of HGB in a measured dilution • MCHC (g/dL) = (HGB/HCT) x 100
RDW	Derived from RBC Histogram	Red Cell Distribution Width • The size distribution spread of the erythrocyte population derived from the RBC histogram • Expressed as a coefficient of variation (%)
RDW-SD	Derived from RBC Histogram	Red Cell Distribution Width - SD • The size distribution spread of the erythrocyte population derived from the RBC histogram • Expressed as a standard deviation in fL
PLT	Coulter Principle	Platelet Count or Thrombocyte Count • The number of platelets derived from the PLT histogram, multiplied by a calibration factor
MPV	Derived from PLT Histogram	Mean Platelet Volume • The average volume of individual platelets derived from the PLT histogram, multiplied by a calibration factor • Expressed in fL

Table 2.1 Parameter Measurement, Derivation, and Calculation *(Continued)*

Parameter (US-1 Format)	Method	Description (Using US1 Reporting Units)
LY	Optical/Impedance	Lymphocyte Percent • [LY events/(NE+LY+MO+EO+BA events)] x 100 • Expressed as a percentage (%)
MO	Optical/Impedance	Monocyte Percent • [MO events/(NE+LY+MO+EO+BA events)] x 100 • Expressed as a percentage (%)
NE	Optical/Impedance	Neutrophil Percent • [NE events/(NE+LY+MO+EO+BA events)] x 100 • Expressed as a percentage (%)
EO	Optical/Impedance	Eosinophil Percent • [EO events/(NE+LY+MO+EO+BA events)] x 100 • Expressed as a percentage (%)
BA	Optical/Impedance	Basophil Percent • [BA events/(NE+LY+MO+EO+BA events)] x 100 • Expressed as a percentage (%)
LY#	Calculated	Lymphocyte Absolute Count LY# (10^3/µL) = (LY/100) x WBC
MO#	Calculated	Monocyte Absolute Count MO# (10^3/µL) =(MO/100) x WBC
NE#	Calculated	Neutrophil Absolute Count NE# (10^3/µL) = (NE/100) x WBC
EO#	Calculated	Eosinophil Absolute Count EO# (10^3/µL) = (EO/100) x WBC
BA#	Calculated	Basophil Absolute Count BA# (10^3/µL) = (BA/100) x WBC

CHAPTER 3

Startup and Daily Checks

Startup

Use your Operator ID and password to log on to the system. If you forget your password, contact your administrator.

Logging On/Logging Off

1 If the instrument is not powered on, press the power button located on the front of the instrument. The button turns red and the logon screen is displayed after about 30 seconds. The light turns green when the instrument is ready.

2 On the initial DxH 500 screen, select the *Operator ID* field. When the on-screen keyboard is displayed, enter your operator ID (minimum of two characters; maximum of eight characters).

3 In the *Password* field, enter a six-digit alphanumeric password and select a language, if required, from the *Language* drop-down list.

NOTE The system defaults to the last selected language.

4 Select  .

5 If the system determines that the waste is full, a message is displayed. Select  to acknowledge the message. To empty the waste and replace the container, see Setting Up or Replacing Waste Disposal in CHAPTER 9, Setup.

NOTE When setting up the instrument for the first time, the waste is set to full (100%) by default. See Setting Up or Replacing Waste Disposal in CHAPTER 9, Setup to set up the waste disposal.

6 If the system determines that the reagents need to be replaced, a message is displayed. Select  to acknowledge the message. To replace the reagents, see Setting Up or Replacing Supplies in CHAPTER 9, Setup.

7 Run Daily Checks. See Running Daily Checks.

8 To log out, select  .

Using the Bar-Code Scanner

Use the bar-code scanner to:

- Scan package labels for supplies setup. See Setting Up or Replacing Supplies in CHAPTER 9, Setup.
- Scan assay sheets and labels for controls and calibrators. See Setting Up and Editing Controls in CHAPTER 9, Setup.
- Scan patient information from specimen tube labels. See Using the Handheld Bar-Code Scanner in CHAPTER 5, Sample Analysis.

The bar-code scanner is already programmed to scan your labels. See Bar-Code Scanner in CHAPTER 1, System Overview for the supported bar-code symbologies.

⚠ CAUTION

Risk of misidentification. Beckman Coulter recommends that you enable checksum for bar-code labels.

Daily Checks

Running Daily Checks ensures that the instrument is operational and ready to process samples. Daily Checks must be run every 24 hours either after a shutdown or at the beginning of the day before specimen processing.

Set up Daily Checks to run on designated days and times. See Setting Up Automatic Power Up and Daily Checks, and Frequency of Auto-Clean Cycles in CHAPTER 9, Setup for more information.

You can view Daily Checks logs with event information. See Viewing Daily Checks History for more information.

Running Daily Checks

1 From the main menu, select  .

2 On the Daily Checks screen, select  .

3 Select  when prompted to run Daily Checks.

NOTE The bottom left corner of the screen displays Daily Checks and the power button is red when Daily Checks is running.

4 Wait for Daily Checks to be completed.

5 Verify that all status indicators display *Pass* and verify the remaining reagent cycles. If the remaining reagents cycles are less than 10, the background is yellow. If no cycles remain, the background is red. Replace the reagent if necessary.

If *Fail* is displayed, select one of the options from the warning window and select  to confirm your selection. If the Daily Checks fails, see General Troubleshooting in CHAPTER 10, Troubleshooting.

Viewing Daily Checks History

The Daily Checks Log stores up to 50 Daily Checks results. When the log is full, the oldest daily check data is automatically removed first. The log is:

- Useful for troubleshooting instrument problems over time
- Available for reviewing, printing, and exporting

1 Select  >  to view the Daily Checks log.

Printing Daily Checks

If auto-print has been set up, the Daily Checks report is automatically printed when the Daily Checks process is complete. See Setting Up Printer Options in CHAPTER 9, Setup. To print manually:

1 From the main menu, select  .

2 Select  >  to print the Daily Check results.

3 From the warning window, select **Current Daily Checks** or **All Daily Checks**.

4 Select  to confirm your selection.

Exporting Daily Checks

1 Insert a USB flash drive into the USB port in front of the instrument.

2 Select  >  >  to export all of the files to the USB flash drive.

3 Select  when prompted to export the files.

4 Remove the USB flash drive from the USB port.

Running a Background Count

Daily Checks includes background counts. A background count can also be processed independently from Daily Checks.

1 From the main menu, select  .

2 Select  .

3 Select  when prompted to perform a Background Count. The system checks values against defined limits. See Background Limits in CHAPTER 1, System Overview. The bottom left corner of the screen displays *Background Count* and the power button is red during the cycle.

NOTE The bottom left corner of the screen displays *Background Count* and the power button is red when during the cycle.

4 Wait for the Background Count to be processed and verify that all status indicators display *Pass*.

If the Background Count fails, see General Troubleshooting in CHAPTER 10, Troubleshooting. If the values do not pass, the background failure is recorded in the logs.

CHAPTER 4

Quality Control

Quality Control Overview

Quality Control is the routine monitoring of performance using commercial 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 system performance to be detected. If the changes detected are significant, you can then take action to improve system performance.

The DxH 500 system lets you use multiple quality control techniques that are outlined in this chapter. Beckman Coulter recommends that Quality Control checks be performed using commercial controls at intervals established by your laboratory. When using a commercial control, refer to the instructions for use. Failure to recover control values within your laboratory's expected limits or the presence of unexplained shifts or trends in any method of presentation should be investigated. If control problems cannot be resolved, call your Beckman Coulter Representative.

Patient results obtained between the last acceptable run and an unacceptable control run should be reevaluated to determine if patient test results have been adversely affected. Take corrective action, if necessary.

Quality Control monitoring includes notification and recovery within the system on an ongoing basis. Instrument sensor and hardware status tracking by event notifications is completed via the icons, alarms, and the History Event Log. Events can be addressed as they occur.

NOTE For information on Beckman Coulter recommended controls, see Controls and Calibrators in CHAPTER 1, System Overview.

Quality Control Principles

The purpose of Quality Control is to monitor various aspects of the instrument's performance. Quality Assurance includes service and maintenance as required along with the use of controls and calibrators. The combination of these methods provides the assurance of complete quality control and should be applied separately or in combination, according to your laboratory and accreditation requirements.

Routine maintenance is also an important quality control method.

Daily Checks

Daily Checks starts a series of quality control checks to determine whether the DxH 500 system is running properly. You can review the results of the Daily Checks on the Daily Checks screen. For

additional information on performing and reviewing Daily Checks, see Daily Checks in CHAPTER 3, Startup and Daily Checks.

Commercial Controls

Run commercial controls, as needed, to verify the performance of the DxH 500 system. See Analyzing Commercial Controls for more information about running controls.

Extended QC

Extended QC rules are derived from the German Quality Control Guidelines for the Medical Laboratory, known in Germany as Rili-BÄK. Rili-BÄK (Guidelines of the Federal Chamber of Physicians), was first published in 1987 and amended in 1990 and 1993 covering clinical chemistry, immunochemistry, and other tests, but not hematology. In 2003, the guidelines were extended to include hematology and they were updated in 2008.

XB Analysis

Dennis B. Dorsey MD, proposed in 1963 that the relatively constant blood cell indices could be used to follow the performance of hematology instrumentation.[19] Brian Bull, MD, improved the technique and it is termed XB Analysis.[20]

XB Analysis uses a "weighted moving average" of patient sample results because Koepke and Protextor said that QC materials "ideally should be similar in structure and in reactivity to the patient constituent being measured. Therefore, freshly drawn patient blood samples seem to be the most appropriate [QC material]." [21] Bull explains, "The analyzer [sic] is considered to be 'in control' when mean MCV, MCH, and MCHC determined on a batch of 20 patients by use of the algorithm XB are within 3% of the expected mean indices of the population." [20]

For information on setting up and enabling XB, see Setting Up XB in CHAPTER 9, Setup.

XM Analysis

XM Analysis is a quality-control method that uses an Exponentially Weighted Moving Average (EWMA) of CBC and Diff. It compares them with known target values, to monitor instrument performance. The first form of moving average statistical analysis in hematology was XB Analysis.

For information on setting up and enabling XM, see Setting Up XM in CHAPTER 9, Setup.

Interlaboratory Quality Assurance Program (IQAP)

The Interlaboratory Quality Assurance Program (IQAP) is a Beckman Coulter program available to you through enrollment that complements and enhances your laboratory in-house quality control. Essentially, IQAP lets you submit your control recovery data to Beckman Coulter. In return, you receive a personalized report that summarizes your results and compares them to the results from your peer group (pool). See Downloading to IQAP.

For more information, go to www.beckmancoulter.com/iqap or contact your local Beckman Coulter Representative.

Controls

See Setting Up and Editing Controls in CHAPTER 9, Setup for information on setting up controls, automatic configuration and printing, and transmission.

Analyzing Commercial Controls

1 Prepare the control according to the instructions for use available at www.beckmancoulter.com.

2 Select  to display the Sample Analysis - Patient Results screen.

3 Select  to acknowledge the message displayed to extend the probe.

NOTE The probe is not extended if the worklist contains orders.

4 Use the bar-code scanner to scan the control bar code OR select  , use the on-screen keyboard to manually enter the control lot number in the *Specimen ID* field, and select  when prompted to confirm the information entered.

NOTE If you have set up auto-incrementing, the Specimen ID field is automatically populated.

5 Mix the control according to the control's instructions for use and then uncap it.

6 Fully immerse the probe into the control and press the aspiration plate to initiate the analysis.

7 Remove the control when the aspiration probe has completely retracted.

8 Recap and store the control according to the instructions for use.

If a Control is OUT

If a control is not within the range configured for the test, the control is considered out and is indicated by  . The values that are out are flagged as low (*L*) or high (*H*) on the Sample Analysis - Patient Results screen. On the Quality Control (Data View) screen, out-of-range values are highlighted in red and flagged as *L* or *H*.

Before rerunning the control:

1. Ensure that the material is properly mixed according to the instructions for use.
2. Ensure that the identification information is entered correctly. If using a bar-code scanner, ensure the bar-code labels are clean and positioned correctly.
3. Ensure that the setup information (assigned values and expected ranges) matches either the Table of Expected Results for the control or your laboratory's established values. If they do not, change the control information to match.
4. Ensure there are no errors during the cycle.
5. Rerun the control. If the control fails again, try running a new tube of that same control level (or another level of control, if desired).
6. If the control recovery failure continues, contact your Beckman Coulter Representative.
7. To accept the out-of-range results and remove the error indicator, select  >  to accept all of the *QC/EQC out* conditions. Accepted results are displayed in blue.
8. To remove the *OUT* runs from data analysis, select the **Exclude** checkbox.

Viewing Control Files

To view control files on the Quality Control (Data View) screen, follow these steps. To view control run details, see Viewing the Details for a Control Run.

1 Select  to display the Quality Control (Data View) screen.

2 Select the **Lot #** from the drop-down list.

3 Review the information on the screen:

Field	Description
N	Number of control runs included in the file
Control	Control name
File	File number for the control file selected from 1 to 12
Lot #	Lot number of the selected control
Expiration Date	Expiration date for the selected control file
Level	The level of the control material for the selected file (Abnormal Low, Normal, Abnormal High)
Source	Control type (BEC or Other)
#	Number of the control run (most recent is at the top of the list)
Excl.	A run, indicated by an X, that is excluded from the statistics calculations
Op. ID	Operator who was logged in when the control was analyzed
Date/Time	Date and time the control was analyzed
Parameter	The parameters from WBC to MCV and other parameters displayed when scrolling to the right of the screen. The left and right arrows toggle between the MCH and Differential parameters. Results that exceed the control's expected range (highlighted in red and containing an *H* or an *L* dependent on result recovery.
Mean	The calculated mean of the included points
2SD	The calculated standard deviation of the included points multiplied by 2
%CV	The calculated Coefficient of Variation of the included points **NOTE** If the Extended QC is enabled, Extended QC limits have been configured, and the CV value is greater than the Random Error limit, the % CV is highlighted in yellow for that parameter if N > 2 and N < 15 or in red if N ≥ 15.
Target	The assigned target of the parameter being used in your laboratory at the time of the control analysis
Limit	The expected limit of the parameter in use in your laboratory at the time of the control analysis
Delta Diff	The difference between the calculated mean and the assigned target of the parameter **NOTE** If the Extended QC is enabled, Extended QC limits have been configured, and the absolute Delta Diff is greater than the Systematic Error Limit, the Delta Diff is highlighted in yellow for that parameter if N > 2 and N < 15, or in red if N ≥ 15.

Field	Description
RMSE	Root Mean Square Error is displayed when Extended QC is enabled. The RMSE is a Single Measurement Error. If the value exceeds the Single Measurement Error limit for a parameter, the RMSE value is highlighted in yellow for that parameter if N > 2 and N < 15, or in red if N ≥ 15.
Comments	Comments added for the highlighted control run
Operator	Operator ID who is logged in (displayed at the bottom of the screen)
Date & Time	Current date and time (displayed at the bottom of the screen)

4 Select the applicable icon to review that information or complete an action:

Icon	Name	Description
	XB	Displays the XB Batch Means screen
	XM	Displays the XM Batch Means screen
	IQAP	Displays the IQAP download screen
	QA	Displays the QA menu
	Accept QC/EQC	Active only when QC and/or EQC is out. See If a Control is OUT.
	Graphs	Displays the QC graphics for the QC file selected
	Display	Displays the results for the control run selected
	Comments	Lets you add a comment for the selected control results
	Delete	Deletes all QC results in the control file. See Deleting Control Files.

Viewing Control File Graphs

1 Select  .

2 Select the **Lot #** from the drop-down list.

3 Select  .

4 Select **CBC** or **Diff** and use the arrows to view the applicable graphs.

5 Verify that the correct lot number is selected and review the graphs:

- The graphs provide a Levey-Jennings style plot of the control data.
- The data is plotted as the result value against the +/- limits for the parameter.
- The graphs show the target value line as blue, and the high and low limits as red lines.
- The most recent point is plotted on the far right side of the graph and indicated by a vertical indicator line (in blue).
- The vertical indicator line is not fixed on the expanded Levey-Jennings graph and can be moved to view control results within the file.
- If the data points are outside the high and low limits, the value on the graph is plotted as a solid red triangle.
- If the results are excluded, they are plotted as empty black circles.
- If the results are within the expected range, they are plotted as a solid black circle.
- Select an individual graph displayed on the CBC and Diff screens to display an expanded graph of the parameter selected.

6 Select  to return to the Quality Control (Data View) screen.

View an Expanded Levey-Jennings Graph

The expanded Levey-Jennings graphic on the Quality Control (Graph View) screen displays up to 150 results for a selected parameter in the control file.

1 Select  .

2 Select the **Lot #** from the drop-down list.

3 Select  .

4 Select the applicable parameter graph from the multiple graphs on the Quality Control (Graph View) screen to display the expanded graph view and summary.

5 Select the applicable icon to review that information or complete an action:

Icon	Name	Description
	View Data	Displays the Quality Control (Data View) screen
	Next Point	Displays the next control result in the file one result at a time
	Previous Point	Displays the previous control result in the file one result at a time
	Exit	Exits the expanded parameter graph

Viewing the Details for a Control Run

1 Select  .

2 Highlight a run and select  .

3 Review the information on the QC Run Details screen:

Field	Description
Lot #	Identification number for the control
File	File number (1 to 12) for a selected control file
Source	Source or type of control (BEC/Other)
Expiration Date	Expiration date for the selected control file
Level	Level of the control material for the selected file (Abnormal Low, Normal, Abnormal High)
Run Date/Time	Date and time analysis completed for the selected specimen
Operator ID	Operator who was logged in when the control was processed
Sequence	Sequence number for the selected control run. *Cycle Sequence* includes all cycle runs (WB, Daily Check, QC, etc.) and it increments by one every time a cycle is run.
Comments	Comments (when entered) for the selected control result
Parameter Results	Parameter results
5PD WBC Scatter Plot	An enlarged 5PD WBC diff plot when selected
RBC Histogram	An enlarged RBC histogram when selected
Platelet Histogram	An enlarged view of the PLT histogram when selected
Flags and Messages	An enlarged view of the flags and messages when selected

4 Scroll as necessary to view the other runs in the control file.

Transmitting Control Files

1 Select  .

2 Select the **Lot #** from the drop-down list.

3 Select  >  .

NOTE If you have set up auto-transmit for the control files, the results are automatically transmitted when the control analysis is complete. See Setting Up and Editing Controls in CHAPTER 9, Setup.

4 From the warning window, select **Selected Result** or **All Results in File**.

5 Select  when prompted to confirm your selection.

Printing Control Files

1 Select  .

2 Select the **Lot #** from the drop-down list.

3 Select  >  .

NOTE If you have set up auto-print for the control files, the results are automatically printed when the control analysis is complete. See Setting Up and Editing Controls in CHAPTER 9, Setup.

4 From the warning window, select one of the following:

- **Selected Result**
- **All Results with Graphs**
- **All Results**

5 Select  when prompted to confirm your selection.

Exporting Control Files

1 Insert a USB flash drive into the USB port in front of the instrument.

2 Select  .

3 Select the **Lot #** from the drop-down list.

4 Select  >  .

5 From the warning window, select **Selected Result** or **All Results in File.**

6 Select  when prompted to confirm your selection.

7 Remove the USB flash drive from the USB port.

Deleting Control Files

You can delete control file records from the Quality Control (Data View) screen.

1 Select  .

2 Select the **Lot #** from the drop-down list.

⚠ CAUTION

Risk of loss of information. When control file data is deleted, it cannot be recovered. Beckman Coulter recommends that you save a copy of your control file data either electronically or as a hardcopy printout. Submit your data to IQAP before deleting any control file data.

3 Select  .

4 From the warning window, select  to delete all of the results for the selected file.

5 Select  >  , highlight the existing control file line, and select  >  to delete the control file.

Reviewing XB Analysis

Review XB analysis results from the Quality Control (Data View) screen. If the batch mean is not within the XB limits configured for the test, the batch is considered out and is indicated by  on the main menu and  on the Quality Control (Data View) screen. The error indicator is removed when  is selected on the XB Batch Means screen.

Reviewing the XB Batch Means Screen

The XB Batch Means screen combines statistics data and thumbnail Levey-Jennings graphs for MCV, MCH, and MCHC for all completed XB batches. Out-of-range batch means and percent differences for MCV, MCH, and MCHC are displayed in red.

