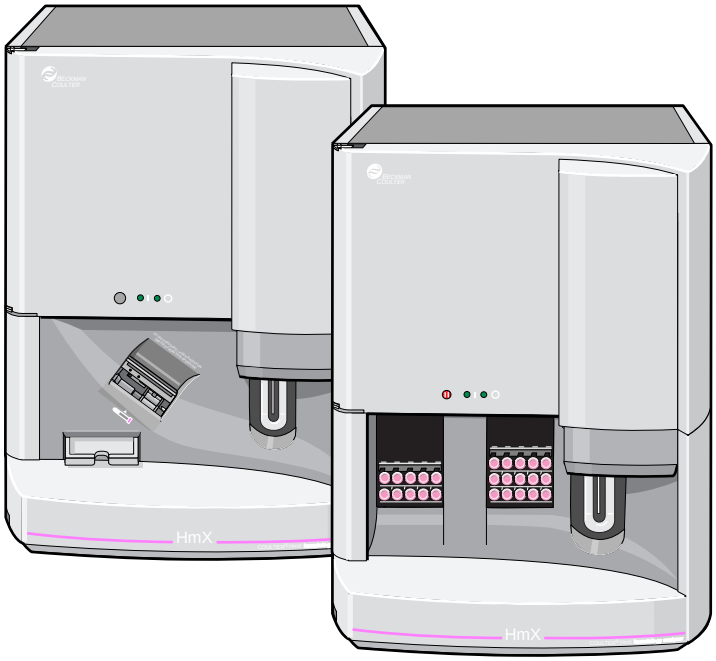
COULTER® HmX Hematology Analyzer
COULTER® HmX Hematology Analyzer with Autoloader

Reference



PN 4237523A (July 1999)

COULTER CORPORATION
A Beckman Coulter Company
Miami, Florida 33196-2500 USA

LEGAL NOTICES

READ ALL PRODUCT MANUALS AND CONSULT WITH BECKMAN COULTER-TRAINED PERSONNEL BEFORE ATTEMPTING TO OPERATE INSTRUMENT.

HAZARDS AND OPERATIONAL PRECAUTIONS AND LIMITATIONS

WARNINGS, CAUTIONS, and IMPORTANTS alert you as follows:

WARNING - Might cause injury.
CAUTION - Might cause damage to the instrument.
IMPORTANT - Might cause misleading results.

CAUTION System integrity might be compromised and operational failures might 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.

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 it is not limited to, protective eyewear, gloves, and suitable laboratory attire when operating or maintaining this or any other automated laboratory analyzer.

WARNING Risk of operator injury if all covers are not secured in place prior to instrument operation or you attempt to replace a part without carefully reading the replacement instructions. Do not attempt to replace any component until you carefully read the instructions for replacing the component.

IMPORTANT If you purchased this product from anyone other than Beckman Coulter or an authorized Beckman Coulter distributor, and, if 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.

REVISION STATUS

Initial Issue, A 7/99
Software version 1.0.

This document applies to the latest software listed and higher versions. When a subsequent software version changes the information in this document, a new issue will be released.

REVISION STATUS

CONTENTS

ILLUSTRATIONS

TABLES

This introductory section contains the following topics:

- How to use your COULTER HmX Hematology Analyzer and HmX Hematology Analyzer with Autoloader Documentation set
- About this Manual
- Conventions
- List of Icons.

HOW TO USE YOUR COULTER® HmX HEMATOLOGY ANALYZER AND HmX HEMATOLOGY ANALYZER WITH AUTOLOADER DOCUMENTATION SET

Use the **Reference** manual for in-depth information about what the instrument does, the methods it uses, its specifications, and information on installation, safety, and software options.

Use the **Special Procedures and Troubleshooting** Manual to run a calibration, perform reproducibility and carryover checks, and to clean, replace, or adjust a component of the instrument. The troubleshooting tables appear at the back of the manual.

Use the **Operator's Guide** for the day-to-day running of your instrument. Read the System Overview chapter to become familiar with the different parts of your system. Then go through the detailed step-by-step procedures of start up, running controls and samples, reviewing data, and shutdown.

Use the **Host Specifications** Manual to locate information about transmission to a host computer.

Use the **Master Index** to locate a subject in your documentation set.

See the Documentation page on the back cover of this manual for the contents of each manual. It can help you to determine quickly which manual contains the information you need.

ABOUT THIS MANUAL

Your COULTER HmX Hematology Analyzer and HmX Hematology Analyzer with Autoloader Reference manual provides in-depth information about what the instrument does, the methods it uses, its specifications, and information on installation, safety, and software options.

This manual covers the total HmX system. Use this manual for reference if you have a HmX Hematology Analyzer or a HmX Hematology Analyzer with Autoloader.

This information is organized as follows:

- Chapter 1, Use and Function
  Contains the intended use of the instrument, a brief history of the methods used by the instrument, the reagents, calibrator, and controls used, and a short description of the major components and options.
- Chapter 2, Installation
  Contains the instrument requirements, the diagrams of the reagent tubing connections, and the interunit cable connections.

- Chapter 3, Operation Principles
  Contains the descriptions of the Coulter Method, the normal sample flow through the instrument, how counting and sizing are accomplished, and how the parameters are derived.
- Chapter 4, Specifications/Characteristics
  Details the instrument and performance specifications, the performance characteristics, and the interfering substances.
- Chapter 5, Laser Safety
  Describes laser safety precautions and the location of the laser-related labels.
- Chapter 6, Reporting Options
  Shows examples of printouts you can select from your graphic printer.
- Chapter 7, Bar-Code Specification
  Describes the specifications for bar-code labels to be used with the system.
- Appendices
  The appendices provide reference material on the following topics:
  - Tube Sizes
  - Diff Comparison.
- References
  Lists the references, by number, as used throughout this manual.
- Glossary
  Contains the definitions for words and terms used in the set of manuals.
- Index
  Contains terms and where you can easily locate information about them in this manual.

CONVENTIONS

This manual uses the following conventions:

- *ITALICS* indicate screen messages such as *RESET THE SYSTEM* or *Press any key.*
- **Bold** indicates
  - a menu item such as **Run Samples**
  - or a function such as **F3 Run**.
- The software path to access the needed function or screen appears in a series separated by double arrow heads. For example, the path to the **REAGENTS** set up screen is:

  Special Functions ▸▸ Set Up ▸▸ System Set Up ▸▸ Reagents.

  To select a menu item, highlight it then press Enter or press the alphabetic key on the keyboard that corresponds to the letter displayed in black within the name of the menu item.
- ▢ indicates a key (such as Enter).
- ▢ ▢ indicates to press and release the first key listed, then press and release the next key listed.
- ▢+▢ indicates to press and hold the first key listed, then press the next key.

LIST OF ICONS

Read this section if you have a HmX Hematology Analyzer with Autoloader.

Read this section if you have a HmX Hematology Analyzer.

COMPUTER PROGRAM STATEMENT

About the HmX Hematology Analyzer Computer Program

HmX Hematology Analyzer Computer Program, Version 1.0

1.1 INTENDED USE

General

The COULTER HmX Hematology Analyzer, Figure 1.1, and the HmX Hematology Analyzer with Autoloader, Figure 1.2, are quantitative, automated hematology analyzers and leukocyte differential cell counters For In Vitro Diagnostic Use in clinical laboratories.

The purpose of the HmX Hematology Analyzer is to separate the normal patient, with all normal system-generated parameters, from the patient who needs additional studies. These studies include further measurements of cell size and cell distribution, biochemical investigation or any other test that helps diagnose the abnormality.

Figure 1.1 The HmX Hematology Analyzer

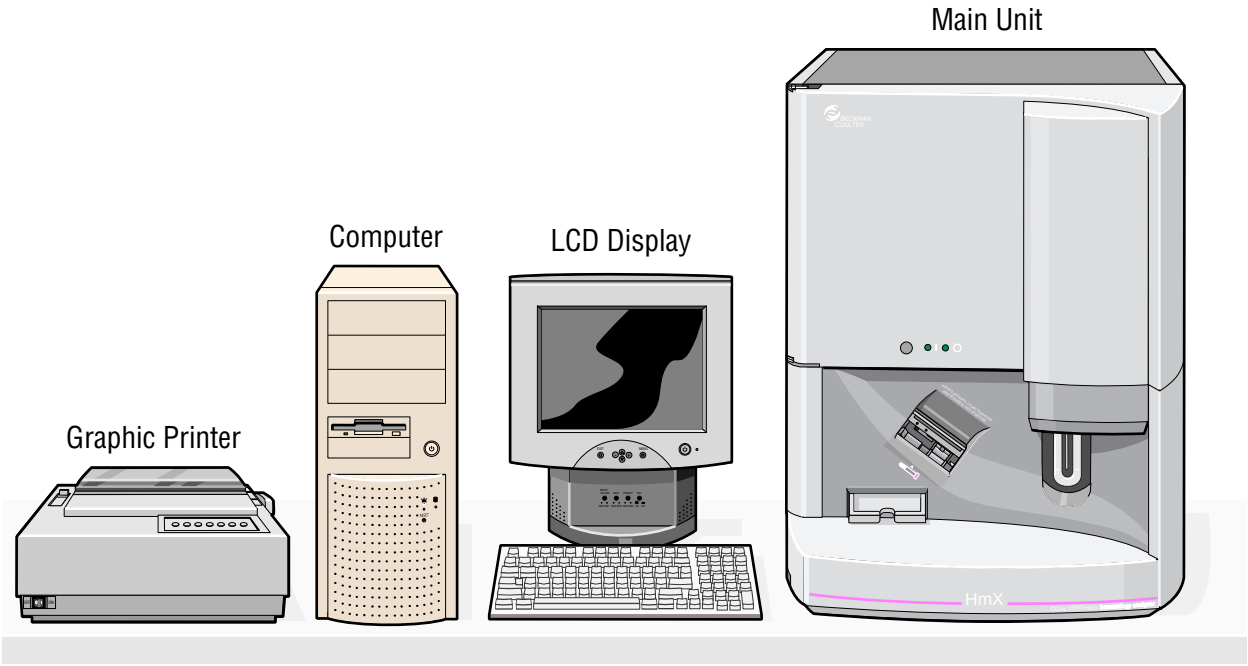
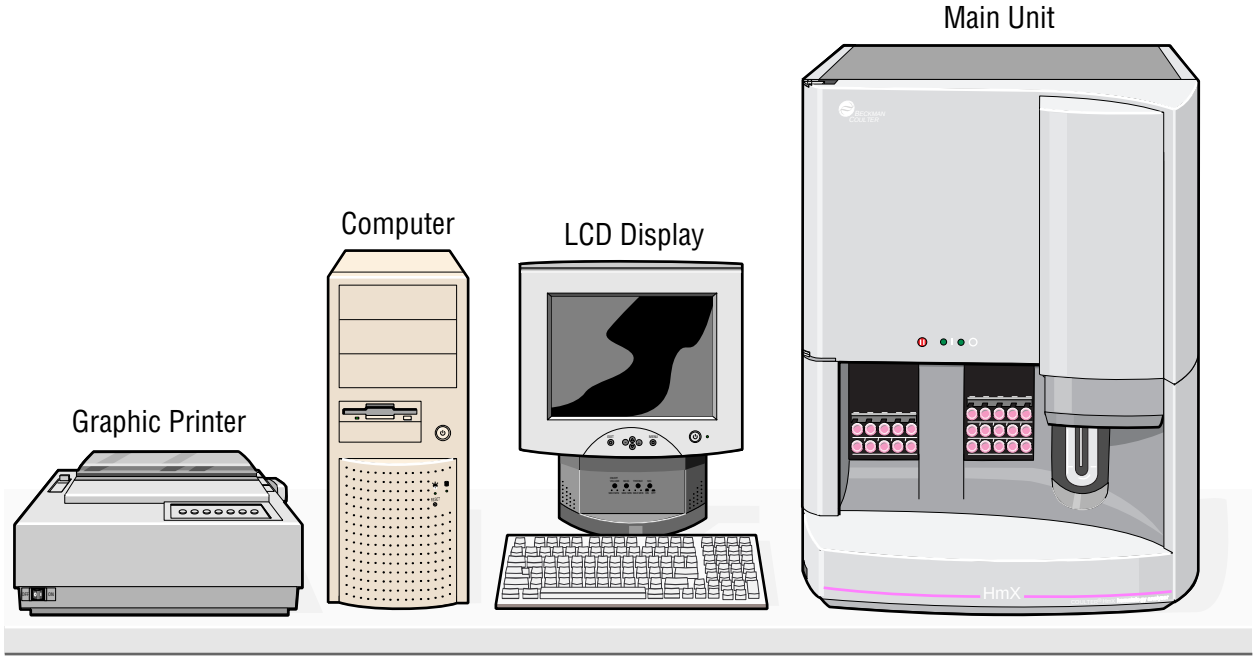


Figure 1.2 The HmX Hematology Analyzer with Autoloader



Parameters

The systems measure these hematologic parameters of whole-blood specimens:

WBC	White Blood Cell (leukocyte) Count
NE%	Neutrophil percent
NE#	Neutrophil number
LY%	Lymphocyte percent
LY#	Lymphocyte number
MO%	Monocyte percent
MO#	Monocyte number
EO%	Eosinophil percent
EO#	Eosinophil number
BA%	Basophil percent
BA#	Basophil number
RBC	Red Blood Cell (erythrocyte) count
Hgb	Hemoglobin concentration
Hct	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
RDW	Red Cell Distribution Width
Plt	Platelet count
MPV	Mean Platelet Volume
*PDW	Platelet Distribution Width
*Pct	Plateletcrit

RET%	Reticulocyte percent
RET#	Reticulocyte number

*In the USA, the PDW and Pct parameters are **Not for Diagnostic Use**. The value for PDW is used as an internal check on the reported platelet parameters Plt and MPV.[1, 2, 3]

Unless otherwise stated, all parameter results are shown in the US unit format throughout the manuals.

CLIA Complexity Categories

See Table 1.1 for the CLIA complexity categories of the HmX Hematology Analyzer and HmX Hematology Analyzer with Autoloader.

Table 1.1 CLIA Complexity Table

Analyte	Category	Analyte Identifier	CDC Test System Code
Hematocrit (Hct)	Moderate	2514	10254
Hemoglobin (Hgb)	Moderate	2515	10254
Platelet count (Plt)	Moderate	4908	10254
Red blood cell count, erythrocyte count (RBC)	Moderate	5502	10254
Reticulocyte	Moderate	5506	10078
White blood cell count, leukocyte count (WBC)	Moderate	7002	10254
White blood cell differential, (WBC Diff)	Moderate	7001	10254

1.2 QUALITY CONTROL (QC)

Your laboratory can use these QC techniques with the HmX Hematology Analyzer:

- Daily instrument checks
- Commercial controls
- $\overline{X}_B$ Analysis
- Patient sample review
- Interlaboratory comparison (IQAP)

Quality Assurance (QA) can include a combination of these methods to provide complete QC. Beckman Coulter manufactures commercial controls for monitoring performance of CBC and differential parameters as well as monitoring flow cell alignment, gains, and VCS for flow-cell volume, conductivity, and light scatter.

You can perform manual differentials as a measure of good QC practice or as recommended by your laboratory, state, or federal protocol.

1.3 METHOD HISTORY

Development

W.H. Coulter (1956) describes the Coulter Principle:[4]

> A suspension of blood cells is passed thru a small orifice simultaneously with an electric current. The individual blood cells passing thru 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.[5]

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.[6, 7, 8]

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 aroused by Price-Jones in 1922.[9, 10]

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 have the trapped plasma error of centrifugal Hct measurements.[11]

Bull et al. described the use of a COULTER COUNTER analyzer for counting thrombocytes.[12] 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.[13, 14] Electronic refinements in the Model S-PLUS™ enhanced the accuracy of the hydrodynamic method. Von Behrens and Paulus also cited the feasibility of counting thrombocytes by the Coulter method.[15, 16]

Hemoglobinometry

The lytic reagent used for the complete blood count (CBC) parameters prepares the blood so the system can count leukocytes and sense the amount of hemoglobin. The lytic reagent rapidly and simultaneously destroys the erythrocytes and converts a substantial proportion of the hemoglobin to a stable pigment while it leaves leukocyte nuclei intact. The absorbance of the pigment is directly proportional to the hemoglobin concentration of the sample.

The accuracy of this method equals that of the hemiglobincyanide method, the reference method of choice for hemoglobinometry recommended by the International Committee for Standardization in Hematology (ICSH).[17]

Differential Measurement

The COULTER VCS established WBC differential technology using three measurements: individual cell volume, high-frequency conductivity, and laser-light scatter.

The combination of low-frequency current, high-frequency current, and light-scattering technology provides abundant cell-by-cell information that is translated by the instrument into conventional stained film leukocyte categories. Correlation between the frequency of the different cell types using stained film microscopy and this system is greater than 0.9 for lymphocytes and granulocytes, and 0.7 for mononuclear cells.

Volume Analysis

Electronic leukocyte volume analysis, using low-frequency current, has been used since 1967.[18] It has been evaluated as a possible adjunct to the differential white cell count.[19, 20, 21, 22]

Conductivity Analysis

Cell walls act as conductors to high-frequency current. As the current passes through the cell walls and through each cell interior, it detects differences in the insulating properties of cell components. The current characterizes the nuclear and granular constituents and the chemical composition of the cell interior.[23, 24, 25]

Light Scatter Analysis

Beckman Coulter's experience in flow cytometry dates back decades to Fulwyler's pioneering use of light scatter for cell analysis.[26] Loken et al. and Jovin et al. discuss the relationship of particle size and refractivity to the angle of light scattered from a laser beam.[27]

Reticulocyte (Retic) Analysis

Reticulocytes are immature, nonnucleated erythrocytes retaining a small network of basophilic organelles, comprised of RNA and protoporphyrin. The enumeration of reticulocytes provides a simple, effective means to determine red cell production and regeneration.[28, 29, 30, 31]

The most common means of measuring reticulocytes is to use supravital dyes, such as New Methylene Blue or Brilliant Cresyl Blue. These dyes precipitate and aggregate the basophilic substances within the reticulocyte, resulting in a granular, staining pattern easily seen with light microscopy.[32]

$\overline{X}_B$ 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.[33] Brian Bull, MD, improved the technique and named it $\overline{X}_B$ Analysis.[34]

$\overline{X}_B$ Analysis uses a "weighted moving average" of patient sample results because Koepke said that QC materials "ideally should be similar in structure and in reactivity to the patient constituent being measured, [and] therefore freshly drawn patient blood samples seem to be the most appropriate [QC material]."[35] Bull explains, "The analyser [sic] is considered to be 'in control' when the MCV, MCH, and MCHC determined on a batch of 20 patients by use of the $\overline{X}_B$ algorithm are within 3% of the expected mean indices of the population."[36]

1.4 SYSTEM COMPONENTS

Main Unit

The Main Unit includes:

- A sample handler
- A Diluter for:
  - The complete blood count (CBC)
  - Leukocyte differential analysis (DIFF) or Reticulocyte analysis
- An Analyzer/Systems Control Module
- An Electronic Power Supply, and
- A Pneumatic Power Supply.

Sample Handler

All HmX Hematology Analyzer instruments have:

- An automated, cassette-based transport for Primary mode - HmX Hematology Analyzer with Autoloader.

OR

- An automated, closed-vial Primary mode of a rotary cap-piercer - HmX Hematology Analyzer.
- An open-vial Secondary mode that uses a self-cleaning manual aspirator tip.
- A bubble/blood detector.
- A bar-code reader.

Diluter

The Diluter is the primary mechanical operating unit of the system. It aspirates, pipets, dilutes, mixes, lyses, and senses.

Analyzer/Systems Control Module

This module controls the timing and sequencing of the operating cycles. As it receives pulses and raw data from both the CBC and VCS (diff) diluters, it counts, measures, and computes parameters. It then sends this information to the DMS.

Electronic Power Supply

This unit supplies the necessary power for all instrument functions.

Pneumatic Power Supply

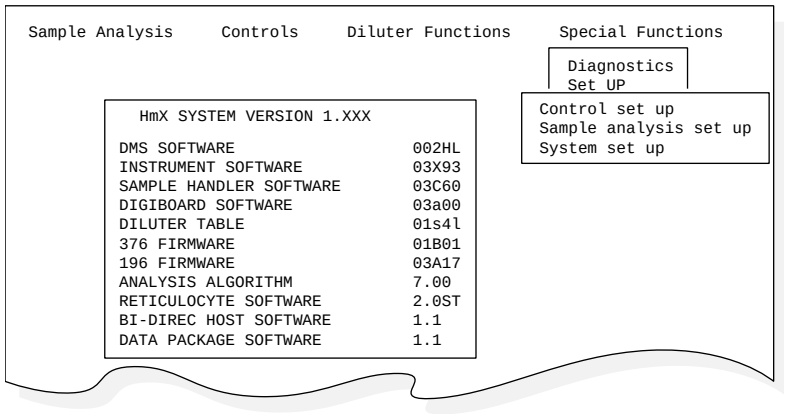
This unit supplies all air pressures and vacuums needed to operate the system.

Data Management System (DMS)

The DMS controls instrument operation, displays, stores, and recalls sample data, and allows the operator to perform quality control and calibration procedures. It stores patient and quality-control data on the hard drive and allows bidirectional communication with a host computer.

The System Version screen, Figure 1.3, displays the version number of the enabled software and the features. If a feature is not enabled, the system displays *****.

Figure 1.3 System Version Display



1.5 OPTIONS

Printers

Up to two graphics printers can be added to your system to produce hard copy reports of sample data.

1.6 REAGENTS

Beckman Coulter recommends these reagents or their equivalents. All stated performance characteristics in this manual refer to the HmX Hematology Analyzer and HmX Hematology Analyzer with Autoloader using these reagents.

Diluent

ISOTON® III (or ISOTON 4, Japan only) diluent is an isotonic electrolyte that:

- Dilutes the whole-blood samples.
- Stabilizes cell membranes for accurate counting and sizing.
- Conducts aperture current.
- Carries and focuses the sample stream in the flow cell to enable the WBC differential measurements.
- Rinses the system between samples.

CBC Lytic Reagent

LYSE S® III diff (or LYSE S 4, Japan only) lytic reagent is a lytic reagent used for the CBC mode. It:

- Rapidly lyses erythrocytes (RBCs), freeing hemoglobin (Hgb), and reducing the size of cellular debris to a level that does not interfere with the leukocyte (WBC) count.
- Causes a substantial conversion of the Hgb to a stable pigment, the absorbance of which is directly proportional to the Hgb concentration over the clinical range.

  Note: If you use LYSE S III diff lytic reagent you must use ISOTON III diluent. If you use LYSE S 4 lytic reagent you must use ISOTON 4 diluent.

HmX PAK

The HmX Pak contains the PAK LYSE (Erythrolyse™ II erythrocyte lytic reagent) and the PAK PRESERVE (StabiLyse™ leukocyte preservative) used for the differential measurement.

PAK LYSE

The PAK LYSE (also called the diff lytic reagent), while maintaining leukocytes (WBCs) in near-native state:

- Dilutes the blood samples.
- Rapidly lyses erythrocytes (RBCs).
- Reduces cellular debris to an insignificant level.

PAK PRESERVE

The PAK PRESERVE preserves the leukocytes (WBCs) in near-native state. It allows the leukocytes to be differentiated into their subpopulations through the volume, conductivity, and light-scatter measurements.

ReticPrep™ Reagent Kit

The COULTER ReticPrep reagent kit (see package insert) includes two reagents: Reagent A and Reagent B. Use these reagents when preparing samples for reticulocyte analysis. Follow the preparation instructions supplied with the kit.

Reagent A

Reagent A is a specially formulated, New Methylene Blue dye that stains the reticulum.

Reagent B

Reagent B is a clearing reagent that removes hemoglobin from the cell without removing the precipitated stain-RNA complex, keeping the cell and its membranes intact. Reagent B needs to be used with the repipetter dispenser available from Beckman Coulter, Inc.

Cleaning Agent

COULTER CLENZ® cleaning agent cleans and rinses the internal surfaces of the Diluter components. Daily use prevents protein buildup and eliminates routine aperture bleaching.

1.7 CONTROLS AND CALIBRATOR

Controls

COULTER 5C® cell control monitors the CBC and differential parameters.

LATRON™ primer prepares the tubing and instrument components for the LATRON control.

LATRON control monitors the performance of the volume, conductivity, and light scatter measurements.

Retic-C™ cell control monitors the Reticulocyte (Retic) parameters.

LIN-C® linearity control verifies the reportable range of the instrument's CBC parameters.

Calibrator

The S-CAL® calibrator kit calibrates Primary mode CBC parameters and is an acceptable alternative to the whole-blood reference method of calibration.

