COULTER LH 750 HEMATOLOGY ANALYZER COULTER LH 780 HEMATOLOGY ANALYZER COULTER LH SLIDEMAKER COULTER LH SLIDESTAINER Training Guide



This Training Guide belongs to:

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.

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 EQUIPMENT.

INTENTION FOR USE

This document is not intended to replace the information in your Instrument Instructions for Use Manual (IFU). Information in the Instructions for Use Manual supersedes information in any other manual.

TRADEMARKS

5C Series Control, Beckman Coulter, Coulter, Coulter Counter, Lin-C, Lyse S, S-Cal, Z Series are trademarks of Beckman Coulter, Inc.; Beckman Coulter, the BECKMAN COULTER logo, COULTER, Coulter Counter, 5C Series Control, Lin -C, LYSE S, S-CAL and Z Series are registered in the USPO.

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

Copyright © Beckman Coulter, Inc. 2016 All Rights Reserved

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

REVISION STATUS

Version 1.1 Initial Release (April 2016) Software release 2D3/1B3 or higher Presented April 2016, Miami, Florida

TABLE OF CONTENTS

Workstation Basics: p. 4 Startup: p. 14 Quality Control: p. 20 LH SlideMaker & LH SlideStainer Set Up: p. 28 **Running Patient Samples: p. 34** Shutdown: p. 41 Reagent Set Up & Replacement: p. 43 Setting Up Controls: p. 48 Flagging Limits: p. 52 Decision Rules: p. 57 Calibration: p. 63 History Logs: p. 70 Sample Flow – Diluter: p. 73 Troubleshooting – Diluter: p. 74 Sample Flow – LH SlideMaker: p. 90 Troubleshooting – LH SlideMaker & LH SlideStainer: p. 92 **Replacing Components: p. 110** Air Filters: p. 120 Reproducibility & Carryover: p. 121 Lab Limits & Patient Control Set Up: p. 125 QC Data Review: p. 129 Security Access: p. 135 XB Analysis: p. 138 Introduction to Truth Tables: p. 144

WORKSTATION BASICS

LH Workstation

• Log On to Windows 2000/LH 700 program

When the Workstation is logged off or if it was Shutdown and then Powered off/on, the Log On to Windows screen appears.

- Both a User Name and Password are required:
- The User Name is not case-sensitive. Passwords are case-sensitive.

NOTE: Upon installation, the password for LabAdmin is blank (no password required). You may set up your own password.

Windows 2000 Professional - LH 700 Desktop



Desktop Icons

The six desktop icons on the upper left are functional windows icons. However, it is best **not** to use them. They are not necessary to operate the LH 700. All functions needed by the operator are accessible through the Command Center. The exception is for optional CD data formatting and burning.

Command Center

The Command Center is the green bar located across the bottom of the desktop area.



• A <u>**Tool Tip**</u> appears over a Workstation button when your cursor moves or "flies" over the button. It remains on screen for a few seconds to tell you the name of the button. Hold the cursor over a button without clicking.

Quality Assurance

• When you move the cursor towards the bottom of the screen, the **Windows Taskbar** may appear. You just move away from the task bar to make it disappear, then move back to make your selection.

🚿 🛏 🕵 ?	User: LABADMIN	Process Type: AUTO A	NALYSIS 🔻 Default T	ype: CD 💌 Random	Access 🔽	8
🏽 🕄 🎯 🎲		🚧 Status Application	Quality Assurance - [D.	- Patient Tests - [Results &.		10:21 AM
	Wind	lows Taskbar				

LH Screen Applications

Use your mouse to view the tool tip name of each of the eight LH 700 screen application buttons.

Refer to the **Easy Reference Guide**, page 15, for the descriptions of these buttons.

When you want to change the area you are viewing, just select a new button from the Command Center. The program automatically closes what was open and then opens the new choice.

There are three exceptions:

- If the **Run Configuration** screen is open, you exit by selecting either (OK, save and close) or the red to cancel any changes you made.
- If the **Help** screen is open, you exit by selecting the small x in the upper right corner.
- If the **History Logs** are open, exit by selecting the small x in the upper right corner.

				S 6:/ 6		37 MG	
5	Þ	Q	?	User: LABADMIN	Process Type: AUTO ANALYSIS	Default Type: CD 💌 Random Access 🔽	0
۵,	į	\diamond	₿•	H A	Barcode:	🗖 Predilute (CBC) 🔲 Body Fluid (CBC)	

Predilute (CBC) and Factor Fields

The LH 700 allows you to run dilutions of samples with very high counts. After you make your sample dilution, select the check box for Predilute. The Enter Dilution Factor window appears as shown below.

Enter Dilution Factor	
Factor: 🛨 1 . 🛛 🛨	
OK Cancel	redilute (CBC) 🗖 Body Fluid (CBC)

You may enter your dilution factor from 1.1 (for sodium citrate tubes used for platelet clumps) to 5.0. Sample dilutions are run only in the Manual aspiration mode and use only the CBC test mode.

Body Fluid (CBC) Field

The Body Fluid field allows you to run various body fluids (CSF, serous and hyaluronidase-treated synovial) to obtain an RBC and WBC (TNC) only.

Traffic-light Icon

The traffic light icon shows red, yellow or green lights to indicate the instrument's status.

- A green light means all is well; there are no errors or messages.
- A yellow light means the instrument recorded a message, but it is information only. The instrument is still operating. You should look at the message when you have a chance (double-click on the yellow light). A

yellow box opens; acknowledge it by clicking on OK).

• A red light means the instrument stopped due to an error, malfunction or Auto-Stop request. An audible alarm sounds. Double-click on the red light to read the message(s). A red box opens, resolve the error condition and then

acknowledge it by clicking on (OK). For help with a specific error, double-click the error message inside the box.

The LH 700 HELP System

The LH 700 program has an extensive multimedia HELP system built-in. Selecting the Help ? button from the Command Center opens the following screen. Do this now.



