COULTER LH 750 System

Operator's Guide





PN 4277249DE (January 2013)



Manufactured by Beckman Coulter, Inc. 250 S. Kraemer Blvd. Brea, CA 92821 U.S.A.



WARNINGS AND PRECAUTIONS

READ ALL PRODUCT MANUALS AND CONSULT WITH BECKMAN COULTER-TRAINED PERSONNEL BEFORE ATTEMPTING TO OPERATE INSTRUMENT. DO NOT ATTEMPT TO PERFORM ANY PROCEDURE BEFORE CAREFULLY READING ALL INSTRUCTIONS. ALWAYS FOLLOW PRODUCT LABELING AND MANUFACTURER'S RECOMMENDATIONS. IF IN DOUBT AS TO HOW TO PROCEED IN ANY SITUATION, CONTACT YOUR BECKMAN COULTER REPRESENTATIVE.

HAZARDS AND OPERATIONAL PRECAUTIONS AND LIMITATIONS

WARNINGS, CAUTIONS, and IMPORTANTS alert you as follows:

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

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

To avoid injury:

- Keep doors, covers and panels closed and secured in place while the instrument is in use.
- Take full advantage of the safety features of the instrument. Do not defeat safety interlocks and sensors.
- Acknowledge and act upon instrument alarms and error messages.
- Keep away from moving parts.
- Report any broken parts to your Beckman Coulter Representative.
- Open/remove and close/replace doors, covers and panels with care.
- Use the proper tools when troubleshooting.

CAUTION System integrity 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.

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.

Issue A, 10/01 Software Version 1A. Converted from Help Version 1A.012431.

Issue B, 5/02

Complete Revision. Software Version 2A. Converted from Help Version 2A.021501.

Issue C, 10/03 Changes were made to:

- comply with the EU IVD Directive (98/79/EC).
- change the company name from Coulter Corporation to Beckman Coulter Inc.
- change product names from LH 750 to LH 700 Series and 5C-ES to 5C Series Control, respectively.

Software Version 2B. Converted from Help Version 2B.031971.

Issue D, 04/07 Software version 2D. Converted from Help Version 2D.071161.

Issue DA, 08/09 Software version 2D1. Converted from Help Version 2D1.091732.

Issue DB, 10/10 Software version 2D1. Updates were made to the company corporate address.

Issue DC, 12/10 Software version 2D1.

Changes were made to:

- STORING SPECIMENS
- USING HANDHELD SCANNER
- Bar-Code ID
- CYCLING SAMPLES IN MANUAL ASPIRATION MODE
- SETTING UP DISPLAY LABELS FOR REPORTING
- SETTING UP A POSITIVE IDENTIFIER
- SPECIFYING THE PARAMETERS YOU WANT TO REPORT
- Including Research Parameters
- SETTING UP REPORTING UNITS
- Manually Setting Up Controls in Units Other Than US1 or US2
- SETTING UP RULES FOR FLAGGING SAMPLE RESULTS
- SETTING UP REPORTS
- Enable Auto Validation Codes
- SETTING UP USER ACCESS LEVELS

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 to the Beckman Coulter website. For labeling updates, go to www.beckmancoulter.com and download the most recent manual or system help for your instrument.

Issue DD, 12/11 Software version 2D1. Manual derived from Online Help version 2D1.10327 Changes were made to:

- Universal Tube Processing
- Tube Sizes
- Control Type

Issue DE, **01/13** Software version 2D3. Manual derived from Online Help version 2D3.

Changes were made to:

- SETTING UP LIS / HIS COMMUNICATIONS
- LIS COM Port Configuration
- Removable Media Entry Window
- Added reference to the Hematology Tube List on the BCI website

Note: Changes that are part of the most recent revision are indicated in text by a bar in the margin of the amended page.

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 to the Beckman Coulter website. For labeling updates, go to www.beckmancoulter.com and download the most recent manual or system help for your instrument.

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This introductory section contains the following topics:

- How to use your COULTER LH 750 System hard-copy manuals
- About this manual
- Online Help System
- Conventions

HOW TO USE YOUR COULTER LH 750 SYSTEM HARD-COPY MANUALS

Use the **Getting Started** booklet to see an overview of the system hardware and software. This document comes with your LH 750 System.

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. The Reference manual for the LH 750 System is included in the online Help system; it is available in hard copy by request.

Use the **Special Procedures and Troubleshooting** manual to run calibration; to clean, replace or adjust a component on the instrument; and for troubleshooting the instrument. This document is made up of procedures from the online Help system; it is available in hard copy by request.

Use the **Operator's Guide** for the day-to-day operation of your instrument. This document is made up of procedures from the online Help system; it includes Startup, running controls and samples, reviewing data, Shutdown, and the software on the Analyzer and the Workstation. This document is available in hard copy by request.

Use the **SlideMaker Opserator's Guide** for in-depth information about what the SlideMaker does, the methods it uses, its specifications, and information on installation, safety and software, as well as day-to-day operating and troubleshooting your SlideMaker. This document is made up of procedures from the online Help system; it is available in hard copy by request.

Use the **SlideStainer Operator's Guide** for the day-to-day operating and troubleshooting of your SlideStainer. This document is made up of procedures from the online Help system; it includes in-depth information about what the SlideStainer does, the methods it uses, its specifications, and information on installation, safety and software. This document is available in hard copy by request.

Use the **Host Transmission Specification** to find the information needed to program the transmission interface between the LH 750 System and your laboratory's host computer. This document is available in hard copy by request.

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

ABOUT THIS MANUAL

Your LH 750 System Operator's Guide is a source of information for the day-to-day operation of your instrument. This information is organized as follows:

- Chapter 1, Controls and Indicators Provides description of controls and indicators on the Analyzer, Diluter, Power Supply and Workstation.
- Chapter 2, Startup Provides procedures to check the instrument during daily Startup.
- Chapter 3, Quality Control (QC) Provides procedures for running and reviewing controls.
- Chapter 4, Run Samples
 Provides description of aspiration and test modes, procedures for collecting and storing specimens, applying bar-code labels, checking instrument setup, identifying samples and cycling samples.
- Chapter 5, Review Data Provides procedures for reviewing, editing and saving results.
- Chapter 6, Shutdown Provides procedures for shutting down the system.
- Chapter 7, DataBase and ToDo List Provides an overview of the window and the common functions available, and procedures for reviewing, editing, searching and saving results.
- Chapter 8, Setup Provides procedures for setting up controls, patient environment, physician list, location list, institution, communications, passwords, control panel and Run Configuration.
- References
- Index, hard copy only.

ONLINE HELP SYSTEM

The Workstation has a comprehensive Online Help System, which includes reference information, all operating, maintenance and troubleshooting procedures. On the LH

Workstation, select 2 to access Help. Select 2 to access the tutorials.

CONVENTIONS

This document uses the following conventions:



indicates a key on the Numeric keypad.



indicates a key on the LH Workstation keyboard.

-

is the icon for Patient results on the LH Workstation.



is the icon for the Printer on the LH Workstation.

1.1 ANALYZER

The Analyzer is a subsystem of the LH 700 Series System that physically sits on top of the Diluter. Move the cursor over the illustration to see links to additional information.



Analyzer Screen and CRT Buttons



The Analyzer has a set of CRT buttons and a screen. The screen displays messages and menu items. Press the buttons to the right of the screen to perform LH 700 Series System functions.

1.2 DILUTER



This is the fluidics portion of the LH 700 Series System. The Diluter is the subsystem that aspirates the sample, dilutes it and mixes it. Move the cursor over the illustration to see links to additional information.

Numeric Keypad

Move the cursor over the illustration to see links to additional information.



The Analyzer contains a keypad and a small Liquid Crystal Display (LCD). Use the keypad to initiate Diluter functions or provide numeric values.

Numeric Keypad--.





Numeric Keypad--0-9

Press these keys to specify a numeric function you want to perform. You also use these keys to provide sample ID information.



F02 Example: Press to specify the Prime CBC Lytic Reagent function.

Numeric Keypad--Alarm Reset

ALARM Press ALARM RESET to silence the alarm that sounds when the instrument encounters a problem, such as a low reagent.

	STOP	PREMIX START ALARM
START UP SHUT DOWN	2 3 D 5 6 E T	POWER ON • • • • • • • • • • • • • • • • • •

Numeric Keypad--CE



Numeric Keypad--CLEAR APERT



apertures by applying pressure behind the apertures. This function also allows the waste chamber to drain.

CLEAR APERTURES appears on the Numeric Keypad during this processing. READY appears upon completion of this processing.

		6	Contraction	N	_	
APERT DRAIN RINSE	CLEAR APERT		READY		STO	PREMIX START ALARM CONT RESET
START UP	F		2	3	D	POWER ON 🔹 🔵
SHUT DOWN		4	5	6	EN	POWER OFF
		CE	8	9	T E R	

ÁLARN

RESET

START CONT

POWER ON .

POWER OFF

3

6 5

9 8

2

0

Numeric Keypad--DRAIN

Press DRAIN to:

Empty the RBC bath and the vacuum isolator chamber into the waste chamber.

Empty the WBC bath through the Hgb cuvette into the waste chamber.

DRAIN appears on the Numeric Keypad during this processing. *READY* appears upon completion of this processing.



Numeric Keypad--ENTER



Press **R** after you provide a sample identification or specify a function.



to specify the Prime CBC Lytic Reagent function.

If a function is active, press this button a second time to perform the function again.



Numeric Keypad--F

Example: Press

before you specify the Press number of a function you want to perform.





to specify the Prime CBC Lytic Reagent function.

N T Ε R to repeat the function. Press

Example: After pressing



(only) to repeat the function.

Numeric Keypad--ID

and then specify the sample Press identifier for a sample you want to cycle in Manual aspiration mode.



Numeric Keypad--POWER OFF



to turn the instrument off. The Workstation and printer remain turned on.

PRIME APERT DRAIN RINSE CLEAR APERT	é	READY	N	STOP PRE	MIX START ALARM RESET
START UP E SHUT DOWN	1 4 7 CE	2 5 8 0	3 6 9	D u n t u r	POWER ON • POWER OFF

Numeric Keypad--POWER ON

Press **POWER ON** • • to turn the instrument on.

The instrument:

Performs reagent and waste level sensing. When level sensing indicates low reagent or full waste conditions, the instrument displays a message on the Numeric Keypad and stops.

Initializes the Analyzer and Diluter hardware and software.

Puts various mechanical devices into the correct starting position.

Displays the current version of the instrument.

When the *POWER ON* process completes its cycle, *READY* appears on the Numeric Keypad and on the Analyzer. To operate the instrument, you must also ensure the Workstation and printer are turned on.

Numeric Keypad--PREMIX

PREMIX

Press to mix samples by rocking the bed for about 1 minute before Automatic aspiration mode starts.

AUTOMATIC MODE appears on the Numeric Keypad during this processing. *READY* appears upon completion of this processing.





Numeric Keypad--PRIME APERT



Ensure pneumatics are ON and at correct operating levels.

Drain and rinse baths.

Apply vacuum to apertures to remove bubbles from lines to vacuum isolators.

Ensure aperture current is ON.

PRIME APERTURES appears on the Numeric Keypad during this processing. *READY* appears upon completion of this processing.



Numeric Keypad--RINSE



Fill the RBC and WBC baths with diluent.

Empty the waste chamber.

RINSE appears on the Numeric Keypad during this processing. *READY* appears upon completion of this processing.

	CLEAR APERT		READY	N	STOP	PREMIX START ALARM CONT RESET
	F		2	3		
SHUT DOWN		7 CE	8	9	E N T E R	POWER OFF

Numeric Keypad--SHUT DOWN



Rinse all lines.

Perform daily instrument cleaning by introducing cleaning agent into the Diluter to prevent protein buildup.

Check Waste level and notify you if a full condition exists to avoid biohazard overflow.

Turn the compressor off.

Note: The LH compressor should not be manually turned off until all slide processing has been completed at the SlideMaker.

SHUTDOWN appears on the Numeric Keypad during this processing. COMPRESSOR OFF appears upon completion of this processing. When the instrument is in SHUTDOWN, the only function that can be performed is

START UP

Numeric Keypad--START UP



Flush the cleaning agent out of the Diluter components and tubing.

Prime the Diluter with CBC, Diff and Retic reagents.

Perform fluidic and electronic checks, such as background, ramp, and precision tests.

START UP appears on the Numeric Keypad during this processing. *READY* appears upon completion of this processing.





Numeric Keypad--START/CONT



Press **CONT** to start or continue automatic sample processing.

The instrument:

Automatically primes.

Rocks the bed at least 14 times to mix samples before aspiration.

Checks reagent, waste, sheath tank and backwash tank levels prior to aspirating each sample.

Checks for flow cell clogs.

Reads the blood detector sensors to determine aspiration quality.

Ignores all other Numeric Keypad entries during processing.

AUTOMATIC MODE appears on the Numeric Keypad during this processing. *READY* appears upon completion of this processing.



Numeric Keypad--STOP

Press STOP to stop processing samples after the current sample cycles. After stopping processing, the instrument drains and rinses the Hgb cuvette.

If the rocker bed is mixing samples, pressing this button stops the mixing process.

If the instrument is performing an function, this button exits function.

Press twice to release the stripper plate.

Before continuing processing, verify the position of the next tube you want sampled. The system does not remember how many aspirations it has already made. When you press

START CONT, the system performs the total number of aspirations originally selected.

Note: Pressing does not stop startup or shutdown cycles.



1.3 POWER SUPPLY

Side/Front



The Power Supply allows you to monitor:

- Pressure
- Vacuum
- Voltage
- Temperature.

The Power Supply also allows you to adjust pressure.

When the Power Supply is unplugged, the system receives no power.



Power Supply Function Levels

The actual level of the function appears on the display. The levels are updated automatically whenever changes occur.



60 PSI pressure level. This should be 60 \pm 5 PSI.

30 PSI pressure level. This should be 30 ± 1 PSI.

5 PSI pressure level. This should be 5 ± 0.1 PSI.

VACUUM supply level. This should be 22 in. Hg minimum at sea level.

AC LINE (input voltage) level. This should be between 90 V and 264 V.

Power Supply Function Status

Green indicates the function is within normal range; red indicates outside normal range.



Input Power (AC) Status

Output Voltage (DC) Status

Pneumatic (PNEU) Status

Power Supply Temperature (TEMP) Status

Power Supply Adjustment Controls

Note: When adjusting PSI pressure, adjust to the midpoint.

Turn adjustment controls clockwise to increase pressure; counterclockwise to reduce pressure.



5-PSI pressure level. This should be 5 ± 0.1 PSI.



30-PSI pressure level. This should be 30 \pm 0.1 PSI.



60-PSI pressure level. This should be 60 ±5 PSI.



Master circuit breaker enables/disables input power reaching internal electrical components of the Power Supply.

1.4 WORKSTATION

CAUTION Possible system damage could occur if the LH Workstation is used to operate personal software that has not been authorized for use by Beckman Coulter. Only use software that is authorized by Beckman Coulter.

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The Workstation:

- Stores and recalls sample data
- Automates QC and calibration procedures
- Assists you in troubleshooting.

CD ROM Drive



Your Workstation uses a Compact Disk Read-Only Memory disk drive to read data from a CD ROM disk, such as the Audio Visual Help CD-ROM. This CD-ROM holds text, graphics and hi-fi stereo sound.

3.5-inch Diskette Drive



Use this diskette drive for inserting diskettes.

Power On/Off (Workstation)



Workstation Keyboard

Before turning the Workstation off, you should try to shut down the Workstation to avoid loss of any data. If you cannot shut down the Workstation, turn the Workstation off, wait 30 seconds and restart the Workstation.

Press this button to turn the Workstation on or off.

You can use the keyboard as an alternate method of interacting with the Workstation. Press



Monitor and Volume Controls

Press Auto to change the monitor settings. Refer to the instructions in the manual that came with your monitor.



Using Command Center

The LH Workstation always appears with a light green Command Center at the bottom of the screen. This area provides quick access to functions and system status.

Buttons

The buttons on the Command Center enable you to access major Workstation functions:

Select	To Access
5	Run Configuration application where you can quickly change defaults for workflow preferences.
	Patient application where you can review, report and modify existing patient sample results and add new patient sample requests.
9	Quality Assurance application where you can review results for the various quality assurance methods, such as controls, Extended QC, XB, XM and calibration.
\diamond	System Setup application where you can customize your LH Workstation to your laboratory workflow preferences, such as flagging limits and decision rules.
E3	History Log Viewer application where you can review and comment on messages posted to various electronic logbooks that identify history.
4	System Status application where you can view current details about the system.
₽+	The Shutdown Type window so you can logoff or shutdown your Workstation.

Process Type

This field displays the current processing of the sample analysis data received from the instrument.

To change the process type:

- 1. Select for the process type.
- 2. Select the type of processing you want for the instrument:

Select	For Results Considered As From
AUTO ANALYSIS	Any automatic identification of the type of run. This includes all patient and bar-coded control analyses.
REPRODUCIBILITY	Reproducibility analysis.
CARRYOVER	Carryover analysis.
CALIBRATION	Calibration analysis.
CONTROL	Control analysis.

Note: If a sample tube does not have a bar-code label and the results are to be sent to a specific Control Folder, select **CONTROL** and select the target Control Folder Lot Number using the Default Cell Control field on the Run Configuration screen. Use the CONTROL mode when using Other Controls (Non BCI) to prevent the SlideMaker from aspirating.

The next time the Workstation receives data from the instrument, it stores it in the database according to your selection.

Bar-Code ID

IMPORTANT

- 1. Risk of sample misidentification. When using the handheld scanner, occasional misread errors can occur as the result of partial label scans and damaged or misapplied labels. Beckman Coulter recommends that you verify each bar-code reading to assure correct patient identification.
- 2. DO NOT use the following characters # @ [\] ` { | } ~ in Specimen or Patient identifiers. There is a potential for Specimen or Patient misidentification to occur. The system will substitute or omit these characters when the system in configured in a language other than English or Chinese.
- 3. DO NOT use leading or trailing spaces in the ID.
- 1. Select the Bar-code ID field.
- 2. Use the handheld scanner to scan the sample ID for the next sample cycled in Manual aspiration mode or perform the following procedure:
 - a. Using the Workstation keyboard, type a sample ID that you want used for the next

sample cycled in Manual aspiration mode, and then press to accept the sample ID at the workstation.

IMPORTANT Risk of missing identifier. If you fail to send the sample ID to the instrument within 60 seconds of data entry in the Barcode ID field, the sample ID provided is cleared. This minimizes the risk of sample misidentification.

b. At the Analyzer's numeric keypad, press D, then to receive the sample at the Analyzer.



c. After the sample ID appears on the Analyzer, press \blacksquare to accept the sample ID or

stop to reject the sample ID.

d. Ensure the sample ID is correctly displayed at the Analyzer screen.

Status Area

Graphics appear in this area to provide status about the system.

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The system is functioning properly. (GREEN)



The system recognized an event that might have caused it to stop processing, but the automatic stop option was turned off. Check for additional status graphics to indicate the nature of the event. You can also check the History Logs for detailed messages. (YELLOW)



The system encountered an event that caused it to stop processing. This could be due to an automatic stop option or error condition. Check for additional status graphics to indicate the nature of the event. You can also check the History Logs for detailed messages. (RED)

When an event causes the system to stop processing, double-click on the traffic light to display the Status dialog box. Place the cursor over an entry in the Status box to display additional information. Double-click on an entry in the Status box if you want to display the error message help topic for that event.

Select **I** to accolade the event and continue processing.



The Review folder contains one or more samples.

An Analytical Station attached to the Workstation stopped processing and sent a message to the Workstation that it should stop. Check the History Logs for detailed messages.


Default Type

Use \square to select the default test type for sample processing. Options are C, CD, CDR, CR, and R.

Last Message

This field displays the last message posted to the Event history log. If the message is too long

to fit in this field, it appears truncated. Select 🕒 to see the complete message and additional messages that may have been posted to the log.

Reviewing System Status

In addition to the Command Center that displays system status, you can select it to display the Status Application window. This window displays information about your system status:

- Monitor serial number
- PC serial number
- Other serial numbers
- Computer name
- Software versions
- Installation identification
- System revisions
- Last Service Maintenance Information

You can also obtain information about the number of records in the database.

CONTROLS AND INDICATORS WORKSTATION

2.1 LOGGING OFF/ON THE WORKSTATION

Logging OFF

- Select **P** on the Command Center to display the Log Off window. 1.
- ${}^{
 ext{W}}$ to confirm that you want to log off the current user name and display the Log 2. Select On window.

Logging ON

- 3. Type your user name that was defined by your laboratory administrator.
- 4. Type your password that was defined by your laboratory administrator. If you forget your password, contact your laboratory administrator. Your laboratory administrator can reset your password.
- Select **I**. The Workstation checks your password and starts the appropriate 5. applications.

2.2 PERFORMING DAILY STARTUP

- 1. Check to see if the instrument is running properly.
- 2. If you have system options, such as the LH SlideMaker, enable the system option.
- START UP 3. Press on the Numeric Keypad to enable the automatic startup cycles.
- 4. Check the startup test results.

Note: SlideMaker only: After the workstation receives startup results from the Analyzer, the LH SlideMaker will automatically go through its startup cycle if the SlideMaker is in Shutdown. If the SlideMaker is not in Shutdown, request a Startup on the SlideMaker.

- Select *Select* on the Command Center to verify the Workstation run configuration. 5.
- 6. Run your controls
- Select **E** to print startup results. 7.

Checking Instrument Operation

- Verify that the instrument has been turned on. 1.
- If the power is off, press **POWER ON** • 2.
 - on the Numeric Keypad.
- 3. While the instrument initializes, you may want to:
 - Collect and prepare samples.
 - Place bar-code labels on sample tubes.
- 4. Ensure the pneumatics are on.
- If you have not already done so, check the baths to ensure they function properly. 5.

Setting Up Analyzer Date and Time

- 1. Go to the Analyzer screen.
- 2. Press MAIN MENU.
- 3. Press ANALYZER FUNCTIONS.
- 4. Press DATE AND TIME.
- 5. Press SET DATE & TIME.
- 6. Press the button for the setting you want to set up. Example: Press MONTH.
- 7. Go to the Numeric Keypad.
- 8. Press the value associated with the setting you want to specify. Each setting must be

entered as a two-digit number. Example: Press **0 9** and then press

- 9. Repeat steps 6 through 8 for each setting you want to specify.
- 10. Press one of the following:

SYSTEM RUN	To cycle samples.
RETURN	To display the DATE & TIME screen.

11. Read about LH 700 Series Year 2000 features.

Setting Up Analyzer Date Format

- 1. Go to the Analyzer screen.
- 2. Press MAIN MENU.
- 3. Press ANALYZER FUNCTIONS.
- 4. Press DATE AND TIME.
- 5. Press FORMAT until the date format you want to use appears:
 - MM/DD/YY
 - DD/MM/YY
 - YY/MM/DD

where MM = Month, DD= Day, and YY= last two digits of the Year

6. Press one of the following:

MAIN MENU	To display the Analyzer MAIN MENU screen.
SYSTEM RUN	To cycle samples.
RETURN	To display the ANALYZER FUNCTIONS screen.

Turn Pneumatics ON

The Pneumatics are OFF if the Power Supply pneumatics light is red, or if the Analyzer screen is blank.

N T E

R

Press PRIME APERT on the Numeric Keypad to activate the pneumatic subsystem.

The pneumatic subsystem has an automatic shutoff feature to prolong the life of the compressor and vacuum pump. If the Diluter is idle (not cycled) for about 1 hour, the pneumatic subsystem turns off. Messages that cause the system to stop processing samples inhibit the time-out function.

Checking Power Supply and Vacuum Level

CAUTION System damage or malfunction can occur if you operate the instrument when any indicator is outside the following limits. Do not operate the instrument if any indicator is outside these limits.

Check the following status and function levels on the Power Supply.

Status or Function Level	Should Appear
Input Power (AC) Status	
Output Voltage (DC) Status	
Pneumatic (PNEU) Status	
Temperature (TEMP) Status	
60 PSI	60 ±5 psi
30 PSI	$30 \pm 1 \text{ psi}$
5 PSI	5 ± 0.1 psi
VACUUM	22 in. Hg minimum at sea level
AC LINE	90 - 264 V

Turn adjustment controls clockwise to increase pressure; counterclockwise to reduce pressure. If the vacuum is out of range, call your Beckman Coulter Representative.

Check Baths

1. Open the aperture compartment door.

2. Press **DRAIN** on the Numeric Keypad.

- 3. Verify that both aperture baths drain completely.
- 4. Press **RINSE** on the Numeric Keypad.
- 5. Verify that both baths fill with liquid.
- 6. Verify that the waste chamber drains.
- 7. Close the aperture compartment door.

Automatic Startup Cycles

Pressing **START UP** starts automatic startup cycles. When you press this button, the system flushes the cleaning agent from all Diluter components and tubing if cleaning reagent is not already removed. It also performs electronic and fluidic checks to ensure the instrument is ready to analyze control or whole-blood samples. Specifically, the instrument:

- Performs reagent and waste level sensing.
- Replaces the cleaning agent with diluent.
- Performs ramp-pulse and precision-pulse tests.
- Performs a background count in the baths and flow cell.
- Measures Hgb-blank and Hgb-sample voltages.
- Performs an electronic check of the Triple Transducer Module (flow cell).
- If a SlideMaker unit is attached, it will perform a vent line calibration.