S-CAL calibrator meets the requirements recommended by the International Committee for the Standardization of Hematology (ICSH).

The diff/retics measurement device is calibrated for optimum performance at the factory.

1.8 MATERIAL SAFETY DATA SHEETS (MSDS)

To obtain an MSDS for reagents used on the HmX Hematology Analyzer:

1. In the USA, either call Coulter Customer Operations (800-526-7694) or write to:

   Coulter Corporation
   Attn: MSDS Requests
   P. O. Box 169015
   Miami, FL 33116-9015
2. Outside the USA, call your Coulter Representative.

2.1 GENERAL

CAUTION Possible system damage could occur if you improperly uncrate the system, install it, or set it up. Keep the system in its packaging until your Beckman Coulter Representative uncrates it for installation and set up.

Your instrument is tested before it is shipped from the factory. International symbols and special handling instructions on the cartons tell the carrier how to handle this electronic system.

Carefully inspect all cartons when they arrive. If you see any sign of mishandling or damage, file a claim with the carrier immediately. If the system is insured separately, file a claim with the insurance company.

2.2 SPECIAL REQUIREMENTS

The system is intended for installation and operation in a conventional clinical laboratory setting. Because the components are interrelated, you must determine the system location and layout before your local Beckman Coulter Representative arrives to install the system. Consider the following special requirements.

Space and Accessibility

In addition to the space required for the individual components and their interconnection, consider:

- Comfortable working height.
- Access to the rear of the system for maintenance and service. Allow:
  - 30 cm (12 in.) behind
  - 30 cm (12 in.) on the sides.

Electrical Input

This system requires:

- An independent protected circuit.
- A ground path capable of carrying the full current of the circuit (confirmed third-wire, earth ground).
- A female outlet:
  - For the 110/120 V, 60 Hz model, it needs to furnish 120 ±10 Vac, 60 Hz, 15 A, single-phase input power.
  - For the 220/240 V model, it needs to furnish 220/240 ±10 Vac, 50/60 Hz, 8 A, single-phase input power.

CAUTION Either of these two hazards can occur if you use an extension cord:

- Introduction of electrical interference can occur and cause instrument performance problems (frequent lock ups and resets), or
- Overheating, melting, and burning of the extension cord can occur.

Plug the primary power cable directly into the electrical outlet. Position the system close enough to an electrical outlet so you do not need to use an extension cord.

Do not use an extension cord.

CAUTION Possible damage can occur if you use a power strip that is not compatible with your instrument. If you plan to use a power strip other than the one recommended by Beckman Coulter, call your Beckman Coulter Representative to be sure that your power strip is compatible with your instrument.

Ambient Temperature and Humidity

Operate the system in a room with a temperature between 16° and 32°C (60° and 90°F) and humidity no higher than 95% without condensation.

Ventilation

Arrange for the ventilation fan on the rear panel to be at least 12 cm (5 in.) from any walls or obstructions that could interfere with the flow of air.

Air Conditioning

Compensate for system-generated heat in air-conditioned environments with an additional 5,000 Btus.

Drainage

CAUTION Incomplete drainage and overflow into the vacuum system can occur if the waste line is longer than the recommended length. Contact your Beckman Coulter Representative if you need to increase the length of the waste line supplied with the system

The maximum waste line length is 3.7 m (12 ft).

WARNING Biohazardous contamination can occur from contact with the waste container and its associated tubing if not handled with care. Avoid skin contact. Clean up spills immediately. Dispose of the contents of the waste container in accordance with local environmental regulations and with acceptable laboratory procedures.

The waste line supplied with the instrument can be connected to either:

- A drain less than 76 cm (30 in.) above the floor.
- A waste container with a recommended minimum capacity of 20 L (5 gal.).

If you use an open drain, mechanically secure the waste tube into the drain so the tube cannot accidentally come out of the drain. This prevents spillage.

Date Format

Choose which of the following date formats fits your location:

- European(DD/MM/YY)
- Japanese(YY/MM/DD)
- U.S. (MM/DD/YY).

Your Beckman Coulter Representative installs your selection at installation.

2.3 INTERUNIT CONNECTIONS

Reagent and Waste Connections

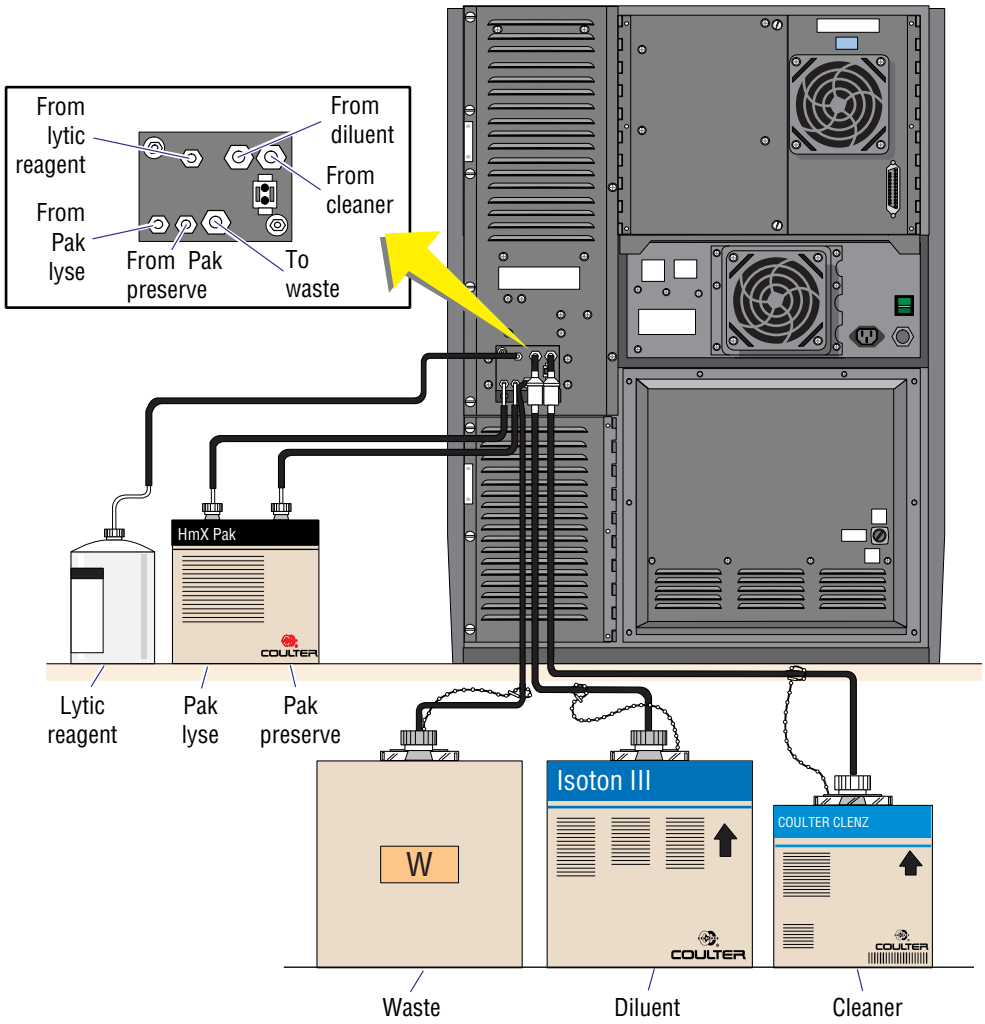
CAUTION Possible reagent siphoning effect and priming problems could occur if a reagent container is placed above the level of the Diluter. Place the reagent containers at the same level as the system or below.

IMPORTANT Possible incorrect platelet counts can be reported due to bubbles in the line, and reagent priming problems could occur if the reagent tubing lengths are too long. Do not exceed 8 ft from the rear of the system to any reagent container.

Figure 2.1 shows the tubing connections from the instrument to the reagent and to the waste containers. The pak lyse, pak preservative, and lytic reagent are placed at the correct level on the counter beside the unit.

Be sure to keep all reagent lines isolated from anything electrical.

Figure 2.1 Reagent and Waste Container Tubing Connections

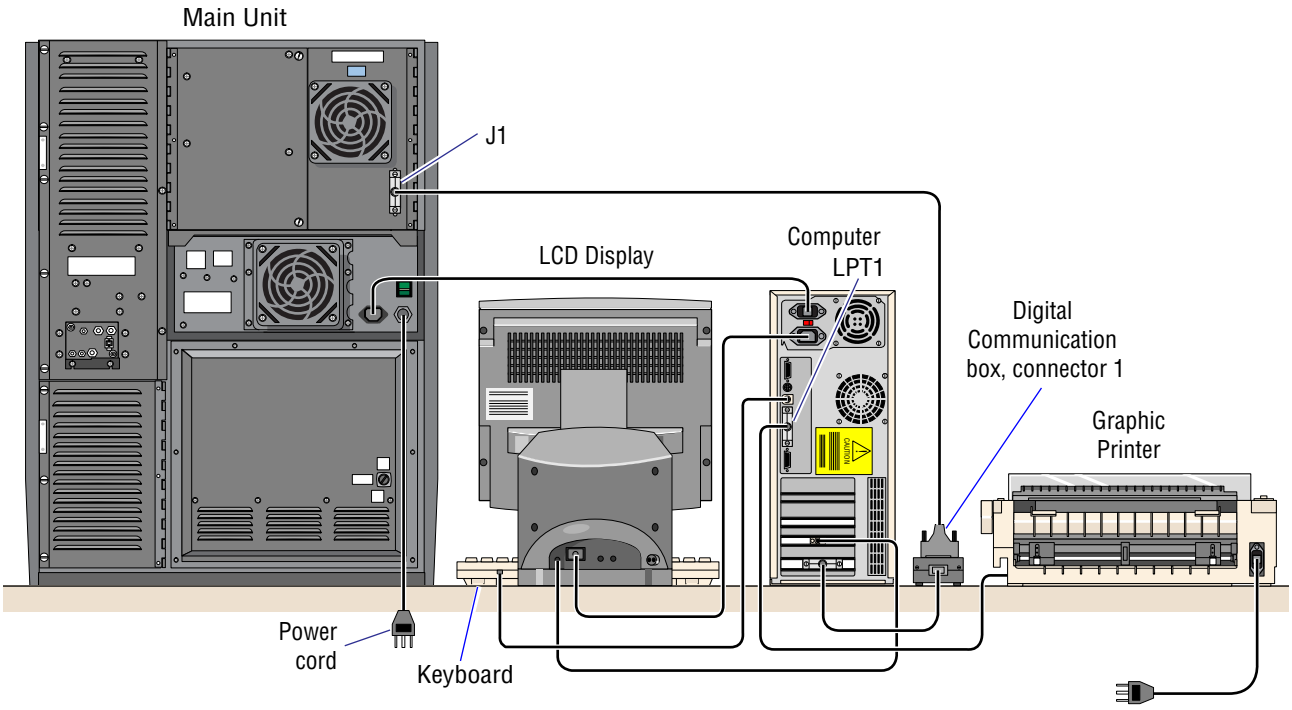


Power and Signal Cables

Figure 2.2 shows interunit connections of the power and signal cables that are supplied with the HmX Hematology Analyzer. Your Beckman Coulter Representative makes these connections when installing and qualifying your system for subsequent use.

Make sure all connections are properly seated and fastened. For example, check all wire clips or screws on cable connectors and make sure they are fully clipped or screwed in.

Figure 2.2 Interunit Connections

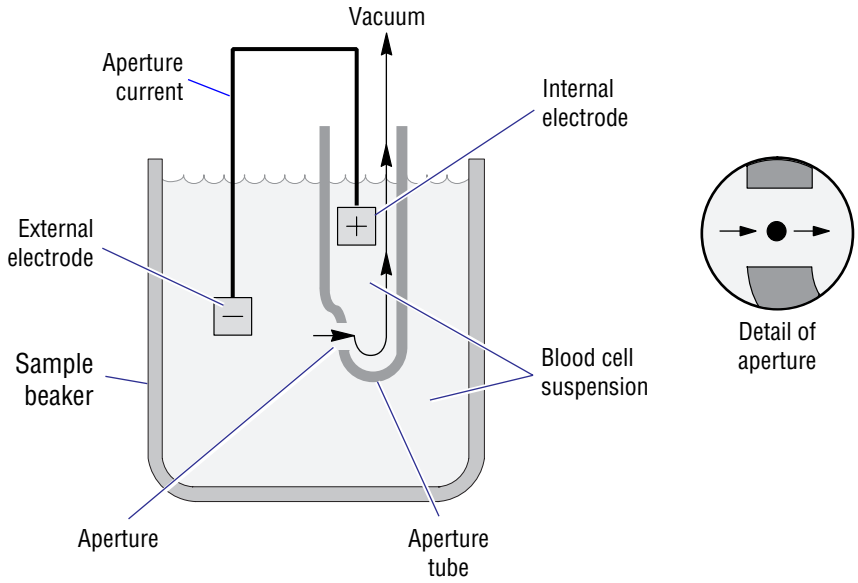


3.1 GENERAL PRINCIPLES

CBC Analysis

The Coulter method 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. See Figure 3.1.

Figure 3.1 Coulter Method of Counting and Sizing



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.

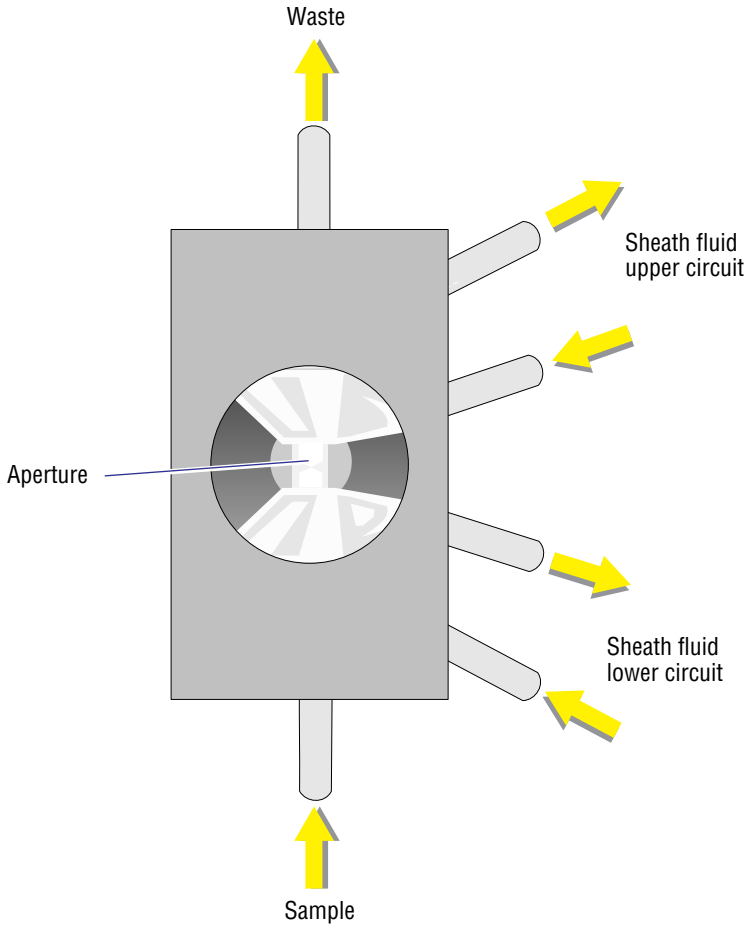
The number of pulses correlates to the number of particles. The height of the electrical pulse is proportional to the cell volume.[37, 38, 39, 40]

Differential Analysis

As the sample, prepared for differential analysis, streams through the flow cell (Figure 3.2) these three measurements occur simultaneously on each individual white cell to classify it:

- Low-frequency current measures volume.
- High-frequency current senses cellular internal content through measuring changes in conductivity.
- Light from the laser bouncing off the individual WBC cells characterizes cellular surface, shape, and reflectivity.

Figure 3.2 Flow Cell



Effect of Reagents

The conductive diluent must affect cells minimally, if at all.

Both lytic reagents must destroy erythrocytes without significantly affecting leukocytes. They must work rapidly to satisfy the speed with which the system works.

The leukocyte preservative must:

- Provide clear separation of the white blood cell populations
- Preserve leukocytes in their near-native state for accurate cytometric measurement.

Retic Analysis

The Coulter Reticulocyte Method is a two-step sample preparation, followed by analysis in the HmX Hematology Analyzer Retic Mode using volume conductivity and scatter (VCS) technology. First, a supravital dye, New Methylene Blue, in a special solution (Reagent A), is incubated with whole blood samples. The dye precipitates the basophilic RNA network found in reticulocytes. Then, when added to the samples, a hypotonic clearing reagent (Reagent B) clears hemoglobin and unbound stain from the cells. After the treatment, and if viewed in a wet prep microscopically, mature erythrocytes appear as clear, slightly spherical cells. Reticulocytes have the same characteristics but with darkly-stained reticulum.

Stained reticulocytes differ from mature erythrocytes (RBCs) and other cell populations by light scatter, direct current measurements, and opacity characteristics.

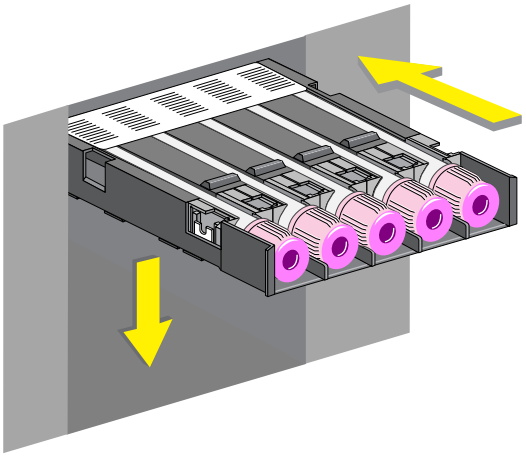
3.2 SPECIMEN TRANSPORT - HmX HEMATOLOGY ANALYZER WITH AUTOLOADER

Samples in the loading bay are automatically transported, mixed, aspirated, and analyzed. Sample tubes which can be identified by bar-code labels are loaded into five tube cassettes. Cassettes and the tube position in the cassette are identified by bar-code labels on the cassette. You can load up to 25 samples in the HmX Hematology Analyzer with Autoloader at one time.

These are the normal steps in specimen transport in an Autoloader:

- Place the cassettes in the loading bay, see Figure 3.3.

Figure 3.3 Loading a Cassette



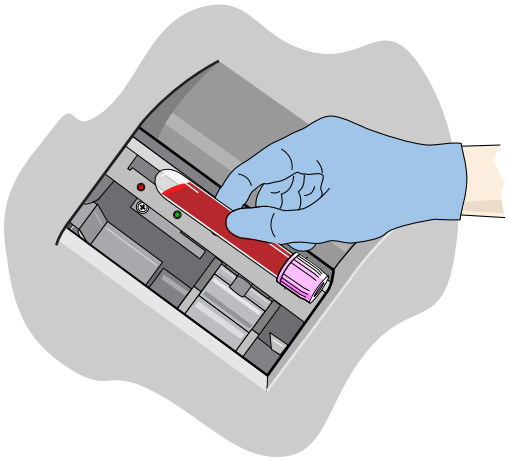
- At the DMS, instruct the instrument to run samples in the Primary mode.
- The right lift platform beneath the stacked cassettes rises and the bottom cassette is deposited on the rocker bed.
- The platform lowers the cassette to the level of the rocker bed where it is rocked back and forth, mixing the samples.
- The cassette moves along the bed, while rocking, until the first tube reaches the piercing station.
- The cassette stops moving forward but continues rocking.
  - The bar-code scanner reads the Cassette/Position label and the tube label.
  - The cassette continues rocking.
  - The Autoloader stops if the Cassette/Position label is not read.
- If the labels are read, the bed is brought forward into the piercing position.
- The needle pierces the tube.
- After aspiration, the needle is retracted.

- The bed resumes rocking.
  - The bar-code scanner reads the Cassette/ Position label and the tube label a second time.
  - If both bar-code scans are identical, the Autoloader continues to rock and moves the cassette until the next available tube has reached the piercing station.
  - If the bar-code scans are not identical, the Autoloader stops. No data is available for the sample. The Autoloader continues sampling at the next available tube when restarted.
- This sequence continues until all tubes in the cassette have been sampled.
- The Autoloader continues rocking and moves the cassette along the bed to the unloading area.
- Once the cassette has reached the fourth pierce position, the second cassette is lowered and placed on the rocker bed.

3.3 SPECIMEN TRANSPORT - HmX HEMATOLOGY ANALYZER

- At the DMS, instruct the instrument to run a sample in the Primary mode.
- Check that the Ready light is green to indicate the system is ready to process a sample.
- Manually mix the sample.
- Read the bar-code label on the sample tube:
  - Hold the sample tube with the bar-code label facing the instrument, in front of the reader. See Figure 3.4.

Figure 3.4 Reading a Bar-Code Label



  - If the bar-code label was read successfully, the system beeps and a green light appears. If a red light appears instead, the bar-code label was not read successfully, wait and try again.
- Insert the sample tube into the carousel. The red light appears indicating the system is busy.
- The sample is rotated to the piercing position.
- The needle pierces the sample tube. Sample is aspirated.

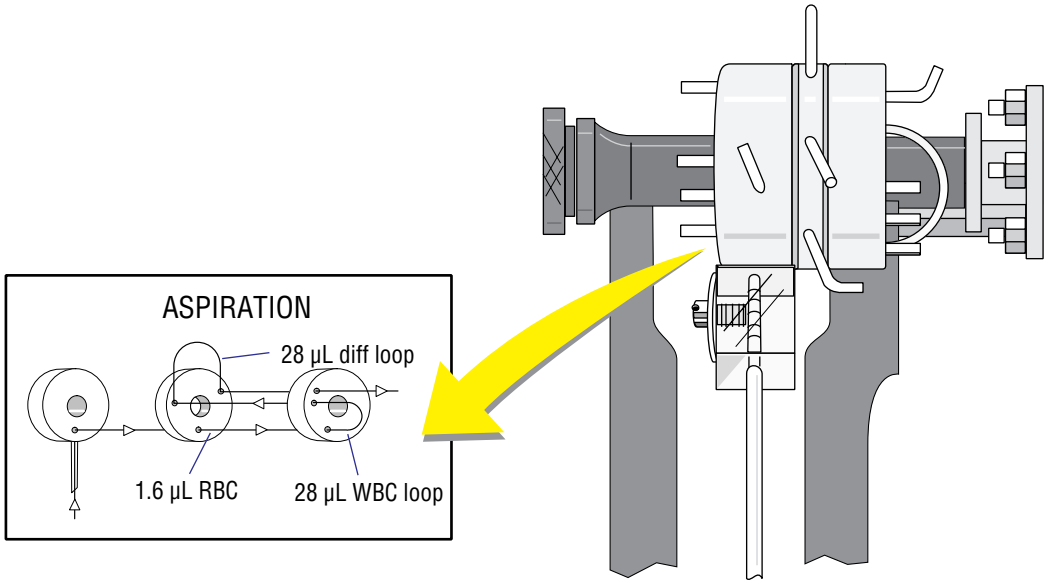
- After aspiration, the needle is retracted.
- The sample tube is ejected from the carousel.
- Sample analysis occurs.
- The Ready light is green to indicate another sample can be processed.

3.4 SAMPLE FLOW

Normal Sample Flow

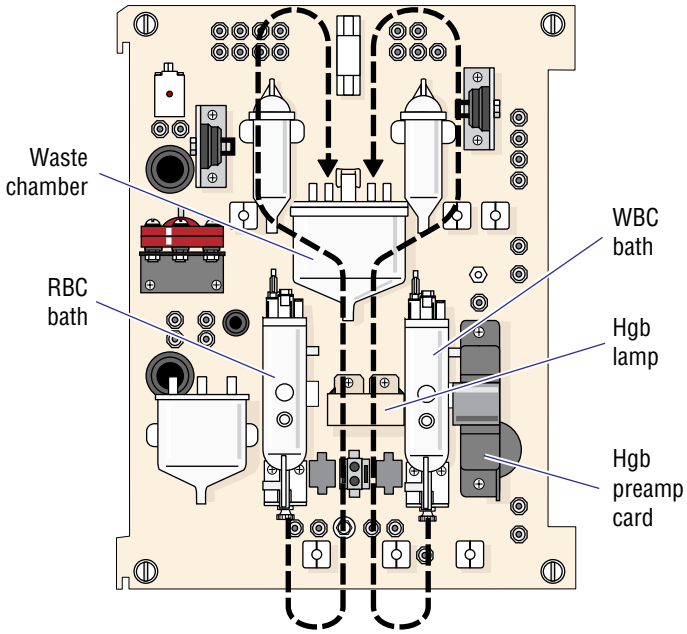
1. The appropriate aspiration pump pulls the sample into the BSV (Figure 3.5):
   - 125 µL in the open vial mode
   - 185 µL in the closed vial mode.