The Help screen uses a format similar to internet browsers such as Internet Explorer and has three main areas:

1. Browser Menu Bar Buttons

Use the buttons located here to navigate Back and Forward (through screens you have just viewed), Print, Go to a Glossary, etc.

2. Help Topic Display Area

The right side of the screen displays the topic chosen. When you choose the Help button ? from the Command Center, it always opens to the topic "Using Command Center".

3. Help Window Navigation Pane

This area has <u>four tabbed sections</u> and may be hidden by selecting the Hide button on the browser menu bar. Use the Show button to redisplay the navigation pane. (Try this now!) Each section provides a different way of accessing or finding the Help topic you want to read. Whatever topic is viewed in the Topic Display Area will also be highlighted in blue in the Navigation Pane Area.

- a) **<u>Contents</u>** used as a Table of Contents, shows broad subject areas.
- b) <u>Index</u> type a keyword in the white box near the top and the index scrolls to the possible topic choices. If you see the topic you want, there are two ways to open it: double-click on it or highlight the topic and then click on the Display button at the bottom of the screen.



If you have Help maximized, this Display button is hidden behind the Command Center. In this case, click on the Restore Down button in the upper right corner (the middle button).

- c) <u>Search</u> similar to Index. Type a word or words in the white box near the top, then select the List Topics button. If the topic you are looking for appears in the list, select it and then select the Display button or double click it. When your topic appears in the display area of the screen, <u>notice</u> that the word or words that you did the search on are highlighted wherever they appear in the topic.
- d) <u>Favorites</u> this tab allows you to bookmark topics that you refer to over and over, so you do not need to look them up each time you open Help. Once you have the particular topic open, select the Favorites tab and then select the Add button at the bottom of the screen.



The next time you need your topic, open Help, select the Favorites tab and double-click the topic you want to display.

Help Mode

Step	Action
1	On the Workstation Command Center , select (Patient Results), the Patient Tests (Results & Graphics) window displays.
Note 1	If the Results & Graphics view does not display, select the button from the common toolbar.
2	For the LH 750, select the Parameters tab. For the LH 780, select he Overview tab,
3	With the left mouse button, click on the K (Help Mode) button on the Common Tool Bar (at the top of the screen).
4	Release the mouse button.
5	Move the cursor (with question mark) to the WBC field .
6	Click on the WBC field .
Note 2	Help Mode gives you additional information about on-screen items without having to access a HELP topic.

7	Close the HELP mode window and the Help window by clicking on the (Close button) at the upper right corner of the windows.
Тір	It is always necessary to close the Help window when finished otherwise it may become "stuck" on another window.

Creating Favorites

Practice

Step	Action	
1	You may add any topic from Help to the Favorites list. Begin by finding the topic you want to add to the list and open it.	
2	Once opened, click on the Favorites tab and you will see the topic title near the bottom. Click the Add button.	
3	Use the Contents, Index or Search tabs to locate the following topics, and then put them in the Favorites tabbed area: (Reminder: you need to locate and open a topic before it can be added to Favorites.)	
	Running Latex Control—Diff and Retic Diluter Functions Solenoid Functions Message List: Any of the messages lists for the LH 700, LH SlideMaker or LH SlideStainer	
4	Topics may be Added or Removed as necessary.	

Log Off The Workstation

Select from the Command Center. The Log Off The System window appears.

• The default selection is Log Off Current User.



• The other choice is Shutdown the Workstation.

Shutting Down the Workstation

You may have to shut down and restart the Workstation in response to certain error situations or if the computer "locks-up" or doesn't respond. Be sure to read any Help message for error recovery carefully for this indication.

In the event of a communication problem between the Workstation and the LH 700 Analyzer, you may need to reset the Analyzer using the **RESET** button on the upper right side of the Analyzer cover. If resetting doesn't restore communication, it may be necessary to shut down and restart the Workstation.

Practice

Step	Action		
1	Select from the Command Center.		
2	Select Shutdown the Workstation, then select OK.		
3	The Workstation will save any unsaved data and display a window notifying you it is shutting down the workstation. This may take a minute.		
	Next a window is displayed that states you may now power off the workstation.		
4	Turn off the computer workstation power using the power button on the front of the computer.		
	Always verify that the power actually is off. Sometimes, you need to hold in the button until all power is off.		
5	After 30 seconds, turn the power back on.		
6	Log on to the workstation when the Log On window reappears.		

Performing Daily Startup

Step	Action
1	At a Workstation, go to ? (HELP) from the Command Center. Go to Index \rightarrow type startup \rightarrow select daily \rightarrow click on Display.
2	Read the Performing Daily Startup procedure.
3	For additional information, read the following hypertext topic: Step 4: Check the startup test results. This opens the topic Checking Daily Test Results .
4	From the Checking Daily Test Results topic screen, select and read the hypertext topic in step 6: appropriate action. This opens Possible Startup Problems and Fixes .
5	From the Possible Startup and Fixes topic screen, select and read the hypertext topic: Background Test . Close HELP.
6	You may decide to have an automatic printout of the Daily Checks For LH 700 without LH SlideMaker go to step 7 to set up automatic print. If you have an LH 700 with LH SlideMaker, do not set up autoprint. When the Analyzer finishes its Startup, the Daily Checks will print and the SlideMaker will not have done its Startup yet. Your printout will have the date and time of the previous Startup on the SlideMaker. Wait until the SlideMaker completes it Startup and then manually print your Daily Checks. Skip steps 7 & 8 and go to step 9.
7	Go to Run Configuration now and select the Daily Checks under QA samples. This will automatically print your Daily Checks after a Startup. QA Samples Controls Calibration Heproducibility Carryover Service
8	Select (OK) to save.
9	Press START UP at the Numeric keypad.