The currently accumulating batch is displayed as the top row. The screen displays the following limited data until the batch is complete:

- Batch Number
- N
- Start Date/Time

1 Select  >  .

2 Review the results.

3 Select the applicable button to review that information or complete an action:

Icon	Name	Description
	Graphs	Displays the QC graphs for the XB batch means
	Details	Displays the XB batch details for the selected batch
	Delete	Deletes the XB batch results. See Deleting an XB Batch.
	Accept XB	Active only when an XB batch is out. Displays a warning message to accept XB out conditions. See Reviewing XB Analysis.

Reviewing the XB Batch Details Screen

The XB Batch Details screen displays the results for the specimens accumulated into a batch and used in the determination of the XB Batch Means. Batch means and percent differences are not available until a batch is complete. If the batch mean and percent differences are outside limits, values are displayed in red.

1 Select  >  .

2 Highlight the desired batch and select  .

NOTE To exclude a run from the statistical calculations, select **Exclude**. A maximum of five runs can be excluded from each batch.

Viewing XB Batch Means Graphs

The XB batch means screen provides a Levey-Jennings style graph data plot for MCV, MCH, and MCHC for each of the group's last 20 batch means. The target value for each parameter is shown as a blue line. The high and low limits are shown as red lines.

1 Select  >  .

2 Highlight the desired batch and select  >  .

The most recent batch is plotted on the right-most side of each graph as follows:

- Points within range are displayed as solid black circles.
- Points above or below the limits are displayed as solid red triangles.
- A point with the vertical indicator displays the batch selected with the *Summary* field values displayed. It can be moved using the arrows.

3 Select the applicable icon to review that information or complete an action:

Icon	Name	Description
	View Data	Displays the XB Batch Means screen
	Next Point	Displays the next batch mean data point
	Previous Point	Displays the previous batch mean data point
	Delete	Deletes the XB batch means results for: • Selected Batch • All Batches

Printing XB Batch Reports

Follow these steps to manually print XB batch reports. To set up automatic printing, see Setting Up XB in CHAPTER 9, Setup.

1 Select  >  .

2 Select  >  .

3 From the warning window, select one of the following:

- **As Table**
- **As Graphs**
- **Both Table and Graphs**

4 Select  to confirm your selection.

Exporting XB Results

1 Insert a USB flash drive into the USB port in front of the instrument.

2 Select  >  .

3 Select  >  .

4 From the warning window, select **Selected Batch** or **All Batches**.

5 Select  to confirm your selection.

6 Remove the USB flash drive from the USB port.

Deleting an XB Batch

1 Select  >  .

2 From the XB Batch Means screen, select  .

3 From the warning window, select one of the following:

- **Current Batch (batch in progress)**
- **Selected Batch**
- **All Batches**

4 Select  to confirm your selection.

Reviewing XM Analysis

Review XM analysis results from the Quality Control (Data View) screen. If the batch mean is not within the XM limits configured for the test, the batch is considered out and is indicated by  on the main menu and  on the Quality Control (Data View) screen. The error indicator is removed when  is selected on the XM Batch Means screen.

Reviewing the XM Batch Means Screen

The XM data is displayed in groups of either CBC or Diff parameters.

The currently accumulating batch is displayed as the top row. The screen displays the following limited data until the batch is complete:

- Batch Number
- N
- Start Date/Time

1 Select  >  .

2 Select **CBC** or **DIFF** from the drop-down list and review the results.

3 Select the applicable button to review that information or complete an action:

Icon	Name	Description
	Graphs	Displays the QC graphs for the XM batch means
	Details	Displays the XM batch details for the selected batch
	Delete	Deletes the XM batch results. See Deleting an XM Batch.
	Accept XM	Active only if an XM batch is out. Displays a warning message to accept XM out conditions. See Reviewing XM Analysis.

Reviewing the XM Batch Details Screen

The XM Batch Details screen displays the results for the specimens accumulated into a batch and used in the determination of the XM Batch Means. See Reviewing XM Analysis.

1 Select  >  .

2 Select **CBC** or **DIFF** from the drop-down list.

3 Highlight the desired batch and select  .

Viewing XM Batch Means Graphs

The XM batch means screen provides a Levey-Jennings style graph data plot for each of the group's last 20 batch means. The target value for each parameter is shown as a blue line. The high and low limits are shown as red lines.

1 Select  >  .

2 Select **CBC** or **DIFF** from the drop-down list.

3 Highlight the desired batch and select  .

NOTE To view the XM Batch Means Details screen, select  .

Points

The most recent batch is plotted on the right-most side of each graph as follows:

- Points within range are displayed as solid black circles.
- Points above or below the limits are displayed as solid red triangles.
- A point with the vertical indicator displays the batch start and end dates.

View an Expanded XM Batch Means Graph

1 Select the applicable parameter graph from the multiple graphs on the XM Batch Means Graphs screen.

2 Display the expanded graph view and summary.

3 Select the applicable icon to review that information or complete an action:

Icon	Name	Description
	View Data	Displays the XM Batch Means screen
	Next Point	Displays the next batch mean data point one result at a time
	Previous Point	Displays the previous batch mean data point one result at a time
	Exit	Exits the expanded parameter graph

Printing XM Batch Reports

Follow these steps to manually print XM batch reports. To set up automatic printing, see Setting Up XM in CHAPTER 9, Setup.

1 Select  >  .

2 Select  >  .

3 From the warning window, select one of the following:

- **As Table**
- **As Graphs**
- **Both Table and Graphs**

4 Select  to confirm your selection.

Exporting XM Results

1 Insert a USB flash drive into the USB port in front of the instrument.

2 Select  >  .

3 Select  >  .

4 From the warning window, select **Selected Batch** or **All Batches**.

5 Select  to confirm your selection.

6 Remove the USB flash drive from the USB port.

Deleting an XM Batch

1 Select  >  .

2 From the XM Batch Means screen, select  .

3 From the warning window, select one of the following:

- **Current Batch** (batch in progress)
- **Selected Batch**
- **All Batches**

4 Select  to confirm your selection.

Downloading to IQAP

1 Ensure that your IQAP participant number has been entered correctly. See Setting Up IQAP Information in CHAPTER 9, Setup.

2 Ensure that you have reviewed the control files, the number of runs, the mean, and 2SD. Verify that the correct control was analyzed in the correct file. See Viewing Control Files.

3 Print the control file, if necessary. See Printing Control Files.

4 Insert the USB flash drive into the USB port on the instrument.

5 Select  > 

.

6 Select the files to download and select  .

7 Select  to download the files.

8 When the download is complete, remove the USB flash drive.

CHAPTER 5

Sample Analysis

Specimen Collection

Collect whole blood in EDTA according to the tube manufacturer's instructions and procedures in *CLSI GP41-A6*[25] for venipuncture and *CLSI GP42-A6*[26] for capillary. Properly inspect all collection devices before use. Follow the recommendations for storage and mixing shown in Sample Stability and Storage - Whole Blood in CHAPTER 1, System Overview.

You are ready to run samples when you have selected the correct analysis mode and verified the sample identification.

⚠ CAUTION

Risk of erroneous results. Running a blood sample in an incorrect analysis mode can cause erroneous results. Run a whole-blood sample only in the whole-blood mode. Run a predilute sample only in the predilute mode.

⚠ CAUTION

Risk of erroneous results. Follow the tube manufacturer's recommended procedure for the correct specimen collection.

⚠ CAUTION

Risk of erroneous results. Use of non-recommended anticoagulants may yield erroneous results.

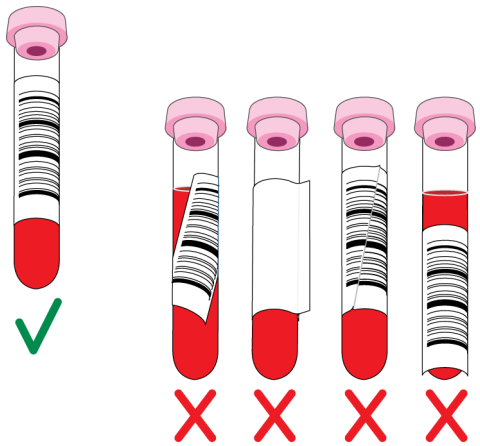
Affixing a Bar-Code Label to a Tube

⚠ CAUTION

Risk of erroneous results. The use of poor quality, dirty, improperly placed, and incompatible or damaged bar-code labels adversely impacts the bar-code scanner’s performance. Do not use long labels and do not cover the bottom of a tube with a label. Do not use more than two labels on a tube.

The correct placement of the bar-code label on the tube allows the bar-code scanner to read the information correctly. Affix a bar-code label to the tube as shown in the following figure.

Figure 5.1 Correct/Incorrect Label Placement on Tube



Identifying Patient Samples

⚠ CAUTION

Risk of misidentification. Do not start the auto-incrementing feature at the same point as previously set.

⚠ CAUTION

Risk of misidentification. Do not use the characters % # @ [\ ] ` { | } ~ ? “ * in demographics, including Specimen or Patient ID. Do not use spaces in the leading or trailing position of a Specimen or Patient ID.

The Specimen ID and the Patient ID are not case-sensitive. For example, Specimen ID *abcd* will match a test order with Specimen ID *ABCD*.

All specimens require a valid specimen ID:

- A specimen ID can be manually entered using the on-screen keyboard, by scanning the bar-code label of a specimen, or by using the auto-incrementing feature. See Setting Up Next Specimen in CHAPTER 9, Setup. If the specimen ID is not entered and the auto-incrementing feature is not enabled, the system automatically assigns an instrument-generated auto-sequence number (AutoSID).
- A specimen ID must be 1 to 16 characters in length, consist of ASCII-printable characters, and must not have two or more consecutive spaces between characters.

Creating a Worklist

Patient information and specimen IDs can be added to a worklist. The information is either downloaded from the Host LIS system or you can manually enter the information into the worklist. To add manual entries, see Setting Up a Test Order in CHAPTER 7, Worklist.

Using the Handheld Bar-Code Scanner

⚠ CAUTION

Risk of sample misidentification. When using the handheld bar-code scanner, occasional misread errors can occur as a result of partial label scans and damaged or misapplied labels. Beckman Coulter recommends that you verify each bar-code reading to ensure correct patient identification.

1 Aim the bar-code scanner at the bar-code label and squeeze the trigger.

2 Verify that the information displayed is in the correct field and matches the information on the label.

Running Sample Analysis

⚠ WARNING

Risk of injury and/or biohazardous contamination:

- **Risk of exposure to biohazardous material if the contents spill out of the tube. Use caution when handling the tube and hold it securely under the probe.**
- **Failure to properly shield yourself while using or servicing the instrument can result in injury and/or contamination. To prevent possible injury and/or biological contamination, you must wear proper laboratory attire, including gloves, a laboratory coat, and eye protection.**
- **Operating the instrument with a full waste container can result in biological contamination due to spillage. To prevent biological contamination, replace the waste container and reset the waste management counter before operating the instrument. See Setting Up or Replacing Waste Disposal in CHAPTER 9, Setup.**
- **Operating the instrument with open covers and doors can cause injury. When you operate the instrument, ensure that all covers and doors are closed.**
- **Operating the instrument with a loose or bent probe can cause injury. If the probe is loose or bent, do not run the instrument. See Replacing the Aspiration Probe in CHAPTER 13, Replacement/Adjustment Procedures for information on how to replace the probe prior to analysis.**

NOTE If the instrument loses power while analyzing a sample, the results are lost. Repeat the sample analysis.

Running Whole-Blood Samples

Beckman Coulter recommends that:

- You analyze samples within the operational temperature specifications.
- If flags appear, see Flags in CHAPTER 6, Data Review. As with any analysis method in which a specimen of suspect quality is used, pay particular attention to the results. Review and verify the accuracy of all flagged results that exceed your laboratory's action limit.

IMPORTANT Specimens that may contain fibrin, cell fragments, or other debris, or have been difficult to collect such as pediatric or oncology specimens may require special handling.

⚠ CAUTION

Risk of erroneous results. The presence of fibrin strands can cause erroneous results. You must thoroughly inspect the sample for fibrin strands or clots.

⚠ CAUTION

Risk of erroneous results. Mix the sample properly according to your laboratory protocol and tube manufacturer before analysis. To allow for proper mixing, do not overfill the sample tube.

---

1 Select  .

⚠ CAUTION

Risk of misidentification. Verify the Specimen ID in the worklist if the worklist contains entries. Confirm that the Next Specimen ID is correct before the processing specimen message is displayed.

2 Note the following:

- If the worklist does not have any entries, the probe is extended.
- If the worklist contains entries, the system displays a warning message. Verify that the *Next Specimen ID* on the bottom right side of the screen is correct and select  . The probe is extended.

---

3 Identify a sample using one of the following methods:

- If the *Next Specimen ID* is correct, verify that  and go to the next step.

- If the *Next Specimen ID* is not correct or entered, scan the specimen tube's bar code and verify that  is selected.
- Select  , use the on-screen keyboard to enter the Specimen ID and Test (**CD** or **CBC**), and verify that the Specimen is *WB*. Select  when prompted to confirm your selection (the probe is extended).

NOTE A valid specimen ID must be entered to analyze a specimen. If you have set up auto-incrementing, the *Specimen ID* field will be automatically populated. If no Specimen ID exists, the system assigns an AutoSID.

⚠ WARNING

Risk of injury and/or biohazardous contamination. Operating the instrument with open covers and doors can cause injury. When you operate the instrument, ensure that all covers and doors are closed.

⚠ WARNING

Risk of injury and/or biohazardous contamination. Operating the instrument with a loose or bent probe can cause injury. If the probe is loose or bent, do not run the instrument. See Replacing the Aspiration Probe in CHAPTER 13, Replacement/Adjustment Procedures for information on how to replace the probe prior to analysis.

⚠ WARNING

Risk of injury and/or exposure to biohazardous material if the contents spill out of the tube. Use caution when handling the tube.

4 Mix the whole-blood sample.

5 Carefully remove the cap from the tube.

6 Clean any residual blood from the rim of the tube prior to sample presentation.

⚠ WARNING

Risk of injury and/or biohazardous contamination. To avoid being pierced by the aspiration probe, use caution when presenting samples for analysis during this procedure.

⚠ CAUTION

Risk of erroneous results if the tube is removed while the system is aspirating. Do not remove the tube until the probe retracts.

7 Fully immerse the probe into the tube.

8 Press the aspiration plate while holding the tube in place during aspiration. The status LED flashes red during aspiration indicating that the sample aspiration is in progress.

9 Remove the tube from the probe when the status LED turns solid red and the probe has retracted. A message is displayed on the bottom left of the screen indicating that the Specimen ID is being analyzed.

10 Recap the tube.

11 Wait for the instrument to process the sample and display the results. The status LED turns green.

12 Transmit or print the patient results:

- To transmit, select  >  or see Transmitting Patient Results in CHAPTER 6, Data Review.
- To print, select  >  or see Printing Patient Results in CHAPTER 6, Data Review.
- To set up auto-transmit and/or auto-print, see Setting Up LIS and Setting Up Printer Options in CHAPTER 9, Setup. If you have already set up auto-transmit and/or auto-print, the data is automatically transmitted and/or printed.

Running Prediluted-Blood Samples

The predilute panel on the DxH 500 offers an alternative sample preparation method for samples that cannot be directly aspirated in a whole-blood mode or for times when very little blood volume is available through collection. The predilute panel is not intended for obtaining results that exceed the upper limit of the analytical measuring range.

The predilute panel accepts a 1:16 dilution, prepared by mixing 20 µL of whole blood with 300 µL of diluent. The diluted sample is analyzed using the predilute mode. The instrument reports the final results and no correction is required.

IMPORTANT Prediluted samples require analysis in the predilute mode and must be analyzed within 15 minutes after preparation.

⚠ CAUTION

Risk of erroneous results. Mix the sample properly according to your laboratory protocol and tube manufacturer before analysis. To allow for proper mixing, do not overfill the sample tube.

1 Ensure that the sample tube volume exceeds 300 µL to allow enough room for mixing the blood/diluent solution.

2 Dispense the diluent as described in Diluent Dispense in CHAPTER 10, Troubleshooting.

3 Dispense 20 µL of blood into the same tube where the diluent was dispensed.

4 Mix the blood/diluent solution.

5 Select  .

⚠ CAUTION

Risk of misidentification. Verify the Specimen ID in the worklist if the worklist contains entries. Confirm that the Next Specimen ID is correct before the processing specimen message is displayed.

6 Note the following:

- If the worklist does not have any entries, the probe is extended.

- If the worklist contains entries, the system displays a warning message. Verify that the *Next Specimen ID* on the bottom right side of the screen is correct and select  . The probe is extended.

---

7 Identify a sample using one of the following methods:

- If the *Next Specimen ID* is correct, verify that  is selected and go to the next step.
- If the *Next Specimen ID* is not correct, scan the specimen tube's bar code, select  >  to accept the specimen to be processed in pre-dilute mode.
- Select  , use the on-screen keyboard to enter the Specimen ID and Test (**CD** or **CBC**), verify that the Specimen is *PD*, and select  when prompted to confirm your selection (the probe is extended).

NOTE A valid specimen ID must be entered to analyze a specimen. If you have set up auto-incrementing, the *Specimen ID* field will be automatically populated. If no Specimen ID exists, the system assigns an AutoSID.

⚠ WARNING

Risk of injury and/or biohazardous contamination. Operating the instrument with open covers and doors can cause injury. When you operate the instrument, ensure that all covers and doors are closed.

⚠ WARNING

Risk of injury and/or biohazardous contamination. Operating the instrument with a loose or bent probe can cause injury. If the probe is loose or bent, do not run the instrument. See Replacing the Aspiration Probe in CHAPTER 13, Replacement/Adjustment Procedures for information on how to replace the probe prior to analysis.

⚠ WARNING

Risk of injury and/or exposure to biohazardous material if the contents spill out of the tube. Use caution when handling the tube and hold it securely under the probe.

⚠ WARNING

Risk of injury and/or biohazardous contamination. To avoid being pierced by the aspiration probe, use caution when presenting samples for analysis during this procedure.

8 Fully immerse the probe into the tube.

⚠ CAUTION

Risk of erroneous results if the tube is removed while the system is aspirating. Do not remove the tube until the probe retracts.

9 Press the aspiration plate while holding the tube in place during aspiration. The status LED flashes red while the sample aspiration is in progress. A message is displayed on the bottom left of the screen indicating that the Specimen ID is being analyzed.

10 Remove the tube from the probe when the status LED turns solid red and the probe is fully retracted.

11 Wait for the instrument to process the sample and display the results. The LED status turns green.

12 Transmit or print the patient results:

- To transmit, select  >  or see Transmitting Patient Results in CHAPTER 6, Data Review.
- To print, select  >  or see Printing Patient Results in CHAPTER 6, Data Review.
- To set up auto-transmit and/or auto-print, see Setting Up LIS and Setting Up Printer Options in CHAPTER 9, Setup. If you have already set up auto-transmit and/or auto-print, the data is automatically transmitted and/or printed.

CHAPTER 6

Data Review

Patient Results

⚠ CAUTION

Risk of erroneous results. The instrument provides default reference ranges. Reference ranges control the low (l) and high (h) flagging of results. Beckman Coulter recommends that the laboratory verify or establish, and then configure reference ranges specific to your patient population.

⚠ CAUTION

Risk of erroneous results. Beckman Coulter does not claim to identify every abnormality in all samples and suggests using all available flagging options to optimize the sensitivity of instrument results. The options include definitive messages, system messages, parameter flags and codes, and reference interval (h/l) and action limits (H/L) flags. Beckman Coulter recommends avoiding the use of single messages or outputs to summarize specimen results or patient conditions. There may be situations where the presence of a rare event may fail to trigger a system message.

⚠ CAUTION

Risk of erroneous results. Flags, codes, and messages are evaluated when the sample is analyzed. Review the results and pay close attention to any flags, codes, or messages that are intended to alert you to issues with results or with the instrument. Look for data patterns when examining flags, codes, and messages. Determine if individual or sets of results (for example, WBC and differential results) exhibit flags, codes, and messages. Some flagging occurs as a result of the flagging or editing of other parameters. In all cases, follow your laboratory's policy for reviewing results.

Flags

IMPORTANT Beckman Coulter recommends that you review all flags according to your laboratory's protocol before reporting any results.

Flags appear to the right of the parameter result. Flagging occurs as a result of the flagging limits, system messages, or editing of parameters. When flagging limits change, flags are not re-evaluated for results that are already in the database.

The flags in the following table are listed from highest to lowest priority. The columns indicate the three positions where flags appear. It is possible to have flags in all or each of the three positions.