Checking Daily Test Results

- 1. Select (M) on the Command Center to display the Quality Assurance application.
- 2. If necessary, select ¹¹ to display the daily startup test results.
- 3. If you want to see past startup test results:
 - a. Select
 - b. Select a row indicating the date, time and type of test results you want to see. The results appear on the window.

Note: Select only 1 row. Daily Checks results will not be displayed if you select more than 1 row of results.

- 4. Check the reagent status, background status and subsystem status for any items that failed.
- 5. Select to see startup test details. You can also select to see background test results on the QA Results & Graphics window.
- 6. Take appropriate action to resolve any failed items.

Checking Background Test Results

- 1. Select $^{(4)}$ to display the Quality Assurance application.
- 2. If necessary, select ¹¹ to display the Daily Checks window.
- 3. Review the results on the window.
- 4. Select ²⁴ to see the specific background Diff test results.

Acceptable background results indicate the count did not exceed the preset tolerances. If results appear with a red background they are unacceptable.

If an incomplete computation (.....) of the Hgb parameter occurs, verify that the Hgb-blank and Hgb-read voltages are acceptable. If the voltages are acceptable, the dots (.....) for the Hgb parameter are acceptable. If the voltages are unacceptable, you must repeat the background test.

Checking HGB Voltage Test Results

- 1. Select (M_{1}) to display the Quality Assurance application.
- 2. If necessary, select III to display the Daily Checks window.
- 3. Review the results on the window.
- 4. Select **i** to see the Hgb voltage blank and read results.

Checking Instrument Setup

- 1. Ensure the instrument is running properly.
- 2. Check the following at the Analyzer:
 - No alert messages exist
 - Blood Detector is ON
 - Desired test mode is set
 - Desired number of aspirations per tube is set (For Automatic aspiration mode)
- 3. If necessary, add tests to the ToDo list.
- 4. Ensure the Workstation run configuration is set up correctly.
- 5. On the Command Center, check the instrument
 - Process Type.
 - Default Type

Checking Precision Test Results

- 1. Select $^{(4)}$ to display the Quality Assurance application.
- 2. If necessary, select ¹ to display the Daily Checks window.
- 3. Review the results on the window.
- 4. Select ***** to see the results for the precision test.

Checking Ramp Test Results

1. Select (M_{1}) to display the Quality Assurance application.

- 2. If necessary, select ¹ to display the Daily Checks window.
- 3. Review the results on the window.
- 4. Select $\stackrel{\text{results.}}{\longrightarrow}$ to see the ramp test results.

Possible Startup Problems and Fixes

When Reagents Fail

- 1. Ensure reagent information was entered properly.
- 2. Replace expired reagents.

When Background Fails

- 1. Perform a background test or rerun startup.
- 2. If the problem occurs again, call your Beckman Coulter Representative.

When Diluter, Analyzer, Power Supply, Communications, HGB Voltage, or VCS Module Fail

- 1. Perform a background test, if necessary rerun startup.
- 2. If the problem occurs again, call your Beckman Coulter Representative.

When Precision Test Fails

- 1. Verify that clean diluent covers the apertures and that there is no bleach or cleaning agent in the baths.
- 2. Repeat the precision test at the Analyzer.
- 3. If the problem occurs again, call your Beckman Coulter Representative.

When Ramp Test Fails

- 1. Verify that clean diluent covers the apertures and that there is no bleach or cleaning agent in the baths.
- 2. Repeat the ramp test at the Analyzer.
- 3. If the problem occurs again, call your Beckman Coulter Representative.

Running Controls

Refer to Chapter 3, Quality Control, for detailed instructions on running your controls.

3.1 QUALITY CONTROL OVERVIEW

IMPORTANT Risk of erroneous results. If you have an LH SlideMaker installed with the LH 750 Analyzer, refer to the special instructions for Quality Control Processing with LH SlideMaker.

Quality control includes monitoring routine performance and service in conjunction with the use of controls and calibrators. You should routinely check results between quality control analyses. The combination of these methods provides the assurance of complete quality control.

The LH 700 Series System incorporates multiple quality control techniques. For the CBC, CBC/DIFF and RETIC parameters, the LH 700 Series uses the established technique of commercial controls. If you report NRBC% and NRBC#, you may use Performing NRBC Quality Control or an equivalent laboratory procedure.

The LH 700 Series uses a stabilized particle suspension, such as LATRON, to verify flow cell alignment, gains, and CVs for flow cell volume, conductivity and light scatter. The Workstation stores information about the control setup and control results in the DataBase.

The LH 700 Series also allows you to customize the way the Workstation displays control results. Your laboratory can establish acceptance limits for control results based on the control source, type and level, as well as the aspiration mode. This can help you better understand control results and interpret them more quickly.

Beckman Coulter recommends that Quality Control checks be performed using patient or commercial controls in both automatic (primary) and manual (secondary) modes at intervals established by your lab. When using a commercial control, refer to the package insert to determine which mode to use. Failure to recover Control values within your lab's expected limits or the presence of unexplained shifts or trends in either mode of analysis should be investigated. If Control problems in either mode cannot be resolved, call your Beckman Coulter Representative.

3.2 LATRON

Running Latex Control—Diff

- 1. Perform instrument startup.
- 2. Check that the instrument process type on the Command Center is set to AUTO ANALYSIS or CONTROL.
- 3. Ensure the latex primer and control are within the correct temperature range. For COULTER LATRON primer and control the correct temperature range is 18-30°C/64-86°F.
- 4. Verify the lot number of the primer and control. If you must use a new lot number, ensure that it has been set up properly.

CAUTION Possible system damage could occur if you aspirate anything except latex control or latex primer using this function. Do not aspirate any other materials with this function.

5. Go to the Numeric Keypad.



CLEAR

- 6. Press to aspirate latex for the Diff test mode. The Numeric Keypad displays *PRESS MANUAL OR CLEAR APERTURE*.
- 7. Press APERT. The Numeric Keypad displays PRESS MANUAL OR PRESENT SAMPLE.
- 8. Remove the cap of the latex primer vial.
- 9. Immerse the aspirator tip in the latex primer vial. The instrument automatically aspirates the primer. The Numeric Keypad displays *DIFF PRIMER* while the instrument performs this function. When this function completes processing, the Numeric Keypad displays *FUNCTION* = 55.
- 10. Remove the vial from the aspirator tip when you hear a beep and the Analyzer Status line displays *PREPARING SAMPLE*. The aspirator tip automatically retracts and the probe wiped cleans it.
- 11. At the Workstation, check the results from the primer.
- 12. If the results in the PRIMER column are less than or equal to 500, proceed to step 12. Otherwise, if the results in the PRIMER column are greater than 500:



- a. At the Numeric Keypad, press **R** to reactivate the function for the control. The Numeric Keypad displays *PRESS MANUAL OR CLEAR APERTURE*.
- b. Perform steps 6 through 9 up to three more times.
- c. If you do not get a result below 500, cycle a new vial of primer.
- d. If you still do not get a result below 500, call your Beckman Coulter Representative.



13. At the Numeric Keypad, press **R** to reactivate the function for the latex control. The Numeric Keypad displays *PRESS MANUAL OR CLEAR APERTURE*.

IMPORTANT Erroneous results could occur if you press **CLEAR APERTURE** before aspirating latex control. **CLEAR APERTURE** is only used before aspirating latex primer in this procedure.

- 14. Gently mix the latex control according to the directions in the package insert.
- 15. Immerse the aspirator tip in the latex control vial. The instrument automatically aspirates the control. The Numeric Keypad displays *LATEX—DIFF* while the instrument performs this function. When this function completes processing, the Numeric Keypad displays *FUNCTION* = 55.
- 16. At the Workstation, verify the results from the control.

twice to exit this function. The Numeric Keypad

17. At the Numeric Keypad, press displays *READY*.

Running Latex Control—Retic

- 1. Perform instrument startup.
- 2. Check that the instrument process type on the Command Center is set to AUTO ANALYSIS or CONTROL.
- 3. Ensure the latex primer and control are within the correct temperature range. For COULTER LATRON primer and control the correct temperature range is 18-30°C/64-86°F.

STOP

4. Verify the lot number of the primer and control. If you must use a new lot number, ensure that it has been set up properly.

CAUTION Possible system damage could occur if you aspirate anything except latex control or latex primer using this function. Do not aspirate any other materials with this function.

5. Go to the Numeric Keypad.



6. Press **C** to aspirate latex for Retic test mode. The Numeric Keypad displays *PRESS MANUAL OR CLEAR APERTURE*.



- 7. Press APERT. The Numeric Keypad displays PRESS MANUAL OR PRESENT SAMPLE.
- 8. Remove the cap of the latex primer vial.
- 9. Immerse the aspirator tip in the latex primer vial. The instrument automatically aspirates the primer. The Numeric Keypad displays *RETIC PRIMER* while the instrument performs this function. When this function completes processing, the Numeric Keypad displays *FUNCTION* = 56.
- 10. Remove the vial from the aspirator tip when you hear a beep and the Analyzer Status line displays *PREPARING SAMPLE*. The probe cleaner retracts the aspirator and automatically cleans it.
- 11. At the Workstation, check the results from the primer.
- 12. If the results in the PRIMER column are less than or equal to 500, proceed to step 12. Otherwise, if the results in the PRIMER column are greater than 500:



- a. At the Numeric Keypad, press **R** to reactivate the function for the control. The Numeric Keypad displays *PRESS MANUAL OR CLEAR APERTURE*.
- b. Perform steps 6 through 9 up to three more times.

- c. If you do not get a result below 500, cycle a new vial of primer.
- d. If you still do not get a result below 500, call your Beckman Coulter Representative.



13. At the Numeric Keypad, press **R** to reactivate the function for the latex control. The Numeric Keypad displays *PRESS MANUAL OR CLEAR APERTURE*.

IMPORTANT Erroneous results could occur if you press **CLEAR APERTURE** before aspirating latex control. **CLEAR APERTURE** is only used before aspirating latex primer in this procedure.

- 14. Gently mix the latex control according to the directions in the package insert.
- 15. Immerse the aspirator tip in the latex control vial. The instrument automatically aspirates the control. The Numeric Keypad displays *RETIC--LATEX* while the instrument performs this function. When this function completes processing, the Numeric Keypad displays *FUNCTION* = 56.
- 16. At the Workstation, verify the results from the control.
- 17. At the Numeric Keypad, press displays *READY*.

twice to exit this function. The Numeric Keypad

Running Latex Control—Diff and Retic

- 1. Perform instrument startup.
- 2. Check that the instrument process type on the Command Center is set to AUTO ANALYSIS or CONTROL.
- 3. Ensure the latex primer and control are within the correct temperature range. For COULTER LATRON primer and control the correct temperature range is 18-30°C/64-86°F.
- 4. Verify the lot number of the primer and control. If you must use a new lot number, ensure that it has been set up properly.

CAUTION Possible system damage could occur if you aspirate anything except latex control or latex primer using this function. Do not aspirate any other materials with this function.

5. Go to the Numeric Keypad.



6. Press to aspirate LATEX primer and LATEX control for combined Diff and Retic test modes. The Numeric Keypad displays *PRESS MANUAL OR CLEAR APERTURE*.



- 7. Press APERT. The Numeric Keypad displays PRESS MANUAL OR PRESENT SAMPLE.
- 8. Remove the cap of the latex primer vial.

- 9. Immerse the aspirator tip in the latex primer vial. The instrument automatically aspirates the RETIC+DIFF primer. The Numeric Keypad displays *RETIC+DIFF PRIMER* while the instrument performs this function. When this function completes processing, the Numeric Keypad displays *FUNCTION* = 57.
- 10. Remove the vial from the aspirator tip when you hear a beep and the Analyzer Status line displays *PREPARING SAMPLE*. The aspirator tip automatically retracts and the probe wipe cleans it.
- 11. At the Workstation, check the results from the primer.
- 12. If the results in the PRIMER column are less than or equal to 500, proceed to step 12. Otherwise, if the results in the PRIMER column are greater than 500:



- a. At the Numeric Keypad, press **R** to reactivate the function for the control. The Numeric Keypad displays *PRESS MANUAL OR CLEAR APERTURE*.
- b. Perform steps 6 through 9 up to three more times.
- c. If you do not get a result below 500, cycle a new vial of primer.
- d. If you still do not get a result below 500, call your Beckman Coulter Representative.



13. At the Numeric Keypad, press R to reactivate the function for the latex control. The Numeric Keypad displays *PRESS MANUAL OR CLEAR APERTURE*.

IMPORTANT Erroneous results could occur if you press **CLEAR APERTURE** before aspirating latex control. **CLEAR APERTURE** is only used before aspirating latex primer in this procedure.

- 14. Gently mix the latex control according to the directions in the package insert.
- 15. Immerse the aspirator tip in the latex control vial. The instrument automatically aspirates the control. The Numeric Keypad displays *RETIC+DIFF--LATEX* while the instrument performs this function. When this function completes processing, the Numeric Keypad displays *FUNCTION* = 57.
- 16. At the Workstation, verify the results from the control.

STOP

to exit this function. The Numeric Keypad

17. At the Numeric Keypad, press displays *READY*.

3.3 5C SERIES CELL CONTROL AND RETIC-C

Cycling Controls

If you have an LH SlideMaker, follow the instructions contained in Quality Control Processing with an LH SlideMaker (reference your LH SlideMaker manual).

1. Ensure the instrument is set up for the appropriate control.

- 2. Prepare the controls according to the directions in the package insert.
- 3. Ensure the controls are properly set up on the Workstation.
 - **Note:** If you run a Beckman Coulter control without setting it up, the Workstation automatically creates control setup information for you. The control information identifies the lot number, source, type and level of the control.
- 4. Load the cassette with the control material.
- 5. Place the cassette firmly and securely into the loading bay. The instrument begins to cycle the controls.
- 6. On the Command Center, select AUTO ANALYSIS as the process type if your control tubes have bar-code labels. See process type if you run controls without bar-code labels.

Note: Use the CONTROL process type only if you are using a non-bar-coded control or a tube with a damaged bar-code.

7. Review the control results.

Aspirate Control in Manual Mode



Optical sensors exist at the bottom of the black activator.

IMPORTANT Risk of misleading results. Holding the tube against the bottom of the aspirator tip can prevent aspiration. Do not hold the tube against the bottom of the aspirator tip.

IMPORTANT Risk of misleading results. Removing a sample tube from the aspirator tip before the STATUS message changes and you hear a beep could cause a short sample aspiration. Wait until the message changes and you hear a beep to remove the sample tube.

WARNING Risk of personal injury. If the optical sensors do not detect an obstruction, the aspirator tip retracts when PRIME appears on the STATUS field on the Analyzer screen. If you have the aspirator tip immersed in the tube when the tip retracts, the aspirator can hit the tube and break it. Be sure to remove the sample tube when the instrument beeps and be clear of the aspirator tip before PRIME appears. If a tube should break, use your laboratory's safety procedure for cleaning the broken glass.

Immerse the aspirator tip in the sample such that the tube or your hand blocks the optical sensors. The instrument automatically aspirates the sample.

When the instrument beeps, remove the sample.

The instrument automatically cleans the aspirator tip with a probe wipe.

Reviewing Control Results

- 1. Select (M) on the Command Center to display the Quality Assurance application.
- 2. Select $\overset{\mathbf{S}}{\mathbf{S}}$ to display the Controls window.
- 3. Select the specific control for which you want to review results. The control results table, statistics and graphs appear on the window. Use the scroll bars on the window to view

CMNT

other parameter results and graphs. Use *interview* to add comments to a control run.

4. If you want to view the results and graphics for a specific latex run:

- a. Select the control run you want to view in the table.
- b. Select **i** to see the Latex Graphs window.
- 5. Select:

This	To Do This
Mean => Lab Target	Adjust assigned values to the current mean values.
Restore Assigned Values	Restore the manufacturer's assigned values and expected ranges.
	Select Active, Accumulating or Inactive from the drop down box

Control Codes and Flags

As appropriate, the LH 700 Series applies instrument-generated and/or laboratory-defined flags, codes, and/or messages to each set of patient results. Flags, codes, and suspect or definitive messages are used to alert you to an instrument malfunction, specimen abnormality, abnormal data pattern, or abnormal results. Beckman Coulter recommends review, appropriate to the requirements of the patient population, of all results displaying a flag, code or message.

The following codes appear in place of results when the system cannot obtain results:

..... Incomplete computation. When this code occurs for a parameter result it indicates an incomplete computation due to problems such as data insufficiency.

When this code appears on all parameter results, it indicates a Power Supply Failure. Check this condition and rerun the sample.

----- When this code appears for CBC parameter results and no average histogram appears for the affected parameter, it indicates a total voteout.

If this code appears for WBC, the WBC subpopulation absolute numbers and the NRBC absolute numbers appear as since they are calculated from the white count and the WBC result was non-numeric.

+++++ The result exceeds the instrument's operating range. Follow your laboratory's policies for reviewing the sample.

IMPORTANT Incorrect results can occur. If the WBC, RBC, HGB, or PLT have +++++ when cycling in Manual mode, run a blank cycle before analyzing the next test sample to prevent carryover to the next sample. When cycling in Automatic mode, rerun the sample immediately following the one with the +++++. Sample dilutions may also result in wrong differential results. The instrument will automatically set to CBC mode when predilute is chosen.

- ::::: The instrument detected a clog in the flow cell. You must clear the clog and rerun the sample.
- ????? Invalid data.

The following flags appear to the right of the parameter result:

- * Result exceeds instrument's counting threshold. Follow your laboratory's policies for reviewing the sample. This flag is applicable to MCV only.
- + Result exceeds linearity (reportable) range. Follow your laboratory's policies for reviewing the sample.
- **H** Result is higher than your reference range. Follow your laboratory's policies for reviewing the sample.
- L Result is lower than your reference range. Follow your laboratory's policies for reviewing the sample.
- **P** Partial aspiration detected.
- **R** Review the result according to your laboratory's protocol. When editing parameter results, this flag requires special handling. Any parameter derived from an R-flagged parameter cannot be recalculated until the parameters with the R flags have been edited.

You may want to look at the messages that appear on the Research Data window. The Research Data window provides more detailed research data.

When a Control is Outside Its Expected Ranges

- 1. Ensure the control:
 - Material was mixed properly. If not, mix it according to the package insert.
 - Identification information was entered correctly. If using a bar-code reader, ensure the bar-code labels are clean and positioned correctly. If using the Numeric Keypad, ensure you typed the correct information.
 - Setup information (assigned values and expected ranges) matches the control package insert. If they do not, change the control's information to match the package insert.
- 2. If any of the problems existed, rerun the control; otherwise, proceed to the next step.
- 3. Rerun the control to ensure the problem was not a statistical outlier.
- 4. Ensure the control material was not contaminated by running another vial or level of control.
- 5. Watch for normal sample flow as part of troubleshooting the instrument. If necessary, call your Beckman Coulter Representative.

When a Latex Control is Outside its Expected Ranges

- 1. Ensure the control setup information (assigned values and expected ranges) matches those on the package insert. If they do not, change the control information to match the package insert, then rerun the control.
- 2. Ensure no bubbles exist in the flow cell by rerunning the primer and the control. If the control is still outside the expected ranges:
 - a. Go to the Numeric Keypad.
 - b. Use F13 to purge the flow cell.
 - c. Run primer and control again.
- 3. Check the control:
 - a. Ensure the control is not contaminated, properly mixed, and not expired:
 - b. Ensure the aspirator tip is clean and dry.
 - c. If necessary, use a new vial of latex control. Be sure to mix it according to the directions on the package insert.
- 4. Ensure the flow cell is clear by performing the procedure for clearing a clogged flow cell.
- 5. Rerun the control. If the control is still outside the expected ranges, call your Beckman Coulter Representative. You can set the instrument to CBC mode and continue to process CBC samples.

Controls Window

This window enables you to see control information stored in the database.

Control Type

This field displays the type of control for which results were run. For non-Beckman Coulter controls and patients controls, this field corresponds to the folder that lists the lot numbers.

Finding Control Results

Use the following guide to find the information and also sort the information displayed on this window.

Use This	To Do This
÷	Select this graphic to expand the list of control categories. You can double-click the folder beside this graphic to perform the same function.
Ξ	Select this graphic to collapse the list of control categories. You can double-click the folder beside this graphic to perform the same function.
🧟 BCI	Double-click one of the source folders to expand or collapse the list of control types for the selected control source.



Double-click one of the folders representing a control type to expand or collapse the list of lot numbers for the selected control source and type.

Select a lot number folder to see the details for the control runs of the selected source, type and lot.

The control results grid displays the results.

Transmit, Print and Archive

Standard buttons appear at the top of this window. These buttons enable you to perform actions on the items that appear in the control results grid. You can perform these actions on multiple items at a time.

1. Select an item in the control results grid on the right side of the window. If you want to

perform the same action on all items, select 🌋

2. Select the relative button to perform the action it represents. For example, select a lot

number and then select *to* print the control results.

Deleting Control Data

- 1. Select \bigotimes in the Quality Assurance application. The CONTROLS window appears.
- 2. Determine what you want to delete:
 - If you want to delete specific control runs, select the control runs you want to delete by selecting the row number that contains the control results. Selected rows appear with a black background.
 - If you want to delete all the control runs for a specific lot number, select the lot number by selecting its file folder.
 - If you want to delete all the information associated with a lot number, including the setup information, select the lot number by selecting its file folder.
- 3. Select is to display the Control Data DELETION REQUESTED window.
- 4. Verify the data you want to delete.
- 5. Select it to delete the data. A message that asks you to confirm your request appears.
- 6. Select is to delete the data. The Workstation deletes the selected data. The data cannot be retrieved.

Adjusting Control Limits

1. Select \square on the Command Center to display the Quality Assurance application.

- 2. Select \mathbf{S} to display the Controls window.
- 3. Select the specific control for which you want to adjust limits. The control results table, statistics and graphs appear on the window.
- 4. Select Mean => Lab Target to replace the assigned values on this window with the values that currently appear as the mean values. The Workstation also replaces the expected ranges. The Workstation now displays the Lab Target and Lab Limit values.

Providing Comments for Quality Assurance

- 1. Select (M_{1}) on the Command Center to display the Quality Assurance application.
- 2. Select the control file and run for comment addition.

CMM

- 3. Select . The Comments window appears.
- 4. Type the comments you want to provide.
- 5. Select it is ave the comments. For control runs, appears in the CMNT column to indicate that it has a comment.

Performing NRBC Quality Control

- 1. Ensure the daily quality assurance for the LH 700 Series CBC and VCS subsystems is acceptable, including:
 - a. Startup, including backgrounds
 - b. For the CBC and DIFF parameters, the LH 700 Series uses the established technique of commercial controls.
 - c. For the DIFF parameters, the LH 700 Series uses a stabilized particle suspension, such as LATRON, to verify flow cell alignment, gains, and CVs for flow cell volume, conductivity and light scatter.
- 2. Use the LH 700 Series to screen for positive and negative control samples.
 - a. A negative control is a sample that reports 0% NRBC.
 - b. A positive control is a sample that reports $\ge 2\%$ and $\le 15\%$ NRBC. NOTE: Positive control samples should be reviewed to ensure that the presence of a known interference is unlikely to affect accuracy of the NRBC. The known interferences are listed in HELP under Performance Characteristics / Known Limitations and Interfering Conditions / NRBC.
- 3. Record all values and calculations on the NRBC Control Table. The reference to the correct column in the table is shown as an upper case alpha character; for example, LH 700 Series values should be recorded in columns A and F.
- 4. Make two peripheral smears for each control sample. Stain according to your laboratory protocol.
- 5. Enumerate the NRBC/100 WBC from each slide using two technologists counting 200 cells per slide, as follows:

	Negative Control	Positive Control
Slide 1	Tech 1, 200 cells (column B)	Tech 1, 200 cells (column G
Slide 2	Tech 2, 200 cells (column C)	Tech 2, 200 cells (column H)

- 6. Calculate an average manual count for both the negative and positive control sample (D and I).
- 7. Calculate the difference between the LH 700 Series NRBC and the manual count (E and J).
- 8. Perform this procedure for 30 days to establish the expected range for the positive control for your laboratory. At the end of 30 days, calculate the mean difference and expected ranges for the positive control as indicated in the table (**K** through **N**). Beckman Coulter suggests using the following range as a guideline until your own expected range can be established:

Minimum Difference -12.8

Maximum Difference 12.8

- 9. Use the following guidelines for results that indicate an 'out of control situation'.
 - a. Negative control: Differences exceed 2.
 - b. Positive control: Differences exceed the established range.
 - c. Differences exhibit a trend or shift.
 - d. Excessive differences between results might be attributable to variability between slide readers.
- 10. Use bias plots to visualize results by plotting the average manual counts on the abscissa (X) and differences on the ordinate axis (Y). For the negative control, plot D on the X axis and E on the Y axis. For the positive control, plot I on the X axis and J on the Y axis.



3.4 EXTENDED QC

Overview

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

User's can enable/disable Extended QC Rules for 5C Cell control.

Note: Extended QC Rules apply to 5C Cell control runs only. Other manufacturers' quality control products will not perform with the LH 750 Extended QC Rules program. If your laboratory decides to use other manufacturers' control products, you may use

manual calculations, other manufacturers' QC programs or certain middleware products for the purpose of extended QC monitoring. Beckman Coulter does not support the use of any such third-party control products or related Quality Control programs. Therefore, validation of non- Beckman Coulter control products and related software is solely the responsibility of the laboratory.