Note 1	After cleaning agent removal cycles are performed, pressing START UP is the <u>only</u> way to activate pneumatics and begin the Electronic Tests and Background Checks.
10	For LH SlideMaker only: After the Workstation receives the Startup results from the Analyzer, the LH SlideMaker will automatically go through its startup cycle if the LH SlideMaker was in Shutdown. If the LH SlideMaker was not in Shutdown, request a Startup on the LH SlideMaker, from the LH SlideMaker Keypad: Main Menu \rightarrow Routine Functions \rightarrow Routine Fluidics. Press the button next to Run Startup. If you want a printout of startup results when the LH SlideMaker startup completes, select in the Workstation Daily Checks screen to print your results.
Note 2	Refer to the Easy Reference Guide for LH SlideMaker keypad functions.

Reviewing Daily Check Results and Details

Step	Action
1	Once the startup cycles are complete, review the Daily Checks results.
2	 The initial Daily Checks Results window shows a status of Pass (green) or Fail (red) for Reagents, Background and Main System. If you have a SlideMaker, its results are the final entry under Main System. In the Reagents field, the Pass/Fail refers to the expiration date. In the Background field, the Pass/Fail refers to the background counts. A Fail for any background count will also cause a Fail under Main System, Diluter. In the Main System field, the Pass/Fail refers to the various main components of the instrument system. If you have a Fail here, you need to look at the Daily Checks Details window (except for Diluter).



6	There is one other place that a daily check summary appears and that is in the History Logs. Select from the Command Center and look at the teb Daily Checks
	Ine tab Dany Checks.
	File Log Help
	🔿 📲 🗋 🌠 ? K?
	Daily Checks Event Instrument Reagent Control Data Reproducibility Carryover Calibration XB XM Maintenance SlideMaker SlideStainer Host / ToDo List
	Date Time Message Comment
	1/31/2008 724-39 Background FETIC test values within limits.
	1/31/2008 7.44/39 Background DIFF test values within limits. 1/31/2008 7.44/39 Background DEE test values within limits.
	1/31/2008 7:43:09 Background DIFF test values within limits.
	1/31/2008 7:43:09 Background CBC test values within limits. 1/31/2008 7:41:47 Baron test values within limits.
	1/31/2009 7-41-24 Precision test values within limits
	1/3U/2U8 /-41:0/ Background HE IU: test values within limits 1/3U/2U8 /-41:07 Background DIE test values within limits
	1/30/2008 7:41:07 Background CBC test values within limits.
	1/30/2008 7:39:37 Background DIFF test values within limits. 1/30/2018 7:39:37 Background FDF test values within limits.
	1/30/2008 7.38.15 Ramptes values within imits.
	1/20/2008 7.37.52 Precision test values within limits 1/20/2008 9.0153 Descator (ARADMIN sectored a shutdow on the analytical station
	Travecoo coolos operado Dobrumin percinited a situtumi un tre anagota statuti.
	Note that for a date/time, there are entries for Ramp. Precision and
-	
1	Background. It states whether the values were within limits or outside of
	limits
	1111105.
8	Close the History Logs by selecting the \mathbf{X} in the upper right corner.

Reviewing Past Daily Check Results

Step	Action		
1	Return to the Daily Checks screen. Select the (History) button from the specific toolbar to display a table with results from past startups, background tests, ramp tests, precision tests and SlideMaker startup results.		
Note	 If the requested Daily Checks (Startup) results do not appear, more than one line may be selected. You can only view one Daily Checks result at a time. After viewing a result, deselect it using the line select button again. The Daily Checks History log holds an unlimited number of results. It stores all Daily Checks results until the next software update or until the workstation is re-imaged. You can delete results from the Daily Checks History log. 		
2	Select a previous (older) Daily Check result to review. Once selected, it may be printed or reprinted.		
3	Look at the Details of your selected results and then close the details window.		
4	Deselect this date, scroll down the list and select several different dates (maybe 2-3 lines).		

5	Now select the button from the common toolbar. For the LH 780, this opens the Daily Checks Output Selection window. LH 780 users continue with all of the next steps (6-10). For the LH 750, all selected rows will print as Individual Reports. Skip to step 9.
6	The selections shown below are the default settings. Unless you want to print everything in the daily checks history, <u>do not use these</u> <u>settings</u> ! Instead, choose the "Selected Rows" radio button.
7	Leave Line List of Summary Data selected and then select
8	Select the button again, choose "Selected Rows" , and this time choose Individual Reports . Select 2 . Your printouts should be full-page individual reports for each of your selections.
9	Select (Current) on the Specific Toolbar to return to the current Daily Checks window.

QUALITY CONTROL

Running Latron Primer and Control

Step	Action
1	Follow the Running Latex ControlDiff and Retic procedure from HELP.
2	When you run Latron Primer, after entering GGO on the Numeric keypad, press Enter, then press before presenting the vial at the aspirator tip. The LH 700 compares the Primer results to the maximum value of 500. When you run Latron Control do not press or erroneous results will occur. Just press and present the vial at the aspirator tip. The LH 700 compares the results to those entered into the Workstation at control set up.
3	Use the Control tree to view your Latron results.
4	Note that you have <u>two entries</u> with the same date, one for the Primer and one for the Control. Use both horizontal scroll bars to view all results for both 5PD (five-part diff) and Retic.

	Lot	# 1073	65	Contr	ol Type Lat	ex	Expiration D	ate 3/10/200	7 Le	vel	
		Des.	Date	Time	PRIMER 5PD	Mn Ch (V) 5PD	Mn Ch (C) 5PD	Mn Ch (S) 5PD	%CV (V) 5PD	%CV (C) 5PD	%C_ (S) 5_
			7/7/2006	14:07:26		28.3	28.2	91.1	3.3	3.7	2.9
Control -			7/7/2006	14:05:25	7						
			6/23/2006	11:14:16		28.0	27.9	90.6	3.2	3.7	2.9
Primer		-	6/23/2006	11:12:16	5						
			6/20/2006	14:21:57		28.0	27.9	90.1	3.3	3.9	3.0
			6/20/2006	14:20:17	11						
			6/20/2006	14:17:48	8192 H						
			6/13/2006	11:27:15		27.9	27.7	90.7	3.2	3.8	2.9
			6/13/2006	11:25:38	7						
		×			Þ						<u>ار</u>
	K				N =	5	5	5	5	5	
Primer				N	lean /	28.1	28.0	90.8	3.2	3.8	3.
Scroll b	ar			Co	ontrol						
				Sc	roll ba	r					

Latex Control Is Outside Expected Ranges

Step	Action				
1	At the Workstation go to not be Command Center. Choose on the Common Toolbar. And then from the Common Toolbar. Topic on the screen is: Reviewing Control Results				
2	In the HELP window at the left of the screen, select the Index tab . Type Latron. Click the Display button. In the popup window choose When a Latex Control is Outside its Expected Ranges. Choose display.				
3	Read the topic. You now have some basic troubleshooting tools to use if LATRON Control is outside its expected ranges.				