Table 6.1 Flags and Positions

Flag and Position			Description
1	**2**	**3**	
E			Manual edit of a primary parameter
e			Automatic edit of a calculated parameter
+			Result is above the analytical measuring range high limit
-			Result is below the analytical measuring range low limit
	R		Review results
	*		Hemoglobin and Hematocrit (H&H) check failure (HCT - 3) < (HGB*3) < (HCT + 3)
		H	• Patient results above the action limit • Control results above the expected range
		L	• Patient results below the action limit • Control results below the expected range
		h	Patient results above the reference interval, but less than the action limit (H)
		l	Patient results below the reference interval, but less than the action limit (L)

Codes

Codes are non-numeric characters that appear in place of values when the system cannot generate results.

IMPORTANT Beckman Coulter recommends that you review all codes according to your laboratory's protocol.

The codes in the following table are listed from highest to lowest priority.

Table 6.2 Codes

Code	Description
-----	Total vote out (dashes). Inconsistent data between count periods.
.....	Incomplete computation (dots). Data cannot be derived.
+++++	Above operating range (plus signs)
?????	Result is outside the range of values that can be formatted for display (question marks)

Messages Displayed

Messages are divided into two categories:

- Specimen/System-generated
- Operator-defined

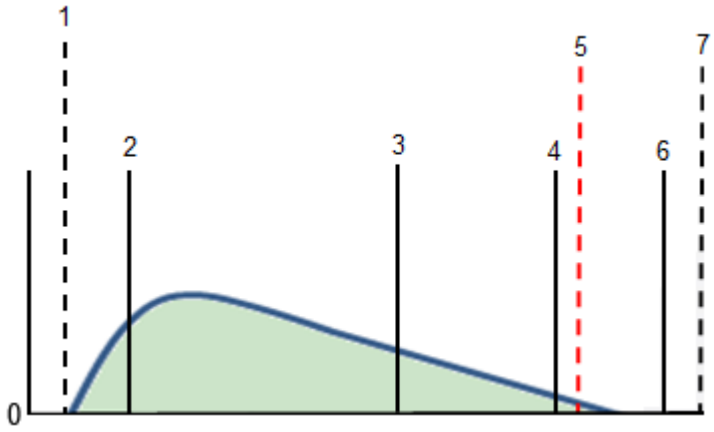
Messages are displayed in the *Flags & Messages* box on the screen and in printouts, and may be accompanied by flags or codes.

IMPORTANT Beckman Coulter recommends that you review and handle all messages according to your laboratory's protocol.

PLT Histogram Threshold Limits

The PLT histogram has four fixed thresholds (CP1, CP2, CP3, and CP3-2) and one variable threshold (P) that moves based on the presence of interference. When threshold limits are surpassed, specific messages are displayed. See Table 6.3, Messages for more information.

Figure 6.1 PLT Histogram Threshold Limits



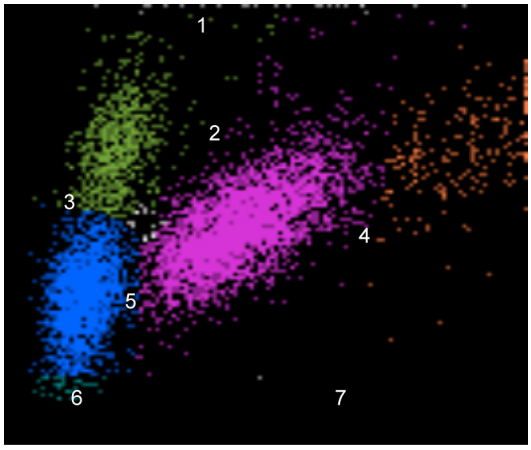
Number	Threshold	Approximate Volume (fL)
1	Minimum PLT	2.0
2	CP1	5.0
3	CP2	18.0
4	P	27.0 *
5	Minimum RBC	28.0
6	CP3	32.0
7	Maximum PLT/CP3-2	34.0

*Variable threshold

Differential Scatter Plot Flagging Areas

Populations that are normally separated generate flags or messages when internal criteria for separation is exceeded. The following figure is a normal population with good separation. Depending on the region of the scatter plot, the presence of too many particles or an unclear separation between populations will trigger a message that informs you of the need to review the differential.

Figure 6.2 Differential Scatter Plot Flagging Regions



Number	Flagging Region	Message
1	Large Immature Cell	Large Cells
2	MN (Monocyte/Neutrophil)	MO/NE Overlap
3	LM (Lymphocyte/Monocyte)	LY/MO Overlap
4	NE (Neutrophil/Eosinophil)	NE/EO Overlap
5	NL (Neutrophil/Lymphocyte)	NE/LY Overlap
6	LLYM (Lower Lymphocyte)	Cellular Interference
7	Debris	Debris

Messages

Messages are displayed in the *Flags & Messages* box under the *Flags* or *System* subtitle on the Sample Analysis-Patient Results screen. Messages are generated when specimen results meet certain conditions or an event occurs that may affect the operation of the system, the quality of results, or when operator intervention is required. Messages may be accompanied by *R* (Review) flags, other flags, or codes.

Table 6.3 Messages

Message	Parameter/Flag	Description
BA Interference	Diff% R, Diff# R	Cannot calculate BA. A non-numeric result (.....) appears for BA and BA#. Multiple populations are overlapped for monocyte, neutrophil, and lymphocyte regions (NL, LM, MN). Abnormal diff appears with this message when a CD is ordered.
Background Failed	All Results R	Specimen processed after Background has failed.
Cellular Interference	WBC R, Diff% R, Diff# R, PLT R	Poor separation between WBC populations and interference below the lymphocytes area. Abnormal Diff appears with this message when a CD is ordered.
Daily Checks Failed	All Results R	Specimen processed after Daily Checks has failed.
Debris	None	Too many events in the Debris area.
Dimorphic RBC	RDW R, RDW-SD R	Evidence of the presence of at least two populations of red cells.
Expired Cleaner	All Results R	Specimen processed with expired Cleaner.
Expired Diluent	All Results R	Specimen processed with expired Diluent.
Expired Lyse	All Results R	Specimen processed with expired Lyse.
H&H Check Failed	HGB *, HCT *, MCH *, MCHC *, RDW *, RDW-SD *	The ratio of HGB to HCT is not in the expected range.
HGB Blank Error	HGB ..... , HCT ..... , MCH ..... , MCHC ..... , RDW ..... , RDW-SD	HGB blank reading exceeds the internal threshold limits.
HGB Out or Range Error	HGB....., HCT....., MCH*, MCHC*, RDW*, RDW-SD*	HGB calculation is not within internal range.
Instrument Temperature Out of Range	All Results R	Specimen processed when the instrument temperature is not within specifications.
Large Cells	Diff% R, Diff# R	High number of events in the Large Immature Cell area. Abnormal Diff appears with this message when a CD is ordered.
Low Diff Events	Diff% R, Diff# R	The scatter plot total number of cells is less than 500.
LY/MO Overlap	Diff% R, Diff# R	Lymphocyte and Monocyte populations are overlapped in the LY/MO threshold area. Abnormal Diff appears with this message when a CD is ordered.
MO/NE Overlap	Diff% R, Diff# R	Monocyte and Neutrophil populations are overlapped in the MO/NE threshold area. Abnormal Diff appears with this message when a CD is ordered.
NE/LY Overlap	Diff% R, Diff# R	Neutrophil and Lymphocyte populations are overlapped in the NE/LY threshold area. Abnormal Diff appears with this message when a CD is ordered.
NE/EO Overlap	Diff% R, Diff# R	Neutrophil and Eosinophil populations are overlapped in the NE/EO threshold area. Abnormal Diff appears with this message when a CD is ordered.
Optical Adjust Failed	Diff% ..... , Diff#	Optical LED adjust failed (out of range 27,500 ± 3%).
Optical LED Mean Error	WBC ..... , Diff% ..... , Diff#	Axial Light Loss mean is less than the defined limit.

Table 6.3 Messages *(Continued)*

Message	Parameter/Flag	Description
Optical LED Value Error	WBC	Axial Light Loss value for at least one count period is lower than the default limit.
PLT1:Debris	PLT R, MPV R	Interference with smaller platelets. Interference at the left side of the PLT histogram is between channel 0 and the CP1 threshold.
PLT2:Debris	PLT R, MPV R	Interference with larger platelets. Interference is at the right side of the PLT histogram between the CP2 and P thresholds.
PLT3:PLT/RBC Overlap	PLT R, MPV R	PLT and RBC populations are overlapped between the CP3 and CP3-2 thresholds.
PLT Carryover	PLT R, MPV R	The estimated PLT carryover, based on the PLT value from the preceding sample and the expected PLT carryover percent, may significantly affect the PLT results for the current specimen. Repeat the specimen run.
RBC Aggregates	RBC R, MCH R, RDW R, RDW-SD R	MCH, RDW, and RDW-SD all exceed threshold limits (MCH > 37.0 pg, RDW > 27.0%, and RDW-SD > 70.0 fL).
Suspect Diff	None	Pattern varies from a normal differential. Suspect Diff appears when Abnormal Diff is present.
WBC/Diff Carryover	WBC R, Diff% R, Diff# R	The estimated WBC carryover, based on the WBC value from the preceding sample and the expected WBC carryover percent, may significantly affect the WBC results for the current specimen.

Definitive Messages

Definitive messages are displayed in the *Flags & Messages* box under the *Messages* subtitle. Definitive messages appear based on limits you have selected as reference intervals or action limits.

Table 6.4 Definitive Messages

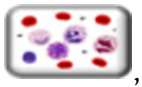
Definitive Message	Description
Anemia	Low RBC and/or Low HGB
Anisocytosis	High RDW
Basophilia	High BA and/or #
Eosinophilia	High EO and/or #
Erythrocytosis	High RBC
Hypochromia	Low MCH
Large Platelets	High MPV
Leukocytosis	High WBC
Leukopenia	Low WBC
Lymphocytosis	High LY and/or #
Lymphopenia	Low LY and/or #

Table 6.4 Definitive Messages *(Continued)*

Definitive Message	Description
Macrocytosis	High MCV
Microcytosis	Low MCV
Monocytosis	High MO and/or #
Neutropenia	Low NE and/or #
Neutrophilia	High NE and/or #
Small Platelets	Low MPV
Thrombocytopenia	Low PLT
Thrombocytosis	High PLT

Reviewing Patient Results

1 Select  to go to the Patient Results screen.

2 Select the applicable icon to view the results for that parameter:  , CBC, WBC DIFF, or RBC PLT.

3 Select the applicable icon to review that information or to complete an action:

Icon	Name	Description
	Search	Displays a screen where you can enter criteria to search the database for a specific sample. See Searching for Patient Results.
	Display	Displays the individual results and graphics for the selected sample. See Displaying Patient Results.
	Rerun	Places the Specimen ID onto the worklist to allow the specimen to be rerun without having to re-enter the specimen information. See Rerunning Patient Samples.
	Edit	Lets you edit the selected sample. See Editing Patient Results.

	Unmatched Results	Displays the Unmatched Patient Results screen where results from an instrument-generated, auto-sequenced SID can be assigned to the proper SID. See Matching Specimen ID (SID) in CHAPTER 7, Worklist.
	Delete	Deletes the selected specimen results. See Deleting Patient Results.

Searching for Patient Results

1 Select  >  .

2 Use the on-screen keyboard to enter information and/or use the drop-down lists to search for patient results by:

- Specimen ID
- Patient ID
- Last Name
- First Name
- Date of Analysis (From [date], To [date])
- Sequence (From [number], (To [number]) - Cycle Sequence includes all cycle runs (WB, Daily Checks, QC, etc.) and it increments by one every time a cycle is run.
- Specimen (All, WB or PD)
- Test (All, CBC, or CD)
- Flags:
  - Any Flags - All patient results with a flag, code, or message
  - No Flags - All patient results with no flags, codes, or messages
  - Non-Parameter Value - All patient results with a code
  - Parameter Flag - All patient results with a flag
  - Outside Reference - All patient results with a parameter outside of the reference limits
  - Outside Action - All patient results with a parameter outside of the action limits

3 Select  to confirm your selection.

Displaying Patient Results

1 Select  .

2 Highlight the desired Specimen ID and select  .

3 Scroll as necessary to display other patient results.

Rerunning Patient Samples

1 Select  .

2 Highlight the desired Specimen ID and select  .

3 Select  when prompted. The probe descends.

4 Prepare and process the sample. See Running Sample Analysis in CHAPTER 5, Sample Analysis.

Editing Patient Results

1 Select  .

2 Highlight the desired specimen ID and select  .

3 From the Edit Samples screen, select **Results** or **Demographics**.

4 Use the on-screen keyboard or drop-down lists to enter changes to demographics or results. Edited results or demographics are flagged with an *E*.

NOTE Specimen ID edits are only allowed on auto-sequenced SIDs.

5 Select  when prompted to save and accept the changes.

Deleting Patient Results

When specimen results information is no longer needed, specimen results can be deleted. This creates room in the database and enables you to access results faster.

1 Select  >  .

2 From the Select Samples window, select **All**, or select **Sequence** and use the on-screen keyboard to enter a number series.

3 Select  .

4 Select  to confirm your selection.

Transmitting Patient Results

1 Select  >  .

2 From the Select Samples window, select **All**, or select **Sequence** and use the on-screen keyboard to enter a number series.

3 Select  .

4 Select  to confirm your selection.

Printing Patient Results

1 Select  >  .

2 From the Select Samples window, select **All**, or select **Sequence** and use the on-screen keyboard to enter a number series.

3 Select  .

4 From the warning window, select **Print in Table Format** or **Print in Report Format**.

5 Select  to confirm your selection.

Exporting Patient Results

1 Insert a USB flash drive into the USB port in front of the instrument.

2 Select  >  .

3 From the Select Samples window, select **All**, or select **Sequence** and use the on-screen keypad to enter a number series.

4 Select  .

5 Select  to confirm your selection.

6 When the export is complete, select  and remove the USB flash drive from the USB port.

Exporting Raw Data Files

The export of raw data files pertains to patient results only and is restricted to the Administrator security access level for troubleshooting purposes.

The res.csv files are deleted every 30 days.

1 Insert a USB flash drive into the USB port in the front of the instrument.

2 Select  >  .

3 From the Select Samples screen, select **All**, or select **Sequence** and use the on-screen keyboard to enter a number series.

4 Select  .

NOTE Exported files are designated by date and time.

5 Select  to export the files.

6 When the export is complete, select  and remove the USB flash drive from the USB port.

CHAPTER 7

Worklist

Worklist Overview

The worklist lets you enter a list of specimens to be processed. The entries on the worklist are sorted in ascending order by Specimen ID with the lowest number displayed at the top of the screen. The information on the worklist can be entered by using the on-screen keyboard or the bar-code scanner, or it can be downloaded from a Laboratory Information System.

As specimens are processed, if any entries exist on the worklist, the *Next Specimen ID* field on the Sample Analysis - Patient Results screen automatically displays the first Specimen ID from the worklist as the next specimen to processed. The Specimen ID is used to match the results to an entry on the worklist.

When there is a match, the specimen being processed is displayed in bold font and the entry cannot be edited or deleted. When the analysis has been completed successfully, the worklist entry is removed and saved with the results. If an error occurs that prevents the cycle from being successfully completed, the worklist entry is not removed.

Setting Up a Test Order

1 Select  .

2 Highlight a blank line and select  .

3 On the Worklist - New Order screen, use the on-screen keyboard to enter the information requested and use the drop-down list to select information, when applicable:

Field	Description
Specimen ID	Identification number assigned to the specimen
Patient ID	Identification number assigned to the patient
Last Name	Patient's last name
First Name	Patient's first name
Date of Birth	Patient's date of birth (entering the date of birth automatically calculates the age)
Age	Patient's age; also select the unit of measure for the age
Gender	Patient's gender
Collection Date/Time	Date and time of the specimen collection
Flagging Set	Type of flagging set to use by age and gender (entering the age or date of birth, and the gender, automatically selects the flagging set)
Physician	Ordering physician's name
Location	Location of the test
Test	Type of test (**CD** or **CBC**)
Specimen	Type of specimen
Comments	Comments about this order

NOTE If auto-incrementing is enabled, Specimen ID displays the value of the next logical auto-incremented ID. If auto-incrementing is disabled, Specimen ID is assigned by the instrument (AutoSID), bar code, or manual entry.

4 Select  to accept the information.

5 Select  to return to the Worklist screen and view orders.

Editing a Test Order

1 Select  .

2 Highlight a test order and select  .

3 On the Worklist screen, use the on-screen keyboard to edit the information:

Field	Description
Specimen ID	Identification number assigned to the specimen
Patient ID	Identification number assigned to the patient
Last Name	Patient's last name
First Name	Patient's first name
Date of Birth	Patient's date of birth
Age	Patient's age
Gender	Patient's gender
Collection Date/Time	Date and time of the specimen collection
Flagging Set	Type of flagging set to use by age and gender
Physician	Ordering physician's name
Test	Type of test
Location	Location of the test
Specimen	Type of specimen
Comments	Comments about this order

4 Select  when prompted to accept the information.

Deleting a Test Order

1 Select  .

2 Highlight a test order and select  .

3 From the warning window, select **Selected Order** or **All Orders**.

NOTE If **All Orders** is selected, all entries on the Worklist are deleted.

4 Select  to confirm your selection.

Matching Specimen ID (SID)

Follow this procedure to match an auto-sequenced SID (formatted as *Auto-SIDxxxxx*) generated by the instrument with a current worklist entry.

1 Select  .

2 Select  to display the unmatched auto-sequenced specimen ID patient results. Scroll through the list as necessary.

3 From the Unmatched Patient Results screen, select the patient result and select  .

4 From the Worklist-Match screen, highlight the worklist entry and select  to match the patient result with the worklist entry.

NOTE To manually add a worklist entry, select  and enter the specimen information. Select  to accept the information. Select  to exit the Worklist-New Order screen and select  to match the worklist entry with the unmatched patient result.

5 Select  when prompted to accept the information. The SID status displays *M* when the specimen has been matched.

CHAPTER 8

Shutdown

Performing a Shutdown

Beckman Coulter recommends performing a shutdown once every 24 hours. Shutdown removes diluent and replaces it with cleaner for 30 minutes. It also checks the expiration date and volume of the reagents. If expired or if the volume is low, the system prompts you to replace the reagent, or to continue and record the expired reagent in the logs.

1 From the main menu, select  .

2 Select  .

3 From the Shutdown dialog box, select one of the following:

- **Power Instrument Down After Shutdown**- this option has the instrument perform a shutdown followed by a power down.
- **Perform Daily Checks After Shutdown**- this option places the instrument in cleaner for 30 minutes plus the duration indicated in the Additional Time in Cleaner followed by Daily Checks.

4 Use the keypad to indicate **Additional Time in Cleaner** (0 minutes to 5 hours) for greater than 30-minute shutdown cycles.

5 Select  .

6 Select  to begin the shutdown.

NOTE The bottom left corner of the screen displays Shutdown and the power button is red when the instrument is in shutdown.

Emergency Stop and Powering Down/Powering Off

The power button and status LED are located on the front of the instrument. See Figure 1.1, DxH 500 Front View in CHAPTER 1, System Overview.

Emergency Stop

An Emergency Stop is activated when you quickly press the power button. It will stop any running cycle. To recover from an emergency stop, see Diluter Reset in CHAPTER 10, Troubleshooting.

⚠ WARNING

Risk of injury and/or biohazardous contamination. If the emergency stop (power button) is pressed when the probe is in the aspirating position, the probe remains exposed. Use caution since the probe is sharp. Perform the Diluter Reset cycle to retract (move up) the probe. See Diluter Reset in CHAPTER 10, Troubleshooting.

Powering Down

A Power Down is activated when you press the power button for a few seconds.

1 From the warning window, select one of the following options:

-  to perform a Shutdown followed by a power down.
-  to power down.

Powering Off

A Power Off is activated when you press and hold the power button.

IMPORTANT A Power Off is not the preferred method for removing power from the instrument. If power needs to be removed from the instrument, perform a Power Down (see Powering Down).

IMPORTANT In the event of a power outage at your facility, the system will stop its operation and all data for the current cycle will be lost. If your system has a printer, ensure that it is connected directly into the facility's power outlet.

CHAPTER 9

Setup

Setting Up the System

The Setup screen displays several options for setting up the system.

Setting Up Security Access

You must have administrator access to perform this function. For information on security access, see Access Levels in APPENDIX A, Access Levels and Reports.

1 Select  >  .

2 On the Security Access Setup screen, select  to add a user OR to edit existing user information, highlight the user, and select  .