Figure 3.5 BSV



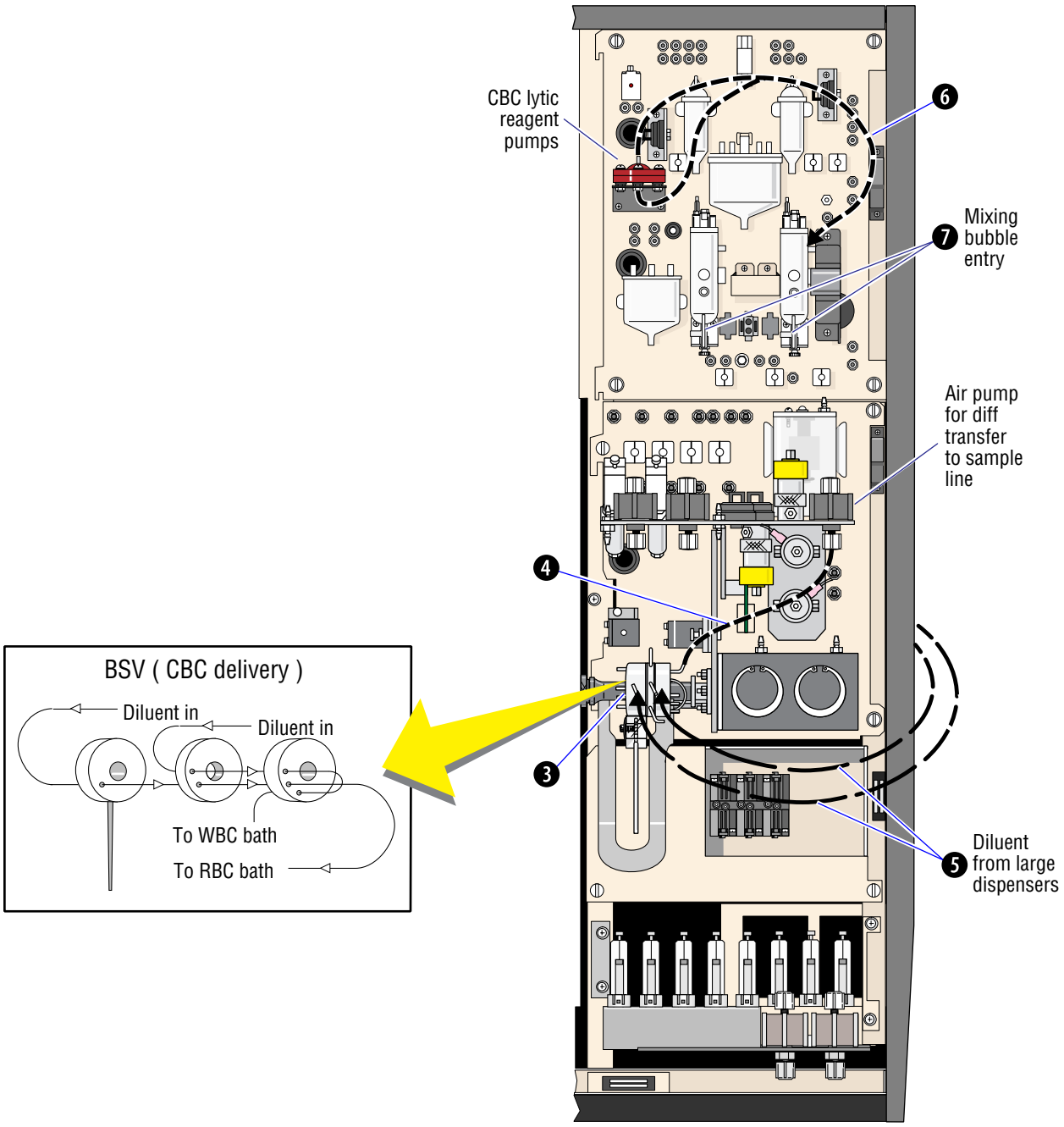
2. The baths drain into the waste chamber (Figure 3.6).

Figure 3.6 Baths Draining



3. Figure 3.7 applies to steps 3 through 7. The BSV rotates to segment three portions of the sample:
   - 1.6 µL for the RBC bath dilution
   - 28 µL for the WBC bath dilution
   - 28 µL for the WBC diff.
4. The air pump transfers the diff portion to the sample line.
5. Dispensers send diluent to the BSV to pick up and dilute the RBC and WBC portions.
6. The CBC lytic reagent pumps send the CBC lytic reagent (LYSE S III or LYSE S 4) to the WBC bath. It lyses the RBCs and converts the hemoglobin into a stable compound.
7. Mixing bubbles enter both baths.

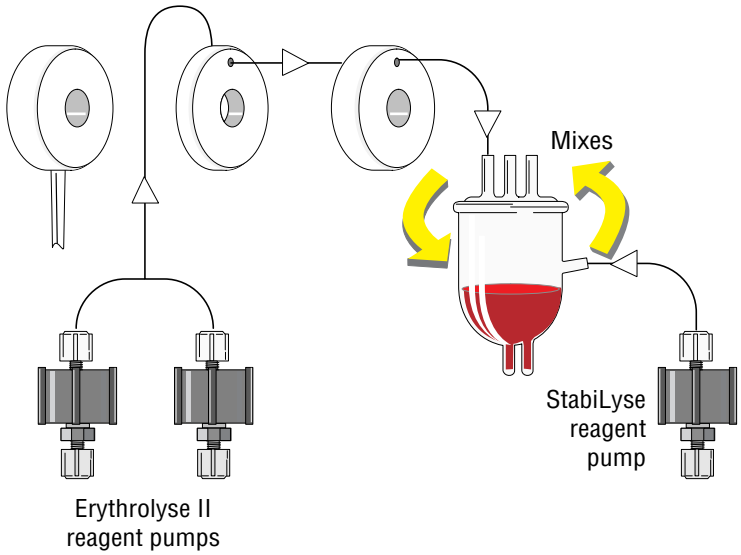
Figure 3.7 Sample Flow



8. The BSV rotates back. The Erythrolyse II (PAK LYSE) reagent pumps send the diff lytic reagent to pick up and deliver the diff portion to the mixing chamber, rupturing red cell membranes and dissolving cell debris in the process.

   The StabiLyse (PAK PRESERVE) reagent pump dispenses diff leukocyte preservative. It enters the mixing chamber to stabilize the leukocyte subpopulations. See Figure 3.8.

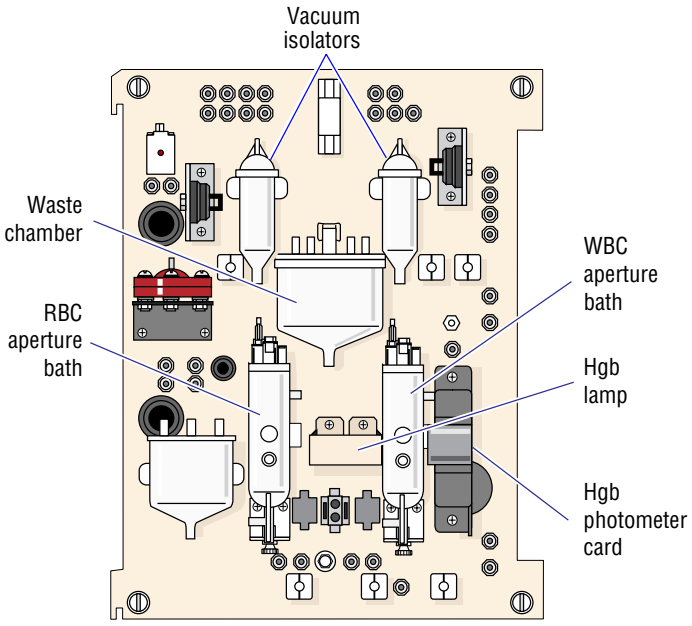
Figure 3.8 Erythrolyse II (PAK LYSE) and StabiLyse (PAK PRESERVE) Reagent Pumps



9. The vacuum isolators supply vacuum to the baths to pull the sample through the apertures for the cell counts. The unit counts and sizes RBCs and Plts at the RBC aperture and WBCs at the WBC aperture.

   It measures hemoglobin photometrically through the WBC bath. See Figure 3.9.

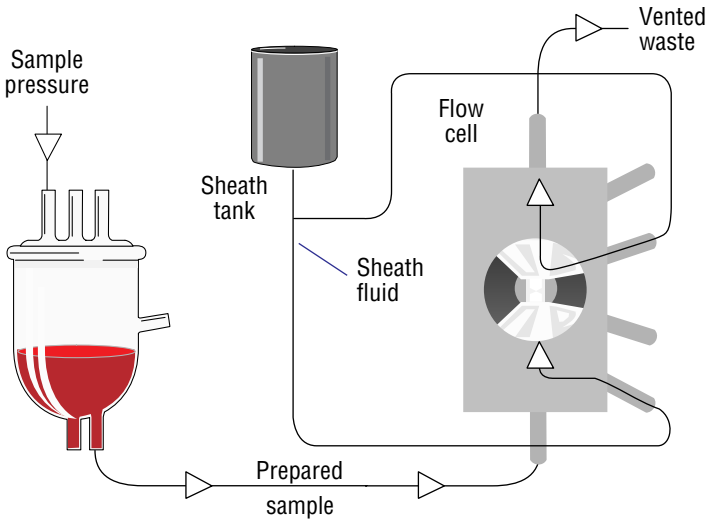
Figure 3.9 Aperture Baths and Vacuum Isolators



10. The unit does the WBC differential in the triple transducer module (TTM) at the flow cell aperture.

    Sample pressure to the mixing chamber pushes the sample through the flow cell for the diff analysis. See Figure 3.10.

Figure 3.10 Sample Movement to the Flow Cell



11. The cycle finishes:
    - The mixing chamber drains into its waste chamber.
    - The CBC baths drain into the waste chamber.
    - The unit cleans the baths and flow cell.
    - The waste chambers drain.

Retic Sample Flow

CAUTION Using undiluted whole blood can clog multiple components of the instrument and might require a service call to clean the components when the HmX Hematology Analyzer is in the Retic Mode. Manually dilute the blood before introducing the sample to the instrument for aspiration when it is in the Retic Mode.

Placing the instrument in the Retic Mode allows the sample to flow directly to the mixing chamber and flow cell of the triple transducer module (TTM). When in this mode, the sample MUST be manually diluted and prepared before being aspirated by the instrument.

3.5 COUNTING AND SIZING

Red and White Blood Cell Counting

Routine Counting

Each bath has one aperture. The regulated vacuum draws a precise volume of sample dilution through each aperture. At each aperture, the system counts cells in three consecutive periods of 4 seconds each. During each counting period, the analyzer gathers and amplifies the cell pulses. It also checks that WBC and RBC data accumulations are above a predetermined low cut-off value.

Pulses from the RBC bath that represent cells as 36 fL or greater are classified as red cells. Pulses from the WBC bath that represent cells as 35 fL or greater are classified as white cells. Both counts then go to the computer for coincidence correction and voting.

Extended Counting

If accumulations are too low, the unit extends the sensing period. This ensures that the size-distribution curves accurately reflect the true cell population.

Coincidence Correction

Occasionally, more than one cell goes through the aperture at the same time. When cells coincide, however, the analyzer counts only one pulse. Because the frequency of coincidence is proportional to the actual count, the system easily corrects results for coincidence.

Triplicate Counting/Voting

The HmX Hematology Analyzer and HmX Hematology Analyzer with Autoloader use triplicate counting, strict voting criteria, and proprietary flagging algorithms to confirm parameter results prior to reporting. After coincidence correction, the system compares the data from the three count periods then votes and rejects any questionable data. Voting occurs for: WBC, RBC, Plt, MCV, RDW, and MPV. If the system finds disagreement among all the count periods or some other internal criteria are not met, the system displays and prints a total voteout code (– – – – –) instead of the parameter result.

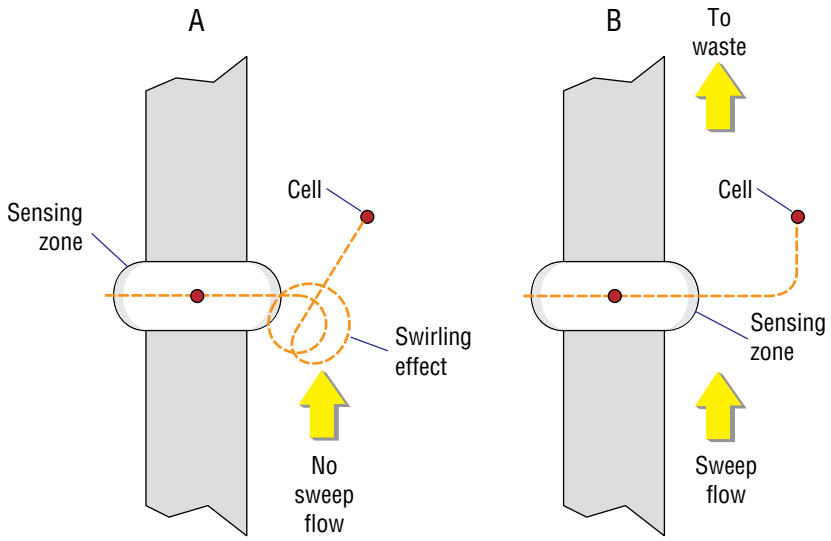
IMPORTANT In rare instances, especially for specimens where fibrin, cell fragments, or other debris are likely to occur, such as pediatric and oncology specimens, a transient or partial aperture blockage may not be detected by any of these methods. Therefore, verify flagged results for accuracy and review any result which exceeds your laboratory action limits.

Beckman Coulter uses triplicate counting and voting to maximize the accuracy of the results.

Sweep Flow

The sweep flow is a steady stream of diluent that flows behind the RBC aperture during the sensing periods (B). This keeps cells from swirling back into the sensing zone. Because these swirling cells (A) would be peripherally sensed, their pulse height would be similar to Plt pulse heights. See Figure 3.11.

Figure 3.11 Sweep Flow



Pulse Editing

When cells pass through the aperture near the edge or at an angle rather than at the center, they create atypical pulses. Pulse editing technology eliminates atypical pulses from the analysis because they distort the true size of the cell. This prevents atypical pulses from influencing size measurements.

RBC Count and Size Distribution

During RBC sensing, pulses that represent cells from 36 fL to 360 fL are classified as RBCs and are sorted by size into 256 channels to build the RBC histogram. Using a system of moving averages, the computer smooths the histogram curve.

Plt Count and Size Distribution

During RBC sensing, pulses that represent cells from 2 to 20 fL are classified as platelets. The system automatically extends the sensing time if platelet accumulation is below a predetermined level. The system sorts the Plt pulses by size into 64 channels to build the Plt histogram.

Plt Fitting Process

Having checked that the Plt count per period is greater than 20 x 10^3 cells/µL, the computer smooths the histogram from each count, and finds a maximum point and two minimum points in each histogram. It uses a least-squares method for a log-normal curve to fit a portion of the histogram between the two minimum points. It then checks that each of the fitted curves is positive, has a mode between 3 and 15 fL, and has a PDW greater than approximately 20%. It votes on Plt, MPV, and PDW derived from the fitted curves. These fitted curves have a range of 0 to 70 fL. If any of the criteria above are not met, an R flag appears next to Plt and MPV.

For no-fit conditions, the computer derives the Plt count from the portion of the histograms between the two minimum points, then votes on Plt, MPV, and PDW derived from the raw data.

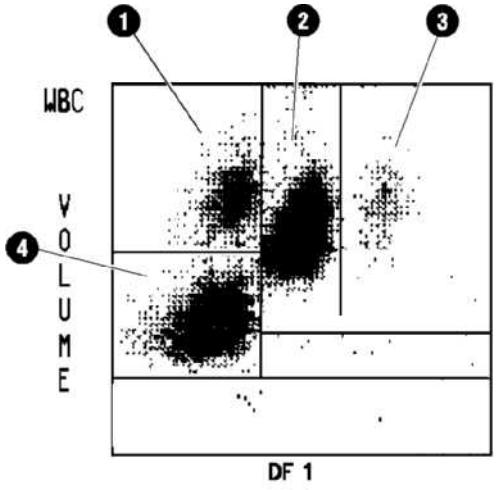
Scatterplot Development

The system performs a series of operations on the stored digital raw data values to identify subpopulations and calculate percentage values. It also produces the scatterplot displays for visual representation of the WBC and Reticulocyte/RBC populations. A scatterplot is a two-dimensional graphic display of the results of the volume, conductivity, and scatter measurements. Largest concentration is indicated on the scatterplot display by intensity.

Differential-Related

The discriminant function (DF) 1 scatterplot, Figure , shows lymphocyte ❹, monocyte ❶, neutrophil ❷, and eosinophil ❸ populations. The basophil population is behind the upper right quadrant of the lymphocyte ❹ population. For purposes of the display, the axes are labeled: Volume and DF 1. DF 1 is derived primarily from the light scatter measurement. Volume is determined by the low-frequency impedance measurement.

Figure 3.12 Scatterplot, DF 1 View



DF 2, Figure 3.13, is another perspective of the five differential populations and is derived from conductivity. DF 2 displays WBC volume on the y-axis and conductivity on the x-axis. This display shows the lymphocyte ❶, monocyte ❷, and granulocyte ❸ populations. The granulocyte population includes the neutrophils, basophils, and eosinophils.

DF 3, Figure 3.14, displays the same data as DF 2 with the eosinophil and primary neutrophil populations gated out. Basophil ❸, lymphocyte ❶, and monocyte ❷ cell populations are easier to see with this display.

Figure 3.13 Scatterplot, DF 2 View

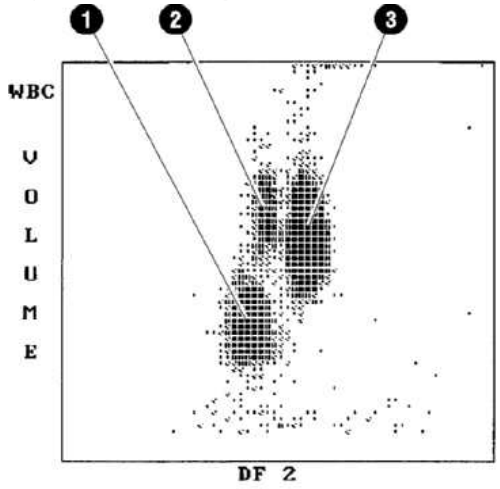
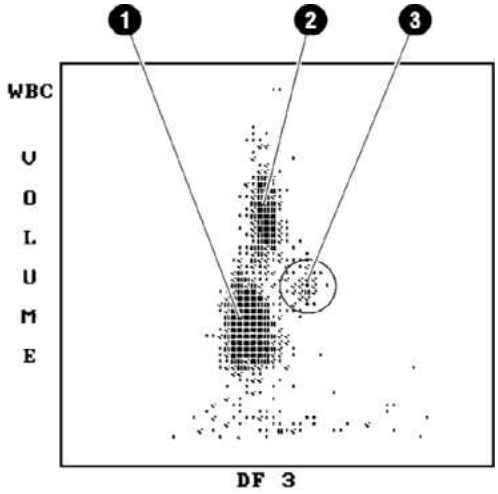


Figure 3.14 Scatterplot, DF 3 View



Retic-Related

DF 5, Figure 3.15, shows mature red cells and reticulocytes. Cell volume is plotted on the y-axis and laser light scatter characteristics are plotted on the x-axis. This graph shows the mature red blood cell population ❶ and the reticulocyte population ❷.

DF 6, Figure 3.16, is derived primarily from reticulocyte conductivity. DF 6 displays Retic volume on the y-axis and conductivity on the x-axis. This graph shows the mature red blood cell population ❶ and the reticulocyte population ❷.

Figure 3.15 Scatterplot, DF 5 View

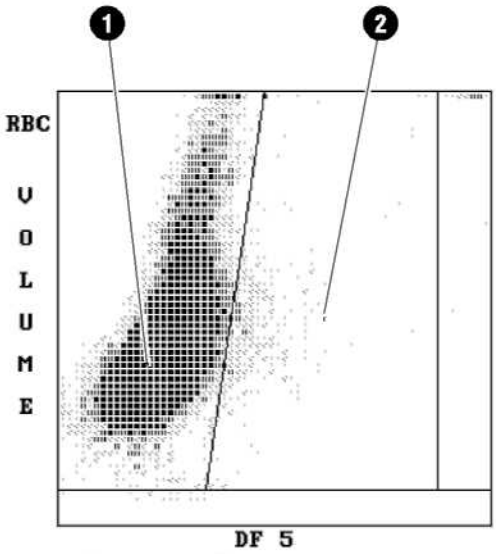
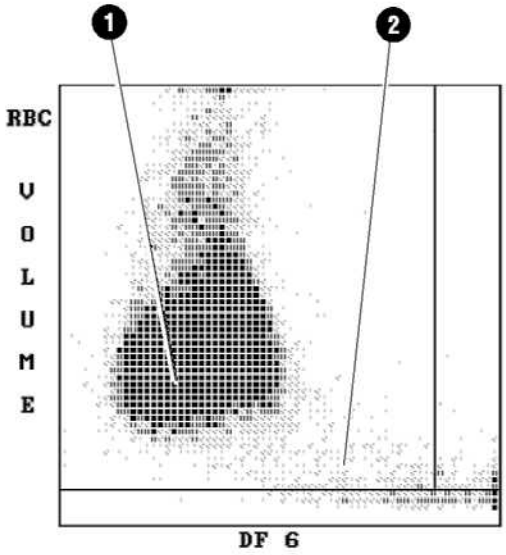


Figure 3.16 Scatterplot, DF 6 View



Retic Parameters

The system makes three measurements as each cell passes through the flow-cell aperture:

- The low-frequency, impedance measurement (which defines the cell's volume)
- The high-frequency impedance measurement (which indicates the cell's internal conductivity)
- The light-scatter measurement (which indicates the cell's structure and shape).

Derived and Computed Parameters

From directly-measured parameters, the computer derives:

- MCV and RDW from the RBC histogram
- MPV and Plt count from the Plt histogram.

From derived and directly-measured parameters, the computer computes Hct, MCH, and MCHC.

3.6 Hgb CONCENTRATION MEASUREMENT

After the WBC dilution is lysed, the system shines a beam of white light through the WBC aperture bath and then through an optical filter. This transmittance of light (525 nm wavelength) through a standard path length of Hgb solution is compared to the transmittance of such light in the same way through a reagent blank. The system converts this ratio to absorbance. It then converts absorbance to Hgb values in g/dL using a calibration factor.

3.7 PARAMETERS AND THEIR DERIVATION

Mathematical expressions in this section are in US units of measurement. You can change parameter units to any of four International Systems of Units or the Japanese system by using the Reporting Units screen. See the Heading, Reporting Units, in the Operator's Guide.

White Blood Cell (WBC) Count

This is the number of leukocytes measured directly, multiplied by the calibration constant, and expressed as

$$\text{WBC} = n \times \frac{10^3 \text{cells}}{\mu\text{L}}$$

Red Blood Cell (RBC)

This is the number of erythrocytes measured directly, multiplied by the calibration constant, and expressed as

$$\text{RBC} = n \times \frac{10^6 \text{cells}}{\mu\text{L}}$$

Hemoglobin (Hgb) Concentration

Weight (mass) of hemoglobin determined from the degree of absorbance found through photocurrent transmittance is:

$$\text{Hgb (g/dL)} = \text{Constant} \times \log_{10}\left(\frac{\text{Reference \%T}}{\text{Sample \%T}}\right)$$

Mean Corpuscular Volume (MCV)

This is the average volume of individual erythrocytes derived from the RBC histogram. The system:

- Multiplies the number of RBCs in each channel by the size of the RBCs in that channel.
- Adds the products of each channel between 36 fL and 360 fL.
- Divides that sum by the total number of RBCs between 36 fL and 360 fL.
- Multiplies by a calibration constant and expresses MCV in femtoliters.

Hematocrit (Hct)

This is the relative volume of packed erythrocytes to whole blood, computed as:

$$\text{Hct (\%)} = \frac{\text{RBC} \times \text{MCV}}{10}$$

Mean Corpuscular Hemoglobin (MCH)

This is the weight of hemoglobin in the average erythrocyte count, computed as:

$$\text{MCH (pg)} = \frac{\text{Hgb}}{\text{RBC}} \times 10$$

Mean Corpuscular Hemoglobin Concentration (MCHC)

This is the average weight of hemoglobin in a measured dilution, computed as:

$$\text{MCHC (g/dL)} = \frac{\text{Hgb}}{\text{Hct}} \times 100$$

Red Distribution Width (RDW)

RDW represents the size distribution spread of the erythrocyte population derived from the RBC histogram. It is the coefficient of variation (CV), expressed in percent, of the RBC size distribution.