Extended QC Rules include:

- Random Error imprecision
- Systematic Error bias
- Total Error inaccuracy

Note: 5C Cell controls are intended for use as a quality control material with assigned values and expected ranges as defined in the Table of Expected Results distributed with each lot of controls. The application of Extended QC Rules on 5C Cell controls does not denote additional product claims; the Extended QC Rules are only an additional quality control tool, such as XB and XM, which can be used in conjunction with the assigned values and expected ranges or mean to lab target values to monitor the status of your analyzer.

Extended QC - Random Error

Random error is Extended QC's measurement of imprecision.

The method is considered out of control if the CV falls outside the Extended QC Random Error Limit.

- If the control file has an $N \ge 2$ and N < 20, and the CV exceeds the Random Error limit, the CV value for that parameter is highlighted in yellow in the statistics section of the QC summary results screen.
- If the control file has an $N \ge 20$, and the CV exceeds the Random Error limit, the CV value for that parameter is highlighted in red in the statistics section of the QC summary results screen. The user must acknowledge the alert, and the event is logged in the QC Event log.

Extended QC- Systematic Error

Systematic error is Extended QC's measurement of bias.

A systematic error is defined as the deviation of the mean from the target value.

The method is considered out of control if the deviation falls outside the Extended QC Systematic Error Limit.

- If the control file has an $N \ge 2$ and N < 20, and the ((absolute Delta Diff / Target Value) x 100) exceeds the Systematic Error limit, the Delta Diff for the parameter is highlighted in yellow in the statistics section of the QC summary results screen.
- If the control file has an $N \ge 20$, and the ((absolute Delta Diff / Target Value) x 100) exceeds the Systematic Error limit, the Delta Diff for the parameter is highlighted in red in the statistics section of the QC summary results screen. The user must acknowledge the alert, and the event is logged on the QC Event log.

Extended QC- Total Error

Total Error is Extended QC's measurement of inaccuracy, as compared to an established limit.

Total Error is defined as the deviation of a single measurement from the Target Value that was setup for your 5C Cell control (e.g. BCI Assigned Value or Mean => Lab Target value).

For each 5C Cell control run, the WBC, RBC, Hgb, HCT and Plt values are evaluated as follows:

Target Value +/- (Target Value * Total Error Limit / 100) for that parameter.

If the result is outside of the upper or lower range, the user is notified by highlighting the result in yellow.

Extended QC Limits

Limits are not lot specific. Limits apply to all controls and all control levels except for platelets, for which there are tiered level limits.

Error Limits:

Parameter	Random Error Limit %	Systematic Error Limit %	Total Error Limit %
WBC	4.0	5.0	13.0
RBC	2.5	3.0	8.0
Hgb	2.0	2.0	6.0
Hct	3.0	3.0	9.0
Plt			
40,000 – 300,000 (Normal, Abnormal II)	9.0	9.0	27.0
Plt	6.0	5.0	17.0
>300,000			

(Abnormal I)

For Platelets there are two limit sets:

- 1. 1. Plt values in the range 40 300 x $10^{3}/\mu$ L are evaluated using 5C Normal and Abnormal II level limits.
- 2. 2. Plt values >300 x $10^{3}/\mu$ L are evaluated using 5C Abnormal I level limits.

Extended QC limits may be edited.

- Editing is restricted to Advance Operator level and above.
- Edits are recorded in the QC Event Log.

3.5 XB ANALYSIS

Overview

XB Analysis is a quality-control method that monitors instrument performance (calibration) by tracking the MCV, MCH, and MCHC parameters of all patient samples. For more information about XB Analysis, refer to the XB Analysis topic in the Reference Information section of the Help.

Using XB

When using XB Analysis, it is important to process samples randomly; for example, chemotherapy or neonate patient samples, if processed as a group, can cause XB to be OUT.

When XB Analysis is on, the Workstation compares the mean values with the target values and the percent limits. If the mean values are within the percent limits of the target values, then the XB is IN.

Setup Options

When you set up XB Analysis, you have options:

- You can specify that you want XB to automatically stop processing on an instrument. Otherwise, XB status appears in the XB history log, and it is up to you to investigate it. You should investigate any batch that is out of the XB limits.
- You can specify if you want to automatically print XB Analysis information.

Reviewing XB Analysis Information

The Workstation displays the batch means for each parameter in graph form. The lines on the graph are from point to point, but when printed on the Graphic Printer, a horizontal bar represents each mean.

The Workstation determines if results should be included in a batch by considering several factors. The following factors cause results to be excluded from a batch:

- No CBC Data
- Blood detector off
- RBC value < 1.0×10^6 cell/µL
- Partial Aspiration
- Body Fluid
- Non-numeric value for MCV, MCH, and MCHC

You can delete individual samples from the batch. The total number of deletes in a batch must not exceed 5.

Reviewing XB Results

- 1. Select (\mathfrak{A}) on the Command Center to display the Quality Assurance application.
- 2. Select \mathbf{x} to display the XB window.



The window refreshes the results table, statistics and graphs based on the changes you made

Adding Comments to an XB Batch

- 1. Select Select on the Command Center to display the Quality Assurance application.

Note: You cannot add comments to a current XB Batch you can only add comments to a prior or previous batch

- 3. To display XB Batch results:
 - a. Select **b** to display the last batch.

or

- b. Select 🗖 to display a previous batch
- 4. Select ¹²⁴ to add a comment
- 5. Type the comment you want to add.
- 6. Select on the Comment window to save Comment. The Workstation adds the comment to the appropriate XB Batch and places an X in the CMNT field.

3.6 XM ANALYSIS

Overview

XM Analysis is a quality-control method that uses an Exponentially Weighted Moving Average (EWMA) of CBC, Diff, NRBC and Reticulocyte parameters and compares them with known target values, to monitor instrument performance. For more information about XM Analysis, refer to Setting Up XM Analysis.

Setup Options

When you set up XM Analysis, you have the following options:

- You can specify that you want XM to automatically stop processing on an instrument. Otherwise, XM status appears in the XM history log, and it is up to you to investigate it. You should investigate any batch that is out of the XM limits.
- You can also specify if you want to automatically print XM Analysis information.

Parameter Groups

There are four XM parameter groups:

- CBC (WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, RDW, MPV, @PCT, and @PDW)
- DIFF (LYMPH%, MONO%, NEUT%, EO%, BA%, NRBC%, LYMPH#, MONO#, NEUT#, EO#, BA#, and NRBC#)
- RETIC (RETIC%, @HLR%, IRF, MRV, and @MSCV)
- RETIC Calc (RETIC#, and @HLR# groups the parameters that require a simultaneous CBC analysis)
- @ For Research Use Only. Not For Use in Diagnostic Procedures.

Note: The workstation does not include runs with a:

- Non-numerical value
- Partial Aspiration
- RBC value < 1.0×10^6 cell/µL
- WBC value < $1.0 \times 10^3 \text{ cell/}\mu\text{L}$
- PLT value < 20 x 10^3 cell/µL
- Over linearity "+"
- System Alarms

Batch Sizes

Users can configure independent batch sizes for each of the four parameter groups. The batch size can be from 2-1000, inclusive, with a maximum of 20 batches.

Target Value

You can configure the target value for each parameter by:

- Manually entering the target value
- Providing a Moving Target equal to the last batch mean. The target shall be updated at the end of each batch. You can set/lock the last batch mean.

Note: if the target value for a parameter is not defined (blank), or if the target value exceeds the error limits, there will be no graph for that parameter.

Limits

You can specify each parameter's limit in Absolute value (Upper and Lower limits) format

You can configure the limit for each parameter by:

- Manually entering a limit
- Automatically calculating a limit.
 - You can specify 2SD or 3SD limits as a deviation from target.
 - The limits are updated once a batch is completed. You can set/lock the last batch limit.

Error Handling

You can specify that you want XM to automatically stop processing on an instrument when the XM batch mean is out of limits.

You can set Logging/Auto-Stop options:

- 1 Batch Out of limits
- 2 Batches Out of limits
- When one or two XM batches are out of limits, depending on your configuration, a message is logged in the XM history log.

Reviewing XM Analysis Information

The ability to view batch means in a graphical and tabular format is provided.

- You can delete the last batch or all batches.
- You can add comments to a completed batch
- You can delete individual samples from the batch. The total number of deletions in a batch must not exceed 25% of the total batch.
 - For example: A batch size of 1,000 would allow for the deletion of up to 250 individual samples.
 - The following table identifies the number of samples allowed for deletion from batches of 20 or less:

Batch Size	Number of samples allowed for deletion
20	5
16-19	4
12-15	3
8-11	2
4-7	1
2-3	0
1	1

Reporting

Auto-Print Reports

You can auto-print batch mean summary report (graphical and tabular) with the following options:

- Every 20 batches
- If batch is out of limits

Upon Demand Reports

The following reports can be printed at your request:

- Batch means summary (graphical and tabular)
- Batch runs

Exporting

You can also export Batch means and runs to CSV format.

Reviewing XM Results

- 1. Select Select on the Command Center to display the Quality Assurance application.
- 2. Select display the XM window.
- 3. Select:

This	To Display This
	Current XM batch results and statistics
	XM batch results and statistics of the batch immediately prior to the current batch (last batch).
	XM batch results and statistics of the batch previous to the last batch (previous batch).
2	Batch Means Table
2	Batch Means Graph
	Add Comments to an XM batch.

Note: You cannot add comments to a current XM Batch, you can only add comments to the last batch or a previous batch.

The window refreshes the XM Statistics Table, XM Means Table and XM Means Graphs based on the changes you made.

Adding Comments to an XM Batch

- 1. Select on the Command Center to display the Quality Assurance application.
- 2. Select 4 to display the XM window.

Note: You cannot add comments to a current XM Batch; you can only add comments to completed batches (any older batch in the Batch Means screen).

- 3. To display XM Batch results:
 - a. Select to display the last batch. or
 - b. Select to display a previous batch.
- 4. Select ^{Leg}o to add a comment
- 5. Type the comment you want to add.
- 6. Select on the Comment window to save the comment. The Workstation adds the comment to the appropriate XM Batch and places an X in the CMNT field.

3.7 PARTICIPATING IN IQAP

Use this procedure to download control folder data from the LH Workstation to your removable media for submission to the Beckman Coulter Interlaboratory Quality Assurance Program (IQAP).

You will be supplied with self-adhesive return labels and pre-addressed mailers. Control data should be submitted to IQAP on a monthly basis as soon as you have finished using a set of controls.

IQAP Setup

An IQAP participant number is assigned to you at the time you enroll in the program. This participant number identifies your data set from all others. Ensure that your IQAP participant number has been entered in your Workstation prior to downloading your data to diskette. You may also choose to participate in eIQAP.

IQAP Download Procedure

At the LH Workstation:

- 1. Select ^(S) on the Command Center.
- 2. Select 🛸 to display the CONTROLS window.

- 3. Select . An IQAP Disk Storage window appears.
- 4. Ensure the removable media (formatted CD, formatted diskette, flash drive) is inserted in the appropriate drive or attached to the computer.
- 5. Select the lot numbers you want copied to the removable media.
- 6. Select 🖾 to begin copying the control information.
- 7. The "Save as" window appears.
- 8. Specify the location of your removable media and select "Save".
- 9. After the download process is complete, take the removable media from the appropriate drive or USB location.
- 10. Use the files downloaded to submit the data through the eIQAP website.

Troubleshooting

If there is a problem downloading QC data to your chosen removable media check the following:

- If using a diskette, make sure the diskette is inserted completely in the a: drive.
- If you are using a blank diskette, make sure it has been formatted.
- If using a CD, make sure it is the CD-R type and that it is formatted.
- If using a flash drive, be sure to remove it properly. Double click on the "Safely Remove Hardware" icon on the task bar and follow the on screen directions to remove.

If all attempts to download are unsuccessful you can submit your control data to IQAP using the Summary Data Entry Form or the COULTER Retic-C Control Data Entry Form. Refer to the Data Entry chapter of the Interlaboratory Quality Assurance Program Procedure Manual for specific instructions.

3.8 PARTICIPATING IN eIQAP

Once you have your IQAP participant number, you may elect to set up an eIQAP internet account through our secure server. Your eIQAP participant account is accessible through the User Name and Password that you setup. The account provides separate administrator and user functions. After enrollment, all eligible hematology instruments in your laboratory will be accessible through your eIQAP account. eIQAP allows you to upload your data via the Internet and to access your own IQAP reports.

Enroll in elQAP

- 1. Go to the company's website at: www.beckmancoulter.com.
- 2. Select Customer Support from the top menu, then select QA & Service Programs.
- 3. Scroll down to the Interlaboratory Quality Assurance Program and select the link "Go to eIQAP"
- 4. You will find information and help in registering your account.

Data Submission for eIQAP

Data is uploaded to your eIQAP account from either a:

- 3.5 inch diskette
- CD-ROM, or
- flash drive.

Follow instruction on the eIQAP site to upload data. Use a CD or flash drive for the eIQAP upload if the computer you use does not have a 3.5 inch floppy drive.

QUALITY CONTROL PARTICIPATING IN eIQAP

4.1 COLLECTING WHOLE BLOOD SPECIMENS

Collect whole blood in a salt of EDTA according to tube manufacturer's instructions and procedures in: $^{\rm 1,\ 2,\ 3}$

- CLSI publication H4-A3 (for capillary) ⁴
- CLSI publication H3-A3 (for venipuncture) ⁵.

Beckman Coulter recommends you use a dipotassium (K₂) or tripotassium (K₃) salt of EDTA.

IMPORTANT Misleading results could occur if you fail to leave space at the top of the tube between the sample and the stopper. Ensure you leave space at the top of the tube between the sample and the stopper to facilitate mixing. Also, ensure that the sample is properly mixed before analysis.

Follow manufacturer's recommendations for use of microcollection and venipuncture devices.

For Automatic aspiration mode, you need at least 1.0 mL of sample with proper proportion of blood to anticoagulant.

For LH 700 Series only systems, the instrument aspirates a maximum of 300 μ L (0.3 mL) of whole blood. In the Automatic aspiration mode, the instrument aspirates approximately 200 μ L (0.2 mL) of whole blood for the Manual aspiration mode.

For LH SlideMaker systems, the instrument will aspirate an additional 250 μL (0.25 mL) of whole blood for the SlideMaker. A total of 550 μL (0.55 mL) will be aspirated.

4.2 STORING SPECIMENS

Analyze specimens as soon as possible for optimum accuracy.

Venipuncture Specimens

For CBC and DIFF:

- Run within 24 hours after collection, if stored at 21.2 to 25.6°C (70 to 78°F).
- Run within 48 hours after collection, if stored at 2 to 8°C (35.6 to 46.4°F).

For Reticulocytes:

- Run within 24 hours after collection, if stored at 21.2 to 25.6°C (70 to 78°F).
- Run within 72 hours after collection, if stored at 2 to 8°C (35.6 to 46.4°F).

NRBC Parameters:

- Run within 24 hours after collection, if stored at 21.2 to 25.6°C (70 to 78°F).
- Stored between 2 and 8°C (35.6 and 46.4°F), up to 24 hours after collection.

Note: Also refer to any pertinent manufacturer's storage recommendations for the venipuncture and microcollection devices used in your lab.

4.3 IDENTIFYING SAMPLES OVERVIEW

Automatic Aspiration Mode

The Workstation identifies a sample by:

- Reading the cassette number and cassette position of each sample at the time it is cycled
- Reading the tube's bar-code label automatically
- Allowing you to provide sample demographic information that includes optional identifiers, such as a patient identifier
- Time-stamping sample results with the date and time they were analyzed.

Manual Aspiration Mode

The Workstation identifies a sample by:

- Reading the tube's bar-code label when you use the handheld scanner
- Reading a sample identifier you provided by using the Numeric Keypad
- Allowing you to provide sample demographic information that includes optional identifiers, such as a patient identifier
- Time-stamping sample results with the date and time they were analyzed.

Setting Up Identifiers

As part of system setup, you must specify whether your laboratory wants the cassette number and position, the tube's bar-code label, or both used as a positive identifier. When you specify a positive identifier, the system links it irrevocably to the date and time of instrument analysis.

If you specify cassette number and position, ensure you provide enough demographic information or use another identifier, such as the sample identifier, to distinguish sample results since you may use a cassette number and position more than once throughout the day.

Using the Predilute Mode

Overview

The Predilute mode on the LH 700 Series may be used to analyze diluted specimens that exceed the reportable range, or to run a citrated tube when clumped platelets are suspected. The Predilute mode runs in the CBC test mode via manual aspiration.

You may enter dilution factors from 1.1 to 5.0. Use adequate sample and diluent volumes to prepare a simple dilution. Manual mode requires 200 mL of sample for aspiration.

A simple dilution is one in which a unit of sample volume is combined with the appropriate unit volume of diluent to achieve a desired concentration. The dilution factor is the total number of unit volumes in which the blood sample will be dissolved. For example, a 1:2 dilution combines one (1) unit volume of blood sample and one (1) unit volume of diluent. The resulting dilution factor is two (2 = 1 + 1). The diluted sample results are automatically multiplied by the dilution factor entered.

4

Procedure for a 1:2 Dilution

Use a sample for which you already have results.

1. Dispense diluent from the instrument, using the **EOO4** function. Have a clean empty tube ready to collect the diluent dispensed (approximately 2 mL) from the

E N T E R

manual probe when you press

- 2. Using a pipette, dispense 200 μL blood into a second clean tube which does not contain any anticoagulant.
- 3. Use a pipette to dispense $200 \ \mu L$ diluent into the same (second) tube.
- 4. Mix well.
- 5. On the Workstation Command Center:
 - a. Enable 🗹 Predilute (CBC).
 - b. Set the Factor to 2.0 in the pop-up box.

Note: A dilution factor is valid for one sample analysis. Once the sample has been processed, the Analyzer disables the Predilute function and the dilution factor returns to a default of 1.0.

- 6. Identify your sample ID using the numeric keypad or bar-code scanner.
- 7. Analyze your sample using the manual mode, as soon as possible after preparing the dilution.

Note: If results are not received at the workstation within approximately two minutes, the predilute function is disabled.

8. Compare the results to the results of the sample analyzed undiluted

Tube Sizes

Beckman Coulter does not recommend the use of one tube in preference to another, nor guarantees the acceptability of the sample tube to produce quality results. Refer to the Hematology Tube List available on the BCI website at www.beckmancoulter.com

Keep the following in mind when using this list:

- Use the tubes listed only with the cassette indicated.
- 13-mm cassettes are also known as 5-mL cassettes.
- 16-mm cassettes are also known as 7-mL cassettes.
- HEMOGARD cassettes are those designed for tubes with HEMOGARD closure.

CAUTION Possible system damage could occur if the adapters for the Beckman Coulter MAXM, MAXM with Autoloaders, JT2 and JT# analyzers are used for the LH700 Series. Do not use these adapters on the LH 700 Series.

• Two sizes (2 ML and 3mL) of sleeve adapters are available to accommodate narrow and short tubes. Place the tube inside the adapter before placing it into a 13-mm cassette. Table 4.1

Sleeve Adapter	Solid Base Length
2 mL	1 inch
3 mL	1/2 inch

Universal Tube Processing

The LH 700 Series contains a universal stripper plate. It permits the instrument to run multiple tube sizes and styles in Automatic aspiration mode. Refer to the Hematology Tube List available on the BCI website at www.beckmancoulter.com

CAUTION Possible specimen leakage or clogging of the aspiration system can occur. Excessive piercing of the sample tubes causes significant coring of the stopper. The number of pierces without problems can vary slightly among sample tube types and manufacturers. Do not pierce a blood collection tube more than five times.

Your instrument also contains a self-adjusting tube detector. This tube detector automatically adjusts to various sizes of tubes in the same cassette. You do not need to manually change the instrument tube detector settings.

Many laboratories run tubes that do not require adapters or clips on the LH 700 Series; however, your laboratory may require tube adapters or cassette clips.

If your laboratory requires adapters or clips, contact your Beckman Coulter Representative.

4.4 USING BAR-CODE LABELS

Beckman Coulter recommends the use of bar-code labels for specimen identification.



The LH 700 Series System comes with cassette and cassette position numbers 1 to 100. You can obtain additional cassettes with numbers 101 to 1000 from Beckman Coulter Inc.

Two labels provide identification:

- Cassette ID label provides a 4-digit cassette number.
- Cassette bar-code label appears as a bar-code and readable number. The cassette bar-code label includes the cassette ID number and the 2-digit position number.
Specimen tube bar-code labels provide sample identification. Bar-code label specifications are in the Reference Information section of this help system.

If you use Interleaved 2-of-5 bar-code specimen labels, you must set the number of digits on the label in the Analyzer.

Labeling Requirements—Tubes Without Adapters or Clips

IMPORTANT Risk of misidentification. Use of poor quality, dirty, improperly placed or damaged bar-code labels could keep the instrument from reading the bar-code labels. Ensure the bar-code labels are undamaged. Ensure the bar-code labels conform to the specifications provided in Chapter 4 of the Reference manual.



You can use up to two labels in addition to the sample tube manufacturer's label.

Do not skew the bar-code label more than 12 degrees.

Place each label so that it does not cover the bottom of the tube and is flat and smooth against the tube. This prevents the adapter from being broken or the tube jammed, and ensures the label can be scanned properly.

Ensure that the bar-code symbol and a 1/4-inch blank space on either side of the bar-code symbol are visible to the scanner.

For tubes with rubber-stopper caps or foil tops:

- 1. Place the bar-code label so that the first bar of the bar-code symbol is at least 1/2 inch from the tube cap.
- 2. Press the label down securely, including edges and corners.
- 3. Ensure the bars on the label are parallel to the stopper.

For all other tubes:

Place the bar-code label so that the first bar of the bar-code symbol is at least 1/4 inch from the tube cap.

Labeling Requirements—Tubes with Sleeve Adapters

IMPORTANT Risk of misidentification. Use of poor quality, dirty, improperly placed or damaged bar-code labels could keep the instrument from reading the bar-code labels. Ensure the bar-code labels are undamaged. Ensure the bar-code labels conform to the specifications provided in Chapter 4 of the Reference manual.



You can use a maximum of two labels in addition to the sample tube manufacturer's label.

Place each label so that it does not cover the bottom of the tube and is flat and smooth against the tube. This prevents the adapter from being broken or the tube jammed, and ensures the label can be scanned properly.

Do not skew the bar-code label more than 5 degrees.

Ensure that the bar-code symbol and a 1/4-inch blank space on either side of the bar-code symbol are visible through the read window when you insert the tube into the adapter.

You must position the gray sleeve adapters in a cassette so that their keys (located on top of their bar-code read windows) fit into the top openings of the cassette.

IMPORTANT Sample misidentification could occur if the label is improperly aligned in the read window. The bar-code reader can only read the portion of the bar-code label within the read window. Make sure the bar-code label appears within the read window.

Labeling Requirements—Tubes with Cassette Clips

IMPORTANT Risk of misidentification. Use of poor quality, dirty, improperly placed or damaged bar-code labels could keep the instrument from reading the bar-code labels. Ensure the bar-code labels are undamaged. Ensure the bar-code labels conform to the specifications provided in Chapter 4 of the Reference manual.



You can use a maximum of two labels in addition to the sample tube manufacturer's label.

Do not skew the bar-code label more than 12 degrees.

Ensure that the bar-code symbol and a 1/4-inch blank space on either side of the symbol are visible to the scanner.

Place labels flush with the tube cap. Place each label so that it does not cover the bottom of the tube and is flat and smooth against the tube. This prevents the adapter from being broken or the tube jammed, and ensures the label can be scanned properly

Make sure the bar-code label faces up when you place a tube into the cassette so that it may be scanned correctly.

4.5 CASSETTE HANDLING



The cassette is the carrier for the sample tubes (patient, control, or special test) used in Automatic aspiration mode where automatic loading, mixing, and sampling occurs.

Tubes should be pushed into the cassette with the tube bar-code labels facing up.

The cassette bar code label should be positioned

Cleaning the Cassette

Wash the cassettes as needed in warm soapy water and rinse thoroughly. Do not use an abrasive. Keep the cassettes free of dried blood, bleach, or diluent. Be careful not to scratch or deface the bar-code labels. Dirt, smears, pencil lead, and grease can affect bar-code label reading.

4.6 LOADING THE CASSETTE

WARNING Risk of personal injury. Forcing a tube into the cassette improperly could cause it to break. Do not force a tube into a cassette. If a tube should break, use your laboratory's safety procedure for cleaning the broken glass.

IMPORTANT Sample misidentification could occur. If not using the appropriate bar-code labels on the sample tubes, ensure you place the tubes in the proper cassette positions.

- 1. Slide each sample firmly into the cassette.
- 2. Ensure the bar-codes are facing up.

Note: If the compressor has timed out and a cassette is placed in the loading bay, the SlideMaker will not automatically start.

PRIME

Before placing a cassette in the loading bay, press **APERT** to place the system in a READY state. Once READY appears on the Numeric Keypad, the cassette can be placed in the loading bay and processed as normal.

Using Cassette Clips



Make sure the bar-code label faces up when you place a tube into the cassette so that it can be scanned correctly.