3 Use the on-screen keyboard to enter or edit the user information on the screen. The Operator ID must contain two characters and the password must contain six characters.

4 Select  when prompted to accept the information.

NOTE To delete the user information, highlight the user and select  . From the warning window, select  to delete the user.

Setting Up Auto Logout

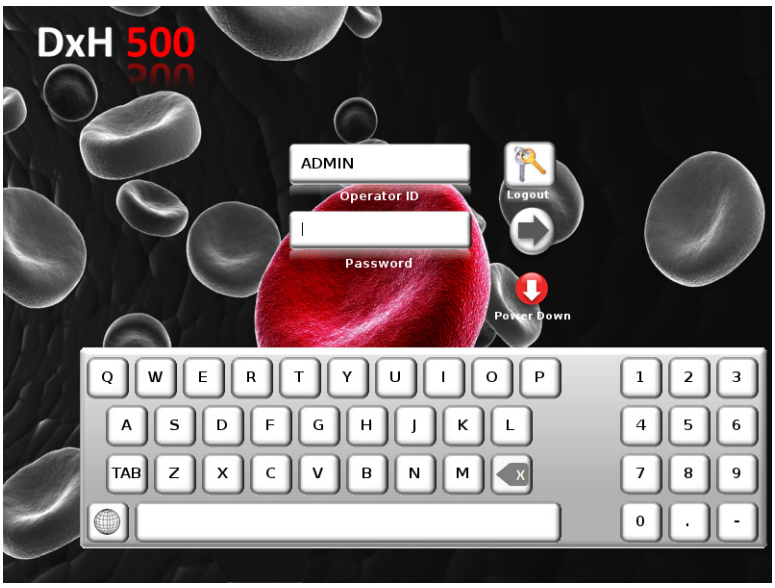
This setup option requires administrator access for setting up the auto-logout time.

1 Select  >  >  .

2 From the Auto Logout dialog box, use the on-screen keypad to enter a time value between 1 and 60 minutes. The default is 60 minutes.

3 Select  when prompted to accept the information.

NOTE If the system is inactive for more than the defined time, you are automatically logged out and the logon screen is displayed as follows:



To log in with a different Operator ID, select  .

Setting Up Date and Time

1 Select  >  .

2 Select a format from the drop-down list in *Date Format*: **MM/DD/YYYY**, **DD/MM/YYYY**, or **YYYY/MM/DD**.

3 Use the on-screen keyboard to enter a date in the *Date* field.

4 Select a format from the drop-down list in *Time Format*: **12 Hr** or **24 Hr**.

5 Use the on-screen keyboard to enter a time in the *Time* field.

6 Select  when prompted to accept the information.

Setting Up Automatic Power Up and Daily Checks, and Frequency of Auto-Clean Cycles

When selected, this setup option can power up the instrument and process Daily Checks automatically. The frequency of auto-clean cycles can also be set.

1 Select  >  .

2 From the Power Up Options screen, use the on-screen keyboard to enter a *Power Up Time* for the instrument to power up if powered off and for Daily Checks to automatically begin.

3 If a 24-hour time format is not used, select a time period from the drop-down list for *AM/PM*: **AM** or **PM**.

4 Select the day(s) of the week for Daily Checks to automatically begin.

NOTE The instrument needs to be in the proper state for the power up and for Daily Checks cycles to occur. For example, if the instrument is already powered on when the programmed power up time is reached, an automatic Daily Checks does not occur.

5 From the Auto Clean Cycle Frequency dialog box, use the on-screen keypad to enter a time value between 25 and 50 cycles.

6 Select  when prompted to accept the information.

Setting Up Next Specimen

This setup option lets you set the default test CBC or CD and enable or disable the Specimen ID from automatically incrementing.

1 Select  >  .

2 On the Next Specimen Setup screen, select an option: **CBC** or **CD**.

3 Select **Auto Incrementing Specimen ID**, if necessary, and specify the number from which the auto-incrementing Specimen ID will begin.

4 Select  when prompted to accept the information.

Setting Up Printer Options

This setup option lets you select the printer, paper size, report format, and automatic printing for patients, Daily Checks, and Quality Assurance.

1 Select  >  with **Printer** under the icon.

2 Select *Patient Report Auto Print* if you want a report to be printed after each sample analysis.

3 Select the **Report Format** from the drop-down list and the type of sample information to be printed. For examples of reports, see Reports in APPENDIX A, Access Levels and Reports.

4 Under *Auto Print*, select the type of quality assurance information to be printed.

5 Select the *Printer* from the drop-down list.

NOTE The printer must already be installed to see it listed in the drop-down list.

6 Select the *Paper Size* from the drop-down list to select a paper size based on the printer's capability.

7 Select  when prompted to accept the information.

⚠ CAUTION

Verify the printer operation by inspecting the printout available at every start-up.

Setting Up Reference Intervals

Reference intervals (displayed as *reference ranges* on the screen) include the high and low limits for normal and action ranges that your administrator sets for your patients.

Reference intervals are used to indicate when a sample result is outside the normal intervals established by your laboratory.

On the Reference Range setup screen, you can set the age ranges for the predefined age- and gender-based reference intervals, define four custom ranges, and set action ranges and reference interval limits for flagging.

When a patient sample is run in the Sample Analysis screen, the system automatically chooses a flagging set based on the age and gender of the patient unless the reference intervals have been manually set. If the age and gender are not defined, the default flagging set is used.

Beckman Coulter recommends that laboratories establish their own intervals based on their current patient population and configure all flagging sets accordingly.

⚠ CAUTION

Risk of erroneous results. Configure reference intervals with action and reference limits before selecting them for analysis to ensure that high, low, and critical results are flagged.

1 Select  > 

.

2 Change the *Age Range Flagging Sets*, as applicable.

3 For *Custom Flagging Sets*, use the on-screen keyboard to enter names and select  to save these names.

4 Select  >  to edit the parameter limits.

5 From the Reference Ranges Setup screen, select the drop-down list to select the flagging set.

6 Use the on-screen keypad to enter values for each parameter.

7 Scroll to access all of the parameters.

8 Select  to save the parameter limits.

NOTE Select  to remove any new settings that were created and return to the flagging sets (7 default and 4 custom ranges), if necessary.

Setting Up Definitive Messages

1 Select  >  >  >  .

2 Select one of the following:

- **None** - to not trigger definitive messages
- **Reference Range Limits** - to assign the applicable definitive message to be triggered when the parameter value is outside the reference range
- **Action Range Limits** - to assign the applicable definitive message to be triggered when the parameter value is outside the action range

3 Select  when prompted to confirm your selection.

Setting Up LIS

If your instrument is connected to a host computer, you can transmit sample results by using this feature.

The host receiver must comply with the ASTM Host Specification for this instrument. See the Host Transmission Manual listed in Related Documents for more information.

1 Select  >  .

2 From the LIS Setup screen, select  to enter the communication settings.

3 Use the on-screen keyboard and drop-down lists to enter the *Ethernet Communication* or *Serial Communication* settings and select  to accept the information.

NOTE If you do not enter any changes and want to return to the LIS Setup screen, select  .

4 Select **Enable Host**, select either **Serial** or **Ethernet**, and enter the Device ID using the on-screen keyboard.

5 Select **Auto Transmit - Patient** and select the type of sample from the options to be automatically transmitted.

6 Select **Transmit DIFF Scatterplot** and/or **Transmit RBC** and **PLT Histogram**.

7 Select  when prompted to confirm your selection.

Performing a Backup or Restore

A backup can save data, setup, and patient (.csv) files to a USB flash drive. A restore can return information such as patient and QC data, logs, and system setup, when selected, to its previous backup state.

On the first log-in of the month, a reminder is displayed if a backup has not been performed within the last 30 days.

⚠ CAUTION

Risk of damage to software. Always scan removable media (USB flash drive) before connecting it to the instrument.

⚠ CAUTION

Risk of loss of results. Back up your files periodically. A restore overwrites the information in the system. Before restoring data to the system, ensure that you have a backup of the current system. Manual backups always overwrite the contents of the backup hard drive.

---

1 Insert the USB flash drive into the USB port on the instrument.

IMPORTANT Backups always overwrite the current content of the USB flash drive.

---

2 Select  >  .

---

3 Back up or restore the information:

- To perform a backup, select the items to back up and select  .

  NOTE If the USB flash drive does not have sufficient space, the backup will not occur.

- To perform a restore, select the items to restore and select 

---

4 Select  when prompted to begin the backup or restore process.

---

5 When the backup or restore process is complete, remove the USB flash drive from the USB port.

---

6 Apply the data restored from the USB:

- Select  to accept the information.
- Power down the instrument. See Powering Down in CHAPTER 8, Shutdown.

- Power ON the instrument to displayed the restored information. See Logging On/Logging Off in CHAPTER 3, Startup and Daily Checks.

Updating the Software

IMPORTANT Perform a backup before updating the software.

1 Select  > 

.

2 Insert the USB flash drive into the USB port on the instrument and select  to confirm that the USB flash drive is in the USB port.

3 Verify that the revision level on the screen matches the label on the USB flash drive and select  to update the software.

⚠ CAUTION

Risk of damage to software. Ensure that you have selected the correct software file to replace the existing software file on the instrument before proceeding.

4 Wait for the system to notify you when the update is completed, select  to complete the software updating process, and the instrument will power OFF.

5 Remove the USB flash drive from the USB port.

6 Power ON the instrument.

7 Verify the software version by selecting  > 

.

Setting Up the Admin Printer

You must have administrator access to perform this function.

This setup option lets you install a new printer, select a default printer, and, if necessary, delete the printing queue, pause printing, or resume printing. See Printer - Optional in CHAPTER 1, System Overview for more information.

Wireless printing capabilities must be disabled and printers should not be connected to the laboratory network. For more information on disabling the wireless setting on the printer, contact your Beckman Coulter Representative.

1. Connect the printer USB cable into any USB port on the back of the instrument.

2. Connect the printer to an electrical outlet.

3. Ensure that the printer is properly connected into the facility's power outlet and power ON the printer.

4. Select  >  (with **Admin Printer** under the icon) to access the Printer Setup screen. The connected printer is displayed on the screen as *Not Installed*.

5. Select the name of the printer to be installed from column 1.

6. Select  to acknowledge the setup.

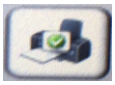
7. Select the correct printer driver from the list.

8. Select  to install the printer. When the setup is complete, the printer displays *Installed*.

9. Set a printer as the default printer by selecting the printer name on the Printer Setup screen and select  .

   NOTE To print a test page, select the printer from the list and select  .

10 Purge the printing queue, if necessary, by selecting the printer and select  .

NOTE To pause the printer, select  . Select  to resume printing.

Supplies

The Supplies screen displays the supplies and amounts available for use. You can select  to view the status of the supplies.

 indicates that supplies are full.

 indicates that a supply has 10 cycles remaining. The instrument can continue processing.

 indicates that a supply has no cycles remaining. The instrument cannot continue processing until you replace the supplies. See Setting Up or Replacing Supplies.

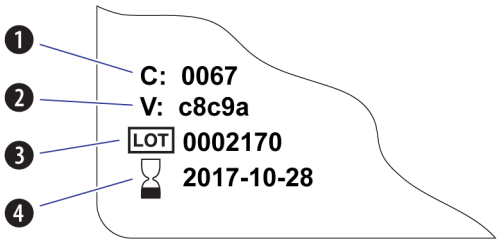
Setting Up or Replacing Supplies

IMPORTANT Follow your laboratory's protocol for recording reagent lot numbers and expiration dates for the new DxH 500 Series reagents.

1 Ensure that you have all of the supplies needed.

2 Select  >  .

3 Use the bar-code scanner to scan the 2D bar code from the supply container and preview it in the Information Preview section. If a bar-code scanner is not connected, select the reagent name by using the drop-down list and enter the related information manually using the values in the following example:



Number	Description
1	Container Number
2	Validation Code
3	Lot Number
4	Expiration Date

4 Select  to accept the information.

5 From the warning window, select **Change another reagent** if you are replacing multiple reagents or select **Prime reagent(s)** when you have completed the replacements, and select  to confirm your selection.

⚠ WARNING

Risk of injury if you have skin contact with the reagent container, its contents, and its associated tubing. The reagent container and its associated tubing must be handled with care. Refer to the Safety Data Sheet for more information. Clean up spills immediately. Ensure that the container is clearly labeled and dispose of its contents in accordance with your local regulations and good laboratory practices. To avoid the risk of spilling reagents, do not place reagent containers on top of the instrument.

⚠ CAUTION

Risk of erroneous results. Ensure that the reagent pickup tubes remain clean and free of contamination. Avoid contact with the interior of the reagent container or its contents, laboratory surfaces, or your gloved hands.

⚠ CAUTION

Risk of erroneous results or damage to equipment. To avoid the risk of erroneous results or damage to the equipment, place the reagent containers at the same level as the instrument. Do not place the reagent containers on top of the instrument nor below the instrument. Store and use the reagents as directed by the reagent's accompanying instructions. Note the expiration dates and open-container stability days of all reagents. Do not use expired reagents. When you change DxH 500 Series Diluent, DxH 500 Series Lyse, or DxH 500 Series Cleaner, be sure to prime the reagent and run a background cycle to see if the results meet the background limits.

---

6 Obtain a new reagent container and transfer the reagent pickup tube into the new reagent container.

⚠ CAUTION

Risk of erroneous results. Ensure the external power supply and other external electrical components are not in contact with the diluent pickup tubing in the back of the instrument.

NOTE The blue sleeve above the cap indicates the Cleaner bottle. The yellow sleeve above the cap indicates the Lyse bottle.

⚠ CAUTION

Risk of erroneous results. Ensure that the reagent(s) is connected before priming.

7 From the warning window, select  when prompted to confirm the replacement. The instrument will prime the reagents.

NOTE To manually prime the reagents, select  to prime all reagents. To prime a single reagent, select **Prime Diluent**, **Prime Lyse**, or **Prime Cleaner**. Select  to confirm your selection.

8 Perform a Background Count. See Running a Background Count in CHAPTER 3, Startup and Daily Checks.

Checking Cycles

The Cycles Counter screen contains information about the number of analytical (WB and PD), Instrument, QA, and Diagnostic cycles the instrument has processed. This is useful for tracking purposes and for aligning the cycle count when cleaning or replacement procedures are needed.

1 Select  .

2 Select  .

3 Review the cycles in each area.

Setting Up and Editing Controls

1 Select  >  .

⚠ CAUTION

Risk of erroneous information. Do not use hyphens when entering lot numbers for Beckman Coulter controls. A hyphen causes the control results to be stored as patient results.

2 Perform one of the following:

- To add a control file, highlight a blank line, select  , and use the bar-code scanner to scan the 2D bar code on the Table of Expected Results. To add the information manually, select  and use the on-screen keyboard (do not use hyphens).
- To edit a control file, highlight the existing control file, select  , and use the on-screen keyboard to edit the information manually.

3 Select **Auto Transmit** to automatically transmit control results to your LIS or **Auto Print** to automatically print control results.

NOTE To delete a control file, see Deleting Control Files in CHAPTER 4, Quality Control.

4 Select  when prompted to confirm your selection.

Setting Up or Replacing Waste Disposal

Waste can be disposed of through an open drain or into a waste container.

⚠ WARNING

Risk of injury and/or biohazardous condition. If the waste line is connected to an open drain instead of a waste container, the waste line must be mechanically secured into the drain so that the tube cannot accidentally come out of the drain. If you are using this method of waste removal, Beckman Coulter recommends that you schedule routine maintenance of the laboratory drain pipes. The waste tubing length must not exceed 1.50 m (5 ft.).

⚠ WARNING

Risk of biohazardous contamination and damage to equipment. Do not replace the waste container while the instrument is cycling. The waste container must be located in a safe place and tubing connection integrity must be verified periodically. Use appropriate barrier protection when performing this procedure. Ensure that the waste container is placed on the lower shelf or on the floor, never at the same level as the instrument.

When the system is configured to use a waste container, the system confirms sufficient empty volume to complete a cycle.

 indicates the waste volume is at 80%. The instrument can continue processing.

 indicates the waste volume is at 90%. The instrument cannot continue processing until you empty the waste container.

The system displays a message when the waste container is full.

---

1 Select  >  .

⚠ WARNING

Risk of injury. Risk of biohazardous contamination if you have skin contact with the waste container, its contents, and its associated tubing. The waste container and its associated tubing might contain residual biological material and must be handled with care. Avoid skin contact and clean up spills immediately. Dispose of the contents of the waste container in accordance with your local regulations and good laboratory practices.

⚠ WARNING

Risk of biohazardous contamination. If you have selected Waste Container for your instrument's waste disposal, you must enter the correct size of the container you are using. The default waste container size is 2,000 mL (0.53 gal). Failure to select the correct waste container size can result in a biohazardous spill or having to replace the container before it is full.

2 From the Waste dialog box, select **External Waste (Drain)** or to set up or replace a waste container, select **Waste Container**. If you select **Waste Container**, enter the waste container's capacity and select  to confirm your selection.

3 Obtain a new waste container and connect the waste tubing to it. If you are replacing a full waste container, place a new waste container next to the full waste container and transfer the tubing from the full waste container to the new waste container.

4 From the warning window, select  for the update to occur.

Setting Up Reports

Follow these procedures to set up report formats.

Setting Up Header Information

1 Select  >  .

2 From the Header Information Setup screen, select a field and enter the header information to be displayed on the reports.

3 Repeat the previous step until you are done with entering the report header information.

4 Select  to accept the information.

5 Select  when prompted to save the information.

Setting Up Report Printing Options

1 Select  >  .

2 From the Report Printing Options screen, select the applicable options under *Option Selections* for Patient Report Format 1 or Patient Report Format 2. See Reports in APPENDIX A, Access Levels and Reports for examples of the reports that are available.

NOTE The report format options selected should match the *Report Format* selected in the printer setup. See Setting Up Printer Options.

3 Select  when prompted to confirm your selection.

Setting Up Parameter Units

The Parameter Units Setup screen lets you set up the format for parameter results.

1 Select  > 
.

2 From the Parameter Units Setup screen, select an option under *Units*.

NOTE Use the up and down arrows to scroll through the list of parameters.

3 Select  when prompted to confirm your selection.

Setting Up XB

1 Select  >  .

2 Select **Enable XB**.

Use the on-screen keyboard to enter the parameter details.

NOTE Select  to restore the default parameter details, if necessary.

3 Select an alert notification option.

4 Select options under *Report Options*.

5 Select  to confirm your selection.

Setting Up XM

1 Select  >  .

2 Select  to enter the parameter details.

3 Select **CBC** or **DIFF**, and use the on-screen keyboard to enter the parameter values.

4 Select  to accept the information.

5 Select **Enable CBC** and/or **Enable DIFF,** and enter a batch size.

6 Select an alert notification option.

7 Select options under *Report Options*.

8 Select  to accept the information.

Setting Up Extended QC

1 Select  >  .

2 Select **Enable Extended QC**.

3 Use the on-screen keyboard to select the error limits for the items listed.

4 Select a *QC Report Format*.

5 Set up an *Alert Notification*:

- Select  .
- Enter the parameter label information.
- Select  to accept the information.

6 Select  to confirm your selection.

Setting Up IQAP Information

1 Select  >  .

2 Use the on-screen keyboard to enter the information for:

- Participant Number
- Laboratory Number
- Instrument IQAP ID
- Instrument Number

3 Select  when prompted to accept the information.

Printing a Setup Report

Setup reports can be printed for Quality Assurance, Reporting, or System.

1 Select  >  >  .

2 From the warning window, select one of the following:

- QC Setup
- Reporting Setup
- System Setup

3 Select  to confirm your selection.

CHAPTER 10

Troubleshooting

Precautions/Hazards

Precautions and hazards when troubleshooting are indicated as follows in the Safety Notice:

- Alerts for Warning and Caution
- Safety Precautions
- Electronic Precautions
- Electromagnetic Compatibility (EMC) Information
- Biological Hazards
- Moving Parts
- Biohazardous Contamination
- Operational Hazards and Hazard Labels
- Disposal of Electrical Instrumentation
- Waste Disposal Warning
- CE Mark
- RoHS Notice

General Troubleshooting

Table 10.1 General Troubleshooting

Description	Probable Cause	Action
Power will not turn ON.	Power cord is loose or not securely connected to the wall or the instrument.	**1.** Turn the power OFF. **2.** Make sure the power cord is securely connected to the instrument and to the wall outlet. **3.** Turn the power ON.
	Defective ON/OFF button	Contact your Beckman Coulter Representative.
	Instrument malfunction	Contact your Beckman Coulter Representative.