Running 5C and Retic-C Cell Controls

Step	Action
1	Open HELP from the Common Toolbar, select Index and type Cycling , click on and display Cycling Controls in the Automatic Aspiration Mode.
2	Read the procedure (the procedure itself is titled Cycling Controls). If you have a SlideMaker, click on the hypertext topic Quality Control Processing with LH SlideMaker . Ensure that you run your controls in the proper sequence.
3	Place your properly mixed controls into cassette(s) with bar code labels facing up . Place cassette(s) into the right-hand loading bay.
4	Use the Control Tree to access control folders and review control results.





5C and/or Retic-C Cell Controls are Outside the Expected Ranges

Step	Action
1	At the Workstation QA/QC screen select ? (from the Common Toolbar).
2	Use HELP to find the following topic: When a Control is Outside its Expected Ranges.
3	Read the topic. You now have some basic troubleshooting tools to use if 5C Cell Control or Retic-C Cell Control is outside expected ranges.

Finding Flagged Control Results

Step	Action
	At the Workstation, from the Command Center, go to 🕵 , 😍
1	On the LH 750 open the Control Tree by clicking on the 🖶 in front of BCI.
	On the LH780 , open the Control Tree by clicking on the 🖶 in front
	of the Active folder and then click on the 🖶 in front of BCI.
2	Click on the the 🖶 in front of 5C, Retic-C or Latron.
3	Click directly on the Control folder you wish to open. The most recent result is at the top of the list.
4	A flagged result will have a red background for the Date and Time fields. Use the scroll bar at the bottom of the results window to find specific flagged results.

Deselecting and Restoring a Control Result

Step	Action
1	For a flagged result, click on the deselect (Des) button at the left of the line.
2	The line is now grayed out and removed from the statistical results below. Note the total number of runs in the control folder after removing one run.
Note	When you print a file with a deselected run, the word "yes" appears in the deselect (des) column.

Add a Comment in a Control Folder

Step	Action
1	Choose a control run. Click on the \Box button.
2	Type a comment in the comment box and select [OK] to save the comment.
3	The Workstation adds the comment to the appropriate control sample and places an X in the CMNT column for the specific control. The comment is also added to the History Logs, Control Data tab.
4	Click on any box with an X in the CMNT column to view a comment, add text or change text.
Note	When you print the file, the comment appears <u>under the run</u> with which it is associated.
5	Select (History Logs) from the Command Center.
6	Select the Control Data Tab and view the comment added to the control file.

Levey-Jennings Graphs

Step	Action
1	Open the QA/QC window again. Select the same control folder to work with.
2	Below the statistical information for a control folder are the thumbnail Levey-Jennings graphs showing the last 10 runs in the control folder.
3	The parameters are grouped in sets of three, starting with WBC, RBC, Hgb. The scroll bar at the top of the graphs lets you access the graphs for other parameters.
4	Scroll to PLT and click on it now. Use the graphs to observe trends and shifts.
5	Double-click on any thumbnail graph to see a larger version called full-page. This graph shows up to 100 data points for the selected control folder.
6	Close the full-page graph by selecting Exit P .

Printing Control Results

Step	Action
1	With the control folder still open, from the Common Tool Bar select the $($ Print $)$ button.
2	By selecting the desired radio buttons on this screen you can print various combinations of control folder data. For this exercise, choose "Selected Lot" and "Thumbnail" graphs.
3	After making your selection, click on 🥝.

Setting Up and Using the Shift Clocks

On the specific toolbar in the QA, QC screen area are a set of clock buttons. These allow you to review control runs by shift. Shift **0** is all runs from all shifts. Shifts **1**, **2** or **3** are the runs by individual shift as defined by your lab. Selecting any of these buttons automatically extracts the correct runs based on the shift time settings. The buttons are active only if shift times are entered. To set up individual shift times go to:

Shifts

System Setup \rightarrow Quality Assurance \rightarrow



Practice

Step	Action
1	Select System Setup And File Help File Help General Settings Quality Assurance
2	Select the Shifts tab.
3	Select Use Multiple Shifts.
4	Enter the starting times of the shifts in your laboratory. Refer to the screens above.
5	Select OK).

LH SLIDEMAKER & LH SLIDESTAINER SET UP

References in HELP

Step	Action
1	Select HELP $?$, go to Contents \rightarrow LH SlideMaker \rightarrow Operating.
2	Display and read: Loading Slides into a Cassette and Loading Slide Cassettes (into the Slidemaker).

Loading Slides into a Cassette

Step	Action		
1	Follow the Help procedure and load the slides into a slide cassette.		
	Watch out for these relatively common <u>errors</u> !		
Note	Don't	Do	
	Frosted bars on the ends of the slides are not facing down in the slide cassette.	Frosted bars should be <u>facing</u> <u>down</u> in the slide cassette.	
	Slides misaligned in the cassette.	Be sure slides are straight.	
	Cassette picked up by holding on sides.	Hold slide cassette on front and back.	

Loading a Slide Cassette into the LH SlideMaker

Step	Actio	on	
1	Review the Loading Slide Cassettes procedure in HELP and load the Slide Cassette into the LH SlideMaker.		
	Watch out for these relatively common errors!		
Note	Don't Place cassette too far forward (toward the LH SlideMaker) in the input queue so that locking arms cannot lock cassette in	Do Instead place the cassette near the center of the input queue.	
	place. Cassette arrow facing rear.	Be sure the slide cassette has the arrow facing you.	