Installing the Cassette Clips

Install the cassette clips into the HEMOGARD cassettes for tubes with HEMOGARD Closure. You can use any of the tubes approved for this cassette with these cassette clips in place.



- 1. Place the bottom of the cassette clip into the opening of the cassette.
- 2. Pressing down on the cassette clip, turn it to the left (counterclockwise) until it clicks into place. Then push down on the cassette clip to position it at the bottom of the cassette opening.
- 3. It is easiest to insert the first cassette clip into the far left opening of the cassette (cassette position one). Then proceed in order from left to right.
- 4. Install cassette clips into all 12 tube openings of each HEMOGARD cassette for tubes with HEMOGARD Closure.

4.7 USING HANDHELD SCANNER

IMPORTANT

- 1. Risk of sample misidentification. When using the handheld scanner, occasional misread errors can occur as the result of partial label scans and damaged or misapplied labels. Beckman Coulter recommends that you verify each bar-code reading to assure correct patient identification.
- 2. DO NOT use the following characters # @ [\] `{|} ~ in Specimen or Patient identifiers. There is a potential for Specimen or Patient misidentification to occur. The system will substitute or omit these characters when the system in configured in a language other than English or Chinese.
- 3. DO NOT use leading or trailing spaces in the ID.
- 1. Ensure the cursor is in the field you want to fill with the scanned information.

WARNING Risk of personal injury. Some handheld scanners use a low-power, visible laser diode which could damage your eye. Avoid staring directly into the beam.



2. Aim the scanner at the bar-code and press the trigger. If necessary, adjust the scanner position so the scan beam is centered on the bar-code and overlaps it on both sides.

- 3. When the scanner has read the symbol, you will hear a beep. If you do not hear a beep:
 - Ensure the scanner is properly connected to your Workstation.
 - Make sure the scanner is properly configured for your labels.

to accept the sample ID at the Workstation.

IMPORTANT Risk of missing identifier. If you fail to send the sample ID to the instrument within 60 seconds of data entry in the Bar-Code ID field, the sample ID provided is cleared. This minimizes the risk of sample misidentification.

5. At the Analyzer's numeric keypad, press D, then to send the sample ID to the Analyzer.

E N T E

6. After the sample ID appears on the Analyzer. Press rest to accept the sample ID or

stop to reject the sample ID.

7. Ensure the sample ID is correctly displayed at the Analyzer screen.

Cleaning the Scan Window

Scanning performance can degrade if the scan window is not clean. If the scan window is visibly dirty, or if the scanner is not scanning well, clean the scan window with a soft cloth or tissue dampened with water (or a mild detergent-water solution). If a detergent solution is used, rinse with a clean tissue dampened with water only.

The scanner housing can also be cleaned the same way.

Setting Up Bar-Code Configuration

Note: Use this procedure to indicate the number of digits only when you use Interleaved 2-of-5 bar-code labels for sample tubes.

- 1. Go to the Analyzer screen.
- 2. Press MAIN MENU.
- 3. Press SYSTEM CONFIGURATION.
- 4. Press NUMBER OF BAR-CODE DIGITS (2 OF 5) XX, where XX represents the current number of bar-code digits.
- 5. Go to the Numeric Keypad. It displays VALUE? XXXX
- 6. Use the Keypad to specify the number of digits (from 03 through 11).



- 7. Press **R** after specifying the number of digits.
- 8. Go to the Analyzer screen.
- 9. Confirm the number you specified appears on the Analyzer screen.
- 10. Press one of the following:

SYSTEM RUNTo cycle samples.RETURNTo display the Analyzer MAIN MENU screen.

4.8 CYCLING SAMPLES IN AUTOMATIC ASPIRATION MODE

WARNING Risk of personal injury. If a problem occurs while the system is cycling, press and wait for the system to stop before you do anything to correct the problem. Attempting to correct an instrument problem while the instrument continues to process samples could injure you.

1. Ensure the instrument is set up for the appropriate test.

IMPORTANT Misleading results can occur if specimens contain clots. Inspect specimens for clots and use good laboratory practices for verifying results to ensure you do not receive misleading results.

- 2. Ensure your specimens have been collected, stored, and mixed properly.
- 3. Load the cassettes.
- 4. Place the cassettes firmly and securely into the loading bay on the right side of the Diluter. The instrument automatically begins cycling the cassettes.
- 5. After the instrument cycles the samples, review the sample results on the Workstation.

4.9 CYCLING SAMPLES IN MANUAL ASPIRATION MODE

IMPORTANT

a.

c.

- 1. If the probe is stuck in the IN position after you entered the patient ID, you can discard that ID only by resetting the Analyzer.
- 2. Misleading results can occur if specimens contain clots. Inspect specimens for clots and use good laboratory practices for verifying results to ensure you do not receive misleading results.
- 1. Ensure the instrument is set up for the appropriate test.
- 2. Ensure your specimens have been collected, stored, and mixed properly.
- 3. You can enter the sample ID for Manual Aspiration three ways, by performing the steps below:

To type the sample ID using only the Numeric Keypad at the instrument:



b. Type sample ID.



- d. Ensure the sample ID is displayed correctly at the Analyzer screen.
- e. If you need to change the ID, go back to step a.

To scan the sample ID into the Barcode field at the Workstation At the Workstation:

a. Place the cursor in the barcode field.

b. Scan the sample ID using the handheld scanner.

IMPORTANT

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

2. DO NOT use the following characters $\# @ [\] \ \{ \ \} \ \sim \$ in Specimen or Patient identifiers. There is a potential for Specimen or Patient misidentification to occur. The system will substitute or omit these characters when the system is configured in a language other than English or Chinese.

3. DO NOT use leading or trailing spaces in the ID.



4. Aspirate the sample.

IMPORTANT Risk of missing identifier. If you fail to send the sample ID to the instrument within 60 seconds of data entry in the Bar-Code ID field, the sample ID is cleared. This minimizes the risk of sample misidentification.

- 5. Immerse the aspirator tip in the tube. The instrument automatically aspirates the sample.
- 6. When you hear a beep, remove the tube from the aspirator tip. The probe cleaner retracts the aspirator and automatically cleans it.
- 7. After the instrument cycles the samples, review the sample results on the Workstation.

Manual Mode Aspirator



Use this area for Manual aspiration mode.

Optical sensors exist at the bottom of the black activator.

IMPORTANT Risk of misleading results. Holding the tube against the bottom of the aspirator tip can prevent aspiration. Do not hold the tube against the bottom of the aspirator tip.

IMPORTANT Risk of misleading results. Removing a sample tube from the aspirator tip before the STATUS message changes and you hear a beep could cause a short sample aspiration. Wait until the message changes and you hear a beep to remove the sample tube.

WARNING Risk of personal injury. If the optical sensors do not detect an obstruction, the aspirator tip retracts when PRIME appears on the STATUS field on the Analyzer screen. If you have the aspirator tip immersed in the tube when the tip retracts, the aspirator can hit the tube and break it. Be sure to remove the sample tube when the instrument beeps and be clear of the aspirator tip before PRIME appears. If a tube should break, use your laboratory's safety procedure for cleaning the broken glass.

Immerse the aspirator tip in the sample so that the tube or your hand blocks the optical sensors. The instrument automatically aspirates the sample.

When the instrument beeps, remove the sample.

The instrument automatically cleans the aspirator tip with a probe wipe.

4.10 CHANGING THE NUMBER OF ASPIRATIONS PER TUBE

CAUTION Needle damage can occur if you pierce a specimen more than five times. Do not pierce a specimen tube more than five times.

- 1. Go to the Analyzer screen.
- 2. If the SYSTEM RUN screen currently appears on the Analyzer screen, skip to step 4. Otherwise, press MAIN MENU.
- 3. Press SYSTEM RUN.
- 4. Press ASPIRATIONS/TUBE.
- 5. Go to the Numeric Keypad.
- 6. Use the Keypad to specify the number of aspirations desired.



- 7. Press R after specifying the number of aspirations.
- 8. Go to the Analyzer screen to verify that the number of aspirations appears on the Analyzer. The SYSTEM RUN screen displays the current number of aspirations. Example: ASPIRATIONS/TUBE 01

4.11 CHANGING TEST MODE

- 1. Go to the Command Center.
- 2. Use **CR I** to select the default test type for sample processing.

CDR	Run samples for CBC, Diff and Retic.
CD	Run samples for CBC and Diff.
C	Run samples for CBC only.
CR	Run samples for CBC and Retic.
R	Run samples for Retic only.

The *CURRENT MODE* message displays the test mode you select. Note: If Random Access is enabled, review Random Access Overview, Heading 7.7.

4.12 ENABLING/DISABLING BLOOD DETECTOR

- 1. Go to the Analyzer screen.
- 2. Press MAIN MENU.
- 3. Press SYSTEM CONFIGURATION.



4. Press BLOOD DETECTOR until the appropriate setting appears.

Note: The system flags all parameters with a P (partial aspiration) when samples are analyzed with blood detectors disabled. P flagged control run results are automatically removed from statistical calculations, and there is no way to reintroduce the flagged runs into the calculations.

5. Press one of the following:

SYSTEM RUN	To cycle samples.
RETURN	To display the Analyzer MAIN MENU screen.

RUN SAMPLES ENABLING/DISABLING BLOOD DETECTOR

5.1 REVIEWING SAMPLE RESULTS

- 1. Select 💻 on the Command Center to display the Patient Tests application.
- 2. If necessary, select to display the Results & Graphics window that contains:
 - Parameters
 - Flags
 - Codes
 - Suspect messages
 - Definitive messages
 - Histograms
 - DataPlots
 - Identification information.
- 3. If necessary, find the sample results you want to review.

Note: Research population data includes mean and standard deviation of each type and measurement of the white blood cell. Therefore, research population data must be verified when WBC differential results are flagged.

4. Specify the way you want the window updated:



Research Data

Select Select on the Results & Graphics window to display the Research Data. Research Data can be used for investigation (based on your laboratory's policies and procedures) and research purposes.

Research Data displays:

- Research Suspect Messages in the message list
- Research Suspect Messages on printouts
- Individual aperture graphs, selected on-screen, are included on printouts

You can also view CBC parameter results and histograms for each aperture.

Menu Access: View Research Data

5.2 REVIEWING 2D DATAPLOTS

By default, DataPlots present a combined view of population density and membership. Colors represent different types of cells. Shades of colors represent the number of cells—bright colors being the most dense.

Button	Population	Color	Button	Population	Color
۲	Lymphocytes	Blue	1000 °	RBCs	Red
	Neutrophils	Purple	۲	Reticulocytes	Blue
*	Eosinophils	Orange			
¢	Monocytes	Green	$<^{(F)}_{\mathcal{Y}}$	Platelets	Green
۲	Basophils	White	۵	WBCs	Purple
200 200 200	Non-white cells	Red			

The Y-axis represents volume, and the X-axis represents relative light scatter.

If the instrument encounters a clog while analyzing the sample, the appropriate code appears on this window:

Code	Means
FC	Flow cell clogged.
PC1	Partial clog 1.
PC2	Partial clog 2.

Enlarged View

Double-click a DataPlot to see an enlarged version of it. Select *to return to the normal size.*

Select the parameter button at the top of the enlarged window to remove the corresponding population from the DataPlot.

Select it display the classic VCS scatterplot (DF1) beside the LH 700 Series DataPlot. You cannot remove populations from the classic scatterplot.

What to Look For

When reviewing DataPlots, inspect:

- Position of individual populations as compared to normal/typical positions
- Amount of separation between populations as compared to normal/typical separation
- Relative concentration of each population as compared to normal/typical concentrations
- Presence of unexpected or non-typical populations.

Refer to the Reference manual for more information about DataPlot development. Refer to your laboratory's operating procedures for details about interpreting DataPlots.

5.3 REVIEWING 3D DATAPLOT

Select Select solution of the 3D DataPlot window to review a three-dimensional (3D) representation of the data for a sample. The 3D DataPlot window appears on top of all other windows until you minimize it.

Initially the 3D DataPlot shows the currently selected full data, static information for the sample run. If the Results & Graphics window is unlocked, the 3D DataPlot displays the last sample received.



To Display This



WBC differential data. This button appears gray and inactive when no data is available.



Reticulocyte data. This button appears gray and inactive when no data is available.

The 3D DataPlot presents a combined view of population density and membership. Colors represent different types of cells. Shades of colors represent the number of cells—bright colors being the densest.

Button	Population	Color	Button	Population	Color
۲	Lymphocytes	Blue	2000 0 2000 0 2000	RBCs	Red
-	Neutrophils	Purple	۲	Reticulocytes	Blue
	Eosinophils	Orange			
¢	Monocytes	Green	1.0	Platelets	Green
۲	Basophils	White	٦	WBCs	Purple
2.00° *300	Non-white cells	Red			

Select a parameter button on the side of the 3D DataPlot window to remove the corresponding population from the 3D DataPlot. The Workstation automatically redraws the 3D DataPlot without the selected population. Select the button a second time to include the corresponding population.

Retrieving Data

You can also view data for results that have previously been saved. By default, the Workstation stores data for the last 2000 samples. You can change the amount of data the Workstation stores as part of setup.

- 1. Select a sample from the Completed Folder.
- 2. Select 44 to view the Results & Graphics screen.
- 3. Select to see a three-dimensional representation of the differential data for the sample selected.

Changing the Perspective

Drag \square to change the angle of the DataPlot. You can also use \blacksquare \blacksquare and \blacksquare \blacksquare .



Minimizing the Window

Select **—** to minimize the window.

5.4 REVIEWING HISTOGRAMS

Histograms show relative cell frequency versus size. They provide information about erythrocyte, leukocyte, and thrombocyte frequency. They also might show the presence of subpopulations. Histograms provide a means of comparing the sizes of a patient's cells with normal populations.

Double-click a histogram to see an enlarged version of it. Select **P** to return to the normal size.

5

What to Look For

IMPORTANT Incorrect results can occur if you estimate the number of cells from the distribution curves. Curves show only the relative, not actual, number of cells in each size range. Do not estimate the number of cells from the distribution curves.

When reviewing histograms, inspect:

- Position of individual populations as compared to normal/typical positions
- Amount of separation between populations as compared to normal/typical separation
- Relative concentration of each population as compared to normal/typical concentrations
- Presence of unexpected or non-typical populations.

Refer to the Reference manual for more information about histograms. Refer to your laboratory's operating procedures for details about interpreting histograms.

5.5 EDITING SAMPLE RESULTS

- 1. Select 😐 on the Command Center to display the Patient Tests application.
- 2. Find the results you want to edit.
- 4. Edit the following as necessary:
 - Preassigned and read identification information
 - Parameter results
 - Demographic information



to move between fields.

Note: Duplicate Sample IDs or Cass/Pos are allowed for the same Patient ID only if the Test Type is different. If the same test type is specified for a Sample ID, the following message will display:

Duplicate Sample ID entry. Sample IDs must be unique within the ToDo list. Original value will be restored.

- 5. If you want to add a test or remove a PENDING test:
 - a. Select the specific test identifiers you want to add or remove.
 - b. Provide the sample identification information for the tests.

IMPORTANT Incorrect results or incorrect identification could lead to misleading results or misidentification. Before saving edits, check that you typed them properly.

6. Select it is save the edits in the database. The Workstation recalculates any derived parameters and reapplies flagging limits. Decision criteria rules are not reapplied. Reports with Pending status include a special message indicating the status. When all tests complete processing, the report includes a special message that indicates the change in status.

5.6 REVIEWING PATIENT HISTORY

- 1. Select ⊨ on the Command Center to display the Patient Tests application.
- 2. Find the most recent sample for the patient you want to review.
- 3. Select **to display the Patient History window that contains:**
 - Patient History Table
 - Patient History Statistics
 - Patient History Graphs

5.7 PROCESSING RESULTS OVERVIEW

The Coulter LH 700 Series System provides many functions to help you identify and process results quickly and effectively. The Workstation includes flags and codes with results to help you. You can also customize the flagging of results and define rules for flagging sample results.

Flagging

The Workstation assigns priorities to flags. Critical flags (cH/cL) are the most important. They are followed by action flags (aH/aL) and then default flags(H/L).

IMPORTANT Flagging is evaluated when the sample is analyzed. Flagging is reevaluated for a sample when the results are manually edited, or when new results are received for a pending sample. Flagging is not reevaluated upon a change of flagging limits for results already in the database. Delta Check and Reflex Decision Rules are not reevaluated.

Beckman Coulter Inc. does not claim to identify every abnormality in all samples. Beckman Coulter suggests using all available flagging options to optimize the sensitivity of instrument results. All flagging options include reference ranges (H/L), action and critical limits, definitive flags, suspect flags, parameter codes, delta checks, decision rules and system alarms. Beckman Coulter recommends avoiding the use of single messages or outputs to summarize specimen results or patient conditions.

You can customize many of the flags to suit the needs of your laboratory. You can define:

- Default high/low limits
- Different high/low limits based on gender and age
- Different high/low limits based on location
- Action limits that exceed the default limits. These appear with a unique aH (action high) and aL (action low) flags
- Critical limits that exceed the action limits. These appear with a unique cH (critical high) and cL (critical low) flags
- Limits (action) that force the display of definitive messages
- Limits that route results to a special Review Folder (Auto Validation).

Of course, you do not need to define these all at once, you can use the default set* and gradually add additional limits based on your laboratory's assessment.

Rules for Flagging Results (Decision Rules & Criteria)

You can define rules for delta checking. When the Workstation finds a sample for a patient that already has sample results in the DataBase, it uses the rules you define to determine how to flag the sample.

You can also define rules (Reflex Manager) to identify sample results that meet a set of criteria. For example, you can automatically generate the message "Perform Retic Count" in the comment field if the Workstation receives a sample result with Hgb <= 10.5 or RBC <= 3.2 and MCV <= 65.

As part of your rule definition, you can specify where you want the results that satisfy the rule to appear. For example, the Workstation can route results to special Reflex Manager, Delta Check and Review folders.

Processing Flagging Limits

The following flow chart illustrates how the system processes flagging limits.



5.8 FLAGS

Flags appear to the right of the result. For some parameters, flagging occurs as a result of the flagging or editing of other parameters.

The LH 700 Series applies instrument-generated and/or laboratory-defined flags, codes, and/or messages to each set of patient results. Flags, codes, suspect and definitive messages are used to alert you to an instrument malfunction, specimen abnormality, abnormal data pattern, or abnormal results. Beckman Coulter recommends review, appropriate to your patient population, of all results displaying a flag, code or other message.

IMPORTANT Beckman Coulter Inc. does not claim to identify every abnormality in all samples. Beckman Coulter Inc. suggests using all available flagging options to optimize the sensitivity of instrument results based on your patient population. All flagging options include reference ranges (H/L), action and critical limits, definitive flags, suspect flags, parameter codes, delta checks, decision rules and system alarms. Beckman Coulter Inc. recommends avoiding the use of single messages or outputs to summarize specimen results or patient conditions. There may be situations where the presence of a rare events may fail to trigger a suspect message.

Look for data patterns when examining codes, flags and messages. For example, determine if some, all or related sets of results (for example, WBC and differential results) exhibit flags, codes and messages. For some parameters, flagging occurs as a result of the flagging or editing of other parameters. In all cases, follow you laboratory's policy for reviewing the sample.

IMPORTANT Flagging is evaluated when the sample is analyzed. Flagging is reevaluated for a sample when the results are manually edited, or when new results are received for a pending sample. Flagging is not reevaluated upon a change of flagging limits for results already in the database.

Flag Definition

The color yellow indicates reference interval low or high.

The color red indicates an action, critical or other flag.

- * The MCV is < 50 fL. Some red cells may be smaller than the instrument's counting threshold.
- + Result exceeds the reportable range.

IMPORTANT Incorrect results can occur. If the WBC, RBC, HGB, or PLT have + (flag), when cycling in Manual mode, run a blank cycle before analyzing the next test sample to prevent carryover to the next sample. When cycling in Automatic mode, rerun the sample immediately following the one with the +. Sample dilutions may also result in wrong differential results. The instrument will automatically set to CBC mode when predilute is chosen.

You may want to look at the messages that appear on the Research Data window. The You may

- **aL** Action low limit was exceeded.
- **aH** Action high limit was exceeded.
- cL Critical low limit was exceeded.
- cH Critical high limit was exceeded.
- **D** Result triggered a Delta Check rule as defined by your laboratory.
- **E** Manual edit or a primary parameter 'E' overwrites +, * and R flags.
- e Automatic edit of a calculated results because the primary parameter was manually edited. 'e' overwrites +, * and R flags.
- **H** Reference interval high limit was exceeded.
- L Reference interval low limit was exceeded.
- P A partial aspiration was detected during sample analysis, or the blood detectors were disabled.
- **R** Review the result. Special handling is required for editing a result flagged with R. Any parameter derived from an R-flagged parameter cannot be recalculated until the R-flagged parameter is edited. R flags may also indicate a system alarm occurred such as a flow cell error). Check the event log for details.

You may want to look at the messages that appear on the Research Data window. The Research Data window provides more detailed research data.

5.9 CODES

Codes appear in place of results when the system cannot generate results. Codes are also called non-numeric results.

The LH 700 Series applies instrument-generated and/or laboratory-defined flags, codes, and/or messages to each set of patient results. Flags, codes, suspect and definitive messages are used to alert you to an instrument malfunction, specimen abnormality, abnormal data pattern, or abnormal results. Beckman Coulter recommends review, appropriate to your patient population, of all results displaying a flag, code or other message.

IMPORTANT Beckman Coulter Inc. does not claim to identify every abnormality in all samples. Beckman Coulter Inc. suggests using all available flagging options to optimize the sensitivity of instrument results based on your patient population. All flagging options include reference ranges (H/L), action and critical limits, definitive flags, suspect flags, parameter codes, delta checks, decision rules and system alarms. Beckman Coulter Inc. recommends avoiding the use of single messages or outputs to summarize specimen results or patient conditions. There may be situations where the presence of a rare event may fail to trigger a suspect message.

Look for data patterns when examining codes, flags and messages. For example, determine if some, all or related sets of results (for example, WBC and differential results) exhibit flags, codes and messages. For some parameters, flagging occurs as a result of the flagging or editing of other parameters. In all cases, follow you laboratory's policy for reviewing the sample.

Codes	
	Incomplete computation occurred. Incomplete computation may occur in place of calculated parameters because a voteout or overrange occurred for a primary parameter used in the calculation.
	Total voteout occurred. No average histogram will appear for the affected parameter. If this code appears for WBC, the WBC subpopulation absolute counts and NRBC absolute count results appear as an incomplete computation () since the absolute counts are calculated from the non-numeric WBC.
•••••	Flow cell clog was detected. PC1, PC2 or FC will be displayed on the y-axis of the dataplot
+++++	Operating range was exceeded.
	Note: +++++ does not apply to NRBC%.

IMPORTANT Incorrect results can occur. If the WBC, RBC, HGB, or PLT have +++++ (code), when cycling in Manual mode, run a blank cycle before analyzing the next test sample to prevent carryover to the next sample. When cycling in Automatic mode, rerun the sample immediately following the one with the +++++. Sample dilutions may also result in wrong differential results. The instrument will automatically set to CBC mode when predilute is chosen.

5.10 SUSPECT MESSAGES

As appropriate, the LH 700 Series applies instrument-generated and/or laboratory-defined flags, codes, and/or messages to each set of patient results. Flags, codes, and suspect or definitive messages are used to alert you to an instrument malfunction, specimen abnormality, abnormal data pattern, or abnormal results. Beckman Coulter recommends review, appropriate to the requirements of the patient population, of all results displaying a flag, code or message.

Establishing Flagging Levels

Laboratories may differ in their desired sensitivity to abnormal cell types with some laboratories requiring more sensitivity than others. Because sensitivity to abnormal cell types varies between laboratories, the LH 700 Series provides the laboratory with the ability to adjust the sensitivity of differential suspect messages (Imm NE 1, Imm NE 2, Variant Lymphs, and Blasts) to meet individual laboratory requirements (Refer to Flagging Preferences).

There may be situations where the presence of a rare event cell may fail to trigger a suspect message. System sensitivity increases when appropriately set suspect messages are used in combination with laboratory-defined definitive messages, action value flags, and critical value flags. In addition, complete review of the peripheral smear, regardless of the nature of the flag, code, or message, will minimize false negatives.

In order to optimize both instrument-generated and laboratory-defined flagging for efficiency and clinical significance, Beckman Coulter recommends completion of LH 700 Series-specific sensitivity and specificity studies prior to adjusting message sensitivity and establishing flagging levels.

IMPORTANT The operating temperature influences the rate of kinetic reactions. The LH 700 Series should be recalibrated whenever the ambient temperature changes by 10 degrees Fahrenheit. If you have to recalibrate the CBC due to a large change in laboratory ambient temperature, you should also re-evaluate the differential flagging sensitivity settings for your typical patient population.

IMPORTANT Beckman Coulter Inc. does not claim to identify every abnormality in all samples. Beckman Coulter Inc. suggests using all available flagging options to optimize the sensitivity of instrument results based on your patient population. All flagging options include reference ranges (H/L), action and critical limits, definitive flags, suspect flags, parameter codes, delta checks, decision rules and system alarms. Beckman Coulter Inc. recommends avoiding the use of single messages or outputs to summarize specimen results or patient conditions. There may be situations where the presence of a rare events may fail to trigger a suspect message.