Table 10.1 General Troubleshooting *(Continued)*

Description	Probable Cause	Action
Grinding noise during initial power ON	Component may have come loose during shipment. Motors are not reaching home.	**1.** Turn the power OFF. **2.** Open the diluter door. **3.** Look for any loose material or components. **4.** Turn the power ON. **5.** If the noise persists, contact your Beckman Coulter Representative.
Screen is dark. Power button is lit.	Defective display or loose connectors	Contact your Beckman Coulter Representative.
No aspiration takes place. Cycle does not start.	Instrument not on Sample Analysis - Patient Result screen	Go to Sample Analysis - Patient Result screen.
	Defective aspiration switch, loose connector	Contact your Beckman Coulter Representative.
Sample drips from probe area after aspiration.	Fluid drips from inside the probe.	There is a leak in the aspiration pathway. **1.** Open the diluter door. **2.** Check for loose tubing on the probe or the rinsing head.
	Component failure	Contact your Beckman Coulter Representative.
WBC/DIFF, RBC, and/or PLT exceed background limits. HGB background may also be high in noted instances.	Reagent lines are not connected correctly.	Verify that the reagent lines are connected tightly to the correct location on the reagent bottles.
	Instrument was not primed correctly.	Perform the Prime function from the Supplies screen. See Setting Up or Replacing Supplies in CHAPTER 9, Setup.
	Contaminated diluent	**1.** Replace the Diluent. **2.** Perform Prime Diluent from the Supplies screen. **3.** Perform the Running Daily Checks procedure in CHAPTER 3, Startup and Daily Checks.
	Contaminated baths	**1.** Perform the Cleaning the Baths procedure in CHAPTER 12, Cleaning Procedures. **2.** Perform the Running Daily Checks procedure in CHAPTER 3, Startup and Daily Checks.
		If the issue persists, contact your Beckman Coulter Representative.

Table 10.1 General Troubleshooting *(Continued)*

Description	Probable Cause	Action
WBC, RBC and/or PLT low or no results	Possible clogged WBC or RBC aperture	**1.** Perform the Backflushing the Apertures procedure in CHAPTER 12, Cleaning Procedures. **2.** Perform the Cleaning the Baths procedure in CHAPTER 12, Cleaning Procedures. **3.** Perform the Running Daily Checks procedure in CHAPTER 3, Startup and Daily Checks. **4.** If the issue persists, contact your Beckman Coulter Representative.
Diff parameters incorrect or no results	Possible clogged WBC aperture	**1.** Perform the Backflushing the Apertures procedure in CHAPTER 12, Cleaning Procedures. **2.** Perform the Cleaning the Baths procedure in CHAPTER 12, Cleaning Procedures. **3.** Perform the Running Daily Checks procedure in CHAPTER 3, Startup and Daily Checks. **4.** If the issue persists, contact your Beckman Coulter Representative.
All parameters display codes	Sample was analyzed in the incorrect mode (WB versus PD)	**1.** Verify the sample analysis mode on the display result screen. **2.** Repeat the analysis in the correct mode.

Individual Troubleshooting

Some of the troubleshooting procedures in this section require you to access diagnostic procedures.

Verifying the Software Version

1 Select  > 

.

2 Verify the software version and select  to end your verification.

Viewing Logs

Logs are messages that are used to provide traceability for system activities and changes, and information related to system warnings and errors.

1 Select  .

2 From the Event Log - All screen, select an event log:

Log	Icon
All Logs	
Traceability	
Warning	
Error	
Daily Checks	
Supplies	

Exporting Logs

1 Insert a USB flash drive into the USB port in front of the instrument.

2 From the main menu, select  .

3 Select  to export all of the logs OR select a specific log to export.

4 Select  .

5 From the Export Log window, select  when prompted to export the files.

6 Remove the USB flash drive from the USB port.

Quality Assurance Troubleshooting

Follow the actions in the following table to troubleshoot issues in quality assurance.

Table 10.2 Troubleshooting - Quality Assurance

Procedure	Issue	Action
Quality Control	Parameter is outside the expected results.	See If a Control is OUT in CHAPTER 4, Quality Control.
Calibration	• %CV • Factor % Diff • Delta Diff	Contact your Beckman Coulter Representative.
Repeatability	> % CV Limit	• Ensure that scheduled maintenance procedures have been performed. • Use a sample within the ranges noted in the specification. • Check for an outlier. • Repeat the test. • If repeatability fails again, contact your Beckman Coulter Representative.
Carryover	> Carryover % Limit	• Obtain fresh diluent. • Repeat the carryover test. • Contact your Beckman Coulter Representative.

Event Messages

Table 10.3 Event Messages

Event Message	Cause/Consequence	Action
Bath Drain Error	Cause: Vacuum failure occurred during the bath draining while in the analysis cycle. Consequence: Emergency stop occurs.	1. Perform Diluter Reset from the Diagnostics screen. 2. If the problem recurs, contact your Beckman Coulter Representative.
Bleach Cycle done. Perform Shutdown and Daily Checks.	Cause: Tried to run an unauthorized cycle after a Bleach Cycle. Consequence: Cycle is refused.	1. Perform a Diluter Reset from the Diagnostics screen, if applicable. 2. Perform a Shutdown and Daily Checks. 3. If the problem recurs, contact your Beckman Coulter Representative.
Bleach Cycle Interrupted	Cause: Bleach Cycle was interrupted. For example, operator initiated an emergency stop, operator initiated a Power OFF, ac line voltage (power failure), etc. Consequence: New entry in Event Log	1. Perform a Diluter Reset from the Diagnostics screen. 2. Restart the Bleach Cycle. 3. If the problem recurs, contact your Beckman Coulter Representative.
Cannot analyze specimens because the reagent temperature is out of range	Cause: Reagent temperature is < target - 2.5°C (36.5°F). Consequence: The run sample is inaccessible and the probe down function is disabled. Samples cannot be processed.	1. Wait 5 minutes. Perform Diluter Reset from the Diagnostics screen. 2. If the problem recurs, contact your Beckman Coulter Representative.
Count Vacuum Error	Cause: Vacuum failure occurred during the counting phase in the analysis cycle OR vacuum stability check failed during the counting vacuum. Consequence: Emergency stop occurs.	1. Perform Diluter Reset from the Diagnostics screen. 2. If the problem recurs, contact your Beckman Coulter Representative.
Diluter Door Opened	Cause: The diluter door opened during the cycle or was not properly closed OR the diluter door close interlock switch may not be working. Consequence: The cycle is refused or stopped.	1. Close the diluter door. Perform Diluter Reset from the Diagnostics screen. 2. Perform Check Sensors from the Diagnostics screen. Ensure that there is a checkmark in the Diluter Door section of the screen if the door is closed. 3. If the problem recurs, contact your Beckman Coulter Representative.

Table 10.3 Event Messages *(Continued)*

Event Message	Cause/Consequence	Action
HGB LED Adjustment Failed	Cause: HGB LED ADJUST failed Consequence: The hemoglobin result is invalid.	1. Perform Diluter Reset from the Diagnostics screen. 2. If the failure occurs during Daily Checks, repeat Daily Checks. If the failure recurs, perform Bleach Cycle from the Diagnostics screen. 3. If the problem recurs, contact your Beckman Coulter Representative.
Instrument Temperature Out of Range	Cause: Instrument temperature < 18°C (64.4°F) or > 34.5°C (94.1°F) Consequence: The run sample is allowed. All results are flagged with R.	1. Ensure that the laboratory temperature is within the instrument operational temperature specifications. 2. If the problem recurs, contact your Beckman Coulter Representative.
Maximum Reagent Temperature Reached. Heating Stopped.	Cause: Reagent temperature > 60°C (140°F) Consequence: The run sample is inaccessible. Samples cannot be processed.	1. Power the instrument OFF. Wait 15 minutes. Power ON the instrument and log in. Perform Diluter Reset from the Diagnostics screen. 2. If the problem recurs, contact your Beckman Coulter Representative.
No Bleach in Bath	Cause: Air detected on bleach cycle or no bleach in bath. Consequence: Emergency stop occurs.	1. Perform Diluter Reset from the Diagnostics screen. 2. Restart the bleach cycle and ensure that bleach is added to the bath when prompted. 3. If the problem recurs, contact your Beckman Coulter Representative.
No Deionized Water in Bath	Cause: No deionized water is in the bath. Consequence: Emergency stop occurs.	1. Perform Diluter Reset from the Diagnostics screen. 2. Restart the Bleach Cycle and ensure deionized water is added to the bath, when prompted. 3. If the problem recurs, contact your Beckman Coulter Representative.
No Diluent	Cause: Vacuum failure occurred at the beginning of the bath draining: no diluent. Consequence: Emergency stop occurs.	1. Ensure that the diluent pickup tubing in the back of the instrument is not pinched or obstructed. Ensure that the diluent has not run out. 2. Perform Diluter Reset from the Diagnostics screen. 3. If the problem recurs, contact your Beckman Coulter Representative.
Pre Aspiration Syringe Vacuum Error	Cause: Vacuum stability check failed before or during blood sampling. Consequence: Emergency stop occurs.	1. Perform Diluter Reset from the Diagnostics screen. 2. If the problem recurs, contact your Beckman Coulter Representative.

Table 10.3 Event Messages *(Continued)*

Event Message	Cause/Consequence	Action
Pre Probe Rinsing Vacuum Error	Cause: Vacuum failure occurred before the probe rinsing. Consequence: Emergency stop occurs.	1. Perform Diluter Reset from the Diagnostics screen. 2. If the problem recurs, contact your Beckman Coulter Representative.
Post Aspiration Syringe Vacuum Error	Cause: Vacuum stability check failed before or during blood sampling. Consequence: Emergency stop occurs.	1. Perform Diluter Reset from the Diagnostics screen. 2. If the problem recurs, contact your Beckman Coulter Representative.
Post Probe Rinse Vacuum Error: Specimen may be diluted. Discard specimen.	Cause: Vacuum failure occurred during the probe rinsing. Consequence: Emergency stop occurs.	1. Perform Diluter Reset from the Diagnostics screen. 2. If the problem recurs, contact your Beckman Coulter Representative.
Probe Home Error	Cause: Home failure. Motor Probe. Consequence: Emergency stop occurs.	1. Perform Diluter Reset from the Diagnostics screen. 2. If the problem recurs, contact your Beckman Coulter Representative.
Probe Home Position Not Found. Perform a Diluter Reset Cycle.	Cause: The home position for the probe was not found during processing. Consequence: Emergency stop occurs.	1. Perform Diluter Reset from the Diagnostics screen. 2. If the problem recurs, contact your Beckman Coulter Representative.
Probe Mechanism Home Error	Cause: Home failure. Motor Probe Mechanism. Consequence: Emergency stop occurs.	1. Perform Diluter Reset from the Diagnostics screen. 2. If the problem recurs, contact your Beckman Coulter Representative.
Probe Mechanism Home Position Not Found	Cause: Home not found. Motor Probe Mechanism. Consequence: Emergency stop occurs.	1. Perform Diluter Reset from the Diagnostics screen. 2. If the problem recurs, contact your Beckman Coulter Representative.
Probe Mechanism Move Error	Cause: Step loss. Motor Probe Mechanism. Consequence: Emergency stop occurs.	1. Perform Diluter Reset from the Diagnostics screen. 2. If the problem recurs, contact your Beckman Coulter Representative.
Probe Move Error	Cause: Step loss. Motor Probe. Consequence: Emergency stop occurs.	1. Perform Diluter Reset from the Diagnostics screen. 2. If the problem recurs, contact your Beckman Coulter Representative.

Table 10.3 Event Messages *(Continued)*

Event Message	Cause/Consequence	Action
Reagent Heating is Stopped	Cause: Reagent heating is at 100% and no temperature increase has occurred during 2 minutes (0.5 increase). Consequence: The reagent heating has failed and the run sample is inaccessible. Samples cannot be processed.	**1.** Power the instrument OFF. Wait 15 minutes. Power ON and log in. Perform Diluter Reset from the Diagnostics screen. **2.** If the problem recurs, contact your Beckman Coulter Representative.
Rinse cycle not done	Cause: No diluent in bath. Consequence: The cycle cannot be initiated.	**1.** Perform Rinse Baths (Rinse Cycle) from the Diagnostics screen. **2.** If Rinse Baths does not resolve the problem, perform Diluter Reset from the Diagnostics screen. **3.** If the problem recurs, contact your Beckman Coulter Representative.
Syringe Home Error	Cause: Home failure. Motor Syringe. Consequence: Emergency stop occurs.	**1.** Perform Diluter Reset from the Diagnostics screen. **2.** If the problem recurs, contact your Beckman Coulter Representative.
Syringe Home Position Not Found	Cause: Home not found. Motor Syringe. Consequence: Emergency stop occurs.	**1.** Perform Diluter Reset from the Diagnostics screen. **2.** If the problem recurs, contact your Beckman Coulter Representative.
Syringe Move Error	Cause: Step loss. Motor Syringe. Consequence: Emergency stop occurs.	**1.** Perform Diluter Reset from the Diagnostics screen. **2.** If the problem recurs, contact your Beckman Coulter Representative.
Syringe Vacuum Error	Cause: Vacuum failure occurred during the test syringe cycle OR vacuum stability check failed during syringe vacuum. Consequence: Emergency stop occurs.	**1.** Perform Diluter Reset from the Diagnostics screen. **2.** If the problem recurs, contact your Beckman Coulter Representative.
System Busy	Cause: A cycle was initiated with a previous cycle processing. Consequence: The cycle cannot be initiated.	**1.** Wait until the cycle is completed. **2.** If the problem recurs, contact your Beckman Coulter Representative.
System Timed Out	Cause: No user action occurred within x seconds. Consequence: The cycle is aborted.	**1.** Perform Diluter Reset from the Diagnostics screen. **2.** If the problem recurs, contact your Beckman Coulter Representative.

Table 10.3 Event Messages *(Continued)*

Event Message	Cause/Consequence	Action
VL X Error (X = a valve number from 1 to 12)	Cause: The command valve failed - valve X. Consequence: Emergency stop occurs.	1. Perform Diluter Reset from the Diagnostics screen. 2. If the problem recurs, contact your Beckman Coulter Representative.
Waste Drain Error	Cause: Pressure failure occurred during the test syringe cycle when draining waste from the syringe. Consequence: Emergency stop occurs.	1. Ensure that the waste tubing in the back of the instrument is not pinched or obstructed. 2. Perform Diluter Resetfrom the Diagnostics screen. 3. If the problem recurs, contact your Beckman Coulter Representative.

Diagnostics

The following procedures are listed on the Diagnostics screen.

NOTE The bottom left corner of the screen displays the name of the Diagnostics procedure in progress when it begins.

Hardware Reset

Hardware Reset resets the syringe, probe, and rocker motors to the home position. If the motors are in the home position, they are moved out and back.

1 Select  > **HARDWARE RESET**.

Clean the Baths

See When, Why, and How to Perform Each Cleaning Procedure in CHAPTER 12, Cleaning Procedures.

Backflush Apertures

See When, Why, and How to Perform Each Cleaning Procedure in CHAPTER 12, Cleaning Procedures.

Bleach Cycle

See When, Why, and How to Perform Each Cleaning Procedure in CHAPTER 12, Cleaning Procedures.

Diluter Reset

Diluter Reset initiates a hardware reset. Then, it performs a fluidic cycle to ensure the system is working correctly.

1 Select  > **DILUTER RESET**.

Prepare to Ship

Prepare to Ship runs a cycle to drain and clean the system before transporting it or for extended storage. The process takes approximately 45 minutes.

1 Select  > **PREPARE TO SHIP**.

2 Select  to confirm the PREPARE TO SHIP function.

3 When you are prompted to pour the deionized water, loosen the two screws on the diluter door with a flathead screwdriver to open the door and expose the coumting area (for the location of the diluter door and baths, see Figure 1.5, DxH 500 Right Side View and Figure 1.6, DxH 500 Right Side View Behind Diluter Door in CHAPTER 1, System Overview).

4 Pour 6 mL of deionized water into the WBC/Diff and RBC baths.

5 Select  to confirm.

6 Close the diluter door by tightening the screws and select  to begin the rinsing process. The instrument automatically primes the fluidic path with deionized water.

7 When the system prompts you to pour bleach, loosen the two screws on the diluter door with a flathead screwdriver to open the door and expose the counting area.

8 Pour 4 mL of the prepared bleach solution (see Preparing the Bleach Solution in CHAPTER 12, Cleaning Procedures) into the WBC/Diff and RBC baths.

9 Select  to confirm.

10 Close the diluter door by tightening the two screws and select  to begin the 10-minute bleaching process. The instrument automatically draws bleach through the apertures.

11 When the system prompts you to pour deionized water, loosen the two screws on the diluter door and expose the counting area.

12 Pour 6 mL of deionized water into the WBC.Diff and RBC baths.

13 Select  to confirm.

14 Close the diluter door by tightening the screws and select  to begin the rinsing process. The instrument automatically primes the fluidic path with deionized water and flushes the bleach out of the system.

15 Place the reagent pickup tubes when prompted in approximately 500 mL of deionized water and select  to confirm.

NOTE The instrument will not use all of the deionized water.

16 Remove the reagent pickup tubes when prompted from the deionized water, place them on a sterile surface, and select  to confirm. The system automatically powers OFF when the cycle is complete.

Check Sensors

Check Sensors provides access to the sensors test/states display.

1 Select  > **CHECK SENSORS**.

2 From the Check Sensors screen, under *Check Device*, select a device to verify that it is operational. Operational items display a checkmark.

Service

You must have a Service login to enter this area of the system.

Drain Baths

See Draining the Baths in CHAPTER 12, Cleaning Procedures.

Rinse Baths (Rinse Cycle)

Rinse Baths initiates a cycle that drains and refills the WBC and RBC baths with Diluent.

1 Select  > **RINSE BATHS**.

2 Wait for the instrument to go through the rinse cycle.

3 Wait for the LED indicator to turn green when the cycle is completed.

Lubrication Pos. (Syringe Assembly Piston Lubrication)

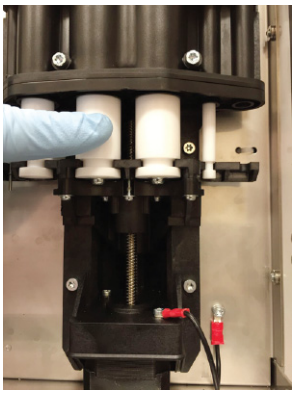
Lubrication Pos. moves the syringes to the proper position for lubricating the syringe assembly pistons. Piston lubrication should be done yearly.

1 Select  > **LUBRICATION POS**. The pistons partially descend.

2 Open the diluter door to access the syringe pistons.

3 Place a small amount of piston silicone grease (about the size of a match head) on a gloved fingertip.

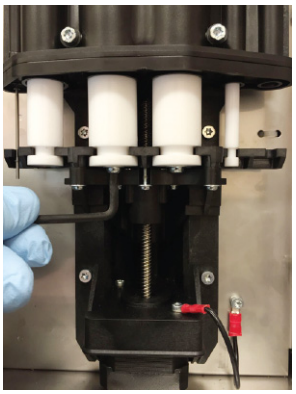
4 Spread a thin film of lubricant around each of the four white pistons.



5 Locate the T20 Torx tool from the accessory kit to access the rear of the larger pistons.

6 Locate the waste pistons (the two large white pistons in the center of the syringe assembly).

7 Insert the T20 Torx tool on the screw directly on the bottom of the left waste syringe piston and turn it 180 degrees to expose the other side of the piston.



8 Continue spreading a thin film of lubricant on the piston.

9 Spread a thin film of lubricant on the right waste syringe piston.

10 Turn the other two smaller pistons by hand and spread a thin film of lubricant on each one.

11 When done, close the diluter door.

12 Select  to finish the lubrication cycle.

Diluent Dispense

Diluent Dispense dispenses 300 µL of diluent to prepare a dilution for use on prediluted samples.

1 Select  > **DILUENT DISPENSE**.

⚠ WARNING

Risk of injury and/or biohazardous contamination. To avoid being pierced by the aspiration probe, use caution when presenting samples for analysis during this procedure.

2 Place a clean empty tube without anticoagulant under the aspiration probe and select  to dispense the diluent.

⚠ CAUTION

Risk of damage to the aspiration probe. Be careful not to bend the aspiration probe when removing the tube.

3 When the dispensing is complete, remove the tube.

Park Syringe

Park Syringe moves the syringe up to the park position to prevent damage to the pistons. *Hardware Reset* brings the syringes back to the home position.