Workstation Set Up for LH SlideMaker

At the Workstation Command Center go to	\diamond	(System Set Up), then	SlideMaker/SlideStainer
From the SlideMaker tab, setup the following	ıg:	-	

Step	Heading	Action
1	Smear Dispense Mode	Choose Alternate Position (this means only six slides will fill a basket)
2	Slide Label Definition	Laboratory ID: Type the name of your lab
		Print Bar Code Tube ID: (leave check box blank)
3	Print Layout	Date & Time: <u>line 1</u>
	Include all of the following in a format of your choice (Use Small Font for Patient Name and Date & Time)	Lab ID: <u>line 2</u>
		Sample ID
		Patient Name
		Cassette / Position
4		Select of to save.

٩

SYSTEM OVERVIEW / COMPONENT LOCATION

Step	Action
1	From the Command Center, go to HELP, Index (tab) and type Use .
2	Select the topic Use and Function – SlideStainer. Select Display.
3	In Index , type the keyword Identifying and select Identifying System Components – SlideStainer .
4	Use the various hypertext links for close up views of the LH SlideStainer to become familiar with components and their locations.
Hint 1	Open the Basket Tray drawer only when the green light on the front of the drawer is ON.
Hint 2	To silence the LH SlideStainer alarm, acknowledge the error message on the Workstation.

SlideStainer State

Step	Action	
1	On the Workstation, go to \bigcirc then $\bigotimes_{\text{SlideMaker/SlideStainer}}$.	
2	Select SlideStainer	
3	Look at the top left corner of the window. Depending on the "state" of the LHSlideStainer, the message you see may be different.	
4	Select the Help Mode button from the bottom of this window.	
5	Click once in the box to the right of SlideStainer State. A pop up window called "SlideStainer State" opens. Read the various states of the LH SlideStainer.	

Fill and Drain Baths

Step	Action	
1	In HELP 7 go to Contents \rightarrow LH SlideStainer \rightarrow Operating Procedures \rightarrow Operating \rightarrow Basic.	
2	Select Draining Baths and Filling Baths and read these topics.	
3	For information on changing reagents go to Help Contents \rightarrow LH SlideStainer \rightarrow Operating Procedures \rightarrow Operating –BASIC \rightarrow Daily Operation.	
4	You must be in Standby Mode to Fill or Drain baths.	
5	Bath 3 contains Stain/Buffer. Get a small (50 mL) bottle of stain to add to Bath 3 as the baths are filling. Slowly pour the stain into Bath 3 after it is about half full.	
6	Follow the procedure for Filling Baths and fill all baths completely.	
Note	When you are running the LH 700 Analyzer with LH SlideMaker and LH SlideStainer, the "empty" basket area contains baskets that the LH SlideStainer will automatically return to the LH SlideMaker. After removing slides from the baskets for manual Diffs, return the empty baskets to the LH SlideStainer in the "empty" basket area. Do Not return the baskets to the front track of the LH SlideMaker.	

Cleaning Procedures

Step	Action
1	At the Workstation in HELP, go to Contents \rightarrow LH SlideStainer \rightarrow Cleaning Procedures \rightarrow Cleaning - Overview.
2	Review all the procedures to familiarize yourself with the cleaning and maintenance of the LH SlideStainer.

Creating a New Staining Protocol

Step	Action
1	At the Workstation, go to HELP, Index and type staining protocol .
2	Under staining protocol , double-click on creating and read this topic.
Note 1	The Default protocols can not be edited. If you want to use a default with slight changes, just create a new protocol with a different name.
Note 2	Any protocol that you create can be edited by selecting it from the list, making your changes and then saving it. You will get a message that asks if you want to change it, just answer yes. Then, remember to download your new protocol.
3	Follow the procedure for " Creating a New Staining Protocol ". Enter the desired name for your new protocol.
4	Set the times for baths 1 , 2 , & 3 and 5 and the Dryer to the desired times.
Note 3	If using Wright protocol, set the time for bath 4 to 0 sec.
5	Save your protocol.
6	Download the protocol to the SlideStainer.
7	Make sure the SlideStainer State is set to Auto Mode.
8	After completing the protocol setup, place an empty basket in the STAT input location to test your protocol.
9	The LH SlideStainer will pick up the basket and "process" it.

Deleting a Selected Protocol

Step	Action
1	At the Workstation in HELP, go to Contents \rightarrow LH SlideStainer \rightarrow Operating Procedures \rightarrow Operating – Advanced .
2	Select the topic: Deleting a Selected Protocol .
3	Read and be familiar with how to delete a stain protocol.
Note	To delete a protocol, it cannot be the Protocol in Use. Be sure to download whatever protocol you want the LH SlideStainer to use <u>before</u> you delete the protocol you do not want to keep.

RUNNING PATIENT SAMPLES

AUTOMATIC MODE – RANDOM ACCESS

Instrument/Workstation Overview

Step	Action		
1	Click on # (Run Configuration) from the Command Center.		
2	If you print sample results in your laboratory, make sure that Automatic Output, Print (tab) is set to All Samples .		
3	 Do you have an LH SlideMaker and LH SlideStainer? Make sure that Enable System Functions, SlideMaker is selected and SlideStainer is selected, if applicable Select Slide Maker tab and select to make slides on SlideMaker Decision Rules Only or All Samples depending on your laboratory protocol Verify a slide cassette with slides is present in the LH SlideMaker Input queue 		
4	Have the pneumatics timed out? If the Analyzer Control Panel display shows "Compressor Off", then the pneumatics are timed out. Press the pneumatics.		

Running Samples

Step	Action
	On the Command Center, verify Random Access is selected. It does not matter which Default type is selected.
1	CD CDR CR R B Default Type: CD ▼ Random Access ▼
	NOTE: If Random Access is deselected, the analyzer runs whatever test mode is in the Default Type field.
2	Place sample tubes into a sample cassette, making sure the bar code labels are facing up.