Suspect Messages

Suspect messages appear for sample results based on an abnormal cell distribution or population. The system generates these messages according to an internal algorithm. The algorithm may be impacted by abnormalities in samples that may be attributed to possible interfering substances such as medication, certain disease states and/or blood disorders.

All sample results with suspect messages automatically appear in the Review Folder. Review the sample according to your laboratory's procedures. System sensitivity increases when appropriately set suspect messages are used in combination with laboratory defined definitive messages, action value flags, and critical value flags. In addition, complete review of the peripheral smear, regardless of the flag, code or message, will minimize false negatives. If you observe a higher rate of suspect flags than usual call your Beckman Coulter Representative.

If an NRBC% is reported as zero and there are any suspect messages or parameter codes, Beckman Coulter, Inc. recommends a slide review per your laboratory protocol.

Message	Notes	Source
Abnormal Retic Pattern	Composite message triggered by any one of the following research messages: Sickle, Thalassemia, RET Interference, Low Volume WBC.	Retic
Aging Sample	Pattern shift detected due to aging cells. This appears on the Research Data Window only.	Diff
Cellular Interference	WBC histogram pattern consistent with interference at the 35 fL region. When the separation between the WBC populations is poorly defined on the histogram, WBC correction will be performed and the corrected WBC will have an R flag.	CBC
DDD (Diff) DDD (Retic)	Data Discontinuity Detector. The instrument used data only while the flow rate was good. This flag appears on the Research Data window only.	Diff/Retic
Dimorphic Reds	Two populations of RBCs.	CBC

REVIEWING DATA SUSPECT MESSAGES

Message	Notes	Source
High Plt Interference	Platelet interference at the high end of the histogram (Microcytic Reds, RBC Fragments or Plt Clumps). This message appears on the Research Data window only. This appears in conjunction with Plt R.	CBC
Giant Platelets	Giant Platelets.	CBC
High WBC Count	When the uncorrected WBC is $\geq 100 \times 10^3$ cells/µL, the Hgb, MCH, and MCHC will display with an R flag. When the uncorrected WBC is $\geq 140 \times 10^3$ cells/µL, the RBC, Hgb, Hct, MCV, MCH, MCHC and RDW will display with an R flag.	CBC
Imm. NE1	Immature neutrophil 1 (immature neutrophils and/or bands). Three levels of sensitivity at Flagging Preferences. Can be disabled at Flagging Preferences.	Diff
Imm. NE 2	Immature neutrophil 2 (metamyelocytes, myelocytes, promyelocytes). Three levels of sensitivity at Flagging Preferences.	Diff
RET Interference	Reticulocyte data pattern exhibits high volume standard deviation and high light scatter mean for mature red cells. Abnormal Retic Pattern message will be displayed. This message appears on the Research Data window only.	Retic
Low Opacity LY	Differential data pattern exhibits a separate population of low conductivity (opacity) events in the lymphocyte area. This message appears on the Research Data window only.	Diff
Low Plt Interference	Platelet interference at the low end of the histogram (electronic noise or small particles). This message appears on the Research Data window only. This appears in conjunction with Plt R.	CBC
Low Volume LY	Differential data pattern exhibits a separate population of low volume events in the lymphocyte area. This message appears on the Research Data window only.	Diff
Low Volume WBC	Reticulocyte data pattern exhibits high light scatter, low volume events, consistent with small white cells. Abnormal Retic Pattern message will be displayed This message appears on the Research Data window only.	Retic
Low Event #	Less than 800 WBC events were counted for the differential. R appears next to DIFF%, DIFF#,NRBC% and NRBC# display incomplete computation () when this message appears.	Diff
LY Blast	Suspect blasts in the lymphocyte area of the dataplot. Three levels of sensitivity at Flagging Preferences.	Diff
MO Blast	Suspect blasts in the monocyte area of the dataplot. Three levels of sensitivity available at Flagging Preferences.	Diff

Message	Notes	Source
NE Blast	Suspect blasts in the neutrophil area of the dataplot. Three levels of sensitivity available at Flagging Preferences.	Diff
NRBC	Nucleated RBCs.	Diff
	Note: This Suspect Message will not be displayed if you have enabled either NRBC parameter.	
Platelet Clumps	Platelet histogram, WBC histogram, and RBC histogram patterns consistent with platelet clumps, fragmented red cells, or small red cells.	CBC
RBC Interference	MCV is less than 50 fL (MCV*). The RBC, Hct, MCH, MCHC, RDW, Plt, @Pct, MPV, @PDW, RET#, and @HLR# will display with an R flag.	CBC
Red Cell Agglutination	The MCV is greater then 110 fL and the MCHC is greater than 40.0 g/dL.	CBC.
Sickle	Reticulocyte data pattern exhibits high volume standard deviation, high volume means for both mature red cells and reticulocyte. Abnormal Retic Pattern message will be displayed This message appears on the Research Data window only.	Retic
Thalassemia	Reticulocyte data pattern exhibits a high light scatter, low volume mean population consistent with incomplete red cell lysis. Abnormal Retic Pattern message will be displayed. This message appears on the Research Data window only.	Retic
Variant LY	Variant lymphocytes. Three levels of sensitivity at Flagging Preferences	Diff
Verify Diff	R appears next to DIFF%, DIFF#, NRBC% and NRBC# when an unexpected data pattern is encountered. The message also is generated when WBC >1.5 x 10 ³ cells/µL and MO% ≥ 20. Verify differential results according to your laboratory's protocol.	Diff
Verify Retic	The RET%, RET#, IRF, MRV, @MSCV, @HLR%, and @HLR# will displayed with an R flag. Verify retic results according to your laboratory's protocol.	Retic
WBC Exceeds Linearity	The uncorrected WBC is greater than 400.0 x 10 ³ . A plus sign (+) appears next to the WBC count and an R appears next to the RBC, Hgb, Hct, MCV, MCH, MCHC, RDW and the differential percentages and numbers. NRBC% and NRBC display incomplete computation () when this message appears.	CBC

5.11 DEFINITIVE MESSAGES

Definitive Messages appear for sample results based on exceeded action limits. The messages are configured as part of your flagging limits set.

The LH 700 Series applies instrument-generated and/or laboratory-defined flags, codes, and/or messages to each set of patient results. Flags, codes, suspect and definitive messages are used to alert you to an instrument malfunction, specimen abnormality, abnormal data pattern, or abnormal results. Beckman Coulter recommends review, appropriate to your patient population, of all results displaying a flag, code or other message.

IMPORTANT Beckman Coulter Inc. does not claim to identify every abnormality in all samples. Beckman Coulter Inc. suggests using all available flagging options to optimize the sensitivity of instrument results based on your patient population. All flagging options include reference ranges (H/L), action and critical limits, definitive flags, suspect flags, parameter codes, delta checks, decision rules and system alarms. Beckman Coulter Inc. recommends avoiding the use of single messages or outputs to summarize specimen results or patient conditions.

Look for data patterns when examining codes, flags and messages. For example, determine if some, all or related sets of results (for example, WBC and differential results) exhibit flags, codes and messages. For some parameters, flagging occurs as a result of the flagging or editing of other parameters. In all cases, follow you laboratory's policy for reviewing the sample

Definitive Messages

Definitive messages appear for sample results based on action limits exceeded for age only. The messages are set up as part of your flagging limits.

Message	Result Exceeds the Action Limit for	Notes
Anemia	RBC or Hgb low	Pancytopenia overrides this message.
Anisocytosis (with gradient ranges)	RDW high	
Basophilia	BA% or BA# high	
Eosinophilia	EO% or EO# high	
Erythrocytosis	RBC high	
H&H Check Failed	Hct < ((Hgb*3) - 3)	
	OR	
	Hct > ((Hgb * 3)+3)	
Hypochromia (X)	MCH low	X indicated 1+ or 2+ gradient range
Large Platelets	MPV high	
Leukopenia	WBC low	Overwritten by Pancytopenia
Leukocytosis	WBC high	
Lymphopenia	LY% or LY# low	
Lymphocytosis	LY% or LY# high	
Macrocytosis (with gradient ranges)	MCV high	

Message	Result Exceeds the Action Limit for	Notes
Microcytosis (with gradient ranges)	MCV low	
Monocytosis	MO% or MO# high	
Neutropenia	NE% or NE# low	
Neutrophilia	NE% or NE# high	
Pancytopenia	WBC, RBC and Plt low	Overwrites Anemia, Leukopenia and Thrombocytopenia
Reticulocytosis	RET% or RET# high	
Small Platelets	MPV low	
Thrombocytopenia	Plt low	Overwritten by Pancytopenia
Thrombocytosis	Plt high	

Auto Validation Overview

The enhanced Auto Validation procedure provides information as to the state of the sample. The sample can have one of three states with respect to validation:

- Auto Validated, meaning that it has passed all criteria for validation
- Validated, meaning that although it failed at least one criteria, the sample has been manually validated
- Not Validated, meaning that the sample failed at least one criteria and has not been manually validated.

On the screen, samples which are Auto Validated will not appear in the Reflex, Delta, or Review folders, and will not have the Validate button enabled. If the sample fails validation for non-decision rule criteria, it would appear in the Review Folder. If the sample fails for Decision Rule criteria, it could appear in either the Delta Check or Reflex folders (depending which one was triggered), or in the Review folder, depending whether they have configured Delta Check and Reflex failures to go to the Review folder. It is possible, if the sample fails both decision rule-related and non-rule related criteria, for the sample to appear in both or all three folders. If the user reviews and manually validates the sample, it would no longer appear in any of these folders, and the validate button would be in a depressed state when that single sample is selected.

For the print and host transmission, these messages are output as "Sample Auto Validated", "Sample Not Validated", or "Sample Validated". In addition, individual codes will provide validation information for predefined parameter sets, referred to as parameter blocks. If at least one parameter from the parameter block is included in the reported results, the appropriate validation code will be displayed. The codes may be disabled for host transmission in the Host Communications Setup area.

The major difference between the screen and print is that the screen is not profile specific. This means that on screen, all parameters, suspect/definitive messages, and rules triggered will be displayed, and the validation status depends on the whole sample. For the print and host transmission, only those parameters, suspect/definitive messages, and rule messages which are part of the profile are output, and the validation codes and messages are based on this output.

The logic for arriving at the validation status is as follows:

We first reduce the parameters to an active set. The set of active parameters starts with the set of parameters which is enabled for the system in parameter setup. It is further reduced to those parameters which were either run on the analyzer or edited into the sample. For printing and transmission, the active set is further reduced to the parameters included in the selected profile. If the status we are looking for is a validation code, the active set is further reduced to the parameters applicable to that code.

For example, suppose that all parameters are enabled for the system except research. Now suppose that a CR sample is run. We are now only looking at CR parameters, except the research ones. Now if we are looking at the printout and the selected profile is CBC, we are reduced to only the CBC parameters. To determine the status of the Validation Message we are looking for all the CBC parameters. To determine the status of the parameter codes, such as the C Code (CBC parameter block), then we're still looking at all CBC parameters. If it is H Code, we're looking at only Hgb and Hct parameters. The W code only looks at the WBC, Hgb and Plt parameters If we're looking for the D code (Diff parameter block) or R code (Reticulocyte block), we have no parameters, and the code would not be displayed.

Now that we know which parameters to include, we will look for anything which causes an Auto Validation failure:

- Any active parameter which exceeds limits, where the limit has been configured as autoverification criteria. This could also be based on a definitive message, where the definitive set has been specified as autoverification criteria.
- H & H Check Failed is a separate check. Since it is not tied to any limit set, it can not be configured as autoverification criteria. It will always trigger a failure when both HGB and HCT are part of the active set.
- Any active parameter which has a nonnumeric value (+++++, :::::,, ----), a Review flag, Partial Aspiration (P), exceeds linearity (+), or MCV exceeds threshold (*).
- Any suspect (non-research) flag, where the active parameter set includes at least one parameter from the suspect message parameter group. Suspect messages are associated with either CBC, Diff, or Retic parameters. If, for example, a CBC suspect message is triggered and at least one CBC parameter is in the active set, we have an autovalidation failure.
- Any reflex or delta rule, where ALL parameters included in the rule must be in the active set.

5

IMPORTANT Several precautions have been taken to ensure integrity of Manual Validation. If new data is collated to a sample, if the sample is edited in a way that would cause a reflag, or if the profile is changed, manual validation for the sample is cleared.

Auto Validation Example

Auto Validation Setup

- Enable Validation Codes
- Enable Auto Validation Criteria for Action Limits
- Enable Decision rules = Reflex rule is defined as "If Retic % < 0.2 then Make Retic Smear and scan slide."

Sample Setup:

- Test Mode = CBC/Diff
- Patient Sample preassigned with a CBC and Retic Report Profile

Sample Results: (printed and transmitted)

Comments: Make Retic Smear and scan slide

WBC	4.8 10 ³ /L	RBC	2.53 10 ⁶ /L	Plt	80 aL 10 ³ /L
		Hgb	6.3 g/dL	MPV	10.3 fL
		Hct	19.6 %		
		MCV	77.4 fL		
		MCH	24.9 pg		
		MCHC	32.1 g/dL		
		RDW	16.1 %		
		Ret %	%		
		Ret #	/pL		

End of Completed Report, Sample Not Validated, C NV, H AV, W NV

Manual Validation:

Once the results are reviewed and manually validated at the workstation the report appears as follows.

Comments:

WBC	4.8 10 ³ /L	RBC	2.53 10 ⁶ /L	Plt	80 aL 10 ³ /L
		Hgb	6.3 g/dL	MPV	10.3 fL
		Hct	19.6 %		
		MCV	77.4 fL		
		MCH	24.9 pg		
		MCHC	32.1 g/dL		
		RDW	16.1 %		
		Ret %	%		
		Ret #	/pL		

End of Completed Report, Sample Validated, C V, H AV, W V

Sample Setup:

Run the sample in the Retic mode, sample results are as follows.

Comments: Make Retic Smear and scan slide

WBC	4.8 10 ³ /L	RBC	2.53 10 ⁶ /L	Plt	80 aL 10 ³ /L
		Hgb	6.3 g/dL	MPV	10.3 fL
		Hct	19.6 %		
		MCV	77.4 fL		
		MCH	24.9 pg		
		MCHC	32.1 g/dL		
		RDW	16.1 %		
		Ret %	0.14 %		
		Ret #	.0035 /pL		

End of Completed Report, Sample Not Validated, C NV, H AV, W NV, R NV

6.1 POWER ON/OFF OVERVIEW

The LH 700 Series System components (Analyzer and Diluter) obtain power from the Power Supply. The Power Supply and the Workstation are connected to a power source in your laboratory.

For troubleshooting purposes, you may find it useful to power on and off selected pieces of the system. The following sections provide information about the pieces of the system that you can power on/off.

Workstation

You can turn the Workstation monitor off while the instrument cycles samples, if you desire; however, a screen saver is available on your Workstation to extend the life of the monitor. It is unnecessary to power off the monitor or the Workstation on a regular basis.

You should only power down the Workstation after shutting it down. Powering down the Workstation also powers down the monitor.

The Workstation and monitor are connected to an Uninterrupted Power Supply (UPS). In the event of a power outage at your facility, the Workstation and monitor will continue to operate for a short time so you can shut down the Workstation without losing data.

Analyzer/Diluter

Use the following guidelines for shutting down the Analyzer.

Every 24 Hours: Beckman Coulter recommends that you shut down the instrument for at least 30 minutes every 24 hours. If you leave your instrument powered on in Shutdown and the pneumatics are off, an automatic purge occurs every 24 hours to prevent flow cell and sample line clogging.

After performing daily shutdown, perform daily startup procedures when you are ready to use the instrument.

3-7 Days: Beckman Coulter recommends that you perform extended shutdown if you plan to have the instrument non-operational for three to seven days. The extended shutdown procedure removes the reagents from the system and replaces the reagents with deionized or distilled water.

To start up your instrument after an extended shutdown, you must perform a special restart procedure.

7+ Days (Long-Term Shutdown): Beckman Coulter recommends that you call your Beckman Coulter Representative to perform long-term shutdown if you plan to have the instrument non-operational for more than 7 days, or if you plan to put the instrument in storage or ship it from its current location. The long-term shutdown procedure drains all liquid from the Diluter and releases the pinch valve tubing.

You must also call your Beckman Coulter Representative to schedule a time when your Beckman Coulter Representative can start up your instrument.

Power Supply

The Power Supply provides power for the Analyzer and the Diluter. You should only turn off the Power Supply after shutting down the instrument. Flip the main breaker switch on the side panel of the Power Supply to turn it off.

6.2 PERFORMING DAILY SHUTDOWN

- 1. At least once every 24 hours, perform the following procedure:
- 2. Go to the Numeric Keypad.

3. Press SHUT DOWN

4. Log off the Workstation.



5. Let the instrument sit in cleaning agent for at least

Note: Per your system configuration, the cleaning agent is automatically removed from the instrument at the time preset in the Analyzer. This can be set from within 30 minutes to 24 hours. Ask your Beckman Coulter Service Representative if the timing needs to be changed.

Note: A Mini-Prime occurs 30 minutes after Shutdown for LH 700 Series with SlideMaker. After the Mini-Prime, the compressor does not turn off. The operator should perform a Startup if the instrument is intended to remain idle for an extended period of time. The compressor will time-out if the instrument is not cycled for one hour after Startup.

6.3 PERFORMING EXTENDED SHUTDOWN AND RESTART

Shutdown

5.

1. Press SHUT DOWN



- 2. Let the cleaning agent remain in the instrument for at least
- Remove the Retic stain pickup tube from its container, rinse the outside of the pickup tube with deionized water and place the pickup tube in a container of deionized water.
 Note: To prevent any possible contamination with the Retic stain, use a separate container for Step 4.
- 4. Remove the rest of the reagent pickup tubes from their reagent containers and place the pickup tubes in the container of deionized water (to prevent any possible contamination with the stain).

Press START UP

- 6. Use F17 to prime the cleaning agent pump lines with deionized water.
- Use F67 three times to prime all of the reagent lines with deionized water.
 Note: Refill the deionized water containers as needed.

- 8. Press **POWER OFF** to power off the system.
- 9. Shut down the Workstation.

Restart

- 1. Power on the Workstation.
- 2. Place the pickup tubes in an empty container.
- 3. Press **POWER ON** • to power on the instrument.
- 4. Use F17 twice to remove the deionized water from the cleaning agent pump.
- 5. Use F67 four times to remove the deionized water from the Diluter.
- 6. Press SHUT DOWN to remove the deionized water from the cleaning agent lines.
- 7. Place the pickup tubes in their respective reagent containers.
- 8. Press START UP
- 9. Use F17 to prime the cleaning agent pump.
- 10. Check daily startup test results. If the daily startup test has failed, perform the following:
- 11. Use F67 to prime the instrument.
- 12. Press START UP

6.4 SHUTTING DOWN THE WORKSTATION

- 1. Select **I**. The Exit window appears.
- 2. Select Shutdown on the Shutdown Type window.
- 3. Select Select
- 4. To restart the Workstation immediately, select Restart. To power down the Workstation, press the Workstation power button.

Note: You should power down only if you have tried to restart the Workstation and you are still experiencing problems after restart.

6.5 RESETTING THE WORKSTATION

Use any of the following methods to reset the Workstation. If these methods fail to work, power down the Workstation and power it back up after approximately 5 minutes.

Using the Command Center

- 1. Select **P**. The Exit window appears.
- 2. Select Shutdown.
- 3. Select Select
- 4. Perform one of the following:

If You Want To	Do This
Restart the Workstation immediately	Select Restart.
Shut down the Workstation	Press the Workstation power button.

Note: You should power down only when you have tried to restart the Workstation and you still experience problems.

Using the Keyboard

- 1. Press Ctrl + Alt + Del . The Windows[®] 2000 Security window appears.
- 2. Select Shutdown... to shut down the Workstation.
- 3. Select Shutdown and Restart.
- 4. Select **OK**. The Workstation logs you off, saves all active data and closes all applications. Several messages appear, such as the Shutdown in Progress window. When the Workstation finishes closing all applications, it restarts the Workstation.
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7.1 DATABASE & ToDo WINDOW

This window enables you to see sample information stored in the database. The tree list on the left side of the window provides an organized view of the database. The DataBase & ToDo list in the upper right portion of the window displays specific records in the database. The lower right portion of the window displays demographic or results information.

You can change the size of the three areas of this window by dragging the divider bars that separate the three areas. You can change the size of columns by dragging the border of the column heading. Each time you shut down and restart your Workstation, the sizes return to the system-defined size.

Columns You May Not Understand

The Report column displays the following codes:

This Code	Means The Sample Has Been
А	Archived
D	Delta Check Rule applied
Н	Received (sample request) from an information system
Р	Printed
R	Reflex Manager Rule applied
S	Protected from DataBase overwrite. Stored permanently for later retrieval
Т	Transmitted to an information system
V	Validated by the operator.

Finding and Sorting

You can use the tree list to locate and sort the information displayed on this window. You can

also use 🎽 to find information.

Double-click the heading of a column to sort the samples or sample requests by that column. For example, double-click Free to sort by patient ID. * appears next to the heading.

Selecting

Select This	То
+	Expand the list of test groups.
-	Collapse the list of test groups.
*	Select all the items in the selected folder.



Deselect all items in the selected folder.

¥

Increment Slides Made column for the selected results.

Transmitting, Printing and Archiving

Similar to the Results & Graphics window, standard buttons appear at the top and side of this window. After selecting records, select a button to perform the action associated with the

button. For example, select a group of sample results and then select *to* print the sample results.

Some of the buttons require you to perform actions on one sample result or pending sample at a time.

Other Actions

Select 🚔 Slide List in the Database & ToDo completed window.

Select sample results in the list on the right side of the window that show slides requested but no slides made.

Select Select to increment the Slides Made column and remove the sample from the ToDo slide list. The Slides Made field in the Completed list will be incremented from 0 to 1.

7.2 COMMON FUNCTIONS (OVERVIEW)

Your LH 700 Series System provides several common functions that work using the same method—select the items you want, then select the function you want applied to the items.

You can set up default settings for most of the common functions to ensure the Workstation handles your data in the same way each time you use the functions. Of course, the flexibility exists to change the settings for the function. For example, you can quickly change the printer to which you print items.

Transmitting Results

You can transmit **state** results automatically or manually to your information system.

Printing Reports

Printing is an important part of working with sample results and controls. Your system automates a lot of printing you do by enabling you to specify which results you want automatically printed.

As part of setup, you can also specify reporting options.

Archiving Data

If you need to be able to retrieve sample results for samples run several months ago, use the

archive function 🗐

Archiving data allows you to copy data (patient demographics, results, and flags) to removable media in a spreadsheet format.

You can later retrieve the data using a spreadsheet application on another (non-LH Workstation) computer.

Deleting Data

When you no longer need to maintain results information, you can delete *iii* it. This saves room on the Workstation, and it may enable you to find results in the DataBase faster.

Deleting Patient Data

- 1. Select the items you want to delete.
 - If you are currently viewing the Results & Graphics window, only the current results can be deleted.
 - If you are currently viewing the DataBase & ToDo window, you can select several samples that appear in the list and delete them as a batch.
- 2. Select it display the Patient Data DELETION REQUESTED window.
- 3. Select ¹²¹ to delete the data. A message that asks you to confirm your request appears.
- 4. Select it delete the data. The Workstation deletes the selected data. The data cannot be retrieved.

Deleting Sample Information

- 1. Find the Sample you want to delete.
- 2. If you are working with the DataBase & ToDo window, ensure the sample is selected. Otherwise, proceed to step 3.
- 3. If the sample is marked as saved, select 💷 to unmark it. The button changes to 🖬 to indicate that the sample results will no longer be saved.
- 4. Select is to display the Patient Data DELETION REQUESTED window.
- 5. Check the number of samples you want to delete.
- 6. Select A confirmation window appears.

7. Select it confirm your deletion. The Workstation deletes the sample information and returns to the previous window.

Printing

- 1. Select the items you want to print.
 - If you are currently viewing the Results & Graphics window, only the current results can be printed.
 - If you are currently viewing the DataBase & ToDo window, you can select several items that appear in the list and print them as a batch.
- 2. Select 💜 to display the Output Selection window.
- 3. Verify that the Output Selection window identifies the items you want to print.
- 4. Select items to print the items. The Workstation sends the selected items to the default printer based on the settings you verified.

Printing Help Topics

To print a Help topic you are currently viewing select Erint

To print a popup Help window, use your right mouse button to click inside the popup window, and then select Print Topic.

Note: Reference Information, Cleaning Procedure, and Replacing Procedure Help Topics that display full screen should be printed using Landscape Orientation.

What Prints When You Select

Run Configuration Application

Prints the information on the Run Configuration window.

7

Patient Application

For This Window	Workstation Prints
Results & Graphics	Sample data based on the parameters specified for inclusion and reporting options defined for the sample.
DataBase & ToDo	Sample data based on the parameters specified for inclusion and reporting options defined for the sample.
Edit Sample	All information displayed on the current window.
Quality Assurance Application	
For This Window	Workstation Prints
Controls	Control information based on your output selection criteria.
Information Calibration Setup	Calibration details for the selected lot number.
All other windows	Information displayed on the current window.
Setup Application	
For This Window	Workstation Prints
System Setup	All setup configuration information.
QA Controls Tab	Control information for the selected controls.
Flagging Limits	Flagging limit information for the selected limit name.
Reporting Options	Reporting options for the selected report.
All other windows	Information displayed on the current window.