1 Select  > **PARK SYRINGE**.

2 Select  to park the syringe.

Valve Checks

Valve Checks allows access to the valve test display.

1 Select  > **VALVE CHECKS**.

2 From the Diagnostics - Check Valves screen, select a valve number to turn it ON or OFF.

You can select **ALL VLs ON** to turn all the valves ON or OFF or **EV CHASER** to turn the valves ON or OFF in sequence.

CHAPTER 11

Quality Assurance

Overview

This chapter contains information and procedures about:

- Calibration
- Running Repeatability
- Running Carryover

Calibration

The calibration procedure consists of comparing instrument measurements to known values for WBC, RBC, HGB, MCV, PLT, and MPV. Calibration assures that sample results generated by the instrument accurately reflect sample input. Calibration is performed using materials traceable to known reference materials. In general, the procedure may indicate that the instrument requires standardization, by first determining the deviation from calibrator reference, and then applying recommended correction factors (CAL factors).

The instrument comes calibrated from the factory. You should verify the calibration status. If verification fails, proceed with calibration.

Your laboratory is responsible for the final calibration of the CBC parameters. Beckman Coulter recommends DxH 500 Series Calibrator, or an exact equivalent, as an acceptable alternative to whole blood calibration. In the normal process of tracking data for an extended period, your laboratory can make a specific decision to recalibrate a given parameter. The differential parameters do not require calibration in the laboratory.

⚠ CAUTION

Risk of erroneous results. The modification of system recommendations for calibration affects instrument results. Use extreme caution when modifying the recommended calibration settings.

When to Verify Calibration

You should verify the calibration of your instrument:

- As dictated by your laboratory procedures and local or national regulations
- When controls show evidence of unusual trends (all levels demonstrate similar parameter recovery)
- When controls exceed the manufacturer's defined acceptable limits

- If the average ambient room temperature changes more than 10°F or 6°C from the calibrating temperature

Verify the calibration by following the instructions on the calibrator's instructions for use.

When to Calibrate

Calibrate if:

- Calibration verification fails.
- Any component involved in dilution or primary measurement was replaced. This includes the aspiration line or probe, and the apertures.
- You are advised to do so by your Beckman Coulter Representative.

Calibrating with DxH 500 Series Calibrator

Follow the steps in the DxH 500 Series Calibrator instructions for use. The Table of Expected Results provided with the DxH 500 Series Calibration kit contains the expected values for the calibrator. You will use the values during the preparation of the software for running the calibrator. The instructions for use contains information about storage, chemical hazards, mixing, intended use, etc. for the calibrator product.

Setting Up Calibration

IMPORTANT Ensure the following before calibrating the instrument:

- The instrument is properly functioning, maintained, and the probe and apertures are clean prior to calibration.
- The instrument has sufficient volume(s) of reagents to complete the calibration procedure. If you run out of reagents during calibration, you must start over and perform a complete calibration.
- Daily Checks passed.
- If calibration fails, see Quality Assurance Troubleshooting in CHAPTER 10, Troubleshooting.

---

1 Select  >  >  to display the Calibration screen.

---

2 If existing data is present, from the warning window, select **Print calibration before deleting** to print and delete the data.

NOTE Select  to display the calibration screen without deleting the data.

3 Select  to confirm your selection and/or delete the data.

4 Select  .

5 Select the applicable icon:

-  and use the bar-code scanner to scan the 2D bar code on the Table of Expected Results
-  and use the on-screen keyboard to enter the information manually (**Lot #**, **Expiration Date**, **Source**, and **Assay Values**). If necessary, select  >  to delete the existing information.

6 Ensure that all of the calibration information entered is correct.

⚠ CAUTION

Risk of loss of data. When calibrating, do not leave the screen until you have finished analyzing the required number of replicates.

7 Select  to accept the information. The probe is extended for sample analysis and an empty run table is displayed.

8 Mix the calibrator as indicated by the instructions for use.

9 Fully immerse the probe into the calibrator and press the aspiration plate.

10 Select the checkbox in the *EXCL* column to exclude the first (prime) run before reaching the tenth run.

11 Follow the handling information in the calibrator instructions for use and complete the required number of replicates (N = 10).

- The number of runs is displayed on the top left corner of the calibration table.
- The table does not contain results until two acceptable runs have been completed.
- Any runs with nonnumeric results are automatically excluded from the calculations. Add another run to reach the required number of runs.
- To exclude a run manually, select the checkbox in the *EXCL.* column.
- The most recent run is shown at the top of the calibration table.

12 Review the calibration results.

The screen displays statistical information and indicates whether the instrument requires calibration or other action.

Information Displayed	**Description**
Mean	Average of results
% CV	Coefficient of variation of included results
Target	Calibration assigned value
Factor % Diff	$\text{Factor \% Diff} = \left[\frac{\text{(New Cal Factor)}}{\text{In Use Cal Factor}} - 1\right] \times 100$
Delta Diff	Delta Diff = Absolute Value (Mean - Reference Value)
In-Use Factors	Current calibration factors (old), default factor is 1.00
New Factor	What the calibration factor will be based on with the selected values in the table (new) $\text{New Cal Factor} = \frac{\text{Reference Value}}{\text{Mean}} \times \text{In Use Cal Factor}$
Status	Recommended calibration is automatically indicated with a checkmark for the parameter when 10 non-excluded runs are completed.

The background color for Factor % diff, % CV, and Delta Diff cells changes when the value is out of range as indicated:

- Yellow for Factor % Diff and/or the Delta Diff indicates that the value is out of range, which means that calibration is recommended.
- Red for % CV, Factor % Diff, and/or Delta Diff indicates that the statistical value is not within range and the system does not allow calibration. Contact your Beckman Coulter Representative.

⚠ CAUTION

Risk of erroneous results. The modification of system recommendations for calibration may affect instrument results. Use extreme caution when modifying the recommended calibration settings. Modify recommended calibration settings only under the direction of your Beckman Coulter Representative.

13 Select  to edit the recommended calibration check boxes. The button changes color and the check boxes are enabled. To cancel any changes and restore the system recommendations, select  .

The calibration by the system is indicated in the following calibration criteria table.

Parameter	Precision (CV%)	Acceptable Cal Factor Value	Calibrate if FAC % Diff is:	Calibrate if Delta Diff is:
WBC	≤ 3.0%	[3] 0.5 or ≤ 1.5	> 2.2 and ≤ 6.6	> 0.20 and ≤ 0.6
RBC	≤ 2.0%	[3] 0.5 or ≤ 1.5	> 2.3 and ≤ 4.1	> 0.07 and ≤ 0.170
HGB	≤ 1.5%	[3] 0.5 or ≤ 1.5	> 1.4 and ≤ 3.8	> 0.20 and ≤ 0.5
MCV	≤ 1.0%	[3] 0.5 or ≤ 1.5	> 2.1 and ≤ 3.2	> 2.0 and ≤ 3.0
PLT	≤ 5.0%	[3] 0.5 or ≤ 1.5	> 4.8 and ≤ 9.6	> 12.0 and ≤ 23.0
MPV	≤ 3.0%	[3] 0.5 or ≤ 1.5	> 8.0 and ≤ 21.0	> 0.7 and ≤ 2.0

14 Select  to accept and complete the calibration.

15 Print the results in one of the following ways:

- To autoprint, see Setting Up Printer Options in CHAPTER 9, Setup.
- To manually print, select  >  , select **Selected Result** or **Calibration Table**, and select  to confirm your selection.

16 Verify calibration using DxH 500 Series Calibrator as indicated in the instructions for use.

Running Repeatability

1 Ensure you have enough normal whole blood (normal WBC, RBC, and PLT values) from a single donor for a minimum of ten cycles.

2 Select  >  >  .

3 If existing data is present, from the warning window, select **Print repeatability data before deleting** to print and delete the data OR select **Delete data without printing** to cancel printing and delete the data.

4 Select  to confirm your selection and/or delete the data.

NOTE When you select  , the data is not deleted and the Repeatability screen is displayed.

Select  to delete the current file and run a new repeatability.

5 Mix the sample, fully immerse the probe into the tube, and press the aspiration plate. Repeat the process until N = 10. Ensure that the sample is mixed between runs.

6 Review the results on the screen.

Information Displayed	Description
N	Number of non-excluded runs
Mean	Average of results
2SD	$SD = \sqrt{\frac{\sum(x - \bar{x})^2}{n}}$
% CV	Coefficient of variation of included results
Minimum	Lowest result
Maximum	Highest result
Range	Difference between the minimum and maximum value of the parameter result

7 Verify that the CV or SD does not exceed the established Repeatability limits. See Repeatability in CHAPTER 1, System Overview.

8 If the results fail, see Quality Assurance Troubleshooting in CHAPTER 10, Troubleshooting.

9 Print the results in one of the following ways:

- To autoprint, see Setting Up Printer Options in CHAPTER 9, Setup.
- To manually print, select  >  , select **Selected Result** or **All Results**, and select  to confirm your selection.

Running Carryover

1 Prepare your samples for carryover. You will need:

- One tube of whole blood
- Three tubes labeled Diluent 1, Diluent 2, and Diluent 3 (for use in step 4)

2 Dispense diluent by selecting  > **DILUENT DISPENSE**.

3 Place the tube labeled Diluent 1 under the probe.

4 Select  to automatically dispense the diluent. Repeat this step for tubes labeled Diluent 2 and Diluent 3.

5 Select  >  >  .

6 From the Carryover screen, select  .

7 Select  to delete the existing information.

⚠ CAUTION

Risk of erroneous results. The carryover process cannot be interrupted. If interrupted, restart the process at step 2.

8 Immerse the probe into the whole-blood tube and press the aspiration plate. Repeat the process two additional times. Ensure the sample is mixed between runs.

9 Immerse the probe into the tube labeled Diluent 1 and press the aspiration plate. Repeat the process with the Diluent 2 and Diluent 3 tubes.

10 Verify the carryover status (Pass or Fail). The system calculates carryover results automatically using this formula:

$$\%\text{Carryover} = \frac{(L1 - L3)}{(H3 - L3)} \times 100$$

The calculated % Carryover and/or Background Limits are compared to specifications (see Carryover in CHAPTER 1, System Overview for more information). If Carryover fails, see Quality Assurance Troubleshooting in CHAPTER 10, Troubleshooting.

11 Print the results:

- To autoprint, see Setting Up Printer Options in CHAPTER 9, Setup.
- To manually print, select  >  , select **Selected Results** or **Final Report**, and select  to confirm your selection.

CHAPTER 12

Cleaning Procedures

When, Why, and How to Perform Each Cleaning Procedure

⚠ WARNING

Risk of injury and/or biohazardous contamination. Use caution as ac voltages may be present. Use appropriate barrier protection when performing these procedures since the instrument may contain biohazardous material.

⚠ CAUTION

Risk of damage to the instrument. Do not attempt any procedures that are not included in this manual. Contact your local Beckman Coulter Representative for service and maintenance beyond the scope of this documentation.

Table 12.1 Matrix of Frequency for Cleaning Procedures

Procedure	Purpose	Tools/Supplies	Frequency
Cleaning the Instrument	To remove and prevent the buildup of dried blood or reagent deposits	Disinfecting wipes	Daily or as needed, based on visual inspection
Performing a Bleach Cycle	To remove clogs	• High-quality, fragrance-free, gel-free bleach (3.6% solution of sodium hypochlorite - available chlorine) • Deionized water • Container for bleach-deionized water solution • Container for deionized water	Every 1,000 cycles or monthly, whichever comes first
Lubricating Pistons (see Lubrication Pos. (Syringe Assembly Piston Lubrication) in CHAPTER 10, Troubleshooting)	To lubricate the syringe assembly pistons	• Piston silicone grease • T20 Torx tool from the accessory kit	Yearly
Cleaning the Baths	To remove clogs	Automated cycle	As needed
Draining the Baths	To remove fluid	Automated cycle	As needed

Table 12.1 Matrix of Frequency for Cleaning Procedures *(Continued)*

Procedure	Purpose	Tools/Supplies	Frequency
Backflushing the Apertures	To remove obstructions	Automated cycle	As needed
Cleaning the Bar-Code Scanner	To remove dirt or dust	• Deionized water • Detergent • Lint-free tissue	As needed, based on visual inspection

Cleaning the Instrument

Clean the outside surface of the instrument with disinfecting wipes approved for laboratory use. To prevent the buildup of dried blood or reagent deposits, clean up spills promptly. Inspect the probe area throughout the day (see Instrument Views in CHAPTER 1, System Overview). Remove blood deposits using disinfecting wipes.

Cleaning the Baths

Clean Baths backflushes the RBC and WBC apertures with Cleaner, and drains and refills them with Diluent.

1 Select  > **CLEAN BATHS**.

2 Wait for the instrument to go through the cleaning cycle.

3 Wait for the LED indicator to turn green when the cycle is completed.

Performing a Bleach Cycle

Bleach Cycle is a special cycle for cleaning the baths and apertures with a bleach solution.

⚠ WARNING

Risk of chemical injury from bleach. To avoid contact with bleach, use barrier protection, including protective eyewear, gloves, and suitable laboratory attire. Refer to the Safety Data Sheet for details about chemical exposure before using the chemical.

⚠ CAUTION

Risk of erroneous results. Complete the entire procedure before proceeding with a sample analysis. Perform a shutdown and Daily Checks.

For a bleach solution, use a high-quality, fragrance-free, gel-free bleach (3.6% solution of sodium hypochlorite-available chlorine) used to clean the probe, fluidic lines, apertures, and baths. Your laboratory may have a higher concentration of bleach. You must dilute the solution prior to performing this procedure. See Preparing the Bleach Solution.

---

1 Select  > **BLEACH CYCLE** and the instrument will prepare for the bleach cycle.

IMPORTANT If the bleach cycle is interrupted for any reason due to an emergency stop or power outage, shutdown and Daily Checks will need to be completed before sample analysis can begin.

---

2 When the system prompts you to pour deionized water, loosen the two screws on the diluter door with a flathead screwdriver to open the door and expose the counting area (for the location of the diluter door and baths, see Figure 1.5, DxH 500 Right Side View and Figure 1.6, DxH 500 Right Side View Behind Diluter Door in CHAPTER 1, System Overview).

---

3 Pour 6 mL of deionized water into the WBC/Diff and RBC baths.

---

4 Select  to confirm.

---

5 Close the diluter door by tightening the screws and select  to begin the rinsing process. The instrument automatically primes the fluidic path with deionized water.

---

6 When the system prompts you to pour bleach, loosen the two screws on the diluter door with a flathead screwdriver to open the door and expose the counting area.

7 Pour 4 mL of the prepared bleach solution (see Preparing the Bleach Solution) into the WBC/Diff and RBC baths.

8 Select  to confirm.

9 Close the diluter door by tightening the screws and select  to begin the 10-minute bleaching process. The instrument automatically draws bleach through the apertures.

10 When the system prompts you to pour deionized water, loosen the two screws on the diluter door and expose the counting area.

11 Pour 6 mL of deionized water into the WBC/Diff and RBC baths.

12 Select  to confirm.

13 Close the diluter door by tightening the screws and select  to begin the rinsing process. The instrument automatically primes the fluidic path with deionized water and flushes the bleach out of the system.

14 Perform a shutdown.

15 Run Daily Checks. You can now run a sample analysis.

Preparing the Bleach Solution

Prepare the bleach solution following the formula and guidelines in *Annex 6, How to Make Chlorine Solutions for Environmental Disinfection*[32] issued by the World Health Organization. The bleach concentration achieved must be 3.6% (see the following example). Begin with a bleach solution that displays its concentration on the container (the example uses 8.2% which is germicidal grade).

Formula:

[% chlorine in liquid bleach/% chlorine desired]-1= parts of deionized water to be added for each one part of bleach

Example:

[8.2 starting concentration/3.6 desired concentration]-1=2.27-1=1.27; Add 1.27 parts of deionized water to each one part of concentrated bleach

NOTE *Parts* can be used for any unit of measure (ounce, liter, or gallon) or any container used for measuring, such as a pitcher. In countries where French products are available, the amount of active chlorine is usually expressed in degrees chlorum. One chlorum is equivalent to 0.3% active chlorine.

Draining the Baths

Drain Baths drains the WBC and RBC baths.

1 Select  > **DRAIN BATHS**.

2 Wait for the instrument to go through the drain cycle.

3 Wait for the cycle to be completed. The LED indicator turns green when the cycle is done.

Backflushing the Apertures

BACKFLUSH APERTURES applies a backflush with Cleaner to the WBC and RBC apertures, and drains the baths refilling them with Diluent.

NOTE *BACKFLUSH APERTURES* cannot be initiated if the baths have been drained. A rinse cycle needs to be performed before processing the backflush cycle. See Rinse Baths (Rinse Cycle) in CHAPTER 10, Troubleshooting.

1 Select  > **BACKFLUSH APERTURES**.

2 Wait for the instrument to go through the backflush cycle.

3 Wait for the cycle to be completed. The LED indicator turns green when the cycle is done.

Cleaning the Bar-Code Scanner

If the scan window is not clean, scanning performance can degrade.

If the scan window is visibly dirty or if the scanner is not scanning well, follow these instructions to clean the bar-code scanner.

⚠ CAUTION

Risk of damage to the bar-code scanner. To avoid damage, do not submerge the bar-code scanner in water. The bar-code scanner is not water-tight. Do not use an abrasive cloth or tissue on the scan window since it may scratch the window. Never use solvents (for example, alcohol, acetone, benzene, ether, or phenol-based agents) on the housing or window to avoid damage to the finish or window.

1 Clean the scan window with a soft cloth or lens tissue dampened with water or a mild detergent-water solution.

NOTE If you use a detergent-water solution to clean the bar-code scanner, rinse it with a clean tissue dampened with water only and then dry it with another clean tissue.

2 Clean the bar-code scanner housing as described above.

CHAPTER 13

Replacement/Adjustment Procedures

When, Why, and How to Perform Each Replacement/Adjustment Procedure

⚠ WARNING

Risk of injury and/or biohazardous contamination. Use caution as ac voltages may be present. Use appropriate barrier protection when performing these procedures since the instrument may contain biohazardous material.

⚠ CAUTION

Risk of damage to the instrument. Incorrectly performed replacement procedures can damage the instrument. Read the manual carefully before you attempt to replace any component. Do not attempt any procedures that are not included in this manual. Contact your local Beckman Coulter Representative for service and maintenance beyond the scope of this manual.

Table 13.1 Matrix of Frequency for Replacement Procedures

Procedure	Purpose	Tools/Supplies	Frequency
Setting Up or Replacing Waste Disposal in CHAPTER 9, Setup	To replace a full waste container	New empty waste container	As needed to replace full waste containers
Setting Up or Replacing Supplies in CHAPTER 9, Setup	To replace empty reagent containers	New reagents	As needed to replace empty reagent containers
Replacing the Rinsing Head O-Ring	To replace a rinsing head O-ring for the aspiration probe	New O-ring	Yearly (every 18,000 cycles)
Replacing the Bar-Code Scanner	To replace a defective bar-code scanner	New bar-code scanner	As needed
Replacing the Aspiration Probe	To replace a defective aspiration probe	• New aspiration probe • Pliers	As needed

Replacing the Rinsing Head O-Ring

Follow this procedure to replace the rinsing head O-ring.

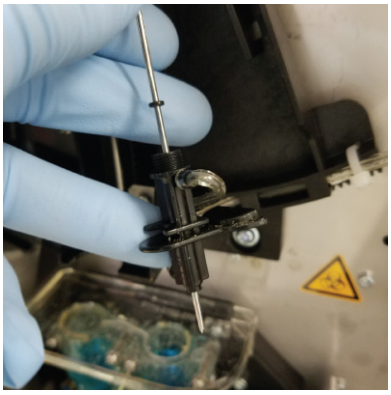
1 Remove the aspiration probe by following the instructions in Replacing the Aspiration Probe.

IMPORTANT Do not invert the rinsing head to avoid accidentally losing the O-ring.

2 Unscrew the black probe guide and remove it from the rinsing head.

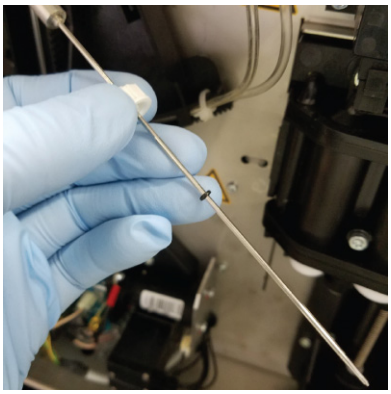
3 Insert the aspiration probe into the O-ring inside the rinsing head and then remove the aspiration probe from the rinsing head. The O-ring should come out with the probe.