3	Place the cassette into the right-hand loading bay of the Diluter. The Smart Start feature senses the presence of the cassette and starts the run automatically without the need to press the button on the Analyzer Control keypad.
4	Select from the Command Center to open the Patient Tests (Results & Graphics) window.
5	Click on the Diff Data tab and the Retic Data tab.
6	Pass the cursor over the populations on the the two-dimensional Dataplot to learn their identification through the ToolTips.
7	Double-click on the two-dimensional Dataplot to enlarge it. There are buttons across the top of the Dataplot that allow you to remove and restore populations. Tool tips identify the population related to the button.
8	Close the Dataplot by selecting (Close).

Manual Mode

Important: Refer to the Help topic "<u>Manual Mode Aspirator</u>" prior to completing these steps.

Using the hand-held scanner to identify samples

Step	Action
1	On the Command Center, place the cursor in the Barcode field.
2	Hold the scanner over the bar code label. Press and hold the trigger until the scanner beeps. The barcode number appears in the Barcode field.
3	At the Analyzer Control keypad, press then to transfer the barcode number to the Analyzer. If these two buttons are pressed too quickly, an echo error (a communication failure) will occur.
Note 1	If an Echo error occurs, reset the Analyzer by pressing the button on the top right corner of the Analyzer top cover. When the instrument returns to Ready, try again.
4	The bar code number transfers to the Analyzer. Make sure the correct bar code number appears on the Analyzer.

5	Press on the Analyzer Control keypad to accept the number.
6	Make sure the sample is well mixed, then open the tube.
7	Immerse the manual mode probe in the sample. The manual aspiration process activates automatically. Be sure your fingers block the sensors. When you hear the "beep" from the Analyzer, remove the tube and re-cap it. The probe retracts, rinses and dries automatically.
Note 2	LH SlideMaker : In the manual mode of operation, slides are never made.
Note 3	If you have a non-bar coded sample, you can manually type the accession or identification number into the Barcode field on the Command Center by using the keyboard. After typing, press the <tab></tab> key on the keyboard, then o and o at the Analyzer Control keypad to transfer it to the Analyzer as you did above. An alternate procedure for entering the accession or identification number for a manual mode sample is to use the Analyzer Control keypad o , key in the numbers, press

Using the Predilute Mode

The Predilute mode on the LH 700 may be used to run diluted specimens that are over the reportable range or to run a citrated tube when you have clumped platelets. When chosen, it runs in the **CBC test mode only**. You may enter dilution factors from 1.1 to 5.0. The sample results are automatically multiplied by the dilution factor entered. After running a dilution, the Analyzer automatically disables predilute. Remember that Manual mode requires 200 μ L of sample for aspiration.

Use a sample for which you already have results.

Step	Action	
1	Make a dilution manually using LH Diluent. Dispense diluent from the instrument, using the FOO function.	
	Have a clean empty tube ready to collect the diluent dispensed (approximately 2 mL) from the manual probe when you press Enter .	
2	When finished, press \bullet to exit function.	
3	Using a pipettor, dispense 200 μ L LH Diluent into a clean tube.	
4	Using a pipettor, dispense 200 μ L blood into the same tube, and mix well.	
5	 On the Workstation, Command Center, make sure Predilute (CBC) is enabled Predilute (CBC) 	
------	---	--
	• Set the Factor to 2.0 in the pop-up box that appears for the dilution just prepared	
6	Identify your sample to the LH 700 Analyzer using the Analyzer Control Keypad.	
7	Run your sample in the Manual mode. (Predilute is only active in the manual mode).	
8	Check these results with the results of the same sample run undiluted .	
Note	Setting a dilution factor is valid for <u>one sample at a time</u> .	

Using the Body Fluid Mode

The Body Fluid mode provides analysis of CSF, Serous (pleural, peritoneal, pericardial) and hyaluronidase-treated Synovial fluids. Application access is similar to predilute, via a check box on the Command Center. Only WBC and RBC values are reported, with the WBC representing the Total Nucleated Count (TNC).

Step	Action	
1	At a Workstation, from $?$ (HELP), go to Contents \rightarrow LH Body Fluids Application .	
2	 Display and read the following Body Fluids topics Body Fluids: Overview Body Fluids: Intended Use Body Fluids: Known Limitations and Interfering Substances Body Fluids: Operation Principles Body Fluids: Processing Body Fluids in the Manual Mode Body Fluids: Specimen Collection and Storage 	

Processing Body Fluids in the Manual Mode

Step	Action		
1	Follow the HELP instructions for Processing Body Fluids in the Manual Mode.		
2	Dispense diluent from the instrument into the tube by using the function.		
3	Perform a Diluent blank and verify acceptable Background count results for WBC and RBC. Acceptable limits are the same as those for background for Daily checks.		

4	From the Workstation Command Center, ensure AUTOANALYSIS is the Process Type and enable the Body Fluid (CBC) checkbox.		
5	Identify your sample to the LH 700 Series Analyzer using the Numeric Keypad or the handheld scanner.		
6	Mix the body fluid sample and aspirate in the manual mode of operation.		
Note	Once you run your sample, the Body Fluid checkbox disables. To run another body fluid, enable the check box again.		
	Review sample results.		
	<u>Do not report the WBC</u> if $< 0.20 \times 10^3$ cells/µL. Obtain WBC by an alternate method.		
	<u>Do not report the RBC</u> if $< 0.010 \times 10^6$ cells/µL. Obtain RBC by an alternate method.		
	 Note on the screen that CBC: BF displays next to the sample ID field with a yellow background. 		
	• The printed report displays the <u>footer</u> "BODY FLUID".		
7	• The comment "TNC=WBC" displays in the Comment field on the Demographics Tab on the screen and in the Comment field on the printed report.		
	• Body fluid results are excluded from XB statistics.		
	• Body fluid results are excluded from patient history statistics.		
	• Body fluid results do not collate with other samples of the same Patient ID.		
	• Body fluid results are not Autovalidated. They must be manually validated.		