Platelet (Plt) Count

This is the number of thrombocytes derived from the Plt histogram and multiplied by a calibration constant. This number is expressed as:

$$\text{Plt} = n \times 10^3 \text{cells}/\mu\text{L}$$

Mean Platelet Volume (MPV)

MPV is the average volume of individual platelets derived from the Plt histogram. It represents the mean volume of the Plt population under the fitted Plt curve multiplied by a calibration constant, and expressed in femtoliters.

Differential Counts

Percentages

The percentages of leukocytes from each category are derived from the scatterplot.

$$\text{NE\%} = \frac{\text{no. of cells inside NE area}}{\text{no. of cells inside NE + LY + MO + EO + BA}} \times 100$$

$$\text{LY\%} = \frac{\text{no. of cells inside LY area}}{\text{no. of cells inside NE + LY + MO + EO + BA}} \times 100$$

$$\text{MO\%} = \frac{\text{no. of cells inside MO area}}{\text{no. of cells inside NE + LY + MO + EO + BA}} \times 100$$

$$\text{EO\%} = \frac{\text{no. of cells inside EO area}}{\text{no. of cells inside NE + LY + MO + EO + BA}} \times 100$$

$$\text{BA\%} = \frac{\text{no. of cells inside BA area}}{\text{no. of cells inside NE + LY + MO + EO + BA}} \times 100$$

Absolute Numbers

The absolute numbers of leukocytes in each category are computed from the WBC count and the differential percentage parameters.

$$\text{NE\#}\ (10^3\text{cells}/\mu\text{L}) = \frac{\text{NE\%}}{100} \times \text{WBC count}$$

$$\text{LY\#}\ (10^3\text{cells}/\mu\text{L}) = \frac{\text{LY\%}}{100} \times \text{WBC count}$$

$$\text{MO\#}\ (10^3\text{cells}/\mu\text{L}) = \frac{\text{MO\%}}{100} \times \text{WBC count}$$

$$\text{EO\#}\ (10^3\text{cells}/\mu\text{L}) = \frac{\text{EO\%}}{100} \times \text{WBC count}$$

$$\text{BA\#}\ (10^3\text{cells}/\mu\text{L}) = \frac{\text{BA\%}}{100} \times \text{WBC count}$$

Reticulocyte (Retic) Parameters

A graphic display of cell populations in a scatterplot form is available for reporting. A flag indicates the sample needs further investigation. Results then should be interpreted by a physician or other qualified, medical professional.

Reticulocyte Percent (RET%)

This is the number of reticulocytes per 100 RBCs. This parameter is directly measured and reported as %, a percentage of RBCs.

Reticulocyte Absolute Number (RET#)

This is the absolute number of reticulocytes. It is calculated from the reticulocyte percent (RET%) and red cell (RBC) count. It is expressed as the number of reticulocytes per liter and reported in the same units selected by the user for RBC.

$$\text{RET\#} = \frac{\text{RET\%} \times \text{RBC Count}}{100}$$

On the HmX Hematology Analyzer, you can enter the red cell count manually, via data base query, if you want the absolute number result. For more information, see the heading, Cycling Retic Samples, in the Operator's Guide.

4.1 INSTRUMENT SPECIFICATIONS

Dimensions

Component	Height	Width	Depth	Weight
HmX Hematology Analyzer	Maximum 84.84 cm (33.40 in.)	61.5 cm (25.10 in.)	61.7 cm (25.20 in.)	94.5 k (210 lb)
	Minimum 80.2 cm (32.75 in.)			
Computer	41.2 cm (16.2 in.)	17.8 cm (7.0 in.)	41.9 cm (16.5 in.)	9.7 k (21.5 lb)
LCD Display	41.9 cm (16.5 in.)	40.4 cm (15.9 in.)	19.6 cm (7.7 in.)	7.34 k (16.3 lb.)
Keyboard	3.6 cm (1.4 in.)	40.4 cm (15.9 in.)	18.0 cm (7.1 in.)	2.8 k (6.2 lb)
Graphic Printer (optional)	13.2 cm (5.2 in.)	43.2 cm (17.0 in.)	33.0 cm (13.0 in.)	7.4 k (16.5 lb)

Power

Installation Category

Category II (per IEC 1010-1)

Input - Dedicated Line

100/120 Vac	50/60 Hz
220/240 Vac	50/60 Hz

Consumption

1440 W This includes the system and all peripherals.

Pneumatic Supplies

Pressure

60 psi	55.0 - 65.0
30 psi	26.0 - 34.0
Sheath/low psi	5.8 - 6.2
Diff psi	0.1 - 1.0

Vacuum

In inches of Hg at sea level:

Low	5.94 - 6.06
High	17.0 - 28.0

Temperature (Ambient Operating Range for Patient Samples)

Ambient operating temperature: 16 to 32°C (60 to 90°F)

Humidity

0 to 95% without condensation

Recommended Reagents

ISOTON III (or ISOTON 4, Japan only) diluent for CBC dilutions, rinsing, and diff sheath flow.

LYSE S III diff (or LYSE S 4, Japan only) lytic reagent for WBC counting and Hgb determination.

HmX Pak reagents for diff analysis.

ReticPrep reagents for preparing reticulocyte analysis samples.

COULTER CLENZ cleaning agent for both modes.

Reagent Usage

Cycle	Diluent	CBC Lyse	Diff Lyse	Diff Preserve	Cleaner
Closed Vial	53 mL	1.1 mL	0.6 mL	0.13 mL	0
Open Vial	60 mL	1.1 mL	0.6 mL	0.13 mL	0
Start Up	360 mL	7.9 mL	6.5 mL	2.2 mL	2 mL
Shut Down	15 mL	0 mL	0 mL	0 mL	160 mL
New Reagent Prime	220 mL	30 mL	22 mL	12 mL	80 mL

Recommended Commercial Controls

These controls are all available from Beckman Coulter, Inc.:

- 5C cell control for CBC and differential parameters
- LATRON control for volume, conductivity, and light scatter parameters used with LATRON primer.
- Retic-C cell control for Reticulocyte (Retic) parameter.
- LIN-C control for reportable range of the instrument.

Recommended Calibrator

S-CAL calibrator kit

Recommended Anticoagulant

A salt of EDTA is the preferred anticoagulant. Beckman Coulter used K_3EDTA for the data collection and verification of claims.

Minimum Sample Volume Required

- 185 µL of whole blood in the closed-vial mode
  - The minimum sample volume per tube in the closed-vial mode is 1 mL with the proper proportion of blood to anticoagulant.
- 125 µL of whole blood in the open-vial mode
- 125 µL of dilution for prediluted samples
  - 50 µL of whole blood is mixed with 100 µL of diluent.
- For Retics, 50 µL of whole blood is mixed with 4 drops of Reagent A. A portion of this dilution is then mixed with 2 mL of Reagent B.

Tube Sizes for Closed-Vial Mode

- Tubes and tube devices that fall within these ranges:

  Diameter - 10-16 mm
  Length - 47-77 mm
  Capacity - 2- 7 mL
- Beckman Coulter control and calibration tubes.
- All tubes are listed in Appendix A.

Recommended Bar-Code Labels

Codabar or NW7
Code 39® bar code
Code 128
Interleaved 2-of-5

DMS Storage

Patient Results

5,000 sets plus all Sample Analysis screen displays

Controls

20 files with 100 runs per file

Conditions of Measurement

Hemoglobin Measurement

Wavelength: 525 nm Bandwidth: 60 nm

Aperture Size

Aperture	Diameter	Length
RBC	50 µm	60 µm
WBC	100 µm	75 µm

Electronic Stability

The change in calibration of the electronic measurement system is less than 1% per month when it is measured in accordance with this manual and is compared at monthly intervals.

Throughput

75 samples per hour, optimal
30 samples per hour, optimal for Retics

4.2 SOFTWARE SPECIFICATONS

Date Format

For two digit date entries, if the year entered/displayed is:

- 00 to 89, the system assumes the year is in the range of 2000 to 2089.
- 90 to 99, the system assumes the year is in the range of 1990 to 1999.

4.3 CBC AND DIFFERENTIAL PERFORMANCE SPECIFICATIONS

Precision

Precision is specified as a coefficient of variation (CV) based on at least 31 replicate determinations of the same sample. See Table 4.1.

Table 4.1 Precision Specifications

Parameter	CV%
WBC at 4.0 - 15.0 x 10^3 cells/µL	≤2.5
RBC at 3.0 - 6.0 x 10^6 cells/µL	≤2.0
Hgb at 12.0 - 18.0 g/dL	≤1.5
MCV at 80.0 - 100.0 fL	≤2.0
RDW at 12.0 - 15.0%	≤2.5
Plt at 200 - 500 x 10^3 cells/µL	≤5.0
MPV at 7.0 - 12.0 fL	≤3.0

Precision of the WBC differential parameters is specified at 95% confidence limits. See Table 4.2.

Table 4.2 Precision, WBC Differential Parameters

Parameter	95% Confidence Limits
LY% at 31; WBC at 4.0 x 10^3 cells/µL	±3.0
MO% at 8; WBC at 4.0 x 10^3 cells/µL	±2.0
NE% at 57; WBC at 4.0 x 10^3 cells/µL	±3.0
EO% at 3; WBC at 4.0 x 10^3 cells/µL	±1.0
BA% at 1; WBC at 4.0 x 10^3 cells/µL	±1.0

Accuracy

Accuracy is defined as agreement between test and reference values at any point within the operating range.

CBC

Accuracy is referenced to a COULTER S-PLUS™ series instrument. See Table 4.3.

Table 4.3 CBC Accuracy Limits

Parameter	Units	Mean Difference: The greater of:
WBC	x 10^3 cells/µL	±0.2 or 3.0%
RBC	x 10^6 cells/µL	±0.05 or 2.0%
Hgb	g/dL	±0.2 or 2.0%
MCV	fL	±2.0%
Plt	x 10^3 cells/µL	±10.0 or 7.0%
MPV	fL	±5.0%

WBC Differential

To determine accuracy of the WBC differential, the binomial is set at a slope of 1.00. The 95% confidence limits are based on the sum of the variances for an 800-cell reference differential and the total instrument count representing random and process error. The reference document is the NCCLS H20 (using an 800 cell count) specification.

Linearity

When tested using a stable sample having no interfering substances, the COULTER HmX Hematology Analyzer values are equal to the expected values within the limits in Table 4.6. To get these same results, subtract background counts from the HmX Hematology Analyzer values and take multiple readings at each point to eliminate statistical effects of imprecision. Linearity of size measurements (MCV and MPV) are tested using appropriate techniques. Linearity limits apply only to directly measured parameters. See Table 4.4.

Table 4.4 Linearity Limits

Parameter	Linearity Range	Limits: The greater of:
WBC x 10^3 cells/µL	0 to 99.9	±0.2 or 3.0%
RBC x 10^6 cells/µL	0 to 7.00	±0.05 or 2.0%
Hgb g/dL	0 to 25.0	±0.2 or 2.0%
MCV fL	50.0 to 150.0	±2.0 or 2.0%
Plt x 10^3 cells/µL	0 to 999	±10.0 or 7.0%
MPV fL	5.0 to 20.0	±5.0%

Mode-to-Mode Matching

Minor differences between the Primary (cap-pierce or autoloader) and Secondary (manual) modes are due to differences in the flow characteristics of the aspiration pathways. Additionally, flow characteristics vary between samples. Verification of the minor mode-to-mode differences seen on the HmX Hematology Analyzer and HmX Hematology Analyzer with Autoloader requires elimination of effects of carryover and within-mode precision in testing. For these reasons, the specification is based on the average values for 10 normal bloods measured in triplicate (three consecutive measurements). When verification is performed according to this protocol, differences between the averages of the two modes do not exceed the following limits in Table 4.5:

Table 4.5 Mode-to-Mode Matching

Parameter	Limits: The greater of:
WBC x 10^3 cells/µL	±0.4 or 5.0%
RBC x 10^6 cells/µL	±0.2 or 2.0%
Hgb g/dL	±0.3 or 2.0%
Plt x 10^3 cells/µL	±20.0 or 7.0%

Data collected using "blind paired" samples has demonstrated that variability observed in the paired samples between Primary and Secondary modes is similar to the variability observed within a mode.

Background Counts

Background count for the WBC differential is ≤100 total counts collected from all regions of the scatterplot. For CBC parameters background count, see Table 4.6.

Table 4.6 Background Counts for CBC Analysis

Parameter	Counts
WBC x 10^3 cells/µL	≤0.4
RBC x 10^6 cells/µL	≤0.0
Hgb g/dL	≤0.1
Plt x 10^3 cells/µL	≤3.0

Carryover

The effect of sample A on the values obtained for the next sample, sample B, is less than 2.0% when the analysis is based on 10 determinations and when calculated:

$$\% \text{ carryover } = \frac{\Delta B}{A} \times 100$$

where ΔB is the error in B due to carryover.

4.4 RETICULOCYTE PERFORMANCE SPECIFICATIONS

Precision

Within-Run Imprecision (total system). Validation limits for 31 separately prepared dilutions of the same specimen are:

	Limits (Whichever is greater)	
RET%	**SD Limit**	**CV Limit**
<1.00	<0.23	≤23%
1.00 - 4.00	<0.23	≤17%
4.01 - 15.00+	<0.68	≤15%

Run-to-Run Precision. Validation of paired imprecision for reticulocytes is based upon the differences of Run 1 and Run 2 specimens. The limits over the clinical range of a minimum of 50 specimens from a general hospital population of no more than 30% abnormally elevated reticulocyte specimens (Retic >4%) are as follows:

Parameter	**Mean Difference***	**SD of Difference***
RET%	±0.4	≤0.8

Paired imprecision limits over the clinical range for a minimum of 50 specimens with the following characteristics are:

- Greater than 50% abnormally elevated Retic values (Retic >4%).
- No greater than 5 of 50 specimens have Retic values >20%.

Parameter	**Mean Difference***	**SD of Difference***
RET%	±0.5	≤1.5

* Both requirements must be met.

Accuracy

Reticulocyte parameter accuracy is the sum of the variables of linearity and imprecision for the test, and the comparator method using specimens covering the reportable range. The reference method for reticulocyte counting is described in the NCCLS document H16-P (n = 4,000) or its pertinent successor document. Analysis is based on the differences [diff = Run 2 (instrument) - Reference].

Limits over the clinical range for a minimum of 50 specimens from a general hospital population of no more than 30% specimens with abnormally elevated Reticulocyte values (Retic >4%) are:

Parameter	Mean Difference*	SD of Difference*
RET%	±1.0	≤1.5

Limits over the clinical range for a minimum of 50 specimens with the following characteristics are:

- Greater than 50% abnormally elevated Retic values (Retic >4%).
- No greater than 5 of 50 specimens have Retic values >20%.

Parameter %	Mean Difference*	SD of Difference*
0.00 - 30.00	±1.5	≤3.0

* Both requirements must be met.

Reportable Range

Table 4.7 shows the reportable range for the HmX Hematology Analyzer with Reticulocyte method.

Table 4.7 Reportable Range

Parameter	Range	Mean Difference
Reticulocyte %	0.2 - 30.0	±0.3

Operating Range

The operating range is 0 - 100 percent reticulocytes.

Flagging

Samples above or below the reportable range are flagged accordingly. Instrument conditions that may interfere with the identification of reticulocytes are also flagged. Refer to the Parameter Codes table in the Operator's Guide.

Limitations

Prepare samples at ambient temperatures between 16 and 30°C (61 and 86°F). Use air displacement pipettes to pipet whole blood and to transfer the blood/stain mixture. Repeated aspiration of Reagent A can cause pipette discoloration. Also see Heading 4.8, INTERFERING SUBSTANCES.

4.5 PERFORMANCE CHARACTERISTICS - HmX HEMATOLOGY ANALYZER

Precision of the CBC Parameters

The tests described in this section were performed on the WBC differential and CBC subsystems as separate, noninteractive entities. This test condition is dictated, in part, by the need to use separately validated reference methods for evaluation of instrument accuracy and

clinical sensitivity. For CBC parameters, a Model S-PLUS IV analyzer provided reference data. The performance of this instrument had been independently validated against the following methods:

WBC:	Model ZBI™/CHANNELYZER® analyzer. Certified volumetric glassware
RBC:	Model ZBI/CHANNELYZER analyzer. Certified volumetric glassware
Plt:	Model ZBI/CHANNELYZER analyzer. Certified volumetric glassware
Hgb:	NCCLS method H15-A
MCV:	NCCLS packed cell volume method H7-A. For WBC differential parameters, the reference values were provided by the method described in NCCLS publication H20 (using an 800 cell count).

The results of replicate precision testing (n = 31) for each parameter measured by the test instrument are given in Table 4.8.

Table 4.8 Imprecision Analysis by Replication WHOLE BLOOD - HmX Hematology Analyzer

Parameter	Units	Mean	SD	CV%
WBC	x 10^9 cells/L	5.15	0.10	1.94
RBC	x 10^{12} cells/L	4.55	0.06	1.32
Hgb	g/dL	13.07	0.12	0.92
MCV	fL	86.1	1.1	1.28
RDW	%	12.56	0.21	1.67
Plt	x 10^9 cells/L	206.7	8.78	4.25
MPV	fL	9.69	0.15	1.55

Table 4.9 lists the results of Pair Difference analysis for 194 paired clinical blood specimens.

Table 4.9 Imprecision Analysis by Paired Sample - HmX Hematology Analyzer

		Clinical Range			
Parameter	Units	Low	High	Mean Diff.	SD
WBC	x 10^9 cells/L	0.4	46.8	-0.01	0.20
RBC	x 10^{12} cells/L	2.06	5.92	0.00	0.04
Hgb	g/dL	7.2	17.7	0.01	0.13
Hct	%	22.1	53.1	0.10	0.68
MCV	fL	67.8	123.9	0.15	1.26
MCH	pg	21.8	41.6	0.35	0.37
MCHC	g/dL	30.7	36.6	-0.04	0.67
RDW	%	11.0	26.4	0.00	0.28
Plt	x 10^9 cells/L	1.0	710.0	0.51	11.85
MPV	fL	8.6	15.0	0.01	0.93

Imprecision Analysis by Paired Sample of the Differential Parameters

Table 4.10 shows imprecision by pair analysis using normal blood for 194 paired observations.

Table 4.10 Imprecision Analysis (Diff Parameters) by Paired Sample - HmX Hematology Analyzer

Cell Type	Mean Difference	SD of Difference
Lymphocyte	0.08	0.84
Monocyte	0.07	1.23
Neutrophil	-0.01	1.26
Eosinophil	-0.01	0.66
Basophil	0.01	0.53

Table 4.11 shows precision by replication 31 times with a single specimen.

Table 4.11 Imprecision Analysis (Diff Parameters) by Replication - HmX Hematology Analyzer

Cell Type	Mean Percentage	Standard Deviation
Lymphocyte	38.30	1.29
Monocyte	14.38	0.86
Neutrophil	43.22	0.55
Eosinophil	3.65	0.28
Basophil	0.34	0.15

The reference range (normal values) for 160 subjects is given in Table 4.12.

Table 4.12 Reference Range (Diff Parameters) for 160 Subjects - HmX Hematology Analyzer

Cell Type	Lower %	Higher %	Lower Absolute #	Higher Absolute #
Lymphocyte	20.50	45.50	1.30	2.90
Monocyte	5.50	11.70	0.31	0.83
Neutrophil	43.00	65.00	2.20	4.80
Eosinophil	0.90	2.90	0.05	0.22
Basophil	0.25	1.00	0.02	0.06

Accuracy of CBC Parameters

Evaluation of accuracy by subtraction of paired test results given for COULTER HmX Hematology Analyzer and for COULTER S-PLUS IV analyzer for 194 specimens is given in Table 4.13

The magnitude of the mean differences expresses accuracy. The dispersion of differences (SD) expresses the inclusive errors of imprecision and bias.

Table 4.13 Accuracy Analysis by Compared Specimens - HmX Hematology Analyzer

Parameter	Units	Clinical Range		Mean Diff.	SD
		Low	High		
WBC	x 10^9 cells/L	0.50	45.80	0.22	0.39
RBC	x 10^{12} cells/L	1.98	5.88	0.06	0.07
Hgb	g/dL	7.30	17.80	0.02	0.24
Hct	%	21.00	51.30	0.60	0.82
MCV	fL	68.80	120.30	0.26	1.32
MCH	pg	22.50	42.10	0.35	0.68
MCHC	g/dL	30.40	36.20	-0.49	0.93
RDW	%	11.40	26.00	-0.59	0.30
Plt	x 10^9 cells/L	7.10	628.00	2.24	15.20
MPV	fL	5.30	14.90	-0.27	0.27

Accuracy of Differential Parameters

The HmX Hematology Analyzer was evaluated in a typical clinical laboratory environment using both normal subjects and hospitalized subjects. The reference method with which the HmX Hematology Analyzer was compared is described in NCCLS publication H20.

Because of the unsuitability of regression analysis, accuracy is expressed as the mean difference between reference method (H20) values and the HmX Hematology Analyzer values for 203 normal subjects. The scatter of the data conformed to the limits of a binomial distribution envelope. Table 4.14 gives the mean difference percent.

Table 4.14 Accuracy Analysis (Diff Parameters) by Compared Specimens - HmX Hematology Analyzer

Cell Type	Mean Difference %
Lymphocyte	-1.19
Monocyte	-0.51
Neutrophil	-0.23
Eosinophil	0.47
Basophil	-0.18

Clinical Sensitivity

The ability of the HmX Hematology Analyzer to "flag" abnormal specimens was compared to the performance of the NCCLS publication H20 (using an 800 cell count) method using the reference limits listed in Table 4.15. Except for nucleated red cells, absolute count values were used.

Table 4.15 Flagging Criteria - H2O Method

Cell Type	Reference Range (x 10^9 cells/L)	Reference Range %
Blast, Meta, Myelo, Promyelo	>0.1	2.0%
Nucleated red cell	>0.02	2.0%
Lymphs (variant forms)	>0.7	N/A
Bands (left shift)	>0.9	6%

Table 4.16 lists the numbers of morphologic abnormalities that were studied.

Table 4.16 Morphologic Abnormalities - HmX Hematology Analyzer

Abnormality Type	Number of Cases
Granulocytosis	43
Granulopenia	10
Lymphocytosis	22
Lymphopenia	34
Monocytosis	42
Eosinophilia	16
Basophilia	13
Metamyelocytes	26
Myelocytes	1
Promyelocytes	3
Blasts	13
Nucleated red cells	17

The clinical sensitivity for morphologic abnormals is shown in Table 4.17.

Table 4.17 Clinical Sensitivity for Morphologic Abnormals - HmX Hematology Analyzer

Criteria	HmX Hematology Analyzer Negative	HmX Hematology Analyzer Positive	Total
Reference (H20) Normal	177 (TN)	26 (FP)	203 (FP% 12.8)
Reference (H20) Abnormal	1 (FN)	26 (TP)	27 (FN% 3.7)
Total	178	52	230

(TN) = True Negative
(FP) = False Positive
(FN) = False Negative (Blasts 0.07 x 10^9 cells/L)
(TP) = True Positive

4.6 PERFORMANCE CHARACTERISTICS - HmX HEMATOLOGY ANALYZER WITH AUTOLOADER

Precision of the CBC Parameters

The results of replicate precision testing (n=31) for each parameter measured by the test instrument are given in Table 4.18.

Table 4.18 Imprecision Analysis by Replication: WHOLE BLOOD - HmX Hematology Analyzer with Autoloader

Parameter	Units	Mean	SD	CV%
WBC	x 10^9 cells/L	10.44	0.11	1.05
RBC	x 10^{12} cells/L	4.98	0.025	0.5
Hgb	g/dL	14.39	0.04	0.28
MCV	fL	85.90	0.65	0.76
RDW	%	12.34	0.15	0.12
Plt	10^9 cells/L	321.60	11.86	3.69
MPV	fL	9.15	0.13	1.42

The results of Pair Difference analysis for 69 paired clinical blood specimens are given in Table 4.19. Evaluation of the Pair Difference analysis of the CBC parameter was by subtraction of 69 paired test results given by the HmX Hematology Analyzer with Autoloader Primary Aspiration Mode.