4 Remove the O-ring from the aspiration probe.



NOTE The white spacer may or may not be seen with the removal of the aspiration probe. Be careful not to lose the spacer if it is removed.

5 Replace the O-ring by inserting the black probe guide first and then inserting the O-ring on the aspiration probe.



6 Install this assembly on the rinsing head and screw back the black probe guide.

7 To reinstall the probe and verify the probe alignment, go to step 14 in Replacing the Aspiration Probe and complete the steps to the end of the procedure.

Replacing the Bar-Code Scanner

1 Disconnect the bar-code scanner from the USB port.

2 Install the new bar-code scanner by connecting the cable to the USB port.

NOTE See APPENDIX B, Bar Codes for more information on bar-code configuration and labels

Replacing the Aspiration Probe

⚠ WARNING

Risk of injury and/or biohazardous contamination. Use caution as ac voltages may be present. Use appropriate barrier protection when performing these procedures since the instrument may contain biohazardous material.

⚠ WARNING

Risk of injury. Ensure that the instrument is not operational before replacing the probe.

1 Select  > **DRAIN BATHS.** This drains the baths, and the vacuum and waste syringes.

2 When the power button turns green, go to the next step.

3 Power OFF the instrument by holding the power button for a few seconds. Select  when the system prompts you to perform a shutdown before powering down.

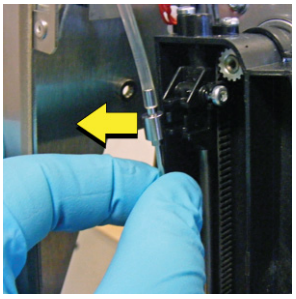
4 Disconnect the power cord from the back of the instrument. The panel is marked as *24v*.

5 Open the diluter door with a flathead screwdriver. When you release the screw, take the panel off of the hinges so it is not in the way.

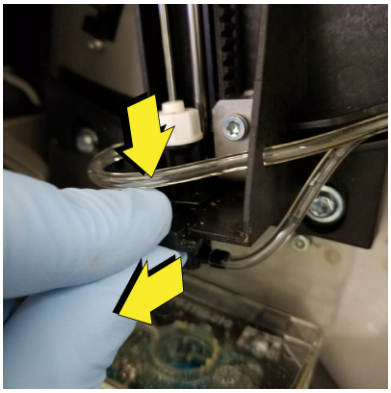
6 Verify that the probe is completely retracted all the way up.

7 Move the probe rocker assembly to the back to access the probe.

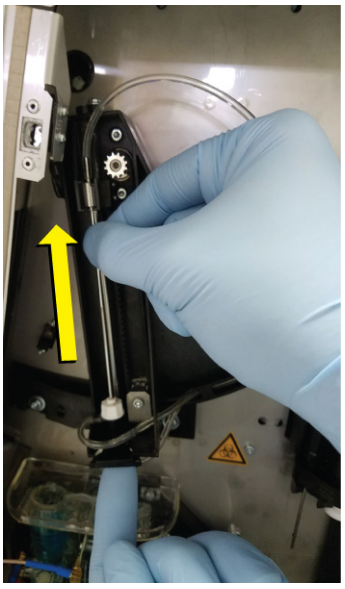
8 Pull the top of the probe to remove it from the probe carriage.



9 Push down and pull the rinsing head to remove it from the rocker.

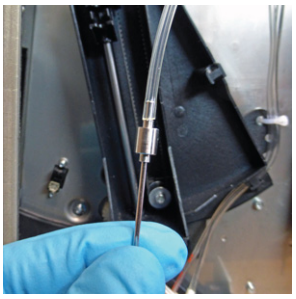


10 Pull up the probe to remove it from the rinsing head.



11 Disconnect the probe from the aspiration tubing and remove it from the instrument.

NOTE Use the tips of the pliers to push the tubing up. Do not crimp the tubing.



12 Discard the probe in accordance with your laboratory's regulations.

13 Remove the new aspiration probe from its packing.

14 Reconnect the aspiration tubing to the top of the new aspiration probe and ensure that the tubing is properly attached to the probe.

NOTE Use the pliers with care to avoid crimping the tubing.

15 Carefully push the probe into the rinsing head.

16 Push the rinsing head into the rocker.

17 Push the top of the probe into the probe carriage.

18 Move the probe rocker assembly forward.

19 Replace the diluter door and secure it.

20 Reconnect the power cord to the back of the instrument. The flat side of the power cord should face the waste tubing.

21 Power ON the instrument by holding the power button for a few seconds.

The instrument software will boot up.

22 From the main screen, log in and select  when prompted to perform Daily Checks.

23 Run a Diluter Reset procedure to initialize the motor and then perform Daily Checks. See Diluter Reset in CHAPTER 10, Troubleshooting.

NOTE The probe rocker motor and the up/down probe motor may not be in the home position.

24 Verify that all Daily Checks status indicators display *Pass*.

APPENDIX A

Access Levels and Reports

Access Levels

The security access levels are listed as either Y (Yes) or N (No) in the following table.

Table A.1 Security Access Levels

Feature	Operator	Administrator
DISPLAY/RUN (SPECIMEN ANALYSIS)	Y	Y
PATIENT RESULTS	Y	Y
Search	Y	Y
Display	Y	Y
Re-run	Y	Y
Edit	N	Y
Unmatched	Y	Y
Delete	N	Y
WORKLIST	Y	Y
New Order	Y	Y
Edit Order	Y	Y
Delete	Y	Y
DAILY CHECKS	Y	Y
Daily Check	Y	Y
Background	Y	Y
Shutdown	Y	Y
History Logs	Y	Y
QC/QA	Y	Y
Graphs	Y	Y
Display	Y	Y
Comments	Y	Y
Delete	N	Y
XB	Y	Y
Graphs	Y	Y
Details	Y	Y
Delete	N	Y
XB Setup	N	Y

Table A.1 Security Access Levels *(Continued)*

Feature	Operator	Administrator
XM	Y	Y
Graphs	Y	Y
Details	Y	Y
Delete	N	Y
XM Setup	N	Y
IQAP	N	Y
QA	Y	Y
Repeatability	Y	Y
Start	Y	Y
Details	Y	Y
Delete	Y	Y
Carryover	Y	Y
Start	Y	Y
Details	Y	Y
Delete	Y	Y
Calibration	Y	Y
Display	Y	Y
Cal Factors	N	Y
Finish	N	Y
Setup	N	Y
Edit	N	Y
SUPPLIES	Y	Y
Setup	Y	Y
Prime All	Y	Y
Cycle Counter	Y	Y
Reset Counter	N	N
Waste Setup	Y	Y
Prime Diluent	Y	Y
Prime Lyse	Y	Y
Prime Cleaner	Y	Y
LOGS	Y	Y
All	Y	Y
Traceability	Y	Y
Warning	Y	Y
Error	Y	Y

Table A.1 Security Access Levels *(Continued)*

Feature	Operator	Administrator
Daily Checks	Y	Y
Export	Y	Y
SETUP	Y	Y
Controls	Y	Y
New QC	Y	Y
Edit QC	N	Y
Delete	N	Y
IQAP	N	Y
XB	N	Y
XM	N	Y
EQC	N	Y
Header Information	N	Y
Printing Options	N	Y
Parameter Units	N	Y
Next Specimen	N	Y
Power Up System	N	Y
Printer	N	Y
Date/Time	N	Y
Security Access	N	Y
Reference Ranges	N	Y
LIS	N	Y
Backup or Restore	N	Y
Other	N	Y
About	Y	Y
FUNCTIONS	Y	Y
Diagnostics	Y	Y
Hardware Reset	Y	Y
Clean Baths	Y	Y
Backflush Aperture	Y	Y
Bleach Cycle	Y	Y
Diluter Reset	Y	Y
Prepare to Ship	N	Y
Drain Baths	Y	Y
Rinse Baths	Y	Y
Lubrication Pos.	Y	Y

Table A.1 Security Access Levels *(Continued)*

Feature	Operator	Administrator
Diluent Dispense	Y	Y
Check Valves	Y	Y
Individual Valves	Y	Y
All	Y	Y
Cycle Valves	Y	Y
Check Sensors	Y	Y
HGB LED	N	Y
OPT LED	N	Y
Aperture Current	N	Y
Vacuum	N	Y
Service	N	N
LOGOUT	Y	Y

Reports

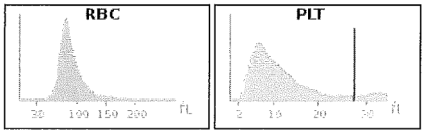
This section contains examples of the reports that are available.

Figure A.1 Patient Results - CBC, Whole Blood - Format 1

DxH 500	Clinical Quality Assurance	LAB
AY040056	Bldg1	12K05

Specimen ID:	15465789	**Test:**	CBC	**Specimen:**	WB
Patient ID:	12PT456	**Gender:**	M		
First Name:	JEFF	**Last Name:**	DALTON		
Run Date/Time:	08/01/2015 11:30	**Date of Birth:**	05/13/1987	**Age:**	28 Year(s)
Collection:	08/01/2015 02:30	**Sequence #:**	36005		
Location:	ICU	**Physician:**	STEPHANY AYERS		

Test	Result	Flags	Units	Low	High
WBC	5.52		x10³/µL	3.60	10.20
RBC	5.39		x10⁶/µL	4.06	5.63
HGB	15.56		g/dL	12.50	16.30
HCT	46.2		%	36.7	47.1
MCV	85.7		fL	73.0	96.2
MCH	28.9		pg	23.9	33.4
MCHC	33.7		g/dL	32.5	36.1
RDW	15.1		%	12.1	16.2
RDW-SD	42.7		fL	36.5	46.0
PLT	132.3	I	x10³/µL	152.4	347.9
MPV	9.87		fL	7.40	11.40



Diluent	0001170	10/11/2015	
Lyse	3935203	10/11/2015	
Cleaner	2935208	11/10/2015	
Control	371408043	06/19/2015	09:31
Calibration	491504200	07/29/2015	16:13

ADMIN	Printed 08/12/2015 11:30	XXMMSSSS	res36005.csv

Figure A.2 Patient Results - CD, Whole Blood - Format 2

DXH 500 SN. AY040057 CLINICAL QUALITY ASSURANCE
BUILDING I. LAB 12-K05

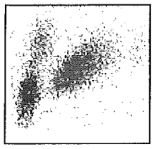
Specimen ID:	2015081105	**Test:**	CD	**Specimen:**	WB
Patient ID:	258745	**Gender:**	F		E
First Name:	LUCY	**Last Name:**	MORGAN		
Run Date/Time:	08/11/2015 04:13 PM	**Date of Birth:**	01/01/1950 E	**Age:**	65 Year(s) e
Collection:	08/11/2015 12:00 PM	**Sequence #:**	956		
Location:	ICU	**Physician:**	DR. ROSS		
Comments:	STAT				

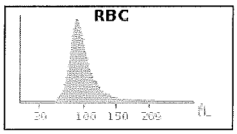
Test	Result	Flags	Units	Low	High
WBC	6.10		x10³/µL	3.60	10.20
LY	25.62		%	15.20	43.30
MO	12.66		%	5.50	13.70
NE	57.88		%	43.50	73.50
EO	3.74		%	0.80	8.10
BA	0.10	I	%	0.20	1.50
LY#	1.56		x10³/µL	1.00	3.20
MO#	0.77		x10³/µL	0.30	1.10
NE#	3.53		x10³/µL	1.70	7.60
EO#	0.23		x10³/µL	0.00	0.50
BA#	0.01		x10³/µL	0.00	0.10

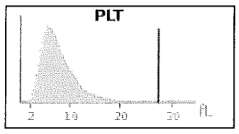
Test	Result	Flags	Units	Low	High
RBC	4.92		x10⁶/µL	4.06	5.63
HGB	15.27		g/dL	12.50	16.30
HCT	46.1		%	36.7	47.1
MCV	93.6		fL	73.0	96.2
MCH	31.0		pg	23.9	33.4
MCHC	33.1		g/dL	32.5	36.1
RDW	13.0		%	12.1	16.2
RDW-SD	41.4		fL	36.5	46.0

PLT	235.3		x10³/µL	152.4	347.9
MPV	8.04		fL	7.40	11.40

Flags & Messages







Neutrophils	___	Metamyelocyte	___	NRBC	___	Microcytosis	___
Segmented	___	Myelocyte	___	Anisocytosis	___	Macrocytosis	___
Band	___	Promyelocyte	___	Poikilocytosis	___	Other	___
Lymphocyte	___	Blast	___	Polychromasia	___		
Monocyte	___	Ab.Lymph	___	Hypochromasia	___		
Eosinophil	___	Other	___				

Comment:

Reviewed by

Diluent	0001170	10/05/2015	
Lyse	3935203	10/05/2015	
Cleaner	2935208	11/04/2015	
Control	361505192	08/11/2015	10:02 AM
Calibration		07/28/2015	03:48 PM

ADMIN Printed 08/12/2015 08:31 AM AY040057 res956.csv

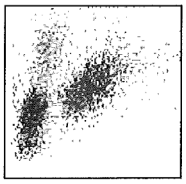
Figure A.3 Patient Results - CD, Prediluted Blood - Format 1

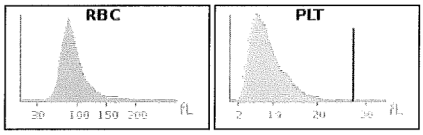
DXH 500 SN. AY040057 CLINICAL QUALITY ASSURANCE
BUILDING I. LAB 12-K05

Specimen ID:	0005888	**Test:**	CD	**Specimen:**	PD
Patient ID:	125478	**Gender:**	F		
First Name:	ANA	**Last Name:**	ROBINSON		
Run Date/Time:	08/13/2015 03:57 PM	**Date of Birth:**	01/01/1950	**Age:**	65 Year(s)
Collection:	08/13/2015 12:00 PM	**Sequence #:**	969		
Location:	BLDG.3	**Physician:**	DR. RAMSEE		
Comments:	CALL FLOOR				

Test	Result	Flags	Units	Low	High
WBC	4.40		x10³/µL	3.60	10.20
LY	33.23		%	15.20	43.30
MO	11.16		%	5.50	13.70
NE	54.53		%	43.50	73.50
EO	0.97		%	0.80	8.10
BA	0.11	l	%	0.20	1.50
LY#	1.46		x10³/µL	1.00	3.20
MO#	0.49		x10³/µL	0.30	1.10
NE#	2.40		x10³/µL	1.70	7.60
EO#	0.04		x10³/µL	0.00	0.50
BA#	0.00		x10³/µL	0.00	0.10
RBC	3.73	l	x10⁶/µL	4.06	5.63
HGB	11.11	l	g/dL	12.50	16.30
HCT	33.6	l	%	36.7	47.1
MCV	90.0		fL	73.0	96.2
MCH	29.8		pg	23.9	33.4
MCHC	33.1		g/dL	32.5	36.1
RDW	16.2		%	12.1	16.2
RDW-SD	48.3	h	fL	36.5	46.0
PLT	301.3		x10³/µL	152.4	347.9
MPV	8.94		fL	7.40	11.40

Flags & Messages





Neutrophils	
Segmented	
Band	
Lymphocyte	
Monocyte	
Eosinophil	
Basophil	
Metamyelocyte	
Myelocyte	
Promyelocyte	
Blast	
Ab. Lymph	
Other	
NRBC	
Anisocytosis	
Poikilocytosis	
Polychromasia	
Hypochromasia	
Microcytosis	
Macrocytosis	
Other	
Reviewed by	

Diluent	0001170	10/05/2015	
Lyse	3935203	10/05/2015	
Cleaner	2935208	11/04/2015	
Control	371505193	08/12/2015	05:48 PM
Calibration		07/28/2015	03:48 PM

ADMIN Printed 08/13/2015 03:59 PM AY040057 res969.csv

APPENDIX B

Bar Codes

Bar-Code Label Specifications

The handheld bar-code scanner scans the number of characters in the symbology used plus a check digit.

By default, the bar-code scanner contains the configuration.

The supported specimen bar-code symbologies are Code 128, Codabar, NW7, Code 39, and Interleaved 2 of 5. The bar-code scanner can read up to 22 characters or the total number of characters that can be printed in the viewable height, whichever is less.

⚠ CAUTION

Risk of misidentification. Beckman Coulter recommends that you enable checksum for bar-code labels.

Table B.1 Printing Parameter Specifications

10 µM 3:1 Ratio Recommended				
Minimum Tube Length Required	**Number of Characters by Code Type**			
	Code 128 *	**Code 39**	**Interleaved 2 of 5**	**Codabar**
55 mm	9	4	12	8
60 mm	11	5	14	9
65 mm	12	6	16	11
70 mm	14	8	18	12
75 mm	16	9	20	14
80 mm	19	10	22	16
85 mm	21	11	-	18
90 mm	22	12	-	19
95 mm	-	13	-	20
100 mm	-	14	-	22

* The instrument supports Codabar with AIM-16 using *A* as the leading and trailing character.

APPENDIX C

Training Checklist

Training Checklist

Go through this checklist before operating the instrument.

Table C.1 Training Checklist

Initials/Date Completed	Topic	Description
	Hardware	CHAPTER 1, System Overview • Identify components and describe their functions. See Instrument Views.
	Software	CHAPTER 1, System Overview • Familiarize yourself with the icons in the Software section.
	System Operations	CHAPTER 3, Startup and Daily Checks • Perform an instrument power up and log on. See Logging On/Logging Off. • Perform Daily Checks and verify that all parameters for Daily Checks display *Pass*. See Daily Checks. CHAPTER 9, Setup • Recognize and successfully replace all supplies. See Setting Up or Replacing Supplies. • Replace waste, if applicable. See Setting Up or Replacing Waste Disposal. CHAPTER 8, Shutdown • Perform an instrument shutdown. See Performing a Shutdown. • Perform a power down. See Emergency Stop, Powering Down, and Powering Off.

Table C.1 Training Checklist *(Continued)*

Initials/Date Completed	Topic	Description
	Quality Control	CHAPTER 9, Setup • Set up new quality control lot numbers. See Setting Up and Editing Controls. CHAPTER 4, Quality Control • Prepare and process quality controls. See Analyzing Commercial Controls. • Review quality controls and verify that all control runs are within limits. See Viewing Control Files. • Recognize quality control runs that are not within limits and troubleshoot, if necessary. See If a Control is OUT. • Add comments, print, export, delete, and transmit quality controls, if applicable. See Viewing Control Files, Printing Control Files, Exporting Control Files, and Deleting Control Files. • Prepare and download IQAP data. See Downloading to IQAP.
	Patient Samples	CHAPTER 2, Operation Principles • Understand abnormal diff scatter plot and histograms from normal results. See CHAPTER 2, Operation Principles. • Read Parameter Measurement, Derivation, and Calculation. CHAPTER 1, System Overview • Review interfering substances. See Limitations. CHAPTER 5, Sample Analysis • See Identifying Patient Samples. • Prepare and process whole-blood patient samples. See Running Whole-Blood Samples. • Prepare and process prediluted blood samples. See Running Prediluted-Blood Samples. CHAPTER 6, Data Review • Review patient samples and successfully search, delete, and print patient results. See Reviewing Patient Results, Searching for Patient Results, Deleting Patient Results, and Printing Patient Results. • Recognize possible flags, codes, and messages. See Flags, Codes, and Messages Displayed. CHAPTER 7, Worklist • Create a worklist. See Setting Up a Test Order. • Successfully match an auto-sequenced SID (Auto-SIDxxxxx) with a current worklist entry, if applicable. See Matching Specimen ID (SID).