History Log Application

Prints the information in the selected log.

Status Application

Prints the information on the Status window.

Color Printouts

Color printouts may not exactly match Workstation screen colors. This a function of how Windows' 2000 supports peripherals such as printers. If the 'normal' colors printed make interpretation difficult, you may be able to perform Halftone Color Adjustment for your printer. You can determine if your printer supports halftone color adjustment by following these steps:

- 1. Press Ctrl + Esc to display the Windows 2000 taskbar.
- 2. Select Settings ► Printers.
- 3. Select the Icon for your color printer.
- 4. Select File ► Properties.
- 5. Select the Device Settings tab and verify the color adjustments, such as Halftone Setup. The available options on the properties screen depend on your printer model, but most

adjustments will be located on the Device Settings tab. Refer to your printer manual for specific instructions.

You may need to experiment with different halftone settings to get the printout to more closely match the colors displayed on the Workstation.

Archiving

Note: Use this procedure to archive to a 3.5 inch diskette or other removable media such as a flash drive (if a USB port is available on your computer). If you wish to archive to a CD, go to Format a CD and Archiving to a CD.

- 1. Select the items you want to archive.
- 2. Select 🗐. An Archive Selection window appears.
- 3. Specify the archive options.
- 4. A window appears with the message "Please insert a disk into drive A:" (the default drive is A). If you are using a 3.5 inch disk, insert it and proceed to step 5. If you are archiving to other removable media or the hard drive, select [CANCEL].
- 5. The SAVE AS window appears. If you are archiving to A, that drive will be active. Otherwise, specify the drive where you want to archive the information.
- 6. Check the filename for the archive file. A default name is suggested, but can be changed as desired.
- 7. Select **OK** to archive the selected items. The Workstation copies the items to the selected location and marks the items in the database as archived. The archived items will remain in the database until deleted.

Formatting a CD for Direct Archiving

Before you begin to archive data, you must format your CD. You can format and label several CDs so that you always have one available. Be sure to store them carefully.

- 1. Place a blank CD in the CD writer drive.
- 2. From the workstation desktop (Beckman Coulter main screen), double click on the "Burn CD and DVDs" icon. The Easy Creator 5 screen appears.

Note: If a dialogue box to register the software appears, just close or select "Remind me later".

- 3. Select "Make a data CD" and then select the Direct CD option.
- 4. Select Format CD. You may name your volume or leave it at the default name "Volume1".
- 5. Select Start Format. This will take about one minute. Wait for the "CD Ready" window to appear and select OK.
- 6. Close the Easy CD Program.

You now have a formatted CD to use directly for archiving purposes. Proceed to Archiving to a CD.

Archiving to a CD

Note: Be sure you have a formatted CD before you begin.

- 1. Go to your Archive screen for Patient Records or Control Records.
 - a. Select 🗐 from the toolbar.
 - b. Choose one of the following three options:
 - All Patient (or Control) Records
 - All Unarchived Patient (or Control) Records
 - Selected Patient (or Control) Records
 - c. If you choose the first or second option, Select *and skip to Step 2*.
 - d. If you choose the last option, select
 - e. Go to the completed Database or Control list to select the records.
 - f. Select 🗐
 - g. Select
 Selected Patient (or Control) Records.
 - Select 🥝

h.

- 2. When the "Insert disk in drive "A" window appears, select Cancel.
- 3. When the "Save as" window appears, double click on My Computer.
- 4. Select the drive for the CD writer (usually H, but may be another letter). Select Open and then select Save.
- 5. Wait until the "Archive Complete" window appears, click OK.
- 6. Press the eject button on the CD drive, an "Eject CD" window will appear. Select "Close to Read on any computer". You may select the checkbox to "Protect" (If you do not want to add data at another time) or leave the checkbox blank (if you want to append data later).
- 7. Select OK. The CD will eject automatically. Select OK again.
- 8. In the future, you may repeat these steps to add more data to the same CD, if you did not write protect it.

Reviewing Archived Information

- 1. Start your spreadsheet program, such as Microsoft Excel.
- 2. Open the archive file. Refer to the product information for the spreadsheet program for details about performing this step.

Understanding the Information

The archived information appears in a tabular format. Each column contains a label, but some columns may appear condensed. This may make it difficult to read the labels. To view the label, you must widen the columns. Refer to the product information for the spreadsheet program for details about widening the columns.

The archived information appears with the same flags and codes that appear on the LH Workstation.

Transmitting

- 1. Select the items you want to transmit to your information system. If you are currently viewing the Results & Graphics window, only the current results can be transmitted. If you are currently viewing the DataBase & ToDo window, you can select several items that appear in the list and transmit them as a batch.
- 2. Select ST to display the Output Selection window.
- 3. Verify that the Output Selection window identifies all the items you want to transmit.
- 4. Select to transmit the items. The Workstation sends the selected items to your information system. The items are sent based on the options set up for communicating with your information system.

Transmitting Control Records

- 1. Select **s** to display the Control Data Transmit Selection window.
- 2. Select to transmit Selected Control Records Only or All Control Records for Selected Lot.
- 3. Select it to transmit the items. The Workstation sends the selected items to your information system. The items are sent based on the options set up for communicating with your information system.

Menu Access: File ► Transmit Result(s)

7.3 SAVING SAMPLE RESULTS

- 1. Select 🛤 on the Command Center to display the Patient Tests application.
- 2. Find the sample you want to save.
- 3. Select the sample on the DataBase & ToDo window, or display it in on the Results & Graphics window.
- 4. Select let to mark the sample results so they are saved in the database. As the Workstation processes new samples, the new samples will not overwrite the saved

samples. The button changes to sample results are saved until you unmark them. To unmark the sample results, you must

select the sample again and then select

7.4 ADDING A SAMPLE REQUEST TO THE TODO LIST

- 1. Select ២ on the Command Center to display the Patient Tests application.
- 2. Select ¹. The Add Test window appears with blank fields.
- 3. If you want to add a test or sample request:
 - a. Select the specific test identifiers you want to add.
 - b. Provide the sample identification information for the tests. Use to move between fields.
 - c. Specify the demographic information.

Note: Duplicate Sample IDs or Cass/Pos are allowed for the same Patient ID only if the Test Type is different. If the same test type is specified for a Sample ID, the following message will display:

Duplicate Sample ID entry. Sample IDs must be unique within the ToDo list. Original value will be restored.

Blank Patient IDs are considered to be the same Patient ID.

IMPORTANT Risk of incorrect identification. Before saving identification information, check that you typed the information properly.

4. Select 🛤 to save the test information and clear the fields on the window so you can add another test.

Adding a Test to an Existing Set of Sample Results

- 1. Select ២ on the Command Center to display the Patient Tests application.
- 2. Find the results to which you want to add a test.
- 3. Select $\overset{\checkmark}{4}$ from the specific (right side) toolbar. The Edit Sample window appears.
- 4. Select the specific test identifiers you want to add or remove.
- 5. Provide the sample identification information for the tests. Use the tab key to navigate between fields.

Note: Duplicate Sample IDs or Cass/Pos are allowed for the same Patient ID only if the Test Type is different. If the same test type is specified for a Sample ID, the following message will display:

Duplicate Sample ID entry. Sample IDs must be unique within the ToDo list. Original value will be restored.

Blank Patient IDs are considered to be the same Patient ID.

IMPORTANT Risk of incorrect identification. Before saving identification information, check that you typed the information properly.

6. Select **I** to save the test information.

Reports with Pending status include a special message indicating the status. When all tests complete processing, the report includes a special message that indicates the change in status.

7.5 DATABASE OVERVIEW

When the Workstation first receives sample information, the Workstation stores the data in a series of files and the DataBase. The series of files is called list mode data. The Workstation uses list mode data to display the 3D DataPlot. The DataBase stores demographic, numeric and 2D DataPlot information.

The LH 700 Series System stores data in a DataBase on the Workstation. This data includes all the numeric and graphic information from:

- Patient sample analysis
- Quality control analysis
- Event logging.

The Workstation windows provide methods for accessing the DataBase.

The Workstation has no practical storage limit for control runs. However, the Workstation will perform better if you delete unused control folders.

How Overwriting and DataBase Storage Work for Sample Results

Initially, the Workstation stores 2,000 sample results. As part of setup, your laboratory administrator can change the limit of sample data that the DataBase stores. The valid range is 1,000 - 20,000.

When the Workstation receives sample results, the Workstation stores the results. When the Workstation reaches its storage limit, it deletes the oldest data. This effect of deleting the oldest data is known as "wrap-around."

Collated results remain in the DataBase based on the time the last sample results were collated (not the time the DataBase received the first results).

DataBase Storage Limits and Saving Results

The Workstation uses the DataBase storage limits to determine how many results the DataBase stores before overwriting the oldest, non-saved results with new results. The Workstation also uses the limits to determine the maximum number of saved results that can be maintained for educational purposes. The Workstation can maintain up to 15% of the numeric (only) data as saved results.

7.6 TODO LIST OVERVIEW

The Workstation provides a ToDo list feature. This feature allows you to work with a list of samples the instrument has not yet processed. You can view a list of all the unprocessed samples or a list of unprocessed samples for a particular mode of operation. You can sort these lists by any column you choose.

Samples appear in the ToDo list when:

- You download information from your information system and the instrument has not yet processed them.
- You generate the list manually because you have no information system and you want to store identification data for your samples in the ToDo list.
- You add a test to an existing sample result. This comes in handy if a physician orders a second test or if you forget to add a test.

To add a sample to the ToDo list, the sample must include:

• At least one positive identifier

Examples: Cassette position

Sample ID

• The specific tests you want to run

Examples: CBC/Diff

CBC only

CBC/Diff/Retic

Retic only

You can also provide further identification information, such as the patient's name, birth date and gender. You can even provide information defined by your laboratory, such as special identification codes and comments. If the Workstation recognizes the patient ID, it automatically fills in all known identification information.

To reduce the amount of typing when you add to the ToDo list, the Workstation provides AutoSequencing for several fields. You can set up which fields you want automatically sequenced and provide default values for them. You can also change these values individually.

The Collate ToDo List option performs the following functions:

- If a sample request is sent from the host that includes two runs (e.g., CD, R), the order is stored as a single CDR run.
- If a sample request is sent from the host that matches an existing pending order on all three IDs (patient, cass/pos, sample) and is a superset of that order's test types, the orders will be combined. For example, if a CD was previously ordered and a CR or CDR order is received, the orders will be combined into a single CDR. If there is nothing to add (e.g., a second CD order is received), a separate order will be created.

Note: Matching includes NULL fields, such as two orders with empty Patient IDs.

The Automatic To Do List Deletion function allows you to determine how long entries remain on the ToDo list. The user-specified timeframe deletes ToDo list entries older than 'x' hours (range = 00 to 720 hours).

Setting Up AutoSequencing

- 1. Select 🗀 on the Command Center to display the Patient Tests application.
- 2. Select $\stackrel{\text{left}}{=}$ to add a sample request to the ToDo list.

- 3. Select **b** to display the AutoSequencing window.
- 4. Select the level at which you want to control AutoSequencing.
- 5. At the patient and test levels, for each identifier you want AutoSequenced:
 - a. Select the identifier—
 - Patient ID
 - Seq #
 - Sample ID
 - Cass/Pos

b. Type the AutoSequence starting number. Use

to move between fields.

6. Select 22 to save the sequence starting numbers. The next time the Workstation requires a sequence number, it uses the numbers you saved.

Tab

7.7 RANDOM ACCESS OVERVIEW

The Random Access function allows dynamic determination of the test mode for processing samples. When Random Access is enabled, the Analyzer requests the test mode from the Workstation whenever a new tube ID is read by the Analyzer. The system performs the following to determine the test mode.

- The Analyzer sends the bar-code information and cass/pos to the Workstation.
- If the Process Type is set to Auto Analysis or Control, and the Sample ID matches a control lot number, the test type of the control is used.
- If the Process Type is not set to Auto Analysis or Control, the Default Type test mode is used.
- The Workstation searches the database for a pre-assigned sample that matches the sample ID or cass./pos or both, as determined by your positive identifier.
 - If no match is found, the Default Type test mode is used.
 - If a single match is found, the test type pre-assigned to the matching sample is used.
 - If more than one match is found, the test type pre-assigned to the first matching sample is used.

Note: Multiple aspirations per tube will interfere with Random Access sample processing. Ensure ASPIRATIONS/TUBE on the Analyzer Screen is set to 01.

Random Access

Random Access on the Command Center indicates specimens can be randomly loaded for processing. The system determines, via the specimen's unique identifier on a specimen-by-specimen basis, what test mode will be utilized. If Random Access is enabled the system checks the ToDo list and control lots to determine the test mode and then performs the test(s). See Random Access Overview for additional information.

If Random Access is not enabled, the Default Type will be used as the test mode.

If your samples have not been preassigned, check that the Default Type is set to the correct operating mode. The Default Type will determine the test mode if a positive identifier is not available.

Note: Multiple aspirations per tube will interfere with Random Access sample processing. Ensure ASPIRATIONS/TUBE on the Analyzer Screen is set to 01.

7.8 COLLATION OVERVIEW

Collation is the process of linking results obtained on the LH 700 Series in one test mode, for example CBC/Diff, with results from another test mode, for example Retic. The two sets of results get linked together in the DataBase. You can then review, print, transmit or archive the collated results using the Workstation.

How Collation Works

The Workstation collates results based on your input before running the samples.

The Workstation can collate results automatically. When you turn on the AutoCollation option on the Run Configuration window, the Workstation automatically collates results when it finds a match of the sample ID within the AutoCollation time interval you specify.

If you add sample information on the Add window that includes more than one positive identifier and more than one test, the Workstation recognizes that you want the results collated. If you do not want to collate the information, you must add each positive identifier and test on a new Add window.

The Workstation also allows you to collate results after running the samples. If you turn off the AutoCollation option and find results from two tests that you want to collate, you can edit one of the sets of results and manually add the results from the additional test.

The Workstation produces separate test results (not collated), if any of the following conditions occur while analyzing samples:

- Partial Aspiration
- NO Read
- NO Match
- Subsequent test is run after the AutoCollation time interval on the Run Configuration window has expired
- Body Fluids

If the Workstation collates two or more sets of results, parameter calculations are performed based on the appropriate test mode (examples: RET# is calculated from RET% of Retic analysis; RBC is derived from the CBC analysis).

Printing Collated Reports

Reports with Pending status include a special message indicating the status. When all tests complete processing, the report includes a special message that indicates the change in status.

7.9 SEARCHING FOR RESULTS OVERVIEW

Searching

All text fields in Database Explorer include From and To fields. To retrieve all Patients IDs beginning with '123', specify '123' in the From field, and '1239999' in the To field. Results of a Search

Results of a Search

Select **Final Explorer** on the DataBase & ToDo window to display the sample identification information the Workstation found the last time you used the DataBase Explorer window.

The Workstation keeps this information to make it easy for you to access information you need on a recurring basis.

Search Criteria

If you need to search for particular types of results on an ongoing basis, save a Search Criteria.

A Search Criteria is a group of attributes you specify on the DataBase Explorer window. The attributes indicate what you want the Workstation to use when searching for results. For example, if you want to find all the results with Critical limits, you would select Specific Flags and Critical limits. Specific Flags and Critical limits are attributes of the Search Criteria.

You can save the Search Criteria and retrieve it later. This keeps you from having to set up search criteria each time you want to look for sample results. It also reduces the chance for error in specifying your search criteria. You can now quickly and easily devise complex searches of the DataBase.

7.10 FINDING SAMPLE RESULTS USING THE DATABASE EXPLORER BUTTON

- 1. Select ២ on the Command Center to display the Patient Tests application.
- 2. Select ¹¹ to display the DataBase Explorer window.
- 3. If you want to use an existing search criteria:
 - a. Select the previously saved search criteria name.
 - b. Select 🚰 to load the search criteria.
- 4. Provide (or check) any or all of the following:
 - Date
 - Time
 - Cass/Pos
 - Patient ID

- Sample ID
- Flag Selection
- Specific Flag Selection
- 5. If you want to save the search criteria to use again later, type a criteria name and select
- 6. Select **W** to begin the search.
 - The list of matches is sorted by numeric characters followed by alphabetic characters.
 - If the Workstation finds one or more matches, the DataBase & ToDo window highlights the appropriate graphic(I and Explorer) and displays a list of the matches.

Using a Search Criteria Name

- 1. If necessary, select ²⁹⁹ to display the DataBase Explorer window.
- 2. Select I next to the Load Saved Criteria field to see a list of available search criteria names.
- 3. Select the search criteria name you want.
- 4. Select $\stackrel{\frown}{=}$ to load the search criteria.
- 5. Select **W** to begin the search.

Saving Search Criteria

- 1. If necessary, select ^M to display the DataBase Explorer window.
- 2. Provide (or check) any or all of the following:
 - By Date
 - By Time
 - By Cass/Pos
 - By Patient ID
 - By Sample ID
 - Flag Selection
 - Specific Flag Selection
- 3. Select ⊟.
- 4. Type the search criteria name you want to use.
- 5. Select is to save the search criteria name.

7.11 VIEWING DATABASE COUNT INFORMATION

- 1. Select in the Command Center to access the Status application.
- 2. Select information.
- 3. The system displays the number of completed records and the number of ToDo records in each database folder.
- 4. Select P to close the window.

8.1 SYSTEM SETUP OVERVIEW

Your COULTER LH 700 Series System provides a lot of flexibility in setup. You can tailor the way your system appears and runs to suit your laboratory's needs. Select a button on the System Setup window to access different setup options you can set to control the processing

on your Workstation. Select 💉 to temporarily override setup options.

Some buttons on the System Setup window may appear gray and inactive depending on the security level of the user name currently logged on. If you need to access an inactive function, contact your laboratory administrator.



To Set Up



General settings, such as display labels, parameters, reporting units and reports.



Quality Assurance options, such as reagent log, setting up new control lots, control values and lab limits.



Methods, such as flagging limits and decision rules, for handling results



A list of valid locations associated with samples.



A list of valid physicians associated with samples.



Address and phone number for your institution for reporting purposes.



Communications with information systems and knowledge-based systems.



SlideMaker and SlideStainer settings.



Your password.



Limits for data storage in the DataBase.



Workstation user names.



Windows 2000 Control Panel settings.

8.2 CHANGING REAGENT INFORMATION

IMPORTANT Misleading results can occur if a diluent is used with the incorrect diff lytic reagent. Use only LH Series Diluent with LYSE S III diff lytic reagent. Use only Isoton 4 Diluent with LYSE S 4 diff lytic reagent.

- 1. If the Quality Assurance Setup window, Reagent Tab is not already visible:
 - a. Select 🎴 on the Command Center to display the System Setup window.
 - b. Select Quality Assurance Setup window.
 - c. Select Reagent to display the reagent information for each reagent set up on the instrument.
- 2. Select Reagent Setup to set up or modify existing reagents. The Reagent Setup window appears.
- 3. Enter the reagent information by using the handheld barcode scanner or manual entry of the barcode.

Tab

Note: Press to move between fields for manual entry.

#1
#1
#V
×

- 4. Select **W** to save and exit the Reagent Setup window.
- 5. Select:



To save the changes. The Workstation stores the changes and updates the date last modified and the user name. The Workstation also updates the Reagents history log.

Another tab To change additional Quality Assurance Setup information. The Workstation asks you if you want to save the changes you made to the

current information. Select **Mess** to proceed.



Press **CONT** on the Numeric Keypad to continue cycling samples.

8.3 SETTING UP CONTROLS

6.

Note: To perform this task, you must log on with a user name that was set up as an Advanced Operator or a Lab Administrator. If you need to access this function, contact your laboratory administrator.

- 1. Select 🔎 on the Command Center to display the System Setup window.
- 2. Select Quality Assurance Ito display the Quality Assurance Setup window.
- 3. Select Control information already set up for your instrument.
- 4. Select ¹. The Setup New Controls Folder window appears.
- 5. Select the source of the control materials.
- 6. Select the type of control.
- 7. Select the level of the control you want to set up.
- 8. Select specify the reference values and ranges for the control. The window you see varies depending on the source and type of control you selected.
- 9. Perform one of the following depending on the source and type of control:

This Control	Do This
Beckman Coulter (non-latex)	Follow the instructions on the Removable Media Entry of Lot Specific Information window.
Other (non-latex)	Specify non-latex reference values.
Latex	Specify latex reference values.

10. If desired, select $\stackrel{\text{desired}}{=}$ to set up lab limits for the control.

11. Select

To return to the System Setup window.

Another tab

r tab To change additional Quality Assurance Setup information. The Workstation asks you if you want to save the changes you made to the

current information. Select **mess** to proceed.

12. If you want to stop the processing of samples automatically based on Controls, specify the AutoStop details.

Removable Media Entry Window

The control selected on the Controls Setup window ships with download instructions from the web for the assigned values and expected ranges.

- 1. Ensure your removable media type is in the appropriate drive.
- 2. Verify the automatic options:

Note: If using the Auto-Stop or Auto-Transmit, ensure the settings are enabled in Control Setup after scanning the assay sheets.

- Auto Transmit indicates that you want the results for control runs automatically transmitted to your information system. Deselect this field to ensure the results are not automatically transmitted.
- Auto Stop indicates that you want the Analyzer to stop when it encounters a control value that is outside the expected range. Deselect this field to ensure the Analyzer continues processing when it encounters a control value that is outside the expected range.
- 3. Select is to load the assigned values and ranges that exist on the removable media and set the automatic options. The Workstation returns to the Setup New Control folder window.
- 4. Select Select Select Select Select I a problem exists with your removable media, the Workstations displays a message that asks you if you want to provide the values manually. You can provide the values from the assay sheet using the keyboard.

Specifying Latex Reference Values

Note: Before performing this procedure, you must perform steps 1 through 8 of Setting Up Controls.

1. Specify whether or not you want results automatically transmitted to your information system.

Tab

2. Type the lot number of the latex control and press

- Tab
- 3. Type the expiration date of the control and press
- 4. Specify whether you want to use this lot number as a default.
- 5. Type the values in the appropriate fields:
 - Diff Mode Parameters
 - Retic Mode Parameters
- 6. Select



To save the reference values and return to the Setup New Control Folder window.

To return to the Setup New Control Folder window without saving changes.

Specifying Reference Values

Note: Before performing this procedure, you must perform steps 1 through 8 of Setting Up Controls.

- 1. Specify whether or not you want results automatically transmitted to your information system.
- 2. Specify whether or not you want results to automatically stop the instrument's processing.
- 3. Type the lot number for the control and press



- 4. Type the expiration date for the control and press
- 5. Specify whether you want to use this lot number as a default.
- 6. Type the values in the appropriate fields:
 - Assigned Values
 - Expected Range
- 7. Select



To save the reference values and return to the Setup New Control Folder window.



To return to the Setup New Control Folder window without saving changes.

Deleting Control Setup Information

Note: To perform this task, you must log on with a user name that was set up as an Advanced Operator or a Lab Administrator. If you need to access this function, contact your laboratory administrator.

1. Select 🤷 on the Command Center to display the System Setup application.

- 2. Select Quality Assurance Setup window appears.
- 3. Select Controls to display the Controls window.
- 4. Select the control setup information you want to delete in the Existing Controls table.
- 5. Select information.
- 6. Verify the information you want to delete and select ^[22]. The Workstation deletes all the control setup information, including lab limits.
- 7. Select 🥙 to return to the System Setup window.

Editing Control Setup Information

Note: To perform this task, you must log on with a user name that was set up as an Advanced Operator or a Lab Administrator. If you need to access this function, contact your laboratory administrator.

1. Select ² on the Command Center to display the System Setup window.



- Select Quality Assurance to display the Quality Assurance Setup window.
- 3. Select Controls to display the control information already set up for your instrument.
- 4. Select the existing control you want to edit.
- 5. Select

2.

This

To Edit This Reference values

<u>~</u>~

Lab limits

- 6. Edit the values as needed.
- 7. Select 2 to save the reference values and return to the list of existing controls set up for your laboratory.
- 8. Select 🥙 to return to the System Setup window.

Setting Up Lab Limits for Controls

Note: To perform this task, you must log on with a user name that was set up as an Advanced Operator or a Lab Administrator. If you need to access this function, contact your laboratory administrator.

1. Select 🤷 on the Command Center to display the System Setup window.

- 2. Select Quality Assurance to display the Quality Assurance Setup window.
- 3. If available, select a control folder with the source, type, and level of the lab limits you want to set up, otherwise, you must set up a control.
- 4. Select 🖾 to display Lab Limits Setup window.
- 5. Type your laboratory's limit value for each parameter.

6. Use to move between fields.

7. Select



To save the lab limits and return to the existing controls list.



To return to the previous window without saving changes.

8. If you returned to the existing controls list, select:



To return to the System Setup window.

Another tab To change additional Quality Assurance Setup information. The Workstation asks you if you want to save the changes you made to the

current information. Select **to** proceed.

8.4 ENABLING EXTENDED QC

Note: To perform this task, you must log on with a user name that was set up as a Lab Administrator. If you need to access this function, contact your laboratory administrator.