Table 4.19 Imprecision Analysis by Paired Sample - HmX Hematology Analyzer with Autoloader

		Clinical Range			
Parameter	Units	Low	High	Mean Diff.	SD
WBC	x 10^9 cells/L	1.10	55.20	0.00	0.13
RBC	x 10^{12} cells/L	2.31	6.59	0.00	0.03
Hgb	g/dL	8.00	17.50	-0.00	0.05
MCV	fL	69.60	125.60	0.01	0.82
RDW	%	11.04	26.50	-0.06	0.32
Plt	x 10^9 cells/L	10.0	715.0	-0.80	10.72
MPV	fL	5.60	10.8	0.02	0.24

Precision of the Differential Parameters - HmX Hematology Analyzer with Autoloader

Evaluation of the Pair Difference Analysis for the five-part differential was by subtraction of 38 paired test results given by the HmX Hematology Analyzer with Autoloader Primary Aspiration Mode. See Table 4.20.

Table 4.20 Imprecision Analysis (Diff Parameters) by Paired Sample - HmX Hematology Analyzer with Autoloader

Cell Type	Mean Difference%	SD of Difference
Lymphocyte	-0.91	6.36
Monocyte	0.43	3.41
Neutrophil	0.09	1.18
Eosinophil	-0.05	0.29
Basophil	0.45	2.27

Accuracy of CBC Parameters - HmX Hematology Analyzer with Autoloader

Evaluation of the CBC parameter accuracy was by subtraction of 69 paired test results given by the HmX Hematology Analyzer with Autoloader Primary Aspiration Mode and the HmX Hematology Analyzer with Autoloader Secondary Aspiration Mode.

Evaluation of the Five-Part Differential Accuracy was by subtraction of 38 paired test results given by the HmX Hematology Analyzer with Autoloader Primary Aspiration Mode and the HmX Hematology Analyzer with Autoloader Secondary Aspiration Mode. See Table 4.21.

Table 4.21 Accuracy Analysis by Compared Specimens - HmX Hematology Analyzer with Autoloader

		Clinical Range			
Parameter	Units	Low	High	Mean Diff.	SD
WBC	x 10^9 cells/L	1.10	55.20	-0.07	0.12
RBC	x 10^{12} cells/L	2.31	6.59	-0.04	0.04
Hgb	g/dL	8.00	17.50	-0.12	0.08
MCV	fL	69.60	125.60	-0.07	1.07
RDW	%	11.04	26.50	-0.04	0.28
Plt	x 10^9 cells/L	10.0	715.0	-10.86	11.57
MPV	fL	5.60	10.8	-0.03	0.30
Lymphocyte	%	11.5	67.1	0.61	4.85
Monocyte	%	1.50	26.20	-0.35	3.00
Neutrophil	%	31.40	74.40	-0.48	4.07
Eosinophil	%	0.00	9.00	0.08	0.36
Basophil	%	0.00	1.7	0.15	0.64

4.7 RETICULOCYTE PERFORMANCE CHARACTERISTICS

Imprecision Analysis by Replication

Imprecision is stated in terms of standard deviation (SD). The SD was determined by replicate testing using 31 dilutions of the same whole blood specimen. The test was repeated at three different reticulocyte levels. See Table 4.22.

Table 4.22 Imprecision Analysis by Replication

Statistic	Level I	Level II	Level III
Mean	0.22	1.54	6.72
SD	0.05	0.20	0.47
n	31	31	31

Table 4.23 shows paired samples imprecision analysis.

Table 4.23 Imprecision Analysis by Paired Samples

Criteria	Mean	Minimum	Maximum
(A) Test 1	2.25%	0.20%	2.25%
(B) Test 2	2.31%	0.30%	2.31%
Difference (A-B)	-0.06%	N/A	N/A
SD of Differences	0.43%	N/A	N/A

n = 145, Test 1 vs. Test 2

Accuracy

Accuracy is shown by analysis of paired tests using clinical specimens. The analysis used the conventional calculation method for Mean Difference and Standard Deviation of differences (SD). Accuracy is defined as the degree of agreement between the reference method, NCCLS H16-P, and the HmX Hematology Analyzer. Clinical specimens with values covering the expected range of performance were used. Table 4.24 displays the results of the accuracy analysis.

Table 4.24 Accuracy Analysis by Compared Specimens

Criteria	Mean	Minimum	Maximum
(A) HmX Hematology Analyzer Reticulocyte Counter	3.43%	0.3%	26.50%
(B) Reference	3.26%	0.12%	24.06%
Difference (A-B)	0.19%	N/A	N/A
SD of Differences	1.01%	N/A	N/A

COULTER HmX Hematology Analyzer analysis based on 145 clinical specimens.

Reference Interval

Reference intervals (normal range) for the HmX Hematology Analyzer are divided into two groups based on sex. The resulting minimum and maximum values of the laboratory normal range are shown in Table 4.25.

Table 4.25 Reference Intervals

Parameter	Low	High	n
Retic-Male	0.6%	2.60%	100
Retic-Female	0.6%	2.60%	128

4.8 INTERFERING SUBSTANCES

A salt of EDTA is the preferred anticoagulant. Beckman Coulter used K_3EDTA for the data collection and verification of claims. Use of other anticoagulants can yield misleading results.

The presence of certain interfering substances, as listed in this section, can also yield misleading results.

WBC

Certain unusual RBC abnormalities that resist lysing, nucleated RBCs, fragmented WBCs, any unlysed particles greater than 35 fL, very large or aggregated platelets as when anticoagulated with oxalate or heparin, specimens containing fibrin, cell fragments, or other debris such as pediatric and oncology specimens.[41, 42, 43, 44]

RBC

Very high WBC count, high concentration of very large platelets, agglutinated RBCs, RBCs smaller than 36 fL, specimens containing fibrin, cell fragments, or other debris such as pediatric and oncology specimens.[45, 46]

Hgb

Very high WBC count, severe lipemia, heparin, certain unusual RBC abnormalities that resist lysing, or anything that increases the turbidity of the sample such as elevated levels of triglycerides.[47]

MCV

Very high WBC count, high concentration of very large platelets, agglutinated RBCs, RBC fragments that fall below the 36-fL threshold, or rigid RBCs.[48, 49, 50, 51]

RDW

Very high WBC count, high concentration of very large or clumped platelets as in blood anticoagulated with oxalate or heparin, RBCs below the 36-fL threshold, two distinct populations of RBCs, RBC agglutinates, or rigid RBCs.[52, 53, 54, 55]

Plt

Very small red blood cells near the upper threshold, cell fragments, clumped platelets as with oxalate or heparin, platelet fragments, or cellular debris near the lower platelet threshold.[56, 57, 58, 59]

MPV

Known factors that interfere with the Plt count and shape of the histogram or known effects of EDTA.[60, 61, 62, 63]

Hct

Known factors that interfere with the parameters used for computation: RBC and MCV.

MCH

Known factors that interfere with the parameters used for computation: Hgb and RBC.

MCHC

Known factors that interfere with the parameters used for computation: Hgb, RBC and MCV.

Diff Parameters

Known factors that affect the WBC count as listed above or high triglycerides that affect lysing.[64]

Reticulocytes

Erythrocyte inclusions stained by New Methylene Blue, if sufficiently numerous within a sample, and some hemoglobinopathies (SS, SC) might affect the accuracy of the reticulocyte enumeration.[65]

5.1 LASER SAFETY PRECAUTIONS

The HmX Hematology Analyzer uses two lasers:

- A laser bar-code reader
- A helium neon laser in the diff module (TTM) for analyzing the WBC differential and Retic counts.

WARNING The laser in the diff module (TTM) can damage both the instrument and your eyes if you do not use it safely. Follow the instructions and procedures in this manual to safely use the instrument and prevent damage.

In its design and manufacture of the HmX Hematology Analyzer, Beckman Coulter has complied with the requirements governing the use and application of a laser as stipulated in regulatory documents issued by the:

- U.S. Department of Health and Human Services
- Center for Devices and Radiological Health (CDRH).

In compliance with these regulatory documents, every measure has been taken to ensure the health and safety of users and laboratory personnel from the possible dangers of laser use.

5.2 GENERAL LASER SAFETY WARNINGS

WARNING Use of controls or adjustments, or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Do not attempt to remove the laser or to open it. If removal is required, it must be done only by your Beckman Coulter Representative.

To ensure your safety, HmX Hematology Analyzer lasers are covered with protective shields held in place by tamper-proof screws. Do not attempt to remove these shields.

This instrument contains components dangerous to the operator. If any attempt has been made to defeat a safety feature, or if this instrument fails to perform as listed in this manual, disconnect power and call your Beckman Coulter Representative.

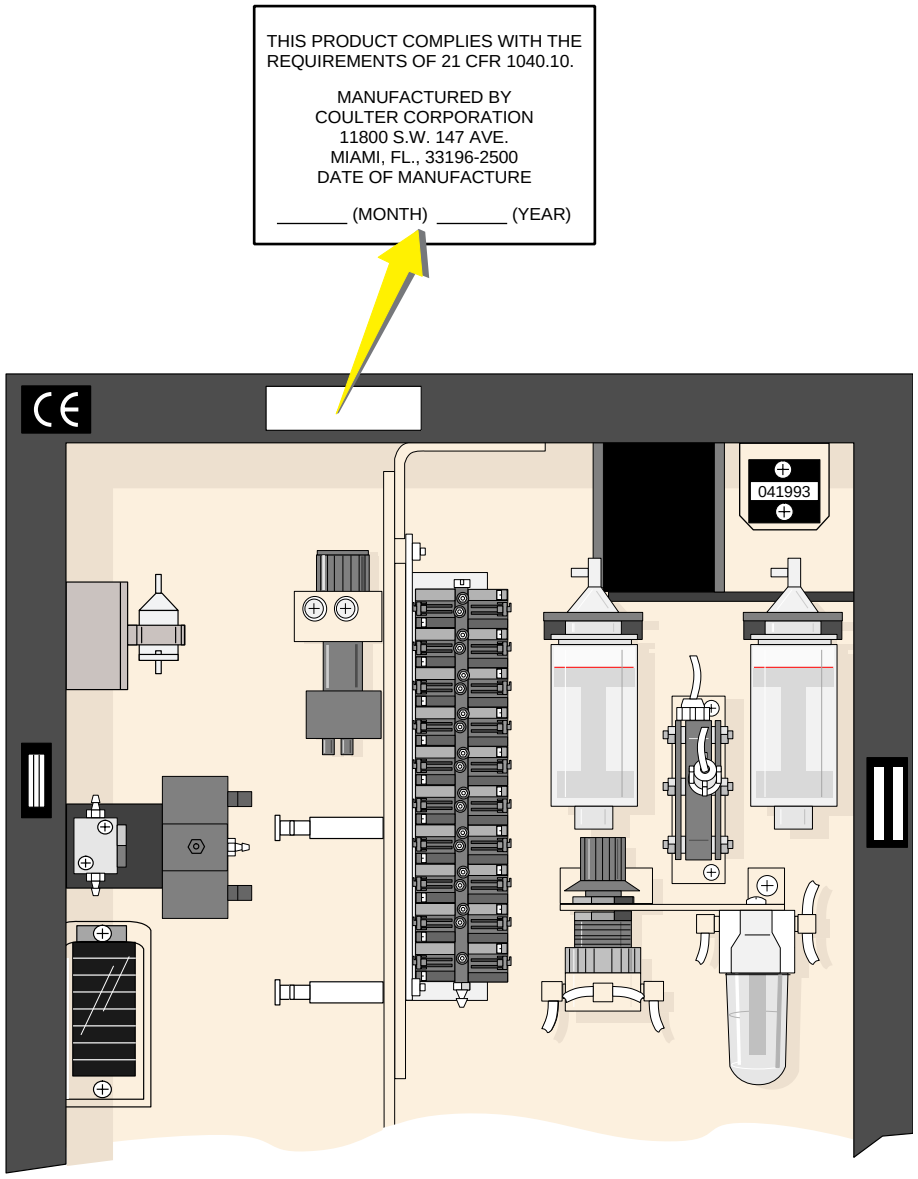
5.3 WARNING LABELS

CDRH-approved labels are placed near or on those covers that, when removed, might expose one to laser radiation.

Note: As installed in the Triple Transducer Module (TTM) safety fixture, the laser presents no radiation hazard to users and complies with 21 CFR 1040.

See Figure 5.1, Figure 5.2, Figure 5.3, and Figure 5.4.

Figure 5.1 Laser Safety Label



Right side view

Figure 5.2 Safety Labels on the TTM

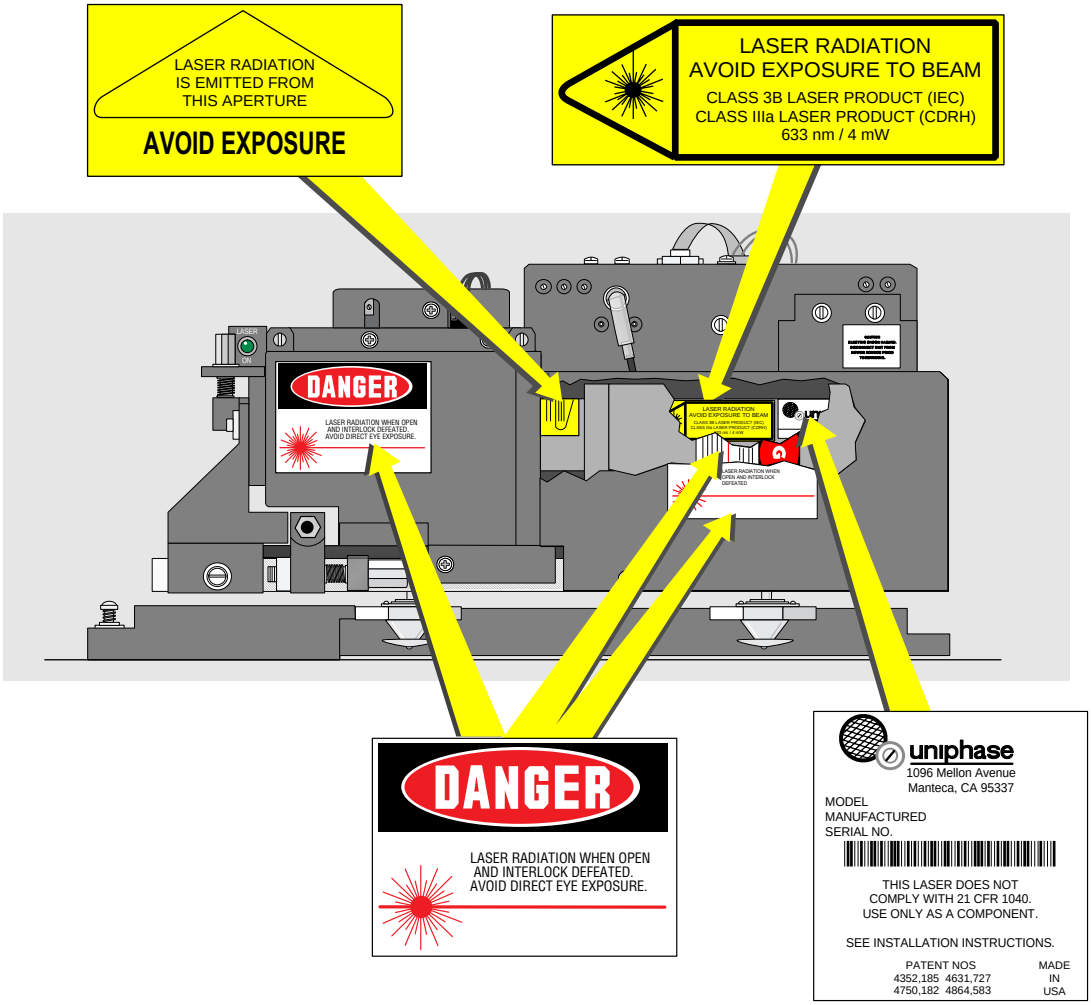


Figure 5.3 Laser Safety Labels for Bar-Code Reader on the HmX Hematology Analyzer

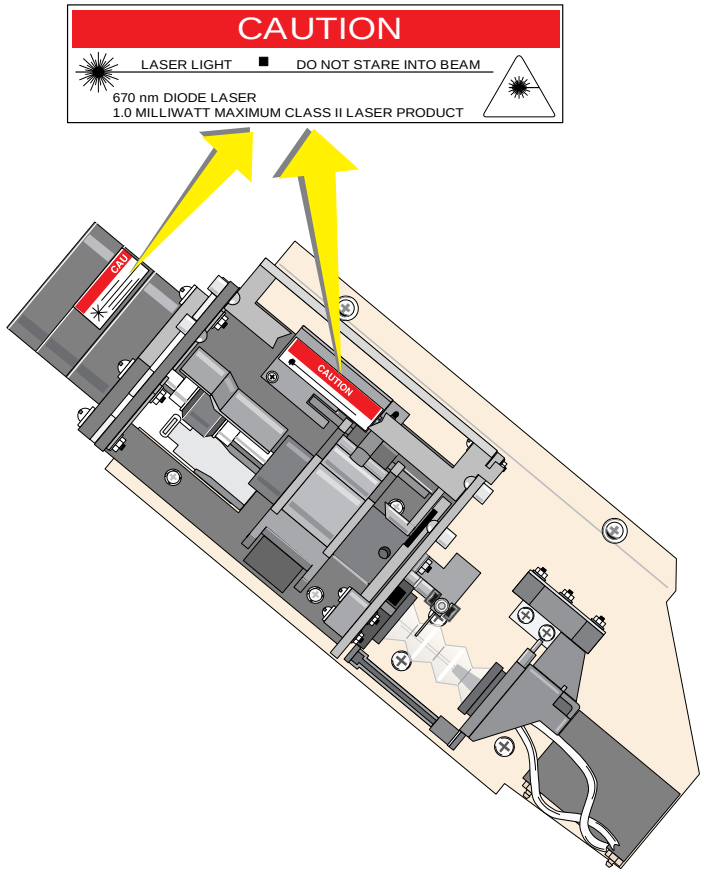
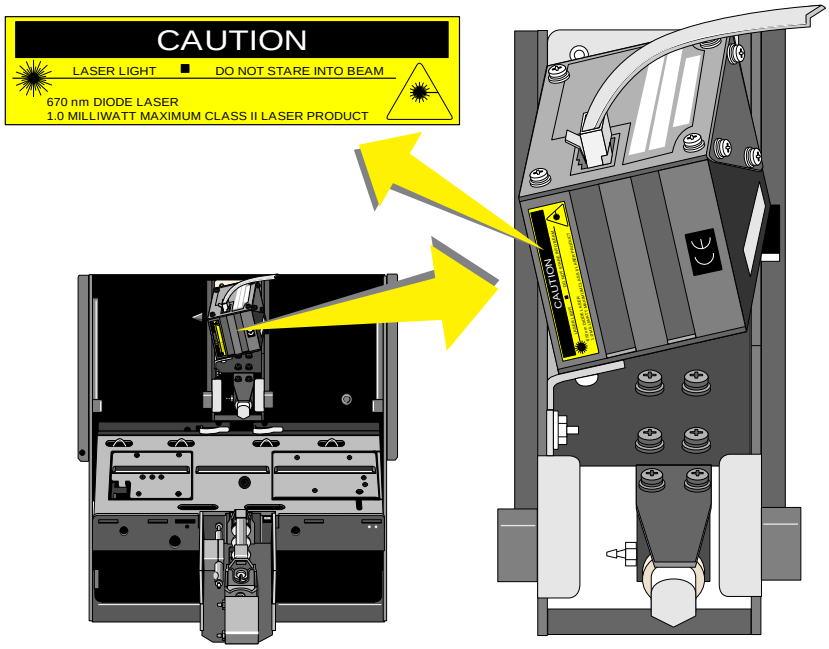


Figure 5.4 Laser Safety Labels for Bar-Code Reader on the HmX Hematology Analyzer with Autoloader



Sample results can be printed on a Graphic Printer either in:

- Ticket format, or
- Graphic format.

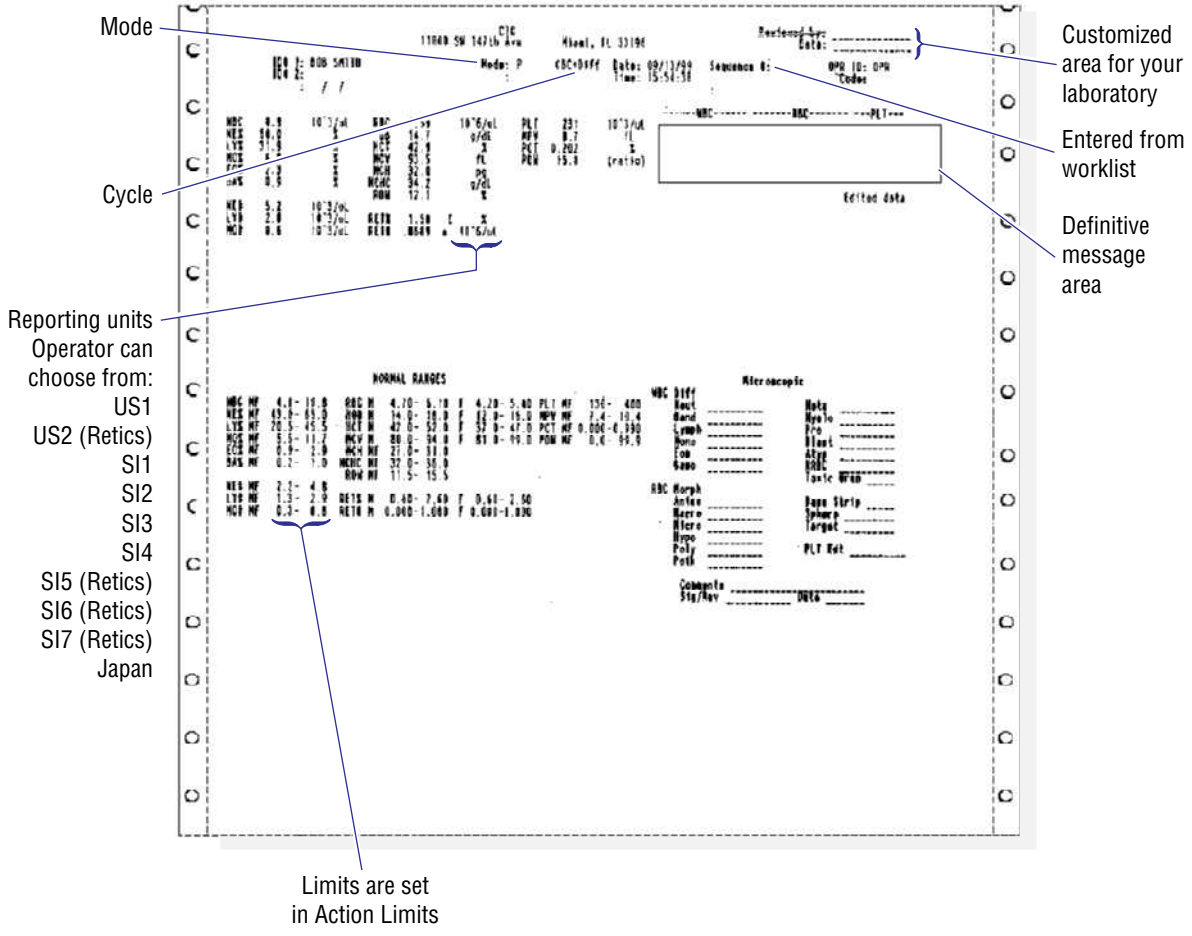
6.1 TICKET FORMAT ON A GRAPHIC PRINTER

Autoprint format must be set to Ticket Format to get this report. Sample reports are automatically printed when you select **ALL**, **NORMALS,** or **ABNORMALS** from the **Auto Print** option. See Figure 6.1 for an example of a printed ticket format.

Note: Batches are always printed in Graphic format.

To manually request a Ticket format printout, press F2 **Ticket** at the Run Samples screen.

Figure 6.1 Ticket Format



6.2 GRAPHIC FORMAT

Autoprint format must be set to Graphic Format to get this report. Sample reports are automatically printed when you select **ALL**, **NORMALS**, or **ABNORMALS** from the **Auto Print** option.

Note: Batches are always printed in Graphic format.

To manually request a Graphic format printout, press F4 **Print** at the Run Samples screen.

Figure 6.2 shows a graphic format report with a wide width/large font page format. Figure 6.3 shows a graphic format report with a narrow width/small font page format.