Using Micro-collection Tubes

<u>Important</u>: Refer to the Help topic "<u>Manual Mode Aspirator</u>" prior to completing these steps.

Step	Action	
1	Using a transfer pipette, fill two or three micro-collection tubes with blood from one of the sample tubes you already have.	
2	Use the hand-held bar code scanner to enter the bar code ID# at the Workstation. Refer to the Manual Mode procedure.	
3	Process sample in the manual mode of operation.	

How to Rerun a Sample Using the ToDo List

When your LH 700 Series System is bidirectionally interfaced, sample requests are automatically downloaded to the LH ToDo List by your Host/LIS system. When you run the samples, they are <u>removed</u> from the ToDo List. **If you need to rerun a sample there are two scenarios:**

- **Rerun it**. The Workstation gives you a **No Match** status along with the Sample ID (from the bar code label) and the results. The instrument uses the Default Test mode selected. There will be no demographics associated with the rerun.
- Manually add it back to the ToDo List. This option eliminates the No Match status and runs the sample in the preassigned Test mode. If you want demographics they have to be entered at the time you add it to the ToDo list.

Adding a Sample Request to the ToDo List

Step	Action	
1	Select (Add Sample Requests) from the common toolbar of the patient results area.	
2	Select a Test Mode check box.	
3	Click once in the Sample ID area to place your cursor, then scan the tube bar code label. Leave the Cassette/Position field blank. Check STAT, if appropriate.	
4	Use the <tab></tab> key to move the cursor to the Patient ID field.	
5	Open the drop-down box to select the Patient ID. (In the classroom, the patient ID is a four-digit number under the date and time on the barcode). The other demographics associated with the sample automatically populate the fields.	
6	Add any other information you may need and then select 🛤 at the bottom of the screen to add it to the ToDo list.	
7	Select (exit).	
8	If you wish to confirm the new entry, go to Database/ToDo View) and then select the test mode folder you assigned to the repeat. Your sample will be at the bottom of the list	
9	Place the repeat tube into any cassette and run it.	

Shutdown the LH SlideMaker (if applicable). If you do not have an LH SlideMaker, proceed to the next page.

Step	Action			
1	 If the compressor has timed out, press the PRIME APERT key on the Analyzer keypad before shutting down the SlideMaker. If you have an LH SlideMaker, from the SlideMaker Keypad, select Main Menu → Routine Functions → Routine Fluidics → Run Shutdown. After Run Shutdown is delected on the SlideMaker menu, the words "Performing fluidics" and then "busy" appear in the bottom left corner of the SlideMaker keypad. This takes approximately 2 seconds. If the status does not change to "Busy", the SlideMaker is not performing shutdown. When Shutdown is complete on the SlideMaker, the SlideMaker status will change to "not ready". 			
Note				
2	When Ready appears on both the Analyzer and the Analyzer Control Keypad, press shur down on the Analyzer Control Keypad. When a Shutdown is requested, an entry is made in the Daily Checks History Log.			
3	At the end of the Shutdown cycles, leave Analyzer power ON so that the cleaning agent removal cycle can start at the programmed time.			

Shutdown the Analyzer

The LH 700 Analyzer allows for programming the length of time the Analyzer is in Shutdown. The default time is 30 minutes. Service can change the default from 30 minutes in one hour increments from 1 to 24.

First	When the " Ready " message displays on the Analyzer and Numeric Keypad, press of the Analyzer Control Keypad to shutdown the Analyzer. An entry is posted to the Daily Checks History Log with the date and time.
Second	The LH 700 Analyzer automatically removes cleaning agent from the Diluter after 30 minutes has elapsed (or whatever time frame you have chosen). No startup checks are done at this time.
Third	The operator must press START UP on the Analyzer Control Keypad. A two minute cycle then performs Electronic Tests and Background Checks.

The instrument software automatically checks for the completion of cleaning agent removal. If cleaning agent has not been successfully removed in the Diluter for any reason, when startup is pressed, the Analyzer will perform the complete Startup cycle including the cleaning agent removal phase.

NOTE: If the Analyzer is in Shutdown and you need to start up the Analyzer to run a STAT, but it has been less than 30 minutes (or whatever time frame you have chosen), you can press **START UP** to interrupt the programmed time.

When you press start up, the instrument will perform a complete Startup cycle: cleaning agent removal, Electronic Tests and Background Checks.

REAGENT SET UP & REPLACEMENT

The Reagent Data Entry screen shows the current reagent lot numbers in use on your instrument. In addition, this screen shows the unopened shelf-life expiration date (the date on the box) and the open container expiration date. When you make an entry in the Reagent Setup screen, there is also an entry made in the History Log Reagent tab that includes the date and time of the reagent change, along with the lot number and expiration date.

The Shelf Life is the System Setup - [Quality Assurance] date to which an Reagents unopened container Last Modified 06/29/2009 may be used. By gfalia Reagent Data Entry **Open Expiration** Use Before Shelf Life Part Lot Date Number BCI Opened Number Expiration Diluent 8547194 510453F 06/17/2009 08/16/2009 11/06/2009 60 12345F 06/25/2009 08/21/2009 08/21/2009 60 8448177 CBC Lyse 12/21/2010 8546917 1234567 06/29/2009 08/28/2009 60 Diff Pack 8547115 1234567 06/29/2009 08/28/2009 12/21/2010 60 **Betic Pack** 09/15/2009 12/21 06/17/2009 90 Cleaner Pack 8721543 1234567 Reagent Setup × 0 ? N? -These are the default open-expiration dates for Beckman Coulter reagents. The open expiration is the date to which an opened container may be used, based on the Date Opened.