Table C.1 Training Checklist *(Continued)*

Initials/Date Completed	Topic	Description
	Maintenance	CHAPTER 10, Troubleshooting • Familiarize yourself with general troubleshooting scenarios. See General Troubleshooting. • View event logs, identify log errors, and export log files. See Viewing Logs and Exporting Logs. CHAPTER 12, Cleaning Procedures • Complete the cleaning procedures. See When, Why, and How to Perform Each Cleaning Procedure. CHAPTER 13, Replacement/Adjustment Procedures • Familiarize yourself with the replacement/adjustment procedures. See When, Why, and How to Perform Each Replacement/Adjustment Procedure.
	Quality Assurance	CHAPTER 11, Quality Assurance • Perform the repeatability procedure and verify that the CV% does not exceed the repeatability limits. See Running Repeatability. • Perform the carryover procedure and verify that all parameters display *Pass*. See Running Carryover. • Read When to Verify Calibration and When to Calibrate. • Perform calibration. Verify and review all calibration results. See Calibrating with DxH 500 Series Calibrator.
Operator Name and Signature:		
Operator Title:		
Trainer Name and Signature:		
Trainer Title:		

APPENDIX D

Implementation Checklist

Performance Verification Checklist

Hematology - To be completed during implementation by laboratory staff

Table D.1 Performance Verification Checklist

Instrument/Serial Number:		
Procedure	**Date Completed or N/A ***	**Technician**
Hardware installation data verified		
Familiarization with software and software icons		
Repeatability verified		
Carryover verified		
Calibration verified		
System and reporting options set up		
QC files set up		
Quality Assurance set up and IQAP/eIQAP enrollment		
Set up and verify LIS interface		
Samples run on new instrument and comparison method: CBC/Diff and manual differentials for truth tables		
Comparison data collated and submitted for data analysis		
Measuring range (linearity) verified		
Reference interval (normal ranges) verified		
QC lab limits (per lab protocol) established		
Method comparison: primary versus backup instrument		
Data analysis reports reviewed with appropriate lab staff		
Pathology/Lab Director sign-off		

* Some items may not apply depending on the instrument, test menu, laboratory protocol, and/or local regulatory agency.

Abbreviations and Acronyms

µ — micron

µL — microliter

µm — micrometer

A — ampere

ASCII — American Standard Code for Information Interchange

ASTM — American Society for Testing and Materials

CBC — complete blood count

CD — CBC/Diff

CLSI — Clinical and Laboratory Standards Institute

cm — centimeter

CV — coefficient of variation

dB — decibel

EDTA — ethylenediaminetetraacetic acid

FDA — Food and Drug Administration

ft — foot or feet

gal — gallon

HCT — hematocrit

HGB — hemoglobin

H&H — HGB/HCT

Hz — hertz

IQAP — Inter-Laboratory Quality Assurance Program

IVD — in vitro diagnostics

L — liter

LIS — Laboratory Information System

m — meter

MCH — mean corpuscular hemoglobin

MCHC — mean corpuscular hemoglobin concentration

MCV — mean cell volume

mL — milliliter

mm — millimeter

mW — milliwatt

n — number

nm — nanometer

PD — prediluted

pg — picogram

PLT — Platelet

psi — pounds per square inch

QA — quality assurance

QC — quality control

SDS — safety data sheets

SID — Specimen identification

STAT — superior turn-around time (urgent or rush, immediately

VAC — Volts of Alternating Current

VDC — Volts of Direct Current

WBC — white blood cell

XB — Bull's moving average

XM — moving average

Glossary

absolute count — Concentration of a cell type expressed as a number per volume of whole blood.

accuracy — A measurement of the ability for the instrument to produce a test result matching a known reference value.

accurate — The reported measurement is in agreement, within acceptable limits, of the preferred reference standard. Sometimes specified as the difference of the means of a sample to the assay or expected value (mean difference) or the percent difference of the means of a sample to the assay or expected value (percent mean difference).

action limits — The limits for a test value, such that if the value is outside of the limits, some future action or review is suggested (for example, repeat test, review blood smear, etc.).

administrator — Someone whose job is to administer the affairs of a business or organization. See *advanced operator*.

advanced operator — An operator who has been given authority beyond that of a basic operator.

alert — A fault condition classification for events occurring on the system. An alert occurs when a condition exists on the system for which corrective actions must be taken in order for specimen results to be reported. This condition has no immediate effect on the system operation as the system does not stop. The system alerts the operator by triggering visual alarms, and if applicable, audible alarms. Alerts are not logged to the Event Log. All alerts require operator review; however, the method of review is specific to the individual event.

algorithm — A particular procedure for performing an analysis.

analytical measuring range — Analytical measuring range is the range of values over which the acceptability criteria for the method are defined.

analyze — To process a sample to determine the results for a test or tests.

anticoagulant — A substance added to blood to prevent clotting.

aperture — An opening of a specific size and length through which cells pass for counting and sizing.

application software — Software that controls and implements the system.

archiving — The process of removing inactive results from the system and storing the results in a format so that the archived data can be retrieved and viewed via the system software (and preferably also read by an external program) at a future date, providing a view similar to the one available for an active or inactive result.

aspiration probe — Device which pierces the cap and through which the sample is aspirated.

assay values — Values established for a control or calibrator by repeat testing of that material.

auto-incrementing — An option, when selected, where the Specimen IDs are automatically assigned numbers in sequential order.

available tests — All the tests which an instrument is capable of performing.

background count — Measure of the amount of electrical or particle interference.

backup — To store data separately from the active data, while leaving the active data in place.

base test — A test that is determined for a method, directly measured by an instrument (for example, WBC, for a CBC analysis), or a test that is derived from the RBC or PLT histogram.

basic operator — An operator with only limited authority to operate the system.

basophil — A mature granulocyte WBC with granules that contain heparin and vasoactive compounds. The granules stain purple-blue with Wright's stain.

batch — A group or set of results.

batch mean — The mean or average of a set of examples.

calibration — The procedure used to set an instrument at a specific value or values using a reference method.

calibration factor — A numerical factor applied to a result determined by an instrument, in order to establish an agreement between the instrument's measurement and a reference value.

calibrator — A substance with values obtained by reference instruments and used to calibrate instruments.

carryover — The amount, in percent, of sample remaining in the system and picked up by the next sample cycled. Low-to-high carryover is the amount of sample with low cell concentrations carried over to samples with high cell concentration, such as diluent to blood. High-to-low carryover is the amount of samples with high cell concentrations carried over to samples with low cell concentrations, such as blood to diluent.

characters — All letters A-Z and numbers 0-9.

cleaning agent — A detergent used to flush sample from tubing and eliminate protein buildup.

coefficient of variation (CV or CV%) — An expression, in percent (%), of the data spread (variation) as related to the mean value. CV, CV%, and coefficient of variation may be used interchangeably.

$$\mathrm{CV\%} = \frac{\mathrm{SD}}{\mathrm{Mean}} \times 100$$

coincidence correction — Mathematical adjustment of cell count and size for coincidence error.

coincidence error — Errors produced in counting and sizing by the presence of more than one cell within the aperture sensing area at the same time. The system senses these as one large cell rather than as two distinct cells.

complete blood count (CBC) — Whole blood parameters RBC, WBC, HGB, HCT, MCV, MCH, MCHC, PLT, RDW, RDW-SD, and MPV.

computed test — A test that is calculated based on the results of one or more other tests.

consumable — A component that is required by the physical system during operation and is typically disposed of after a single use or a finite number of usages. This includes such items as calibrators, controls, liquid reagents, etc.

control — A substance with predetermined values used as a standard to verify accuracy of instrument results.

control file — A set of retrieved control results and the expected results associated with them. Each control file contains results from a single instrument and a single control lot or specimen.

Control ID — A specimen ID that cannot be used for patient specimens because a control has been configured with a lot number that matches the Specimen ID.

critical limits — The limits for a test value, such that if the value is outside of the limits, the patient's life may be threatened and immediate action and notification is required.

critical result — A result considered sufficiently abnormal as to warrant immediate notification of the physician.

dataplot — A graphic representation of results. Dataplots present a combined view of population density and membership. Colors represent different types of cells. Shades of colors represent the number of cells--bright colors are the most dense.

deciliter (dL) — A unit of volumetric measurement equal to 0.1 liter.

default — Original setting in the software.

default tests — The tests that may be assigned to a test order for a specimen that cannot be positively identified, or for which a test order cannot be located.

deionized water — Water freed of salt and some organisms by an ion exchange process. This water can be used interchangeably with distilled water in procedures. Also referred to as DI H2O or DI water.

density — The number of cells in a particular region, regardless of the type of cell. On dataplots, as more cells appear in a particular region, the color of the region gets brighter.

Diff # — Used to represent the individual count tests, which includes: NE#, LY#, MO#, EO# and BA#.

Diff % — Used to represent the individual differential % tests, which includes NE, LY, MO, EO, and BA.

differential (Diff) — Leukocyte or white blood cell differential.

discrete test — Refers to either a single base test or a single computed test (for example, WBC which is a base test or HCT which is a computed test).

distilled water — Water freed of solids and organisms by distillation. This water can be used interchangeably with deionized water in procedures.

down-time — Any time the system is not available for testing.

eosinophil — A mature granulocyte WBC that responds to parasitic infections and allergic conditions. Granules are stained a bright reddish orange with Wright's stain.

erythrocyte (red blood cell) — A biconcave disc, 6.2 to 8.2 µm, that carries oxygen to the tissues in the body and carries carbon dioxide away from the tissues.

ethylenediaminetetraacetic acid (EDTA) — A common anticoagulant used for hematological testing.

event — A noteworthy occurrence; something that needs to be logged.

expiration date — A manufacturer's recommended last day of use for a reagent, control, or calibrator.

export — To format and store data so that it can be used by external programs (for example, Microsoft Excel or Word).

extended QC — Additional QC rules for verification of the following:

- Random error or Imprecision
- Systematic error or Bias
- Total error or Inaccuracy

femtoliter (fL) — Femtoliter, a unit of volumetric measurement equal to 10-15 liter.

final report — Any patient report dispatched subsequent to the entire set of patient's results being final released.

five-part differential — Classifying leukocyte cells into five sub-populations (neutrophils, lymphocytes, monocytes, eosinophils and basophils).

flagging — The ability of a system to identify and alert the operator to the presence of possible anomalies that may affect the accuracy of a test result or require additional work to be performed.

flags — A flag is a single letter or symbol and will always appear to the right of a result. A flag can be instrument generated (R, P), or laboratory-defined (H, L, c, a). On screens and printouts, the letters, such as H, L, and R appear next to parameter results to indicate specific conditions.

giant platelets — Platelets above 20 fL in size.

gram (g) — A unit of weight

hematocrit (HCT) — Red cell packed volume. The percentage of packed red cells compared to the entire blood sample.

hemoglobin (HGB) — A protein component of red cells that carries oxygen and carbon dioxide.

hemoglobinometry — Measurement of hemoglobin in the blood.

hertz (Hz) — A unit of frequency

histogram — A graphical display of the cell size distribution of a blood sample, where size is on the X-axis and frequency is on the Y-axis.

hold — When an individual test value, panel or set of test results is identified as requiring further review and verification prior to release.

imprecision — The degree to which a result will vary due to random error when measured several times on the same instrument.

in vitro — Outside of a living organism, such as in a laboratory or in an artificial container.

in vivo — Inside a living organism, associated with the physiological system.

indices — In hematology, refers to the following calculated values for red cell properties: MCV, MCH, and MCHC.

instrument — An analytical or preparation unit composed of one or more modules.

interfering substances — Components within a blood sample that complicate or obstruct the measurement of the desired parameters.

Inter-laboratory Quality Assurance — Program (IQAP) — A program administered by Beckman Coulter, Inc. for users of its hematology instruments and controls. It allows a laboratory to

compare its performance to all other laboratories in the program that use the same or similar instrument category and control products.

lab administrator — An individual who has responsibility for running a laboratory.

leukocyte (white blood cell) — Cells that defend the body against disease.

linearity — The ability (within a given range) of an instrument to provide results that are directly proportional to the concentration (amount) of the analyte in the test sample.

LIS query — When a clinical instrument requests test information for a particular specimen from the LIS system.

liter (L) — A unit of volumetric measurement

log — A record of certain system occurrences or events

lot number — An identifier assigned by a manufacturer to identify a control, reagent or calibrator

lymphocyte — WBC originating in the lymph system. The key to the body's immune system, the lymphocyte recognizes and eliminates foreign pathogens in the body.

lyse — To break apart or dissolve.

mean — Arithmetic average of a group of data.

mean cell volume (MCV) — Average volume of red blood cells expressed in fL.

mean corpuscular hemoglobin (MCH) — The weight of hemoglobin in the average red blood cell expressed in picograms.

mean corpuscular hemoglobin concentration (MCHC) — The weight of hemoglobin in the packed red cell volume expressed in g/dL or g/L.

mean platelet volume (MPV) — Average volume of platelets expressed in fL.

membership — The different types of cells in a particular region, regardless of the number of cells. On dataplots, membership is represented showing different types of cells in different colors.

meter (m) — A unit of linear measurement

micron (µ) — One millionth of a meter

milliliter (mL) — A unit of volumetric measurement equal to 10^{-3} liter.

millimeter (mm) — A unit of linear measurement, equal to one-thousandth of a meter.

monocyte (MO) — A large, mononuclear, phagocytic WBC found in the peripheral blood and in the lymphoid system.

mononuclear — Having only one nucleus.

nanometer (nm) — A unit of linear measurement equal to 10^{-9} meter.

open tube — See open vial.

open vial — The sampling of a specimen (blood) by removing the cap from the container.

operating range — The range over which the instrument displays, prints and transmits results.

operating system (OS) — Operating system files, libraries, drivers, and so forth, required for running the application.

operator — An individual with authority to operate the system.

operator ID — Uniquely identifies the processor of the samples.

outlier — Control results that fall outside the expected or established range.

parameter — Component of blood that the instrument measures and reports.

partial voteout — An individual aperture count that is not used in the average parameter value.

patient ID — The instrument considers this field as an optional sample identifier.

Your laboratory may use it as a specific identifier for the patient, such as the medical record or Social Security number. It is intended for laboratories that want to track results of several different samples or tests for the same patient.

platelet (thrombocyte) — The cytoplasmic fragments of megakaryocytes, circulating as small discs in the peripheral blood, and an essential component for blood clotting.

PLT Histogram — The portion of the PLT distribution curve between 0 fL and 36 fL.

pounds per square inch (psi) — A unit of pressure measurement.

power OFF — To remove power from an instrument.

power ON — To provide power to an instrument.

precision — A measure of the ability of the instrument to reproduce similar results when a sample is run repeatedly. May also be referred to as repeatability.

predilute — Dilution of a sample prior to analysis on the analyzer.

preliminary report — Any patient report dispatched prior to the entire set of patient's results being final released.

primary identifier — The unique identifier that will be used by the system to positively identify a patient specimen.

privilege — Permission to perform some particular function, for example, enter a test order or review patient results.

quality control (QC) — A set of procedures that a laboratory sets up to ensure that an instrument is working accurately and precisely.

random error — Imprecision or variance

range — The difference between the highest and lowest measurement in a series.

raw data — Unanalyzed data; data not yet subjected to analysis.

RBC histogram — An RBC distribution curve. The normal curve ranges from 36 to 360 fL. The display starts at 24 fL.

RDW (red distribution width) — The size distribution spread of the erythrocyte population derived from the RBC histogram. Expressed as coefficient of variation (%).

RDW-SD — The size distribution spread of the erythrocyte population derived from the RBC histogram. Expressed as a standard deviation in fL.

reagent — A substance used (as in detecting or measuring a component, or in preparing a product) because of its chemical or biological activity. (Webster)

red blood cell (RBC) — See *erythrocyte (red blood cell)*.

red cell indices — In hematology, refers to the following calculated values for red cell properties: MCV, MCH, and MCHC.

reference range — A range of test values determined by statistical analysis of specimens collected from a normal (non-diseased) population.

released — The test results have been automatically or manually validated and identified as reportable outside the system's domain, as defined by your laboratory.

repeatability — The closeness of agreement between the results of successive measurements of the same substance carried out under the same conditions of measurement. Also known as reproducibility, precision, within-run precision, within-assay, within-run, intra-assay, and intra-run precision.

report — A formatted printed and/or electronic record of compiled specimen or system data.

reportable range — The range over which the instrument is accurate.

reported — The test results have been automatically or manually dispatched to a user specified destination. The test results may or may not have been released.

rerun — The ability to repeat an analysis on a specimen using the same test.

restore backup — To bring backed-up data back into the system so that it replaces the active data in the system and becomes the active data itself.

result — A numerical value or values obtained by performing the analysis for a particular test.

root mean squared error (RMSE) — Measured within a control file Extended QC is enabled, and N is greater than or equal to 15 runs. RMSE is a statistical result that is compared to the limits for Single Measurement Error.

$$\Delta = \sqrt{\frac{n-1}{n}} \cdot s^2 + \delta^2$$

run — One analysis of a specimen which generates test results.

sample — A portion of a specimen taken for analysis on an instrument.

sample volume — The volume of a specimen removed from a specimen container.

Also, the volume of a specimen that is conditioned for a specific measuring function. When the volume removed from a specimen container exceeds the conditioning requirement and a portion is discarded, or when portions of the sample are allocated to several conditioning processes, the sample may be called an intermediate sample volume.

secondary identifier — An identifier not configured to be the primary identifier, that can be used by the system to identify a patient specimen in cases where the primary identifier cannot be read.

sheath — A liquid which surrounds and aligns another liquid.

shift — Consecutive values that abruptly move from one level (mean) to another and then maintain a constant level.

single measurement error — The possible deviation for a single measurement of a result. Single measurement error is flagged when Extended QC is enabled, and the result exceeded the upper or lower limit for Single Measurement Error limits entered by the operator. The Single Measurement Error is measured within the control file as the Root Mean Squared Error (RMSE).

specifications — An exact statement of particulars, especially a statement prescribing materials, and dimensions for something to be installed.

specimen — The discrete portion of whole blood taken for examination, study, or analysis.

standard deviation (SD) — A measure of deviation from the mean. For example, a measure of the range of channel deviation within a measurement.

$$SD = \sqrt{\frac{\sum \langle \bar{x} - x \rangle^2}{N-1}}$$

system administrator — An individual who has responsibility for administering the system who may also perform activities such as configuring the modules and system and performing the more non-routine maintenance activities.

system identifier (SID) — An identifier entered at installation time and used to identify the system when calling your Beckman Coulter Representative.

systematic error — The bias or deviation of the mean from the target value.

test — Individual parameter for which an instrument can determine a value, either directly measured or computed.

test order — A description of what tests are to be performed on each given specimen.

throughput — A measurement of rate at which an instrument can produce test results, conventionally measured as tests per hour.

total voteout — A code (-----) that replaces the average parameter result when there is disagreement between the two counts. The aperture counts for the two count periods were too far apart to give a reliable average parameter value.

trend — Consecutive values that increase or decrease gradually.

uninterruptible power supply (UPS) — A device with a battery that allows limited continued operation of an instrument or other device during a power outage.

upload — Data transmitted from a clinical instrument to an LIS system or other host.

user — See *basic operator*.

user interface — The display and mechanical devices (keyboard, mouse) used by an operator to interact with the instrument or instruments.

validated — The test results have been automatically or manually reviewed and confirmed according to laboratory protocols.

WBC differential — A determination of the types and numbers of leukocytes found in a blood specimen. This may be accomplished by the instrument or by examination of a stained blood smear.

white blood cell (WBC) — White Blood Cell count results from the CBC analysis.

worklist — A listing of specimen analysis status.

XB — Bull's Moving Average. A quality control mechanism used by hematology instruments that monitors the stability of the instrument by using the red cell indices MCV, MCH and MCHC.

XB batch — A set of XB results for up to 20 runs, and the associated XB statistics, if there are any.

XB current batch — The batch of 20 XB results into which results are currently being placed. The batch will remain the current batch until the first specimen after this batch is run, at which time it will become the last XB batch.

XB last batch — The last XB batch for which results are available, immediately preceding the current XB batch.

XB previous batch — The XB batch immediately preceding the last XB batch.

XB results — The parameter results (for example, MCH, MCHC) that have been incorporated into an XB batch.

XB run — A single analysis of a specimen, the results for which are used as XB results. The run also has ID information associated with it in addition to the results.

XB statistics — Statistics resulting from the analysis of results in an XB batch, or in a set of XB batches.

XM — Moving Average. A quality control method that uses the Exponentially Weighted Moving Average (EWMA) to monitor the stability of the instrument using the CBC, Diff, and Retic parameters.

XM batch — A set of XM results, configured between 20 to 500 runs, and the associated XM statistics, if any.

XM batch mean — The average value calculated for the batch of XM results.

XM current batch — The batch of XM results, configured between 20 to 500 runs, into which results are currently being placed. The batch remains the current batch until the first specimen after this batch is run, at which time it will become an XM completed batch.

XM completed batch — The XM batch for which the maximum number of runs for the batch are available.

XM group — The group (CBC or DIFF) into which results are placed for XM analysis.

XM results — The parameter results that have been incorporated into an XM batch.

XM run — A single analysis of a specimen, the results for which are used as XM results. The run also has ID information associated with it in addition to the results.

XM statistics — Statistics resulting from the analysis of results in an XM batch, or in a set of XM batches.

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- Quality Assurance
- Cleaning Procedures
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