Figure 6.2 Graphic (Wide/Large Page) Format

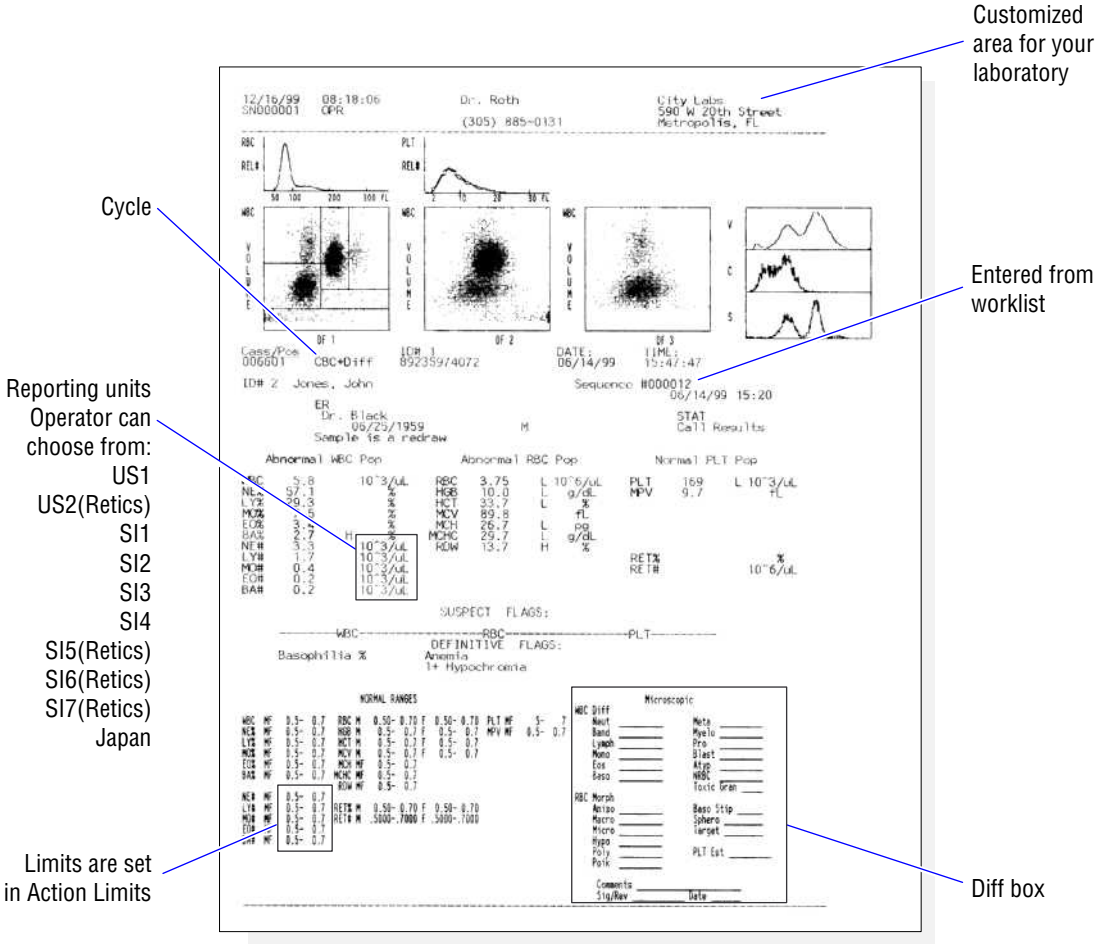
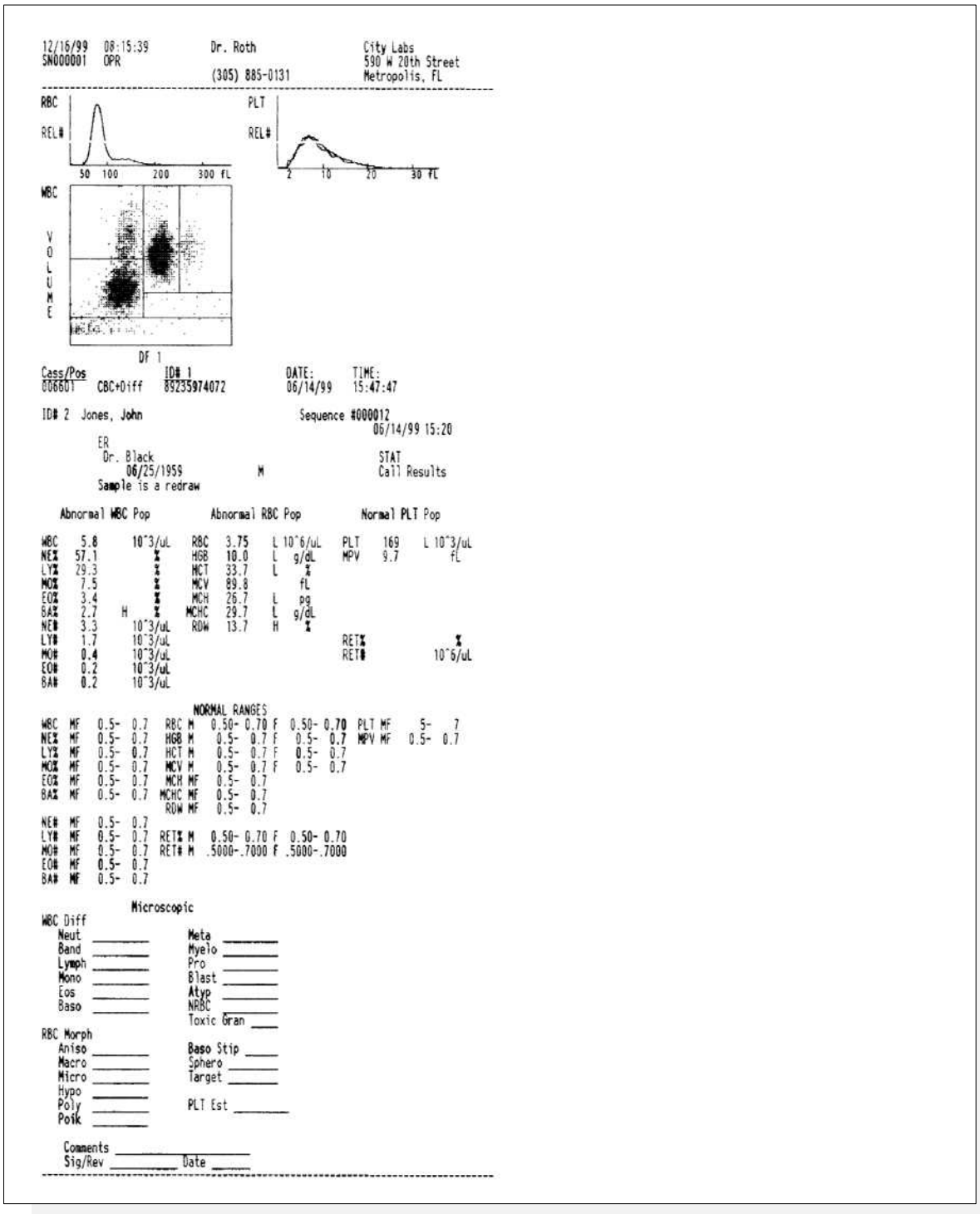


Figure 6.3 Graphic (Narrow/Small Page) Format



12/16/99 08:15:39 Dr. Roth City Labs
SN000001 OPR (305) 885-0131 590 W 20th Street
Metropolis, FL

RBC REL# 50 100 200 300 fL
PLT REL# 2 10 20 30 fL
WBC VOLUME
DF 1

Cass/Pos 006601 CBC+Diff ID# 1 89235974072 DATE: 06/14/99 TIME: 15:47:47

ID# 2 Jones, John Sequence #000012
06/14/99 15:20
ER
Dr. Black STAT
06/25/1959 M Call Results
Sample is a redraw

Abnormal WBC Pop			Abnormal RBC Pop			Normal PLT Pop		
WBC 5.8		10^3/uL	RBC 3.75	L	10^6/uL	PLT 169	L	10^3/uL
NE% 57.1		%	HGB 10.0	L	g/dL	MPV 9.7		fL
LY% 29.3		%	HCT 33.7	L	%			
MO% 7.5		%	MCV 89.8		fL			
EO% 3.4		%	MCH 26.7	L	pg			
BA% 2.7	H	%	MCHC 29.7	L	g/dL			
NE# 3.3		10^3/uL	RDW 13.7	H	%			
LY# 1.7		10^3/uL				RET%		%
MO# 0.4		10^3/uL				RET#		10^6/uL
EO# 0.2		10^3/uL						
BA# 0.2		10^3/uL						

NORMAL RANGES

WBC	MF	0.5- 0.7	RBC	M	0.50- 0.70	F	0.50- 0.70	PLT	MF	5- 7
NE%	MF	0.5- 0.7	HGB	M	0.5- 0.7	F	0.5- 0.7	MPV	MF	0.5- 0.7
LY%	MF	0.5- 0.7	HCT	M	0.5- 0.7	F	0.5- 0.7			
MO%	MF	0.5- 0.7	MCV	M	0.5- 0.7	F	0.5- 0.7			
EO%	MF	0.5- 0.7	MCH	MF	0.5- 0.7					
BA%	MF	0.5- 0.7	MCHC	MF	0.5- 0.7					
			RDW	MF	0.5- 0.7					
NE#	MF	0.5- 0.7								
LY#	MF	0.5- 0.7	RET%	M	0.50- 0.70	F	0.50- 0.70			
MO#	MF	0.5- 0.7	RET#	M	.5000-.7000	F	.5000-.7000			
EO#	MF	0.5- 0.7								
BA#	MF	0.5- 0.7								

Microscopic

WBC Diff
Neut _____ Meta _____
Band _____ Myelo _____
Lymph _____ Pro _____
Mono _____ Blast _____
Eos _____ Atyp _____
Baso _____ NRBC _____
Toxic Gran ____

RBC Morph
Aniso _____ Baso Stip ____
Macro _____ Sphero _____
Micro _____ Target _____
Hypo _____
Poly _____ PLT Est _____
Poik _____

Comments _____
Sig/Rev _____ Date _____

IMPORTANT Inaccurate reading by the scanner could occur if you use bar-code labels for specimen tubes that do not conform to the specifications given in this appendix. Only use bar-code labels that comply with these specifications.

7.1 BAR-CODE LABELS

A bar code consists of black lines (bars) and white lines (spaces) called elements. They are narrow elements (NE) and wide elements (WE), and the code determines their arrangements.

The HmX Hematology Analyzer and HmX Hematology Analyzer with Autoloader accept four bar-code symbologies:

- Code 39® bar code
- * Codabar or NW7
- Interleaved 2-of-5
- Code 128.

* Only one of these types (Codabar or NW7) can be active at the same time. The NW7 code used on the instrument is the same as the Codabar symbology with a checkdigit.

IMPORTANT Inaccurate reading by the scanner could occur if you use the characters listed below in your bar-code label. Do not use the following Code 128 characters:

Subset	Character values
A	0, 64-95, 101, 102
B	0, 95, 100, 102
C	102

Table 7.1 contains Code 128 characters.

Table 7.1 Code 128 Characters

Value	Code A	Code B	Code C	Value	Code A	Code B	Code C	Value	Code A	Code B	Code C
0	Space	Space	00	36	D	D	36	72	BS	h	72
1	!	!	01	37	E	E	37	73	HT	i	73
2	”	”	02	38	F	F	38	74	LF	j	74
3	#	#	03	39	G	G	39	75	VT	k	75
4	$	$	04	40	H	H	40	76	FF	l	76
5	%	%	05	41	I	I	41	77	CR	m	77
6	&	&	06	42	J	J	42	78	SO	n	78
7	’	’	07	43	K	K	43	79	SI	o	79
8	(	(	08	44	L	L	44	80	DLE	p	80
9	)	)	09	45	M	M	45	81	DC1	q	81
10	*	*	10	46	N	N	46	82	DC2	r	82

Table 7.1 Code 128 Characters *(Continued)*

Value	Code A	Code B	Code C	Value	Code A	Code B	Code C	Value	Code A	Code B	Code C
11	+	+	11	47	O	O	47	83	DC3	s	83
12	,	,	12	48	P	P	48	84	DC4	t	84
13	-	-	13	49	Q	Q	49	85	NAK	u	85
14	.	.	14	50	R	R	50	86	SYN	v	86
15	/	/	15	51	S	S	51	87	ETB	w	87
16	0	0	16	52	T	T	52	88	CAN	x	88
17	1	1	17	53	U	U	53	89	EM	y	89
18	2	2	18	54	V	V	54	90	SUB	z	90
19	3	3	19	55	W	W	55	91	ESC	{	91
20	4	4	20	56	X	X	56	92	FS	|	92
21	5	5	21	57	Y	Y	57	93	GS	}	93
22	6	6	22	58	Z	Z	58	94	RS	~	94
23	7	7	23	59	[	[	59	95	US	DEL	95
24	8	8	24	60	\	\	60	96	FNC 3	FNC 3	96
25	9	9	25	61	]	]	61	97	FNC 2	FNC 2	97
26	:	:	26	62	^	^	62	98	SHIFT	SHIFT	98
27	;	;	27	63	_	_	63	99	CODE C	CODE C	99
28	<	<	28	64	NUL	’	64	100	CODE B	FNC 4	CODE B
29	=	=	29	65	SOH	a	65	101	FNC 4	CODE A	CODE A
30	>	>	30	66	STX	b	66	102	FNC 1	FNC 1	FNC 1
31	?	?	31	67	ETX	c	67	103	START (CODE A)		
32	@	@	32	68	EOT	d	68	104	START (CODE B)		
33	A	A	33	69	ENQ	e	69	105	START (CODE C)		
34	B	B	34	70	ACK	f	70				
35	C	C	35	71	BEL	g	71				

Optical Characteristics at 670 nm ±10%

1. Print Contrast Signal (PCS): 80% minimum.
2. Reflectivity of Media (RW): 80% minimum.
3. Reflectivity of Ink (Rb): 16% maximum.
4. No spots or voids; no ink smearing.
5. Edge roughness is included in the bar and space tolerances.

$$PCS = \frac{Rw - Rb}{Rw} \times 100\%$$

Bar-code labels used in the system must be grade C or better, according to American National Standards Institute's guidelines, X3.182-1990.

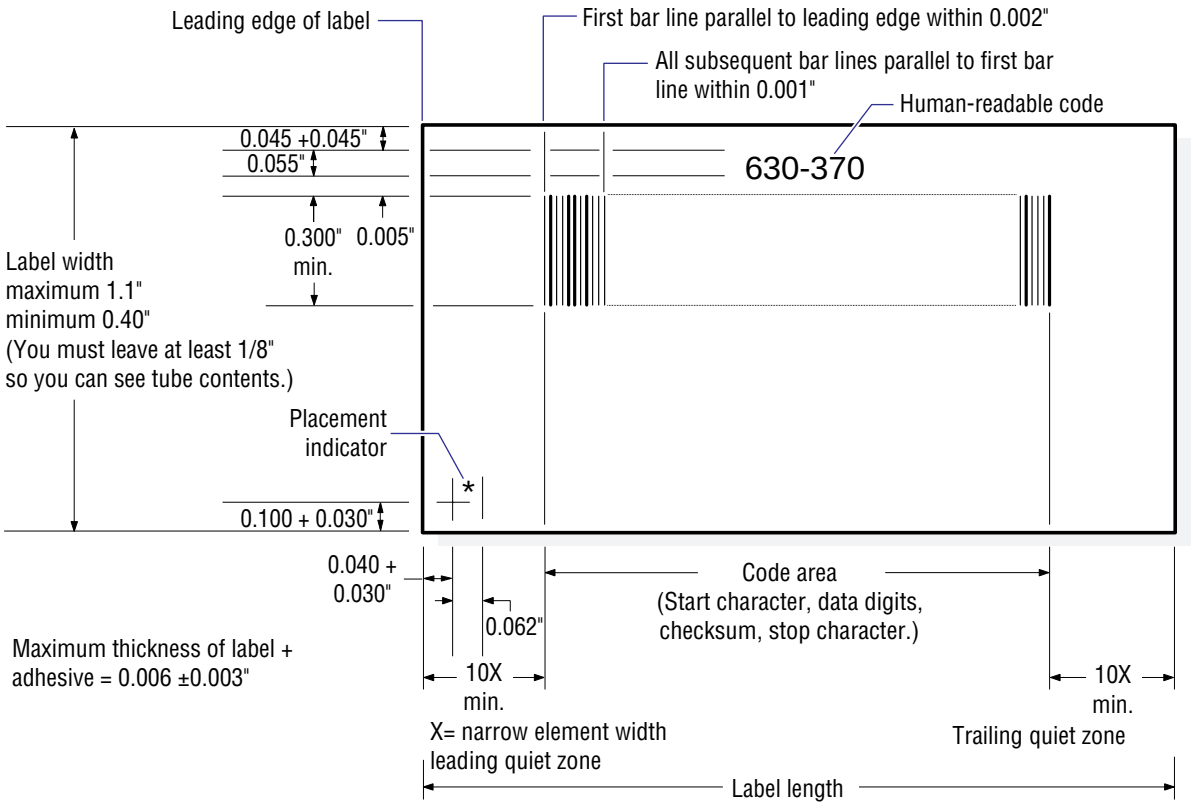
Label Specifications

IMPORTANT Use of bar codes is an extremely accurate and effective method of data capture. Certain features, such as checksum digits, maximize accuracy in reading Codabar, NW7, Code 39, and Interleaved 2-of-5 labels. In one study, the use of checksum digits detected 97% of misread errors.

Use checksums to provide protection against occasional misread errors caused by problems such as damaged or misapplied labels. If you must use bar codes without checksums, it is recommended that you verify each bar-code reading to assure correct patient identification.

See Figure 7.1 for bar-code label specifications.

Figure 7.1 Bar-Code Label Specifications



Code-Related Specifications

See Table 7.2 for code-related specifications.

Table 7.2 Code-Related Specifications

Code	Interleaved 2-of-5	Codabar/NW7	Code 39	Code 128
NE width	0.010 - 0.020"	0.010 Scaling* Factor = 1.538	0.010 - 0.020"	0.010 - 0.020"
WE/NE ratio	(2.2 to 3):1	N/A	(2.21 to 3):1	N/A
Intercharacter gap	No	0.010" Min.	≥NE	N/A
Data digits	2 to 16	3 to 16	3 to 16 (3 to 8 with HEMOGARD tubes	3 to 16

*According to American National Standard for bar-code specifications that yield 10 characters per inch at NE = 0.0065".

Printing Methods

Photographic, thermal transfer, dot matrix, and laser printer.

7.2 BAR-CODE READER

Description

The HmX Hematology Analyzer uses a visible laser-type reader containing a Class II laser, operating at a wavelength of 670 nm, with a maximum power output of 1 mW.

Settings and Defaults

Table 7.3 lists the available settings for the bar-code reader and the default setting for each feature. To change a setting call your Beckman Coulter Representative. The **default** setting appears in **bold** typeface.

Table 7.3 Bar-Code Reader Settings and Defaults

Feature	Interleaved 2 of 5	Codabar/NW7	Code 39	Code 128
Code Type	**Enabled**/Disabled	**Enabled**/Disabled	**Enabled**/Disabled	**Enabled**/Disabled
Fixed Length	N/A	**Enabled**/Disabled	**Enabled**/Disabled	**Enabled**/Disabled
Code Length No. 1	0, 2, 4, 6, 8, 10, **12**, 14, 16	3, 4, 5, 6, 7, 8, 9, **10**, 11, 12, 13, 14, 15, 16	3, 4, 5, 6, 7, 8, 9, **10**, 11, 12, 13, 14, 15, 16	3, 4, 5, 6, 7, 8, 9, **10**, 11, 12, 13, 14, 15, 16
Code Length No. 2	**0**, 2, 4, 6, 8, 10, 12, 14, 16	N/A	N/A	N/A
Check Digit	**Enabled**/Disabled	**Enabled**/Disabled	**Enabled**/Disabled	N/A
Check Digit Output	**Enabled**/Disabled	**Enabled**/Disabled	**Enabled**/Disabled	N/A
Check Digit Type	N/A	**AIM-16**/MOD-16 (Coulter)/NW7	N/A	N/A
Intercharacter Gap	N/A	**Enabled**/Disabled	**Enabled**/Disabled	N/A
Start/Stop Match	N/A	**Enabled**/Disabled	N/A	N/A

Table 7.3 Bar-Code Reader Settings and Defaults *(Continued)*

Feature	Interleaved 2 of 5	Codabar/NW7	Code 39	Code 128
Start/Stop Output	N/A	**Enabled**/Disabled	N/A	N/A
Narrow Margins	**Enabled**/Disabled	**Enabled**/Disabled	**Enabled**/Disabled	**Enabled**/Disabled

7.3 BAR-CODE DECODER

Normal Operation

HmX Hematology Analyzer

The decoder

- Turns the scanner ON for a maximum of 1 second.
- Decodes information from the scanner.
- Beeps.
- Turns the scanner OFF.
- Transmits the decoded data (or no read message) to the sample handler.

The sample handler

- Flashes the green light to signal you to place the sample tube in the entry slot.

HmX Hematology Analyzer with Autoloader

The decoder

- Turns the scanner ON for a maximum of 1.5 seconds.
- Decodes information from the scanner.
- Turns the scanner OFF.
- Transmits the decoded data (or no read message) to the sample handler.

IMPORTANT Use bar-code labels with checksum capabilities; checksums verify the number is correct. Also, whenever possible, enable the fixed-length option as another way of ensuring a correct reading. Using these two methods minimizes any chance of misidentification.

The closed-vial sampling system has been tested with the following collection devices.

A.1 BECKMAN COULTER

5C cell control tubes.

13 x 62 mm control tubes.

A.2 BECTON DICKINSON

Worldwide

VACUTAINER® collection tubes with lavender rubber stoppers. All are K_3EDTA unless otherwise noted.

BD No.	Volume Draw	o.d. x L (mm)
6405 (6564)	2.5 mL	13 x 75
6385	3 mL	10.25 x 64
6458	3.5 mL	16 x 75
6545	4 mL	16 x 75
6452 (Europe)	4.5 mL	13 x 75
6452 (U.S.A.)	5 mL	13 x 75

VACUTAINER tubes with HEMOGARD™ closure. All tubes are 13 x 75 mm.

U.S.A.

BD No.	Volume Draw	Content
367650	3.0 mL	K_3EDTA
367651	2.0 mL	K_3EDTA
367653	5.0 mL	K_3EDTA
367658	5.0 mL	K_3EDTA
367661	3.0 mL	K_3EDTA
367662	5.0 mL	K_3EDTA
368261*	2.0 mL	K_2EDTA
368262*	3.0 mL	K_2EDTA

* Also available in South America.

Europe

BD No.	Volume Draw	Content
367652	3.0 mL	K_3EDTA
367654	4.5 mL	K_3EDTA
367656	4.0 mL	K_2EDTA
367657	4.5 mL	K_3EDTA
367663	4.0 mL	K_3EDTA
367664	5.0 mL	Na_2EDTA
368241	2.0 mL	K_2EDTA
368242	3.0 mL	K_2EDTA

U.K. and Australia

BD No.	Volume Draw	Content
368247	2.0 mL	K_2EDTA
368248	3.0 mL	K_2EDTA

Japan

BD No.	Volume Draw	Content
367648	2.0 mL	K_2EDTA
367649	2.0 mL	K_2EDTA
367660	2.0 mL	K_3EDTA
368253	2.0 mL	K_2EDTA

A.3 GREINER

Vacuette Brand

Greiner No.	Volume Draw	o.d. x L (mm)
454087	2.0 mL	13 x 75
454086	3.0 mL	13 x 75
457045	3.0 mL	16 x 75
454036	4.0 mL	13 x 75
457046	4.0 mL	16 x 65
457047	5.0 mL	16 x 65

A.4 JOHNS

See Labco listing.

A.5 LABCO

Exetainer Brand

Labco No.	Volume Draw	o.d. x L (mm)*
EXPDL/KE/1	1.0 mL	12.5 x 54
EXBG1/KE/3e19	3.0 mL	12 x 78
367860	4.0 mL	
Glass Vials		
GSPD/KE/1	1.0 mL	12.5 x 44
GSPD/KE/2	2.0 mL	12.5 x 44

* All lengths include caps.

A.6 LABO EXPRESS SERVICE (L.E.S.)

4 mL, plastic, cap-pierceable tube with a purple latex stopper.

A.7 LDM

4 mL, plastic, cap-pierceable tube with a blue latex stopper.

5 mL, plastic, cap-pierceable tube with a blue latex stopper.

5 mL, glass tube with perforated plastic cap cover, 12 x 75 mm, 911213.

5 mL, plastic tube with perforated plastic cap cover, 12 x 75 mm, 920416.

A.8 L.I.P.

TRI KE/4 No.	Volume Draw	o.d. x L (mm)*
38917 (glass)	4.0 mL	12 x 81
72110 (plastic)	4.0 mL	12 x 81

* All lengths include cap.