- 1. Select $\stackrel{\frown}{\simeq}$ on the Command Center to display the System Setup window.
- 2. Select Quality Accurance to display the Quality Assurance Setup window.
- 3. Select Controls
- 4. Select to display the Extended QC Settings window.
- 5. Enable Extended QC.
- 6. Select loss to save the changes.When you enable Extended QC rules for a control file:

- An Extended QC Summary Report is available at user's request.
- A Single Run Control Printout, including Extended QC limits, total differences and an indicator of whether the run is out of range, is available at user's request, or autoprinted if configured to do so.

8.5 SETTING UP XB ANALYSIS

Note: To perform this task, you must log on with a user name that was set up as an Advanced Operator or a Lab Administrator. If you need to access this function, contact your laboratory administrator.

1. Select $\stackrel{\frown}{\frown}$ on the Command Center to display the System Setup window.



- 3. Select select to display the XB setup information for the instrument.
- 4. If you want XB Analysis information to print automatically, specify the auto-print details.
- 5. Specify the Log/AutoStop details.
- 6. Type the target and limit values for each parameter. Use **based** to move between fields.
- 7. Select:



To save the changes. The Workstation stores the changes and updates the date last modified and the user name. The changes to XB Analysis take effect with the next batch you process.

Tab

Another tab To change additional Quality Assurance Setup information. The Workstation asks you if you want to save the changes you made to the

current information. Select **Mess** to proceed.

8.6 SETTING UP XM ANALYSIS

Note: To perform this task, you must log on with a user name that was set up as an Advanced Operator or a Lab Administrator. If you need to access this function, contact your laboratory administrator.

1. Select $\stackrel{\frown}{\simeq}$ on the Command Center to display the System Setup window.

2. Select Quality Accurance to display the Quality Assurance Setup window.

- 3. Select to display the XM setup information for the instrument.
- 4. If you want XM Analysis information to print automatically, specify the auto-print details.
- 5. Specify the Log/AutoStop details.

۲

- 6. Enter the batch size, for the CBC, Diff, Retic, and Retic Calc Parameters. You can enter an integer between 2 and 1000.
- 7. Select Configure Targets and Limits... to display the Targets and Limits for CBC, Diff, and Retic parameters.
- 8. Select the **CBC Diff Retic** tabs to display target and limit values for each parameter.

Use to move between fields.

9. Select 22 to save the changes. The Workstation stores the changes and updates the date last modified and the user name. The changes to XM Analysis take effect with the next batch you process.

8.7 SETTING UP SHIFTS FOR CONTROLS

Note: To perform this task, you must log on with a user name that was set up as an Advanced Operator or a Lab Administrator. If you need to access this function, contact your laboratory administrator.

- 1. Select 🎴 on the Command Center to display the System Setup window.
- 2. Select using to display the Quality Assurance Setup window.
- 3. Select shifts to display the shift setup information for the instrument.
- 4. Select Multiple Shifts. The three sets of shift fields become active.
- 5. Type the start times for each shift. The Workstation automatically changes the end times for you.

Press Tab

- to move from field to field.
- 7. Select:

6.



To save the changes. The Workstation stores the changes and updates the date last modified and the user name. When you review workload reports, the information now appears based on the shifts you specified.

Another tab To change additional Quality Assurance Setup information. The Workstation asks you if you want to save the changes you made to the

current information. Select to proceed.

8.8 SETTING UP DISPLAY LABELS FOR REPORTING

Note: To perform this task, you must log on with a user name that was set up as a Lab Administrator. If you need to access this function, contact your laboratory administrator.

1. Select $\stackrel{\frown}{\frown}$ on the Command Center to display the System Setup window.

- 2. Select to display the General Settings window.
- 3. Select Display Labels to display the Display Labels that currently appear on reports and Workstation windows.
- 4. Verify that the appropriate positive identifier for your laboratory appears selected.
- 5. For each identifier, type the label you would like to appear, next to the data associated with the field, when it appears on your Workstation or on a report.
- 6. Select:



To save the changes. The Workstation stores the changes and updates the date last modified and the user name. The Workstation windows update immediately. The next report that prints contains the new labels you provided.

Another tab

To change additional Patient Setup information. The Workstation asks you if you want to save the changes you made to the current

information. Select **Mes** to proceed.

8.9 SETTING UP A POSITIVE IDENTIFIER

Note: To perform this task, you must log on with a user name that was set up as a Lab Administrator. If you need to access this function, contact your laboratory administrator.

1. Select ² on the Command Center to display the System Setup window.



- Select General Settings to display the General Settings window.
- 3. Select Display Labels information.
- 4. Select the positive identifier for your laboratory.
- 5. If you would like to change display labels for each identifier, type the label you want to display next to the data associated with the field when it appears on your Workstation or on a report.
- 6. Select:

2.

```
\oslash
```

To save the changes. The Workstation stores the changes and updates the date last modified and the user name. The next sample cycled will use the positive identifier you specified.

Another tab To change additional Patient Setup information. The Workstation asks you if you want to save the changes you made to the current

information. Select **Test** to proceed.

8.10 SETTING UP AUTOSEQUENCING

1. Select ២ on the Command Center to display the Patient Tests application.

- 2. Select \bowtie to add a sample request to the ToDo list.
- 3. Select 👛 to display the AutoSequencing window.
- 4. Select the level at which you want to control AutoSequencing.
- 5. At the patient and test levels, for each identifier you want AutoSequenced:
 - a. Select the identifier—
 - Patient Sequence Number
 - Patient ID
 - Sample ID
 - Cass/Pos

b. Type the AutoSequence starting number. Use **to move between fields**.

Tab

6. Select we to save the sequence starting numbers. The next time the Workstation requires a sequence number, it uses the numbers you saved.

8.11 SPECIFYING THE PARAMETERS YOU WANT TO REPORT

Note: To perform this task, you must log on with a user name that was set up as a Lab Administrator. If you need to access this function, contact your laboratory administrator.

1. Select 읻 on the Command Center to display the System Setup window.



General Settings to display the General Settings window.

- 3. Select Parameters to display the parameters available on the LH 700 Series System.
- 4. If you want to include research parameters on Workstation windows, select . This button invokes a certification process.
- 5. Specify each parameter you want to appear on reports.
- 6. Select:

2.



Select

To save the changes. The Workstation stores the changes and updates the date last modified and the user name. The Workstation windows, such as the Results & Graphics window, update immediately. The next report that prints contains the parameters you specified.

Another tab To change additional Patient Setup information. The Workstation asks you if you want to save the changes you made to the current

information. Select **Mes** to proceed.

Including Research Parameters

Note: To perform this task, you must log on with a user name that was set up as a Lab Administrator. If you need to access this function, contact your laboratory administrator.

- 1. Select 🎐 on the Command Center to display the System Setup window.
- 2. Select General Settings to display the General Settings window.
- 3. Select Parameters to display the parameters available on the LH 700 Series System.
- 4. Select **invoke** a certification process.
- 5. Specify each parameter you want to appear on reports.
- 6. Select:



To save the changes. The Workstation stores the changes and updates the date last modified and the user name. The Workstation windows update immediately. The next report that prints contains the parameters you specified.

Another tab To change additional Patient Setup information. The Workstation asks you if you want to save the changes you made to the current

information. Select **Wes** to proceed.

Certifying Research Parameters

- 1. After selecting , the Workstation displays a User Agreement Notice. Read the notice.
- 2. Select **2**. The Certification Form window appears.
- 3. Check that the institution details are correct.
- 4. Type your name.
- 5. Type your title.

Note: The Workstation reads the user and computer name from the current logon information.

- 6. Select 🧖 to print the certification information.
- 7. Mail the certification information to Beckman Coulter Inc.
- 8. Select *log* to save the changes.

8.12 SETTING UP REPORTING UNITS

Note: To perform this task, you must log on with a user name that was set up as a Lab Administrator. If you need to access this function, contact your laboratory administrator.

1. Select $\stackrel{\frown}{\simeq}$ on the Command Center to display the System Setup window.



- Select General Settings window.
- 3. Select Reporting Units to display the reporting information for your Workstation.
- 4. Select the reporting units format for your laboratory. You can create formats SI5, SI6 and SI7 by selecting CUSTOM and then specify the units for each parameter.
- 5. Specify the groups of parameters you want to display with an extra digit.

Note: You must reset the Workstation after each time you select or deselect extra digit. Results, and the calculations performed on those results, appear as a preset number of decimal places on the screen. However, the Workstation uses more decimal places than it displays and rounds off to the result you see on the screen.

6. Select:

2.

2.



To save the changes. The Workstation stores the changes and updates the date last modified and the user name. The Workstation updates the reporting units immediately.

Another tab To change additional Patient Setup information. The Workstation asks you if you want to save the changes you made to the current

information. Select **Mes** to proceed.

Manually Setting Up Controls in Units Other Than US1 or US2

Note: Prior to setting up controls, ensure that the Reporting Units are set to US-1.

1. Select 🔎 on the Command Center to display the System Setup window.



- Select General Settings to display the General Settings window.
- 3. Select [Reporting Units] to display the reporting information for your Workstation.

4. Set the unit selection to US-1 or US-2 from the drop-down menu and wait for the system message *ADMS* will logoff now to allow the application to restart and reflect this unit change to display on the screen.

-Unit Selection	n
US-1	-
US-1	
US-2	
SI-1	- 1
SI-2	- H
SI-3	
SI-4	- E
JAPAN	P6
CUSTOM	

- 5. Log on to the Workstation.
- 6. Follow steps 1 9 under SETTING UP CONTROLS.

Note: When entering values manually, it is necessary to enter one level at a time.

- a. Select BCI and the level you want to enter under step 9.
- b. Select **NO** when the following message displays: *File not found. Would you like to browse for the file?*

Load SC® Serie	s Cell Control Reference Values		
	Step 1: Select Automatic Data Handler		
50	🗖 Auto Transmit 🔲 Auto Stop		
	etup 🛛 🛛		
	File not found. Would you like to browse for the file?		
	Yes No		
Scan 2D Barcode now			
	Ø 🗙 ?		

c. Select **YES** when the following message displays: *Could Not Open Control Folder, Would You Like to Enter the Values Manually?*

Load SC® Series Cell C	ontrol Reference Values		
	Step 1: Select Automatic Data Handler		
<u>5C</u>	Auto Transmit 🔽 Auto Stop		
Setup			
Could No	t Open Control Folder, Would You Like to Enter the Values Manually?		
	Yes No		
Scan 2D Barcode now			
	Ø 🗙 ?		

7. After completing the **SETTING UP CONTROLS** procedure, repeat steps 1 - 5 as stated above, and select the Reporting Units in step 4.

8.13 SETTING UP FLAGGING LIMITS

Note: To perform this task, you must log on with a user name that was set up as a Lab Administrator. If you need to access this function, contact your laboratory administrator.

IMPORTANT Flagging is evaluated when the sample is analyzed. Flagging is reevaluated for a sample when the results are manually edited, or when new results are received for a pending sample. Flagging is not reevaluated upon a change of flagging limits for results already in the database. Delta check and Reflex Decision Rules are not reevaluated.

Beckman Coulter suggests using all available flagging options to optimize the sensitivity of instrument results. All flagging options include reference ranges (H/L), action and critical limits, definitive flags, suspect flags, parameter codes, delta checks, decision rules and system alarms. Beckman Coulter recommends avoiding the use of single messages or outputs to summarize specimen results or patient conditions.

1. Select 🎴 on the Command Center to display the System Setup window.



2.

to display the Patient Setup window.

- 3. Select [Flagging Limits] to display the list of flagging limits set up for your laboratory.
- 4. Select it to create a new limit.
- 5. Type the name you want associated with the attributes you specify.
- 6. Specify the location you want associated with the limit.
- 7. Specify the age range you want associated with the limit.

Note: Use the age range monitor to ensure you do not specify overlapping ranges for the same location.

- 8. Select on the Setup New Limit Set window to save the limit name, location and age range.
- 9. Select the limit name that you want to set the flagging limits for.
- 10. Select ¹⁶ and display the Laboratory Flagging Limits Setup window.
- 11. Specify whether you want to Auto Validate the results that match this limit.
- 12. Type the lower and upper limits for each parameter of the default Male category. Use



to move between fields.

13. Select:

Female	To define low and high limits for samples originating from a female and whether you want to AutoVerify the results that match this list.
Action Limits	To define low and high limits for samples that require action by your laboratory and whether you want to AutoVerify the results that match this list.
Critical Limits	To define low and high limits for samples that are critical and require immediate action by your laboratory and whether you want to AutoVerify the results that match this list.
Definitive Limits	To identify the definitive messages you want to appear and whether you want to AutoVerify the results that match this list.

- 14. Repeat steps 9 through 12 for each category you want to use for this limit name.
- 15. Select 2. The Workstation saves the limit information with the limit name and returns you to the Flagging Limits tab on the Patient Setup window. The Workstation flags future sample results based on the attributes you specified. If you review existing results in the database, they appear with the OLD attributes.
- 16. Select:

\oslash

To close the Patient Setup window and return to the System Setup window.

Another tab To change additional Patient Setup information. The Workstation asks you if you want to save the changes you made to the current

information. Select **Mes** to proceed.

Flagging Preferences

Note: To perform this task, you must log on with a user name that was set up as a Lab Administrator. If you need to access this function, contact your laboratory administrator.

On this screen you can adjust flagging sensitivity at three levels for these differential flags,

- Blast
- Variant Lymph

- Imm NE 1
- Imm NE 2

2.

Select

The REPORT checkbox default is ON (^[]]) for Imm NE 1. If REPORT is deselected, then Imm NE 1 reporting is disabled (OFF).

The Software Release Number is printed below the Institution Name and is indicated as D:X.X [00000] R:X.X. The values in brackets indicate the Differential Preference selections made in the order they appear on the Setup - Flagging Preferences screen. Differential Preference selections are the low level (1), mid level (2) or high level (3).

Select 🤷 on the Command Center to display the System Setup window. 1.

- to display the Patient Setup window.
- Select Flagging Preferences to display the Flagging Preferences window. 3.
- Click on a slider bar and move it up or down. 4.

Lower flagging sensitivity is selected by moving the slider near the bottom of the control. The down arrow indicates lower flagging. Higher flagging sensitivity is selected by moving the slider near the top of the control. The up arrow indicates higher flagging. The slider will not travel fully to the top or bottom of the control.

IMPORTANT The operating temperature influences the rate of kinetic reactions. The LH 700 Series System should be recalibrated whenever the ambient temperature changes by 10 degrees Fahrenheit. If you have to recalibrate due to a large change in laboratory ambient temperature, you should re-evaluate the differential flagging sensitivity settings for your typical patient population.

Defining Definitive Messages

- 1. Specify whether you want to Auto Validate the results that match this limit.
- 2. Specify each definitive message you want to appear when a result exceeds its default limit.
- If necessary, specify the gradient morphology comments for the parameter. 3.

Editing Existing Flagging Limits

Note: To perform this task, you must log on with a user name that was set up as a Lab Administrator. If you need to access this function, contact your laboratory administrator.

- Select 🤷 on the Command Center to display the System Setup window. 1.
- to display the Patient Setup window. 2. Select
- Select Flagging Limits to display the list of flagging limits sets already set up for your 3. laboratory.
- 4. Select the limit name you want to edit.

- 5. Select ¹ to change the Name, Location or Age associated with the limit set.
- 6. Select $\stackrel{{}_{\textstyle{}}}{\checkmark}$ change the limits associated with the named limit set.
- 7. Modify as appropriate:
 - Auto Validation Criteria
 - Lower
 - Upper
 - Limits that you want to force the display of definitive messages.
- 8. Select 22 to save the attributes with the limit name and return the list of existing flagging limits. The Workstation flags future sample results based on the attributes you specified. If you review existing results in the database, they appear with the OLD attributes.
- 9. Select:

\sim

To close the Patient Setup window and return to the System Setup window.

Another tab To change additional Patient Setup information. The Workstation asks you if you want to save the changes you made to the current

information. Select	Yes	to	proceed
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8.14 SETTING UP RULES FOR FLAGGING SAMPLE RESULTS

Note: To perform this task, you must log on with a user name that was set up as a Lab Administrator. If you need to access this function, contact your laboratory administrator.

IMPORTANT Flagging is evaluated when the sample is analyzed. Flagging is reevaluated for a sample when the results are manually edited, or when new results are received for a pending sample. Flagging is not reevaluated upon a change of flagging limits for results already in the database. Delta check and Reflex Decision Rules are not reevaluated.

Beckman Coulter suggests using all available flagging options to optimize the sensitivity of instrument results. All flagging options include reference ranges (H/L), action and critical limits, definitive flags, suspect flags, parameter codes, delta checks, decision rules and system alarms. Beckman Coulter recommends avoiding the use of single messages or outputs to summarize specimen results or patient conditions.

- 1. Select ᅌ on the Command Center to display the System Setup window.
 - Select Patient

2.

_____ to display the Patient Setup window.

- 3. Select Decision Rules & Criteria to display a list of the existing rules set up for your laboratory.
- 4. Select \checkmark to set up the rule environment.
- 5. Select **i** to create a new rule.

- 6. Specify the rule name.
- 7. Specify the type of rule.
- 8. Specify a Rule Short Title.

IMPORTANT REVIEW YOUR DECISION RULES THAT CONTAIN MULTIPLE PARAMETERS. If you create a rule that has more than one parameter or contains more than one item that is related to a parameter, all of the parameters included in the rule (even if an OR condition is used) must also be included in the parameters reported in your report profile.

- 9. Define the delta check criteria or the reflex manager criteria.
- 10. Select 🥝 to return to the Patient Setup Decision Rules & Criteria tab.
- 11. Use \blacksquare and \frown to prioritize the decision rules.
- 12. Select:

$\mathbf{\overline{M}}$ or $\mathbf{\overline{M}}$ in the enabled column.	To enable or disable decision rules individually.
0	To close the Patient Setup window and return to the System Setup window. The Workstation tests for the rule you defined the next time it receives a sample result.
Another tab	To change additional Patient Setup information. The Workstation asks you if you want to save the changes you
	made to the current information. Select 🚾 to proceed.

Note: If decision rules are to be used for sample flagging, the decision rules must be enabled on the Decision Rules & Criteria screen and Decision Criteria must be enabled on the Run Configuration screen

Defining Delta Check Criteria

Note: To perform this task, you must first perform steps 1 through 8 of setting up rules for flagging sample results.

- 1. Select whether you want to apply a specific Location or Physician to the rule.
- 2. Specify the Delta Check Rules you want to use:

Run 1	Most recent sample result in the database (current run) that matches the patient identifier (after the sample result that matches the delta check limit).
Run 2	Most recent sample result stored in the database (prior to the current run) that matches the patient identifier and the delta check time limit.
(Run 1 - Run 2)#	Absolute value of the difference between the two most recent results expressed as a number.
(Run 1 - Run 2)%	Absolute value of the difference between the two most recent results expressed as a percent.

- 3. Select the specific parameter.
- 4. Specify the value you want used for the criterion.
- 5. If you want more than one condition included in this criterion, specify the logical operator you want to use.
- 6. Specify the rule action you want used.
- 7. Select **1** to save the criterion.

Defining Reflex Manager Criteria

Note: To perform this task, you must first perform steps 1 through 8 of setting up rules for flagging limits.

1. Specify an item you want to check.

IMPORTANT REVIEW YOUR DECISION RULES THAT CONTAIN MULTIPLE PARAMETERS. If you create a rule that has more than one parameter or contains more than one item that is related to a parameter, all of the parameters included in the rule (even if an OR condition is used) must also be included in the parameters reported in your report profile.

- 2. If you selected a parameter:
 - a. Select the operator you want used for the criterion.
 - b. Specify the value you want used for the criterion.
- 3. If you want more than one condition included in this criterion, specify the logical operator you want to use.
- 4. If you want more than one condition included in this criterion, repeat steps 1 through 3 up to two times.
- 5. Specify the rule action you want used.
- 6. Select \swarrow to save the criterion with the criterion name you specified.

Setting Up the Rule Environment

Note: To perform this task, you must first perform steps 1 through 3 of setting up rules for flagging limits.

When you select on the Decision Rules & Criteria Setup window, you can set up characteristics for the Reflex Manager and for delta checking.

Reflex Manager

- 1. Type a message you want used as a rule action.
- 2. Select \blacksquare to save the message.
- 3. Select where you want sample results that match the rule to appear.

Delta Check

1. Specify the time limit for delta checking.
- 2. Specify the unique patient identifier to use for delta checking.
- 3. Specify where you want sample results that match the delta checking criteria to appear.

After setting up the Reflex Manager and Delta Check characteristics, select ¹²² to save the changes and return to the Decision Rules & Criteria Setup window.

Editing Rules for Flagging Sample Results

Rules for flagging sample results cannot be edited. If you want to change an existing rule, you must delete the existing rule and create a new rule with the characteristics you want.

8.15 SETTING UP REPORTS

Note: To perform this task, you must log on with a user name that was set up as a Lab Administrator. If you need to access this function, contact your laboratory administrator.

- 1. Select 🤗 on the Command Center to display the System Setup window.
- 2. Select General Settings to display the General Settings window.
- 3. Select Reporting Options to display the content for each report defined for your Workstation.
- 4. For each report number (tabs 1 through 7):
 - a. Specify report format you want used.
 - b. If necessary, specify whether you want a chartable or laboratory report.
 - c. Specify the printout options.
- 5. For each report number (tabs 8 through 10):
 - a. Select the parameters you want included for printing and transmission.
 - b. Specify report format you want used.
 - c. If necessary, specify whether you want a chartable or laboratory report.
 - d. Specify the printout options.
- 6. Select:

 \oslash

To close the Patient Setup window and return to the System Setup window. The next report the Workstation prints uses the items you selected.

Another tab

r tab To change additional Patient Setup information. The Workstation asks you if you want to save the changes you made to the current

information. Select **Mes** to proceed.

7. If you want your institution's information, such as name and address, to appear on the report, verify the Institution Details Setup.

8.16 SETTING UP INSTITUTION DETAILS

Note: To perform this task, you must log on with a user name that was set up as a Lab Administrator. If you need to access this function, contact your laboratory administrator.

1. Select 🤷 on the Command Center to display the System Setup window.



- 2. Select to display the Institution Details window.
- 3. Type the name of your laboratory.
- 4. Type the name of your laboratory director.
- 5. Type the mailing address of your laboratory.
- 6. Type the city where your laboratory is located.
- 7. Type the state where your laboratory is located.
- 8. Type the zip code where your laboratory is located.
- 9. Type the country where your laboratory is located.
- 10. Type the phone number for your laboratory.
- 11. Type your laboratory's IQAP number.
- 12. Type your laboratory's account number.
- 13. For each type of information, specify whether you want the information to appear in the header of printed reports. The header appears on all reports.
- 14. Select 21 to close the Institution window and return to the System Setup window. The next time you print a report, the institution details you specified appear in the header of the report.

8.17 SETTING UP LIS / HIS COMMUNICATIONS

IMPORTANT The current LIS cable that connects to the Equinox Host 1 port is different from the LIS cable that connects to the COM Port 1 (pin layout is different). UI COM Port selection and physical communication cable connection are based upon workstation type. See Figure 8.2, Space for tower-type computers, Figure 8.3, Space for Small Form Factor (SFF)-type computers, and Figure 8.4, Rear of instrument and accessories with DB-25 pin for tower-type computers.

To perform this task, you must log on with a user name that was set up as a Lab Administrator. Consult with your information system administrator to ensure you have the correct information to perform this procedure, and that you have available the latest Host Transmission manual (PN 4277303).

1. Select $\stackrel{\frown}{\simeq}$ on the Command Center to display the System Setup window.



LIS/HIS Instrument LH Workstation Enable Body Fluid Tag Last Modil Enable Validation Codes Enable Validation Codes Replace DLE E with DLE C Colla Com Port COM 1 Time Out 90 Seconds Baud Rate 19200 Parity OFF Stop Bits 1	ied 8/28/2012 By LabAdmin e ToDo List IV shake IV ics lics
Enable Body Fluid Tag Last Modil Enable Validation Codes Colla Replace DLE E with DLE C Colla Com Port COM 1 Time Out 90 Seconds Baud Rate 19200 Parity OFF Stop Bits 1	ied 8/28/2012 By LabAdmin e ToDo List 🔽 shake 🔽 ics ics
Colla Hand Com Port COM 1 Time Out 90 Seconds Graph Baud Rate 19200 V Data I Data I Diff Parity OFF V Retic	e ToDo List 🔽 shake 🔽 ics 'lots: Histograms:
Hand Com Port COM 1 Time Out 90 Seconds Baud Rate 19200 Parity OFF Stop Bits 1 Hand	shake 🔽 ics Nots: Histograms:
Com Port COM 1 Time Out 90 Seconds Baud Rate 19200 Parity OFF Stop Bits 1	ics Ylots: Histograms:
Time Out 90 Seconds Graph Baud Rate 19200 Data I Parity OFF Diff Stop Bits 1 V	ics Plots: Histograms:
Baud Rate 19200 Data I Parity OFF Image: Constraint of the second	Plots: Histograms:
Parity OFF Stop Bits 1	
Stop Bits 1 Retic	
	WBC
Data Bits 8	PLT 🔽
Block Size 256	
Compatibility LH 750 Workstation	•

Figure 8.1 System Setup Communication screen

3. Select US/HIS to display the communications settings for transmitting data from your instrument to your information system.

Note: The options that are available are dependent on the setting you selected in the Compatibility Drop Down menu.