A.9 SARSTEDT

Monovette brand, plastic, cap pierceable tube with red stop.

Volume Draw (mL)	o.d. x L (mm)
2.7 mL	11.5 x 66
3.2 mL	16 x 65

A.10 SHERWOOD MEDICAL

S No.	Volume Draw	o.d. x L (mm)
8881-311149	2 mL	10.25 x 50
8881-311248	3 mL	10.25 x 64
8881-314440	3 mL	13 x 75
8881-311446	5 mL	13 x 75
8881-311644	7 mL	16 x 75

A.11 TERUMO (Worldwide)

VENOJECT® tubes with lavender rubber stoppers.

T No.	Volume Draw	o.d. x L (mm)
Y-573DK (Japan)	3 mL	16 x 75
T-272SQS	2 mL	10.25 x 50
T-273SQS	3 mL	10.25 x 65
T-274SQS	4 mL	10.25 x 85
T-206SQS	5 mL	13 x 75
T-202SQS	7 mL	16 x 75

B.1 INTRODUCTION

You can perform manual differentials as a measure of good QC practice or as recommended by your laboratory, state, and federal protocols.

At the end of this appendix are blank log sheets used in the procedure.

B.2 PROCEDURE

1. Collect two different normal blood samples. Follow NCCLS H3-A2 procedures.

   The samples must be:

   - Collected in K_3EDTA with 1.5 mg/mL of anticoagulant to blood
   - Maintained at room temperature
   - Within the reference range of:

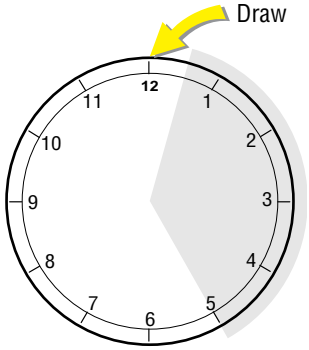
     NE 40 to 72%

     LY 17 to 45%

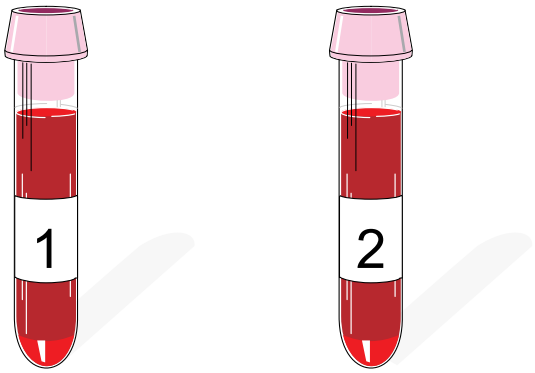
     MO 4 to 12%

     EO 0 to 10%

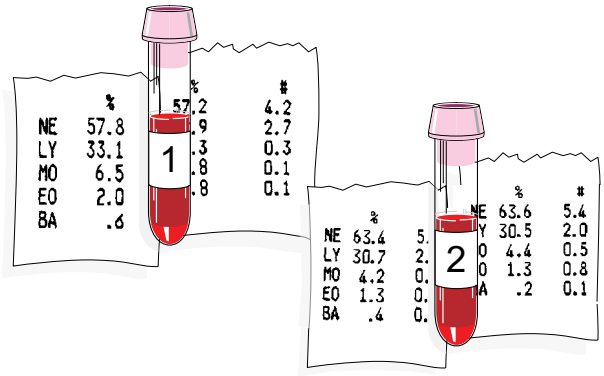
     BA 0 to1%
   - Analyzed between 30 minutes and 5 hours after draw.



2. Label the samples.



3. Cycle each sample two times. Print the results for your logbook.



4. Record your results on the Daily QC Worksheet.
5. Add the results for each parameter.
6. Divide each parameter total by 2.

Daily QC Worksheet (For Manual Differential Check)

Date: 5/17/99

Specimen 1

	Cycle	NE%	LY%	MO%	EO%	BA%
Record Results	1	57.8	33.1	6.5	2.0	.6
	2	57.2	32.9	6.3	2.8	.8
Add	Total (Σ)					
Divide by 2	$\frac{\Sigma}{2}$ = HmX 1					

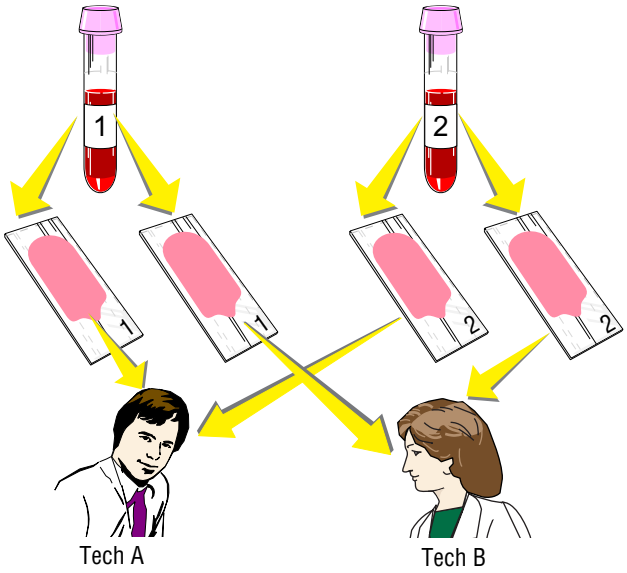
	Tech	NE%	LY%	MO%	EO%	BA%
	1					
	2					
	Total (Σ)					

Specimen 2

	Cycle	NE%	LY%	MO%	EO%	BA%
Record Results	1	63.4	30.7	4.2	1.3	.4
	2	63.6	30.5	4.4	1.3	.2
Add	Total (Σ)					
Divide by 2	$\frac{\Sigma}{2}$ = HmX 1					

7. Make slides using NCCLS H20 procedures.
   - 2 slides of sample 1
   - 2 slides of sample 2.
8. Give the slides to Techs A and B:
   - 1 slide of sample 1 to Tech A
   - The other slide of sample 1 to Tech B
   - 1 slide of sample 2 to Tech A
   - The other slide of sample 2 to Tech B.

9. Ask them for manual cell diffs (NCCLS H20).



10. Record the techs' counts on the Daily QC Worksheet.
11. Add the results for each parameter.
12. Divide each parameter total by 2.

Daily QC Worksheet (For Manual Differential Check)

Date: 5/17/99

Specimen 1

Cycle	NE%	LY%	MO%	EO%	BA%
1	57.8	33.1	6.5	2.0	.6
2	57.2	32.9	6.3	2.8	.8
Total (Σ)	115.0	66.0	12.8	4.8	1.4
$\frac{\Sigma}{2}$ = HmX 1	57.5	33.0	6.4	2.4	.7
Tech	NE%	LY%	MO%	EO%	BA%
1	55	32	7	3	1
2	56	33	6	3	0
Total (Σ)	111	65	13	6	1
$\frac{\Sigma}{2}$ = Ref 1	55.5	32.5	6.5	3.0	.5

Record Results — Add — Divide by 2

Specimen 2

Cycle	NE%	LY%	MO%	EO%	BA%
1	63.4	30.7	4.2	1.3	.4
2	63.6	30.5	4.4	1.3	.2
Total (Σ)	127.0	61.2	8.6	2.6	.6
$\frac{\Sigma}{2}$ = HmX 2	63.5	30.6	4.3	1.3	.3
Tech	NE%	LY%	MO%	EO%	BA%
1	65	28	4	2	0
2	65	30	4	1	1
Total (Σ)	130	58	8	3	1
$\frac{\Sigma}{2}$ = Ref 2	65.0	29.0	4.0	1.5	.5
Graph Point					

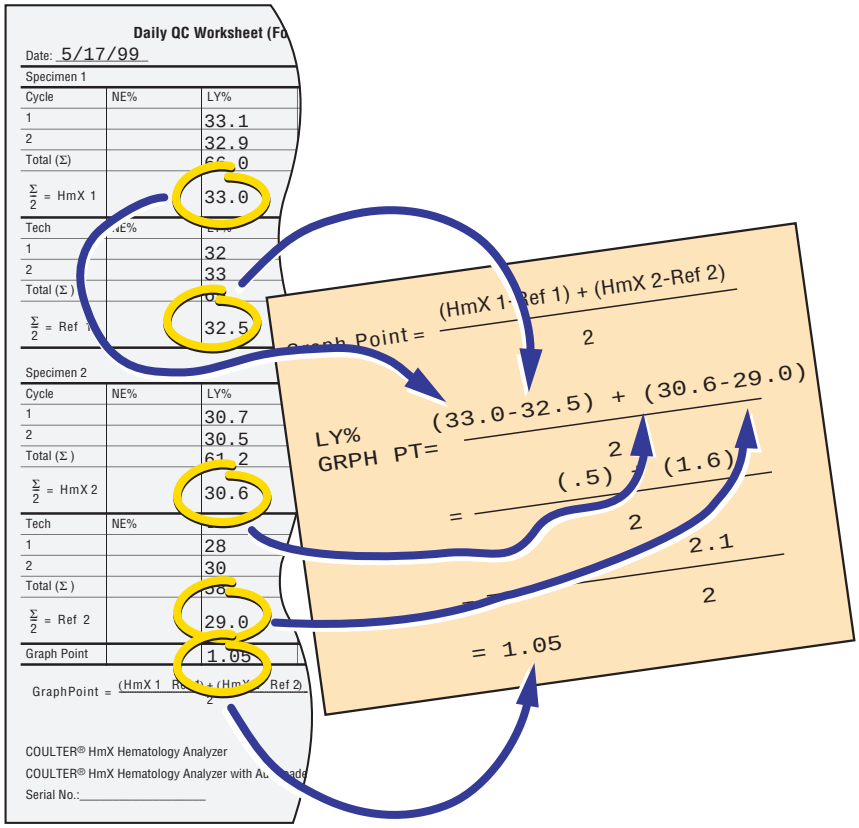
Record Results — Add — Divide by 2

$$\text{GraphPoint} = \frac{(\text{HmX 1 Ref 1}) + (\text{HmX 2 Ref 2})}{2}$$

COULTER® HmX Hematology Analyzer
COULTER® HmX Hematology Analyzer with Autoloader
Serial No.:_____

BECKMAN COULTER™

13. Calculate the graph points.

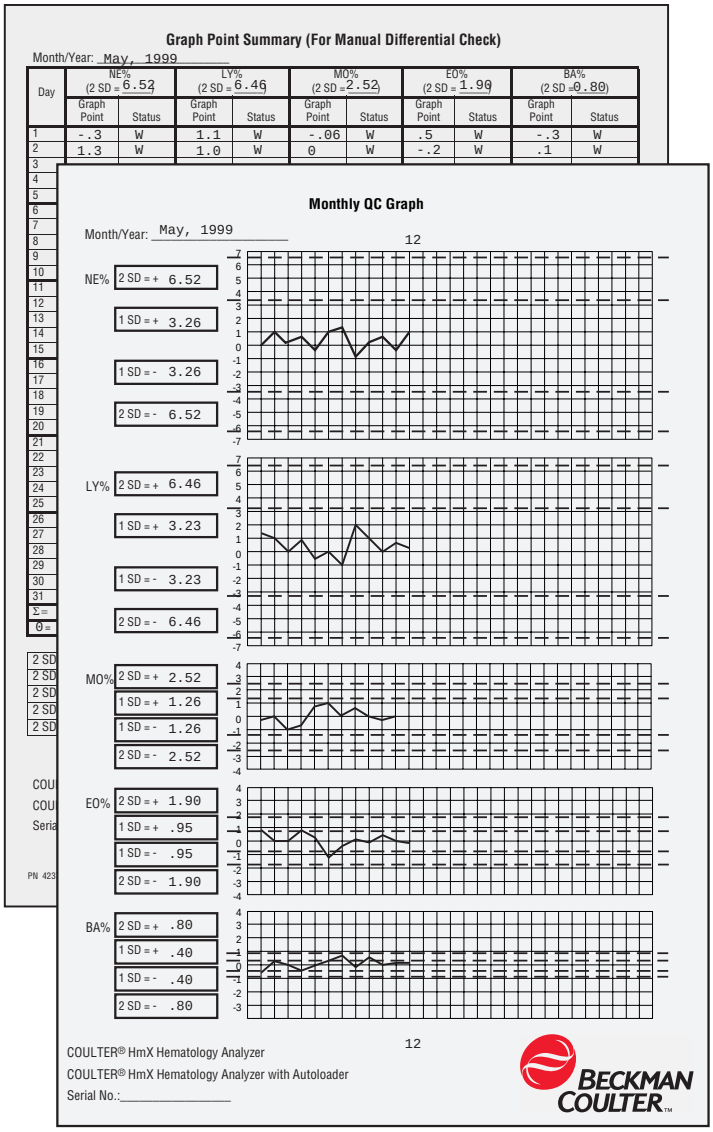


14. Record the graph points on these log sheets:
    - Graph Point Summary
    - Monthly QC Graphs.

    For your first month use:
    - Zero as the mean.
    - These values:

	1 SD	2 SD
NE	3.26	6.52
LY	3.23	6.46
MO	1.26	2.52
EO	0.95	1.90
BA	0.40	0.80

After you accumulate values for 31 days, calculate your own laboratory's mean and standard deviations.



Graph Point Summary (For Manual Differential Check)

Month/Year: May, 1999

Day	NE% (2 SD = 6.52)		LY% (2 SD = 6.46)		MO% (2 SD = 2.52)		EO% (2 SD = 1.90)		BA% (2 SD = 0.80)	
	Graph Point	Status	Graph Point	Status	Graph Point	Status	Graph Point	Status	Graph Point	Status
1	-.3	W	1.1	W	-.06	W	.5	W	-.3	W
2	1.3	W	1.0	W	0	W	-.2	W	.1	W
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										
17										
18										
19										
20										
21										
22										
23										
24										
25										
26										
27										
28										
29										
30										
31										
Σ =										
0 =										

2 SD
2 SD
2 SD
2 SD
2 SD

COU
COU
Seria

PN 423

Monthly QC Graph

Month/Year: May, 1999

12

NE% 2 SD = + 6.52 | 1 SD = + 3.26 | 1 SD = - 3.26 | 2 SD = - 6.52

LY% 2 SD = + 6.46 | 1 SD = + 3.23 | 1 SD = - 3.23 | 2 SD = - 6.46

MO% 2 SD = + 2.52 | 1 SD = + 1.26 | 1 SD = - 1.26 | 2 SD = - 2.52

EO% 2 SD = + 1.90 | 1 SD = + .95 | 1 SD = - .95 | 2 SD = - 1.90

BA% 2 SD = + .80 | 1 SD = + .40 | 1 SD = - .40 | 2 SD = - .80

12

COULTER® HmX Hematology Analyzer
COULTER® HmX Hematology Analyzer with Autoloader
Serial No.:_____

BECKMAN COULTER

15. Call your Beckman Coulter Representative if 95% of your graph points do not fall within 2 SDs.

B.3 LOG SHEETS

This section contains these log sheets, used in the diff comparison procedure:

- Daily QC Worksheet
- Graph Point Summary
- Monthly QC Graphs.

Make photocopies as needed.

Daily QC Worksheet (For Manual Differential Check)

Date: _____

Specimen 1

Cycle	NE%	LY%	MO%	EO%	BA%
1					
2					
Total (Σ)					
$\frac{\Sigma}{2}$ = HmX 1					
Tech	**NE%**	**LY%**	**MO%**	**EO%**	**BA%**
1					
2					
Total (Σ)					
$\frac{\Sigma}{2}$ = Ref 1					

Specimen 2

Cycle	NE%	LY%	MO%	EO%	BA%
1					
2					
Total (Σ)					
$\frac{\Sigma}{2}$ = HmX 2					
Tech	**NE%**	**LY%**	**MO%**	**EO%**	**BA%**
1					
2					
Total (Σ)					
$\frac{\Sigma}{2}$ = Ref 2					
Graph Point					

$$\text{GraphPoint} = \frac{(\text{HmX 1} - \text{Ref 1}) + (\text{HmX 2} - \text{Ref 2})}{2}$$

COULTER® HmX Hematology Analyzer

COULTER® HmX Hematology Analyzer with Autoloader

Serial No.:_____

Graph Point Summary (For Manual Differential Check)

Month/Year: _____

Day	NE% (2 SD = _____)		LY% (2 SD = _____)		MO% (2 SD = _____)		EO% (2 SD = _____)		BA% (2 SD = _____)	
	Graph Point	Status	Graph Point	Status	Graph Point	Status	Graph Point	Status	Graph Point	Status
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										
17										
18										
19										
20										
21										
22										
23										
24										
25										
26										
27										
28										
29										
30										
31										
Σ =										
$\bar{x}$ =										

2 SD NE% =
2 SD LY% =
2 SD MO% =
2 SD EO% =
2 SD BA% =

$$SD = \sqrt{\frac{\Sigma\,(\text{Each graph point} - \text{The mean for that column})^2}{\text{The number of graph points} - 1}}$$

Status W = Within 2 SDs

H = More than 2 SDs ABOVE the mean

L = More than 2 SDs BELOW the mean.

COULTER® HmX Hematology Analyzer

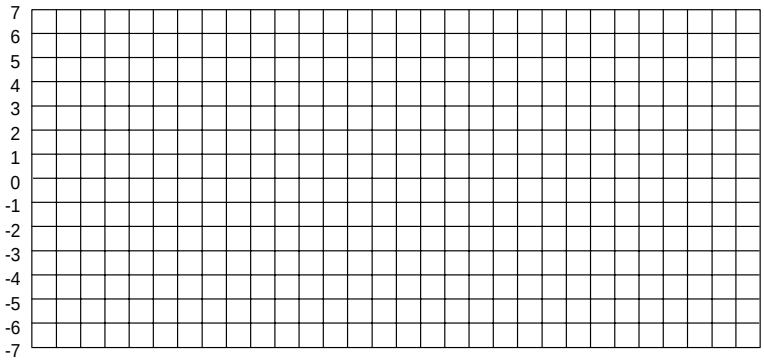
COULTER® HmX Hematology Analyzer with Autoloader

Serial No.:_____

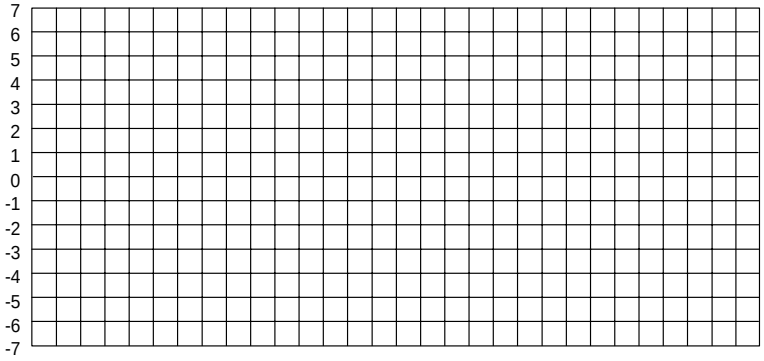
Monthly QC Graph

Month/Year: _____

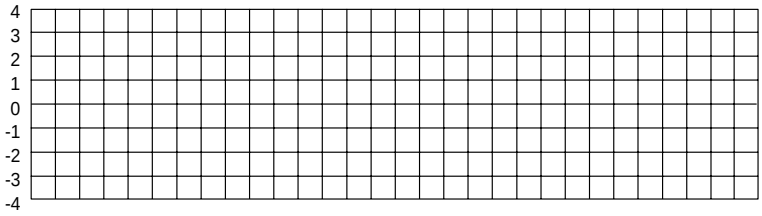
NE%
2 SD = +
1 SD = +
1 SD = -
2 SD = -



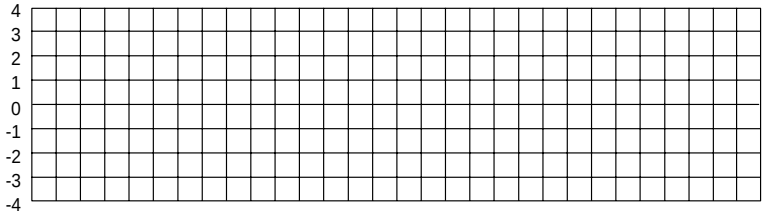
LY%
2 SD = +
1 SD = +
1 SD = -
2 SD = -



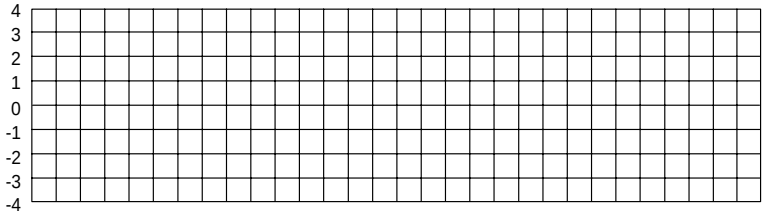
MO%
2 SD = +
1 SD = +
1 SD = -
2 SD = -



EO%
2 SD = +
1 SD = +
1 SD = -
2 SD = -



BA%
2 SD = +
1 SD = +
1 SD = -
2 SD = -



COULTER® HmX Hematology Analyzer
COULTER® HmX Hematology Analyzer with Autoloader
Serial No.:_____

BECKMAN COULTER™

PN 4237523A

LIMITED WARRANTY

This instrument, when purchased from Beckman Coulter, Inc. or from an authorized distributor or subsidiary company, is warranted against defects in materials and workmanship for a period of one (1) year from date of the original invoice to the customer for this instrument or for longer periods if purchased.

This warranty is limited to the repair and replacement of parts which prove to be defective during the warranty period. This warranty is not valid for parts damaged, lost or which fail because of accident, fire, theft, acts of nature (storms, floods, etc.) negligence of the use of chemicals which have a deleterious effect.

This warranty is conditioned upon Beckman Coulter, Inc. retaining the unqualified option of replacing parts up to and including an entire instrument.

This warranty will not extend to any repairs or modifications made to the instrument by some party other than Beckman Coulter, Inc., or a party authorized to do so by Beckman Coulter, Inc. Also, this warranty shall be effective only upon written notice of the defect to Beckman Coulter, Inc. or its authorized distributor within five (5) days after occurrence of said defect.

This warranty shall apply only to use of the instrument at a location within a state of the United States and in Canada and shall not apply to use of the instrument at a location outside the continental limits of the United States, including any territory, possession, military or government facility therein and in any other Country foreign to the United States. Upon request of the purchaser, Beckman Coulter, Inc. can undertake to arrange for special warranty service upon agreed written terms only at a location where this warranty does not apply. No other warranty of any kind is made, expressed, or implied.

COULTER CORPORATION
A Beckman Coulter Company
Miami, Florida 33196

REFERENCES

1. Corash L. Platelet Sizing: Techniques, Biological Significance, and Clinical Applications. Current Topics in Hematology. New York, New York: Alan R. Lise, Inc. 1983.
2. Threate GA, Andrados C, Ebbe S, and Brecher G. Mean Platelet Volume: The Need for a Reference Method. AJCP, 1984; 81, 769-772.
3. Thompson CB, Diaz DD, Quinn PG, Lapins M, Kurtz SR, and Valeri CR. The Role of Anticoagulant in the Measurement of Platelet Volumes. AJCP, 1983: 327-332.
4. Coulter WH. High speed automatic blood cell counter and cell size analyzer. Paper presented at National Electronics Conference, Chicago, IL, 1956; October 3.
5. Brecher G, Schneiderman M, and Williams GZ. Evaluation of electronic red blood cell counter. Am J Clin Path, 1956; 26:1439-1449.
6. Brittin GM, Brecher G, and Johnson CA. Evaluation of the COULTER COUNTER Model S. Am J Clin Path, 1969; 52(6):679-689.
7. Gottmann AW. Multiple hematologic analyses by means of a COULTER COUNTER Model S. Paper presented at International Symposium of Standardization of Hematological Methods, Fondazione, Carlo Erbe, Milan, Italy, November 9 and 10, 1970. Symposium proceedings published in Haematologica Latina, 1969.
8. Hamilton PJ and Davison RL. The interrelationships and stability of Coulter S-determined blood indices. J Clin Path, 1973; 26:700-705.
9. Bessman JD and Johnson RK. Erythrocyte volume distribution in normal and abnormal subjects. Blood, 1975: 46(3):369-379.
10. Price-Jones C. The diameters of red cells in pernicious anaemia and in anaemia following haemorrhage. J Path Bact, 1922; 25:487-504.
11. England JM, Walford DM, and Waters DAW. Re-assessment of the reliability of the haematocrit. Brit J Haemat, 1972; 23:247-256.
12. Bull BS, Schneiderman MA, and Brecher G. Platelet counts with the COULTER COUNTER. Am J Clin Path, 1965; 44(6):678-688.
13. Mundschenk DD, Connelly DP, White JG, and Brunning RD. An improved technique for the electronic measurement of platelet size and shape. J Lab Clin Med, 1976; 88(2):301-315.
14. Schulz J and Thom R. Electrical sizing and counting of platelets in whole blood. Med Biol Engr, 1973; 73:447-454.
15. Von Behrens WE. Mediterranean macrothrombocytopenia. Blood, 1975; 46(2):199-208.
16. Paulus JM. Platelet size in man. Blood, 1975; 46(3):321-336.
17. International Committee for Standardization in Haematology. Recommendations for reference method for haemoglobinometry in human blood (ICSH Standard EP 6/2: 1977) and specifications for international haemiglobincyanide reference preparation (ICSH Standard EP 6/3: 1977). J Clin Path, 1978; 31(2):139-143.
18. Gauthier J et al. Human leukocytes: their size distribution and mean corpuscular volume. Can Med Assoc J, 1967; 97:793-796.

19. Hughes-Jones NC et al. Differential leucocyte counts by volume distribution analysis. Brit J Haemat, 1974; 28(1):148.

20. England JM et al. A semi-automatic instrument for estimating the differential leucocyte count. Biomed Engr, 1975; 10(8):303-304.

21. Wycherley PA and O'Shea MJ. Abridged differential leucocyte counts provided by a Coulter Channelyzer in a routine haematology laboratory. J Clin Path, 1978; 31(3):271-274.

22. Oberjat TE, Zucker RM, and Cassen B. Rapid and reliable differential counts on dilute leukocyte suspensions. J Lab Clin Med, 1970; 76(3):518-522.

23. Hoffman RA and Britt WB. Flow-system measurement of cell impedance properties. J. Histochem Cytochem, 1979; 27(1):234-240.

24. Leif RC, Schwartz S, Rodriguez CM, Pell-Fernandez L, Groves M, Leif SB, Cayer M, and Crews H. Two-dimensional impedance studies of BSA buoyant density separated human erythrocytes. Cytometry, 1985; 6(1):13-21.

25. Coulter WH et al. Signal modulated apparatus for generating and detecting resistive and reactive changes in a modulated current path for particle classification and analysis. U.S. Patent 3,502,974, March 24, 1970.

26. Fulwyler MJ. Electronic separation of biological cells by volume. Science, 1965; 150:910-911.

27. Loken MR, Sweet RG, and Herzenberg LA. Cell discrimination by multiangle light scattering. J Histochem Cytochem, 1976; 24(1):284-291.

28. Miale, JB. Laboratory Medicine: Hematology. CV Mosby Company, St. Louis, MO, 4th ed., 1972; 22.

29. Corash L, Rheinschmidt M, Lieu S, Meers P, and Brew E, Fluorescence-activated flow cytometry in the haematology clinical laboratory. Cytometry, 1988; Supplement 3:60-64.

30. Friedman EW. Reticulocyte counts: how to use them, what they mean. Diagnostic Medicine, 1984; 7(6):29-33.

31. Williams WJ et al. Hematology. McGraw-Hill, Inc., New York, NY, 4th ed., 1990; 416.

32. Brecher, G. New methylene blue as a reticulocyte stain. Am J Clin Path, 1949; 19: 895-896.

33. Dorsey DB. What can quality control do for hematology? Am J Med Tech, 1965; Mar-Apr:150-153.

34. Bull BS. A statistical approach to quality control. Quality Control in Hematology, Symposium of the International Committee for Standardization in Haematology. Lewis SM and Coster JF, eds, Academic Press, London, England, 1975.

35. Koepke JA. Drug interference with leukocyte counting (spurious leukopenia). Drug Therapy, 1974; 79.

36. Bull BS. A statistical approach to quality control. Quality Control in Hematology, Symposium of the International Committee for Standardization in Haematology. Lewis SM and Coster JF, eds, Academic Press, London, England, 1975.

37. Eckhoff RF. An experimental indication of the volume proportional response of the Coulter Counter for irregularly shaped particles. J Sci Inst, 1967; 44:648-649.

38. Grover NB, Naaman J, Ben-asson S, and Dojanski F. Electrical sizing of particles in suspension III. Rigid spheroids and red blood cells. Biophys J, 1972; 12:1099-1116.

39. Waterman CS, Atkinson EE, Wilkins B, Fischer CL, and Kimsey SL. Improved measurement of erythrocyte volume distribution by aperture-counter signal analysis. Clin Chem, 1975; 21:1201-1211.

40. Kachel V and Ruhenstroth-Bauer G. Methodik and Ergebissne Optiseher Formfatorunter-suchungen bei der Zellvolumenmessung nach Coulter. Micros Acta, 1976; 75:419-423.

41. Luke RG, Koepke JA, and Siegel RR. The effect of immunosuppressive drugs and uremia on automated leukocyte counts. Am J Clin Path, 1971; 56:503-507.

42. Koepke JA. Drug interference with leukocyte counting (spurious leukopenia). Drug Therapy, 1974; 79.

43. Dale NL and Schumacher HR. Platelet satellitism -- new spurious results with automated instruments. Lab Med, 1982; 13:300-304.

44. Kjeldsberg CR and Hershgold EJ. Spurious thrombocytopenia. JAMA, 1974; 227:628-630.

45. Brittin GM, Brecher G, Johnson CA, and Stuart J. Spurious macrocytosis of antibody-coated red cells. Am J Clin Path, 1969; 52:237-241.

46. Hattersley PG, Gerard PW, Caggiano V, and Hash DR. Erroneous values on the COULTER COUNTER Model S due to high titer cold autoagglutinins. Am J Clin Path, 1971; 55:442-446.

47. Nosanchuk JS, Roark MF, and Wanser C. Anemia masked by triglyceridemia. Am J Clin Path, 1974; 62:838-839.

48. Brittin GM, Brecher G, Johnson CA, and Stuart J. Spurious macrocytosis of antibody-coated red cells. Am J Clin Path, 1969; 52:237-241.

49. Nosanchuk JS, Roark MF, and Wanser C. Anemia masked by triglyceridemia. Am J Clin Path, 1974; 62:838-839.

50. Waterman CS, Atkinson EE, Wilkins B, Fischer CL, and Kimsey SL. Improved measurement of erythrocyte volume distribution by aperture-counter signal analysis. Clin Chem, 1975; 21:1201-1211.

51. Fales W. Water distribution in blood during sickling of erythrocytes. Blood, 1978; 51:703-709.

52. Kjeldsberg CR and Hershgold EJ. Spurious thrombocytopenia. JAMA, 1974; 227:628-630.

53. Dale NL and Schumacher HR. Platelet satellitism -- new spurious results with automated instruments. Lab Med, 1982; 13:300-304.

54. Waterman CS, Atkinson EE, Wilkins B, Fischer CL, and Kimsey SL. Improved measurement of erythrocyte volume distribution by aperture-counter signal analysis. Clin Chem, 1975; 21:1201-1211.

55. Fales W. Water distribution in blood during sickling of erythrocytes. Blood, 1978; 51:703-709.

56. Zucker-Franklin D and Karpatkins S. Red cell and platelet fragmentation in idiopathic autoimmune thrombocytopenic purpura. NE J Med, 1977; 297:517-523.

57. Akwari AM, Ross DW, and Stass SA. ASCP, 1982; 77:220-221.

58. Dale NL and Schumacher HR. Platelet satellitism -- new spurious results with automated instruments. Lab Med, 1982; 13:300-304.

59. Kjeldsberg CR and Hershgold EJ. Spurious thrombocytopenia. JAMA, 1974; 227:628-630.

60. Richardson-Jones A. Mean platelet volume: clinical utility and the variables of measurement. 1986; Coulter Electronics, Inc., Hialeah, Florida.

61. Corash L. Platelet Sizing: Techniques, biological significance, and clinical applications. Current topics in hematology. New York, New York: Alan R. Lise, Inc. 1983.

62. Threate GA, Andrados C, Ebbe S, and Brecher G. Mean Platelet Volume: The need for a reference method. AJCP, 1984; 81, 769-772.

63. Thompson CB, Diaz DD, Quinn PG, Lapins M, Kurtz SR, and Valeri CR. The role of anticoagulant in the measurement of platelet volumes. AJCP, 1983: 327-332.

64. Nosanchuk JS, Roark MF, and Wanser C. Anemia masked by triglyceridemia. Am J Clin Path, 1974; 62:838-839.

65. Miale JB, Laboratory Medicine - Hematology. 3rd Edition 1967, CV Mosby, pages 592-595.

A - Ampere, a unit of electric current.

Accuracy - Ability of the instrument to agree with a predetermined reference value at any point within the operating range.

Algorithm - A particular procedure for performing an analysis.ANSI

ANSI - Acronym for American National Standards Institute.

ASCII - Acronym for American Standard Code for Information Interchange.

Assay Values - Values of all parameters in a control established by extensive assay of that control.

ASTM - Acronym for American Society for Testing and Materials.

Average Value - A value determined by adding a set of results and dividing by the number of results. Usually referred to as the simple arithmetic mean.

Background Count - Measure of the amount of electrical or particle interference.

Batch - An $\overline{X}_B$ group of 20 patient samples used for monitoring MCV, MCH, and MCHC as an automatic QC procedure or a group of patient results that you specify in Database Query for group printing and/or transmitting to a host computer.

Batch Mean - The mean or average of a set of samples. For $\overline{X}_B$ Analysis the batch mean is a value based on a statistical averaging technique and is a type of "weighted moving average." It is used to estimate what a simple average result of a very large number of samples (population mean) might be by using a small number of samples.

Baud - A rate defining how many data bits per second are transferred during communications between two pieces of equipment.

BSV (Blood Sampling Valve) - A three-sectioned valve that separates the aspirated sample into three parts for analysis in red cell bath, white cell bath, and flow cell.

Btu - British Thermal Unit.

Calibration - A procedure to standardize the instrument for accuracy by determining its deviation from calibration references and applying any necessary correction factors.

Calibration Factors - Called CAL FAC on the CBC Calibration screen. These are values the system uses to fine-tune instrument accuracy.

Carryover - The amount, in percent, of WBC, RBC, Hgb, and Plt remaining in diluent following the cycling of a blood sample.

CBC (Complete Blood Count) - All blood parameters that the instrument measures except for the leukocyte differential parameters.

Cell Control - A preparation made of human blood with stabilized cells and surrogate material. It is used for daily instrument QC.

Check Valve - A one-way valve that routes liquid or air through the Diluter.

CLIA - Clinical Laboratory Improvement Amendments.

Closed-Vial Sampler (CVS) - In the instrument, a carousel cap-piercing mechanism for the closed-vial mode.

cm - Abbreviation for centimeter, a unit of linear measurement equal to 0.01 meter.

Codes - On the screen and printouts, symbols such as ++++, – – – –, • • • •, H/L, R, *R, :::: that further explain the sample results. See the Parameter Codes Table in the Operator's Guide for more explanation.

Coefficient of Variation (CV) - An expression, in percent, of data spread as related to the mean.

$$CV\% = (SD/Mean)\ 100$$

Coincidence - More than one cell within the aperture sensing boundaries at the same time. The system senses these as one large cell rather than as two distinct cells, so it generates one large pulse.

Conductivity Analysis - In the flow cell, high-frequency electromagnetic energy probes white cell content to measure nuclear size, density, and granularity.

Control Disk - A data diskette that contains the assay values for the lot number of the control being used.

Current Batch - The $\overline{X}_B$ batch that the instrument is accumulating data on right now.

Cursor - On a computer screen, a place shown by a little blinking indicator or by a highlighted area. The cursor shows where you can select an option or type in information.

CV (Coefficient of Variation) - An expression, in percent, of data spread as related to the mean.

$$CV\% = (SD/Mean)\ 100$$

CVS (Closed-Vial Sampler) - In the instrument, a carousel cap-piercing mechanism for the closed-vial mode.

Data Management System (DMS) - Computer software that controls instrument operation. It displays, stores, and recalls sample data, and allows you to communicate with the instrument.

Defaults - Original settings in the DMS. You can change these to tailor operation to your situation.

Definitive Flags - Labels displayed when results exceed limits your laboratory set for indicating such conditions as leukopenia, anemia, thrombocytosis, and so forth.

DELTA DIFF - For CBC calibration, the absolute difference between the mean and the reference values for WBC, RBC, Hgb, MCV, Plt, and MPV.

DF Displays (Discriminant Function) - DIFF scatterplots as seen in two dimensions from two angles of the distributional cube. See the Operator's Guide for explanation and examples.

Diff -

1. Leukocyte differential parameters, items, and processes relating to them.
2. On the REPRODUCIBILITY screen, the difference between the minimum and maximum results for each parameter.
3. On the Startup and System test screens, diff psi = difference between sheath pressure and sample pressure.

Differential Analysis - Analysis of individual WBCs with VCS technology to differentiate and group them into subpopulations.

Diluter - Primary operating unit of the instrument. It aspirates, pipets, dilutes, mixes, lyses and senses.

dL - Deciliter, a unit of volumetric measurement equal to 0.1 liter.

DMS (Data Management System) - Computer software that controls instrument operation. It displays, stores, and recalls sample data, and allows you to communicate with the instrument.

EDTA - Ethylenediaminetetraacetic acid.

Expiration Date - The last day when you can use a lot number of a reagent, control, or calibrator.

FAC % DIFF - In CBC calibration, the percentage difference between the old (OLD CAL FAC) and the new (NEW CAL FAC) calibration factors.

Field - Area on a screen for entering data. Whenever you move a cursor, you are moving it from field to field.

Flags - Codes which appear such as H, L, R, * next to parameter results. These indicate possible abnormal conditions.

Flow Cell - A device through which white cells flow, one cell at a time, to be simultaneously assessed for cell volume, conductivity, opacity, and light scatter.

ft - Foot or feet, a unit of linear measurement.

fL - Femtoliter, a unit of volumetric measurement equal to 10^{-15} meter.

Function Key - Any of the keys labeled F1 to F12. You use these to command system and individual screen processes.

g - Gram, a unit of weight.

gal. - Gallon, a unit of volumetric measurement.

H - A code representing a high value.

Hemoglobinometry - Measurement of hemoglobin in the blood. In Beckman Coulter instruments, this is done by comparing the amount of light that passes through a diluted lysed sample in which the released Hgb has been chemically converted, with the amount of light that passes through a blank.

Hg - Mercury.

Histogram - A graph showing the relative number and distribution of particles. Size is on the horizontal X-axis and number is on the vertical Y-axis.

Hz - Hertz, a unit of frequency.

ICSH - Acronym for International Committee for the Standardization of Hematology.

i.d. - Inner diameter.

IEC - International Electrical Commission.

in. - Inch, a unit of linear measurement.

In Vitro - Outside of a living system, as in a laboratory system, or in an artificial container.

IQAP (Interlaboratory Quality Assurance Program) - This quality control program offered only through Beckman Coulter compares your laboratory's instrument performance to the performance of similar instruments.

k - Kilogram, a unit of weight equal to 1,000 grams.

K3EDTA - Tripotassium ethylenediaminetetraacetic acid.

L - A code designating a low value.

Laser (Light Amplification by Stimulated Emission of Radiation) - Two lasers are used in the instrument: one for reading bar codes and one in the flow cell assessing white blood cells.

lb - Pound, a unit of weight.

Light Scatter Analysis - In the instrument, monochromatic laser light using forward angle scatter analyzes the internal structure, granularity, and surface characteristics of white blood cells as each cell passes through the flow cell.

Linearity - The ability of an instrument to recover expected results for directly measured parameters for such parameters as WBC, RBC, Hgb and Plt at varying levels of concentration within specified limits.

Lot Number - A manufacturer's code that identifies when the reagent was manufactured.

m - Meter, a unit of linear measurement.

Mean - Arithmetic average of a group of data.

mg - Milligram, a unit of weight equal to 0.001 gram.

mil - A unit of linear measurement, equal to 0.001 inch.

mL - Milliliter, a unit of volumetric measurement, equal to 10^{-3} liter.

mm - Millimeter, a unit of linear measurement, equal to 0.001 meter.

Mode - 1) The way you choose to run a sample: closed vial (primary mode) or open vial (secondary mode). 2) The number (or set of numbers) that occur most frequently as shown by histogram peaks.

Mode-to-Mode Matching - Agreement among patient results in open- and closed-vial modes. See Chapter 4 for specifics.

mW - Milliwatt, a unit of power equal to 0.001 watt.

N or n - Number.

NCCLS - National Committee for Clinical Laboratory Standards.

NEW CAL FACTOR - Values the system calculates as you go through the calibration procedure that makes mean values equal the reference values.

nm - Nanometer, a unit of linear measurement, equal to 10^{-9} meter.

o.d. - Outer diameter.

OLD CAL FACTOR - Values the system has been using and still is using as you go through the calibration procedure.

Opacity - For white blood cells analyzed in a flow cell using high-frequency measurement. Subtracting the volume measurement from the conductivity measurement yields cell opacity.

Outlier - Control results that fall outside the expected or established range.

Parameters - Components of blood that the instrument measures and reports.

Parity - Methods of detecting errors in data handling. The computer generates a parity bit such that the sum of the bits and the parity bit are odd or even for each data word.

Patient Population - A large number of patient sample results for $\overline{X}_B$ Analysis, used to give fairly consistent average results for each of the three red blood cell indices: MCV, MCH, and MCHC.

pg - Picogram, a unit of gravimetric measurement.

psi - Pounds per square inch, a unit of pressure measurements.

Precision - Ability of the instrument to reproduce similar results when a sample is run repeatedly. Precision of the instrument is CV based on at least 31 replicate determinations of the same sample. Precision of the closeness of test results when repeated analyses of the same material are performed. Also called reproducibility.

Primary Mode - Closed-vial sampling mode in the instrument.

Purge - An option that clears clogs and bubbles from apertures and flow cell.

QC (Quality Control) - A comprehensive set of procedures your laboratory sets up to ensure that the instrument is working accurately and precisely.

Quality Control (QC) - A comprehensive set of procedures your laboratory sets up to ensure that the instrument is working accurately and precisely.

REF. VALUES - Reference values for CBC calibration. You find these on the calibrator package insert and enter them on the CBC calibration screen.

Reproducibility - This procedure checks that the system gives similar results (within established limits) every time it measures the same sample. It is also called precision.

Scatter - Light scatter analysis.

Scatterplot - A two-dimensional display of three-dimensional white cell data.

SD (Standard Deviation) - A measurement of deviation from the mean.

Secondary Mode - In the instrument, the open-vial mode of sampling.

Shift - Consecutive values that abruptly move and maintain a constant level.

Solenoid - An electronically controlled valve that routes vacuum, pressure, air or liquids.

Standard Deviation (SD) - A measurement of deviation from the mean.

Stop Bit - A computer code that indicates the end of a character.

Suspect Flags - Messages generated by the instrument algorithm to denote abnormal WBC, RBC, and/or Plt populations.

Sweep Flow - A steady stream of diluent that flows behind the RBC aperture during sensing periods to keep RBCs from swirling back into the sensing zone and becoming incorrectly sensed as platelets.

Time-out - After a predetermined time of no operator input, the instrument reverts to a waiting state (the compressor turns off and the DMS screen blanks). If input to a prompt is not received in a predetermined amount of time, a time-out occurs and the system displays *SELECT FUNCTION*.

Trend - Values that continue to increase or decrease gradually over a period of time (five or more consecutive values).

TTM - Triple Transducer Module, the module that contains the laser and makes the diff measurements.

µL - Microliter, a unit of volumetric measurement.

UL - Underwriters Laboratory.

µm - Micrometer, a unit of linear measurement.

V - Volt, a unit of electrical potential.

Vac - Volts of alternating current.

VCS - Volume, Conductivity and Scatter (along with opacity), the white cell measurements taken in the HmX Analyzer flow cell.

Voting - In Beckman Coulter hematology instruments, the system compares the three counts for RBC, WBC, Plt, and MCV. If the unit finds disagreement among all count periods or other internal criteria are not met, the DMS displays a total voteout.

W - Watt, a unit of power.

X - See mean.

$\bar{X}_B$ **Analysis** - A method of quality control that automatically compares patient indices (MCV, MCH, MCHC) with known target values. It is used to monitor automated instruments in hematology.

Zap - Multiple Aperture Zap under Special Functions, fills the baths with cleaning agent and activates a series of quick electronic burns that rid apertures of any accumulated protein. The Zap function then rinses the apertures and baths and readies the instrument for continued operation.

Symbols

Numerics

A

B

C

D

E

F

G

H

I

K

L

M

N

O

P

Q

R

S

T

U

V

W

X

Y

Z

INDEX

BECKMAN COULTER, INC. CUSTOMER END USER LICENSE AGREEMENT

This Product contains software that is owned by Beckman Coulter, Inc. or its suppliers and is protected by United States and international copyright laws and international trade provisions. You must treat the software contained in this Product like any other copyrighted material. This license and your right to use the Product terminate automatically if you violate any part of this agreement.

This is a license agreement and not an agreement for sale. Beckman Coulter hereby licenses this Software to you under the following terms and conditions:

You May:

1. Use this software in the computer supplied to you by Beckman Coulter;
2. Maintain one copy of this software for backup purposes (the backup copy shall be supplied by Beckman Coulter);
3. After written notification to Beckman Coulter, transfer the entire Product to another person or entity, provided you retain no copies of the Product software and the transferee agrees to the terms of this license agreement.

You May Not:

1. Use, copy or transfer copies of this Software except as provided in this license agreement;
2. Alter, merge, modify or adapt this Software in any way including disassembling or decompiling;
3. Loan, rent, lease, or sublicense this Software or any copy.

Limited Warranty

Beckman Coulter warrants that the software will substantially conform to the published specifications for the Product in which it is contained, provided that it is used on the computer hardware and in the operating system environment for which it was designed. Should the media on which your software arrives prove defective, Beckman Coulter will replace said media free of charge within 90 days of delivery of the Product. This is your sole remedy for any breech of warranty for this software.

Except as specifically noted above, Beckman Coulter makes no warranty or representation, either expressed or implied, with respect to this software or its documentation including quality, performance, merchantability, or fitness for a particular purpose.

No Liability for Consequential Damages

In no event shall Beckman Coulter or its suppliers be liable for any damages whatsoever (including, without limitation, damages for loss of profits, business interruption, loss of information, or other pecuniary loss) arising out of the use of or inability to use the Beckman Coulter Product software. Because some states do not allow the exclusion or limitation of liability for consequential damages, the above limitation might not apply to you.

General

This agreement constitutes the entire agreement between you and Beckman Coulter and supersedes any prior agreement concerning this Product software. It shall not be modified except by written agreement dated subsequent to the date of this agreement signed by an authorized Beckman Coulter representative. Beckman Coulter is not bound by any provision of any purchase order, receipt, acceptance, confirmation, correspondence, or otherwise, unless Beckman Coulter specifically agrees to the provision in writing. This agreement is governed by the laws of the State of Florida.

BECKMAN COULTER™

TRADEMARKS

The BECKMAN COULTER logo, 5C, CHANNELYZER, COULTER, COULTER CLENZ, COULTER COUNTER, Erythrolyse, ISOTON, LATRON, LIN-C, LYSE S, Retic-C, ReticPrep, S-CAL, S-PLUS, Stabilyse, and ZBI are trademarks of Beckman Coulter, Inc.

All other trademarks, service marks, products, or services are trademarks or registered trademarks of their respective holders.

COULTER HmX Hematology Analyzer and HmX Hematology Analyzer with Autoloader Documentation

▪ Reference PN 4237523	Use and Function • Installation • Operation Principles • Specifications/Characteristics • Laser Safety • Reporting Options • Bar-Code Specifications • Sample Tube Sizes • Diff Comparison • References • Glossary • Index
▪ Operator's Guide PN 4237519 PN 4237521 (Autoloader)	System Overview • Startup and Controls • Sample Analysis • Data Review • Shutdown • Set Up • References • Index
▪ Special Procedures and Troubleshooting PN 4237520 PN 4237522 (Autoloader)	Calibration • Reproducibility and Carryover • Cleaning Procedures • Adjust/Replace Procedures • Troubleshooting • Index
▪ Host Specifications PN 4237518	Defines the contents of records transmitted from a HmX Hematology Analyzer to a host computer
▪ Master Index PN 4237524 PN 4237525 (Autoloader)	Combined index for the Operator's Guide, Special Procedures and Troubleshooting, and Reference manuals.

Come visit us at www.beckmancoulter.com

BECKMAN COULTER™

COULTER CORPORATION
A Beckman Coulter Company
Miami, Florida 33196-2500 USA