- 4. Select whether to enable body fluid.
- 5. Select whether to transmit validation codes to your information system.
- 6. Select whether to Replace DLE E with DLE C in the standard data set transmitted to your information system.
- 7. Select the LIS COM Port option.
 - When using the Small Form Factor (SFF)-type computer, select COM Port 1, and use a DB 9-pin connector.
 - When using the tower-type computer, select COM Port 6, and use a DB 25-pin connector.
 - Whenever the port number is changed in the *COM Port* field, the LH System will prompt you to reboot.

- 8. Select the time out interval you want used.
- 9. Select the baud rate your information system can receive.
- 10. Select the type of parity you want used for communications with your information system.
- 11. Select the stop bits for your information system.
- 12. Select the data bits you want used for transmission to your information system.
- 13. Select the block size for transmissions to your information system.
- 14. Select the data format for compatibility.
- 15. If a handshake with your information system is necessary, verify that Handshake is turned on.
- 16. Select Collate ToDo List to enable the ability to request additional tests for the same patient.
- 17. If you specified the LH 700 Series compatibility format, specify the graphics data you want to transmit to your information system.
- 18. Select:



To close the Communications Setup window and return to the System Setup window. The next time the Workstation transmits a result to your information system, it transmits the result with the settings you specified.

Another tab To change additional Communications Setup information. The Workstation asks you if you want to save the changes you made to the

current information. Select to proceed.

Changing the COM Port

If the port number in the *COM Port* field was changed when **SETTING UP LIS / HIS COMMUNICATIONS**, the LH system will automatically display the following message:



- 1. Click **OK** for the system to shudown.
- 2. Connect the new cable.
- 3. Re-start the workstation.

LIS COM Port Configuration

IMPORTANT The current LIS cable that connects to the Equinox Host 1 port is different from the LIS cable that connects to the COM Port 1 (pin layout is different). UI COM Port selection and physical communication cable connection are based upon workstation type. See Figure 8.2, Space for tower-type computers, Figure 8.3, Space for Small Form Factor (SFF)-type computers, and Figure 8.4, Rear of instrument and accessories with DB-25 pin for tower-type computers.

To perform this task, you must log on with a user name that was set up as a Lab Administrator. Consult with your information system administrator to ensure you have the correct information to perform this procedure, and that you have available the latest Host Transmission manual (PN 4277303).

For the LH 700 Series workstations, the COM Port can be configured to COM 1 or COM 6, depending on the workstation.

- For the LH 700 Series tower-type computers, the default **COM Port 6 must be used** with a DB 25-pin connector. See Figure 8.2, Space for tower-type computers and Figure 8.4, Rear of instrument and accessories with DB-25 pin for tower-type computers.
- For the LH 700 Series Small Form Factor (SFF)-type computers, **COM Port 1 must be used** with a DB 9-pin connector. See Figure 8.3, Space for Small Form Factor (SFF)-type computers and Figure 8.5, Rear of instrument with the DB-9 pin connector for SFF-type computer.

Refer to the following table for the correlation between ports and hardware configuration:

Table 8.1 COM Port Mapping

Software COM Port Configuration	Workstation Type	Labeling on Computer Cable	
COM 6	Tower-type computer	Host 1 on Equinox cable	
COM 1	Small Form Factor-type computer	COM Port 1	

Figure 8.2 Space for tower-type computers





Figure 8.3 Space for Small Form Factor (SFF)-type computers

8.18 Interunit Connections

Power and Signal Cables

Figure 8.4 shows the interunit connections of the power and signal cables, highlighting the **DB-25 pin connector**, if being used. Your Beckman Coulter Representative makes these connections when installing the instrument.

Figure 8.4 Rear of instrument and accessories with DB-25 pin for tower-type computers



Changing 9-pin and 25-pin connectors

For LH 700 Series workstations, the COM PORT can be configured to COM 1 or COM 6. The COM PORT depends on the workstation being used. Figure 8.5, Rear of instrument with the DB-9 pin connector for SFF-type computer shows the connector location when using the LH 700 Series Small Form Factor computer.

Figure 8.5 Rear of instrument with the DB-9 pin connector for SFF-type computer



Note: The DB 9-pin connector on the computer base, designated as COM 1, is located beside the video display connector.

Setting Up Auto Validation

Before performing this procedure, read the Auto Validation Overview so that you understand how the LH 700 Series software assigns validation codes to sample results.

- 1. Enable the Auto Validation codes on the Communications screen if you want the validation codes to be transmitted to your information system.
- 2. Enable Auto Validation Criteria on the Flagging Limits Setup screen.
- 3. Setup Decision rules for your laboratory. If Decision Rules are enabled and a decision rule is met for a sample, this will cause an Auto Validation failure.

IMPORTANT REVIEW DECISION RULES THAT CONTAIN MULTIPLE PARAMETERS. If you create a rule that has more than one parameter or contains more than one item that is related to a parameter, all of the parameters included in the rule (even if an OR condition is used) must also be included in the parameters reported in your report profile. Refer to Example A.

Example A:

Rule Setup:	Reflex rule is defined as "If WBC is < 2.0 OR Hgb is < 6.0 then Repeat sample and call results".
Sample Setup:	Test Mode = CBC
Preassigned Sample:	includes only Hgb and Hct (Report Name)
Sample Results:	(As printed and transmitted to LIS.)
	Hgb 5.8 g/dL
	Hct 17.8 %

Note: The decision rule <u>will not</u> be applied to this sample even though the Hgb value is below 6.0. This is because the WBC parameter is not reported. In order for the Decision Rule to be applied to the sample, all parameters in the rule have to be reported. Therefore this sample would not result in an Auto Validation failure since the decision rule was not applied.

IMPORTANT If the Validation Codes are going to be used on either the printout or in the LIS, all parameters specified in a rule must be included in a parameter block in order for all of the Validation codes to be CORRECT. Refer to Example B.

Example B:

Rule Setup:	Reflex rule is defined as "If Hgb < 6.5 OR Hct < 19.5 then Rerun Sample and Phone Results".			
Sample Setup:	Test Mode = CBC			
Preassigned Sample:	Report all CBC parameters (Report Name),			
Sample Results:	(As printed and transmitted to LIS.)			
	WBC	4.8	10 ³ /L	
	RBC	2.53	10 ⁶ /L	
	Hgb	6.3	g/dL	
	Hct	19.6	%	
	MCV	77.4	fL	
	MCH	24.9	pg	
	MCHC	32.1	g/dL	
	RDW	16.1	%	
	Plt	80	10 ³ /L	
	MPV	10.3	fL	

The parameter blocks that will be evaluated against the Decision Rule are the H and C blocks, because both Hgb and Hct are included in these blocks. The Decision Rule is not applied to the W block because Hct is not included in this block. Therefore, the Auto Validation message/codes will print and transmit "Sample Not Validated, C NV, H NV, W AV". In order for the Decision Rule to be applied to the W block, you must create a Decision rule for Hgb and then a Decision rule for Hct, in order to get "Sample Not Validated, C NV, H NV, W NV".

Enable Auto Validation Codes

Enable the Auto Validation codes on the Communications screen if you want the validation codes to be transmitted to your information system. These codes will always print on the patient reports, even if disabled on this screen. To enable transmission of the validation codes:

- 1. Select 🎴 on the Command Center to display the System Setup window.
- 2. Select communications window.
- 3. Select the LIS/HIS tab.
- 4. Select 🗹 Enable Validation Codes.
- 5. Select \swarrow to save the changes.

Enable Auto Validation Criteria

The system allows you to configure Auto Validation for Reference, Action and Critical limits and also for Definitive messages for each Flagging Range that you set up in the Workstation.

If you have not set up flagging limits for your laboratory, follow the steps in Setting Up Flagging Limits to assign limits and enable Verification criteria.

If your flagging limits have already been set up and you want to enable Verification Criteria for either Reference, Action and Critical limits or Definitive messages, then perform the following.

1. Select 🎐 on the Command Center to display the System Setup window.

Palient

2.

- Select Patient to display the System Setup Patient window.
- 3. Select Flagging Limits to display the limits table.
- 4. Select the limit name you want to configure with Auto Validation Criteria.
- 5. Select $\stackrel{{}_{\textstyle{}}}{\checkmark}$ to display the Laboratory Flagging Limits Setup window.
- 6. Select the limits tab that you want Auto Validation Criteria enabled on.
- 7. Select 🗹 Auto Validation Criteria.
- 8. Select *log* to save the changes.
- 9. Repeat steps 3 through 8 for each limit that you want enabled.

8.19 CHANGING AN INSTRUMENT NAME

To perform this task, you must log on with a user name that was set up as a Lab Administrator. If you need to access this function, contact your laboratory administrator. 1. Select $\stackrel{\frown}{\frown}$ on the Command Center to display the System Setup window.

- 2. Select Communications to display the Communications window.
- 3. Select Instrument to display the settings for the instruments attached to your Workstation.
- 4. Type the in-lab name you want used for the instrument.
- 5. Select:

To close the Communications Setup window and return to the System Setup window.

Another tab To review or change additional Communications Setup information. The Workstation asks you if you want to save the changes you made to

the instrument name. Select to proceed.

8.20 REVIEWING WORKSTATION SETTINGS

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Note: To perform this task, you must log on with a user name that was set up as a Lab Administrator. If you need to access this function, contact your laboratory administrator.

- 1. Select 🤗 on the Command Center to display the System Setup window.
- 2. Select communications to display the Communications window.
- 3. Select Instrument to display the settings for the instrument attached to your Workstation.
- 4. You can change the in-lab name for the instrument. You cannot change any other fields on this window. To change additional information on this window, contact your Beckman Coulter Representative.
- 5. Select [IH Workstation] to display the settings for the Workstation.
- 6. Select:



To close the Communications Setup window and return to the System Setup window. The Workstation immediately updates the instrument name on all windows and reports.

Another tab To change additional Communications Setup information.

8.21 SETTING UP USER ACCESS LEVELS

1. Select 🤷 on the Command Center to display the System Setup window.

- 2. Select Security Access to display the Security Access window.
- 3. Select the type of access you want to grant the person.



To reset a password, an administrator must delete the user name and then create a new user name with the same name.

1. Select 🔎 on the Command Center to display the System Setup window.



- 3. Select the user name you want to reset.
- 4. Select **b** to delete the user name.
- 5. Select **Mes** to confirm the deletion.
- 6. Select the type of access the user name you just deleted was assigned.
- 7. Type the user name you just deleted and press



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- 8. Type a password for the user name and press
- 9. Type the same password you just typed for verification.
- 10. Select it is save the current user name and clear the fields so you can add another user name.
- 11. Select **I** to close the window.

8.22 CHANGING PHYSICIAN LIST

Note: If your LIS is bidirectional, the Physician list will be populated by the LIS.

Adding to the List

1. Use any of the following methods to access the Physician List window:

• Select , then select

- Select 🖳, then select 🚔, then select 🗥
- Select Men editing sample results.

Tab

- 2. Type the last name of the physician in Last Name and press
- 3. Type the first name of the physician in First Name.
- 4. Select it add the physician to the Physician List.
- 5. Select **I** to close the window and save the changes to the list.

Editing the List

1. Use any of the following methods to access the Physician List window:



- Select \blacksquare , then select \blacksquare , and then select ھ.
- Select when editing sample results.
- 2. Select the physician's name you want to edit. The last and first name fields fill with the name.
- 3. Type the changes to the name fields.
- 4. Select **save** the changes to the physician's name.
- 5. Select **I** to close the window and save the changes to the list.

Deleting from the List

1. Use any of the following methods to access the Physician List window:



- Select 🔄, then select 🛤, and then select 🗥
- Select M when editing sample results.
- 2. Select the physician's name you want to delete.
- 3. Select it remove the physician's name from the Physician List.
- 4. Select **I** to close the window and save the changes to the list.

8.23 CHANGING LOCATION LIST

Note: If your LIS is bidirectional, the location list will be populated by the LIS.

Adding to the List

- 1. Use any of the following methods to access the Location List window:
 - Select , then select
 - Select \blacksquare , then select \blacksquare , and then select \blacksquare .
 - Select when editing sample results.

- 2. Type the location name in the field below the Location List.
- 3. Select 💷 to add the location to the Location List.
- 4. Select **I** to close the window and save the changes to the list.

Editing the List

- 1. Use any of the following methods to access the Location List window:
 - Select 🔷, then select
 - Select 💻, then select 🖼, and then select 📠
 - Select when editing sample results.
- 2. Select the location name you want to edit. The Location field fills with the name.
- 3. Type the changes to the Name field.
- 4. Select **Select** to save the changes.
- 5. Select **I** to close the window and save the changes to the list.

Deleting from the List

- 1. Use any of the following methods to access the Location List window:
 - Select , then select
 - Select 😐, then select 🚔, and then select 🛋
 - Select when editing sample results.
- 2. Select the location name you want to delete.
- 3. Select it remove the location name from the Location List.
- 4. Select Let to close the window and save the changes to the list.

8.24 SETTING UP DATABASE STORAGE LIMITS

Note: Maintaining a large number of sample results can degrade Workstation performance when searching for results. To optimize searching, reduce the number of samples stored in the database.

1. Select 🎴 on the Command Center to display the System Setup window.

- 2. Select ^{Database Preferences} to display the DataBase Configuration window.
- 3. Type the maximum number of samples you want stored in the database. (The valid range is 1,000-20,000.)
- 4.
- 5. For Automatic ToDo List Deletion:
 - a. Enable 🗹 the Delete To Do list entries checkbox.
 - b. Specify the ToDo list entries to be deleted after 'x' hours. Where 'x' can be within the range of 00 to 720 hours.
- 6. Select 🖾 to save the changes you made to database configuration.

Setting Up Screen Saver

Note: To perform this task, you must log on with a user name that was set up as an Advanced Operator or Lab Administrator. If you need to access this function, contact your laboratory administrator.

1. Select 🔷 to display the System Setup window.

Ci i

- 2. Select Control Panel to display the Windows 2000 Control Panel.
- 3. Double-click window.
- 4. Select Screen Saver and specify the details for your screen saver.
- 5. If you need additional information about the fields on the display properties window, select
- 6. Select **OK** to exit and save the new settings.

Setting Up Colors

Note: To perform this task, you must log on with a user name that was set up as an Advanced Operator or Lab Administrator. If you need to access this function, contact your laboratory administrator.

- 1. Select 앋 to display the System Setup window.
- 2. Select Control Panel to display the Windows 2000 Control Panel.

- 3. Double-click window.
- 4. Select Appearance and specify the details for your screen saver.
- 5. If you need additional information about the fields on the display properties window, select
- 6. Select **OK** to exit and save the new settings.

Setting Up Date and Time

Note: To perform this task, you must log on with a user name that was set up as an Advanced Operator or Lab Administrator. If you need to access this function, contact your laboratory administrator.

- 1. Select 🖄 to display the System Setup window.
- 2. Select Control Panel to display the Windows 2000 Control Panel.
- 3. Double-click Date/Time to display the Windows 2000 Date/Time window.
- 4. Specify the details for date and time.
- 5. Shutdown and restart the Workstation after adjusting clock time.

Note: Service selects workstation regional, date and time settings at installation. Call Service if you desire modification of a regional setting. Modifications attempted at the LabAdmin security level may cause incorrect displays of information such as date format in some applications.

6. Read about LH 700 Series Year 2000 features.

Note: If the date/time on either the Workstation or Analyzer clock must be moved backwards, temporarily suspend operations for the period of the time change. Ensure no data is downloaded from the LIS, and no data is edited at the Workstation, until that adjusted time period has passed. For example, if you adjust the clock back from 2 AM to 1 AM, takes steps to ensure no activity occurs on the system until the clocks reach 2 AM after the adjustment.

If you cannot suspend operations as stated above:

- Ensure that you do not change reagents using a date/time earlier than any currently configured reagents.
- Delete any XB and XM data with date/time more recent than you will be updating to.
- Delete any startup data with a date/time that is more recent than you will be updating to.

If operations cannot be suspended, be aware that incoming samples into the database may have a date/time earlier than existing samples, or that duplicate date/times instances can occur. This may affect the displays and/or your lab's workflow. For example, controls

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and samples run after a date/time adjustment may appear earlier in the control files or patient worklist, respectively, due to overlapping date/time.

Setting Up Your Default Printer

Note: To perform this task, you must log on with a user name that was set up as a Lab Administrator. If you need to access this function, contact your laboratory administrator.

- 1. Select **Start > Settings > Delivers** to display the Windows 2000 Print Manager window.
- 2. Select the printer you want to use. If the printer you want to use does not appear in this list, you will need to set up a new printer.
- 3. Select File >> Set As Default to make the selected printer your default printer.
- Select File ➤ Close to save the default information and close the Print Manager.
 Note: The ability to print multiple copies of any report through the printer setup in Windows is not supported.

Setting Up a New Printer

Network Printer

Note: To perform this task, you must log on with a user name that was set up as a Lab Administrator. If you need to access this function, contact your laboratory administrator.

- 1. Ensure your network cable is connected to your network adapter.
- 2. Select Start >> Settings >> Diviters to display the Windows 2000 Print Manager window.
- 3. Double click on $\stackrel{[\equiv}{=}$ and follow the instructions in the Add Printer Wizard
- 4. Select File >> Properties and verify the printer properties, paper size, and print orientation.
- 5. Select **OK** to save the changes.

Local Printer

Note: To perform this task, you must log on with a user name that was set up as a Lab Administrator. If you need to access this function, contact your laboratory administrator.

- 1. Select Start >> Settings >> Settings to display the Windows 2000 Print Manager window.
- 3. Select File >> Properties and verify the printer properties, paper size, and print orientation.
- 4. Select **OK** to save the changes.

Note: The ability to print multiple copies of any report through the printer setup in Windows is not supported.

8.25 RUN CONFIGURATION WINDOW

This window allows you to quickly change standard options for individual tests or studies you may perform.

Changes to this window take effect the next time the Workstation receives a sample. The changes remain in effect until you or another user change the options again.

You can change:

- Which results to print
- Which default report you want to use
- Which results to transmit to your information system
- When to make a slide
- Which Quality Assurance Analysis feature option is used
- Which results should cause the instrument to stop processing
- Whether the Decision Criteria Rules are used
- Whether the AutoNumbering option is used
- Whether the AutoCollation option is used.
- Whether to enable SlideMaker Communication
- Whether to enable SlideStainer Communication
- Whether to Match the Run Type to the ToDo list
- Whether to enable limit-independent flags H&H Check Failed and Pancytopenia.

No Match, No Read and Partial Aspiration are not flags, but Run Status messages. As a selectable item within Run Configuration, these Run Status messages are not included in 'Any Flags'. If you wish to implement a function based on all flags and the Run Status message, select Specific Flags, then select all the pertinent checkboxes.

Research flags are included in 'Any Flags', but are not included in 'Suspect'. If you wish to implement a function based on all Suspect flags, including the Research flags, select Specific Flags, then select all the pertinent checkboxes.

Note: Once the desired changes have been made, close the Run Configuration window by

pressing 🖉 to save or 🔀 to cancel.

Changing Your Default Printout Format

- 1. Select $\overset{\checkmark}{=}$ on the Command Center to display the Run Configuration window.
- 2. Specify the print profile you want used for all results unless otherwise specified as part of the sample result information. The report layout changes automatically.
- 3. Select 2 to save the changes. The next item that prints from the Workstation prints using the report you selected.

Changing Your Default Report Layout

Since the report layout is linked to the report name, you can change the default report format by changing the default printout format. You can also use the following procedure to change the report layout linked to the default report.

- 1. Select 🧖 on the Command Center to display the Run Configuration window.
- 2. Note the print profile name identified on the window. This is the default report.
- 3. Select **X** to close the window.
- 4. Select 🤷 on the Command Center to display the System Setup window.
- 5. Select General Settings to display the General Settings window.
- 6. Select Reporting Options to display the reported parameters and print options for each report defined for your Workstation.
- 7. Select the report number used as the default.
- 8. Specify a different report layout.
- 9. Select 2 to save the changes. The next item that prints from the Workstation prints using the report you selected.

Setting Up Which Results to Print Automatically

- 1. Select 🧖 to display the Run Configuration window.
- 2. Select Find as the type of Automatic Output.
- 3. Select the flag type you want to use to determine printing.
- 4. Select the QA Sample runs that you want to automatically print.
- 5. Select its save the changes. The next item prints based on the flags you selected.

Setting Up Which Results to Transmit Automatically

- 1. Select 💆 to display the Run Configuration window.
- 2. Select LIS/HIS as the type of Automatic Output.
- 3. Select the flag type you want to use to determine which results are sent to the information system.
- 4. Select the QA sample runs that you want to automatically transmit. Only the Controls option is enabled for transmission.
- 5. Select \blacksquare to enable or disable transmission of controls

6. Select losave the changes.

Turning AutoStop OFF/ON

Note: AutoStop is disabled whenever someone logs off the Workstation. Someone must be logged onto the Workstation to enable AutoStop when the system is processing samples

- 1. Check that your controls and XB analysis are set up with the AutoStop options you want.
- 2. Select \checkmark to display the Run Configuration window.
- 3. Select the AutoStop options you want:

AutoStop Criteria	After # Runs		
Controls	🔽 No Match	10	
⊏ ×B	🔽 No Read	10	
₩ ×M	Partial Aspiration	10	
✓ SlideMaker	Voteout	3	

4. Select 22 to save the changes. The Workstation stops processing samples the next time it encounters the conditions you selected.

Note: AutoStop does not function when you log off the Workstation.

Turning SlideMaker OFF/ON

- 1. Select 🧖 to display the Run Configuration window.
- 2. Select SlideMaker to change the option.
- 3. Select 21 to save the changes. The Workstation uses the SlideMaker for the next sample analysis. You must reset this option on this window to change SlideMaker analysis back to its original state.

Setting Up When to Make a Slide

- 1. Select 🧖 to display the Run Configuration window.
- 2. Select SlideMaker

Note: These selections are not currently available for samples that are processed in Retic only mode.

3. Ensure decision criteria is enabled then select the flag type you want to use to determine when a slide is made.

- Select SlideMaker Decision Rules Only and enable decision criteria if you want to use only your decision rules to determine when a slide is made.
- Select Specific Flags if you want to make slides on specific conditions that cause a sample result to be sent – slides will also be made using the SlideMaker Decision Rules.
- 4. Select *log* to save the changes.

Turning Decision Criteria OFF/ON

- 1. Select 💆 to display the Run Configuration window.
- 2. Select Decision Criteria to change the option.
- 3. Select 2 to save the changes. The Workstation uses the customer rules based on the selection you made. You must reset this option on this window to change the customer rules option back to its original state.

Turning AutoNumbering OFF/ON

- 1. Select 🧖 to display the Run Configuration window.
- 2. Select AutoNumbering to change the option.
- 3. If necessary, type the first number you want used.
- 4. Select 22 to save the changes. The Workstation performs AutoNumbering based on the selection you made. The number appears in the sequence number field for the sample. You must reset this option on this window to change the AutoNumbering option back to its original state.

Turning AutoCollation OFF/ON

- 1. Select 🧖 to display the Run Configuration window.
- 2. Select AutoCollation to change option.
- 3. If necessary, specify the time limit you want used.
- 4. Select 22 to save the changes. The Workstation performs AutoCollation based on your selection. You must reset this option on this window to change AutoCollation back to its original state.

Turning XB Analysis OFF/ON

- 1. Select *s* to display the Run Configuration window.
- 2. Select the type of quality assurance analysis that you want to change:
 - XB

3. Select 2 to save the changes. The Workstation includes the next results in quality assurance analysis based on the selections you made. You must reset this option on this window to change quality assurance analysis back to its original state.

Turning XM Analysis OFF/ON

- 1. Select to display the Run Configuration window.
- 2. Select the type of quality assurance analysis that you want to change:
 - ☑ XM CBC In this field indicates that you want the workstation to store CBC parameter results in the XM current batch.
 - ☑ XM Diff In this field indicates that you want the workstation to store Diff parameter results in the XM current batch.
 - ☑ XM Retic In this field indicates that you want the workstation to store Retic parameter results in the XM current batch.
 - ☑ XM Retic Calc In this field indicates that you want the workstation to store Retic Calculated parameter results (only available in you run in CR or CDR mode) in the XM current batch.

Note: The workstation does not include runs with a:

- Non-numerical value
- Partial Aspiration
- RBC value < $1.0 \times 10^6 \mu L$
- WBC value < $1.0 \times 10^3 \mu L$
- PLT value < $20 \times 10^3 \mu L$
- Over linearity "+"
- System Alarms
- 3. Select 21 to save the changes. The Workstation includes the next results in quality assurance analysis based on the selections you made. You must reset this option on this window to change quality assurance analysis back to its original state.

Specifying Default Control Lot Numbers

- 1. Select 🧖 to display the Run Configuration window.
- 2. Select the default lot number.

Note: Once the default lot number has been selected, close the Run Configuration window by

pressing \swarrow to save your changes or \checkmark to exit without saving.

Changing the Active Printer

1. Select Start Restart Restar

- 2. Select the printer you want to use and set it as your default printer. If the printer you want to use does not appear in this list, you will need to set up a new printer.
- 3. Select File >> Properties and verify the printer properties, paper size, and print orientation.
- 4. Select **OK** to save the changes. The Workstation prints the next item to the printer you just selected.

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