Reagent Data Entry Screen

History Log/Reagent tab

trument	? K?	st
48	Message Comment Operator SER installed Cleaner Pack BCI Reagent Lot to: 102120F. opened on	Comme
48	Operator SER installed Retic Pack, BCI Reagent Lot to: 57094k, opened on 5/1	
48 40	Operator SER installed Diff Pack, BCI Reagent Lot to: 110897K, opened on 5/1 Describe SER installed CRC Lines PCI Research Let to: 101513C, exceed on 5/1	
40 48	Operator SER installed DiluentBCI Reagent Lot to: 51029F, opened on 5/10/2	

Reagents Used on the LH 700 Series

Diluent	LH Series Diluent	PN 8547194	Isotonic diluting fluid
CBC Lyse	LYSE S III diff	PN 8546983, 1L; PN 8546796, 5L	CBC lysing fluid
Diff Pack	LH Series Pak	PN 8547195	Differential reagents (ErythroLyse II and Stabilyse)
Retic Pack	LH Series RETIC PAK	PN 8547196	Reticulocyte reagents (New Methylene Blue and Clearing Agent)
Cleaner Pack	LH Series Cleaner	PN 721542, 5L; PN 721543, 10L	Cleaning agent

Setting Up a New Reagent

Step	Action	
1	In HELP select Search \rightarrow type reagent \rightarrow click on List Topics \rightarrow select Changing Reagent Information \rightarrow click on Display. Read this topic.	
2	On the instrument Workstation from the Command Center go to: (System Set Up) \rightarrow (Quality Assurance Set Up). The Reagents tab is the first tab on the QA Set Up window.	
3	Select the Reagent Setup button to setup new or modify existing reagents. The Reagent Setup window appears.	

4	Enter the reagent information using the handheld barcode scanner or manual entry of the barcode. If manually entering, enter all of the characers, numbers, and letters that make up the barcode.	
5	Press on the keyboard to move between the fields for manual entry.	
6	Select (OK) to save and exit the Reagent Setup window.	
7	Select in the Reagent Data Entry window to save the changes.	
Note	When the audible reagent alarm signals that a reagent container is low, you must replace the reagent container immediately. The Workstation automatically displays the reagent set up screen and a red message box. See the example on the following page.	



The LULA netwoon displays a code letter for the response that is low		
The Lr	A Analyzer displays a code letter for the reagent that is low.	
C	The cleaning agent is low.	
D	The diluent is low.	
L	The CBC Lyse is low.	
Р	The Diff Pack is low.	
R	The Retic Pak is low.	
W	The Waste is Full. (Only applies if you collect waste into a waste container.)	

4/24/2006

14:02:00



SETTING UP CONTROLS



	If you are setting up <u>either</u> 5C Cell Control or Retic-C Cell Control, follow directions on the pop-up window.	
5	• You may select to have the LH 700 Analyzer AutoStop when a control is out of limits.	
	If you select AutoStop, go to <i>(Run Configuration)</i> and also select AutoStop Criteria/ Controls.	
	• You may select to AutoTransmit control results to a Laboratory Information System if the LIS has a QC package.	
6	Select 🖉 [OK]	
7	When you are setting up LATRON, after selecting the button, you enter information from the package insert starting with Lot # and expiration date.	
Warning	Use the Tab key to move from field to field. If you press the "Enter" key, the screen will close. To continue, you need to select the Latron file from the control list by using the line select button and then select the Edit solution.	
Note 2	You do not have to enter the (+/-) or (\leq) signs when typing numbers.	
8	Select OK).	
9	Select (Close) to close the Setup New Control Folder window.	
10	Select (OK) to close the System Setup / Quality Assurance window.	
11	There should now be seven files in the table on the Controls tab.	

Organizing Control Folders (LH 780 ONLY)

Once you set up a control file, you may designate the status. You may change the control status at any time. You may access the status from either the control setup/edit screen or from the QA/QC screen. Your status choices are:

Active	Use Active for the control files that are currently in use.
Accumulating	Use Accumulating for the control files during cross-over study.
Inactive	Use Inactive for control files that you have completed.



Practice (LH 780 ONLY)

On your LH Workstation, where you just setup your control folders, you may practice marking your folders as follows:

5C	1 Active, 1 Accumulating, 1 Inactive
Retic-C	1 Active, 1 Accumulating, 1 Inactive
Latron	Accumulating

FLAGGING LIMITS

Setting Up Flagging Limits (a new set)

Step	Action		
Note 1	Follow these steps to create your own new flagging set. This is an just an exercise on how values are entered into the LH Workstation.		
1	a.) Select from the Command Center, select and then select Flagging Limits.		
	b.) To create a <u>New</u> flagging set, click on .		
	c.) Enter Test Adult in the Limit Name box.		
	d.) Select the drop-down arrow under Location and choose a location from the list.		
	e.) Enter an Age Range , From 0 hours To 150 years in the boxes. Note: The drop down boxes may be used to change from years to hours, days, or months.		
	f.) Choose of to Save your new flagging limit set.		
2	Highlight the Test Adult set you just created and then select the button (Modify Limit Values) to display the Laboratory Flagging Limits Setup window. On this window are tabs for each of the subsets: Male (Def.), Female, Action Limits, Critical Limits, and Definitive Messages.		
3	Use the copy function (Copy Existing Limits) and copy the Adult Default to your Test Adult for the following: Male (Def.), Female, Action Limits and Critical Limits.		
Note 2	Make sure you first select the tab you want to copy before selecting the copy button		
	a.) Choose the Male (Def). tab.		
	b.) Choose the Copy Existing Limits button.		
4	c.) From the Limit Set dropdown box, choose Adult.		
	d.) From the Limit Category dropdown box, choose Male (Def).		
	e.) Click on 🖉. The Adult Male (Def) Limits will copy into your Male (Def) Limits page.		
5	Repeat steps a) through e) from above for Female, Action and Critical Limits.		

	Make the following changes to your Test Adult:				
1	Reference Limits for Male/Female				
			Male (Def)	Female	
		WBC	30 - 35	30 - 35	
		RDW	10 - 11	10 - 11	
		PLT	50 - 100	50 - 100	
6			00 100	00 100	
	Action and	Critical Li	mits		
			Action	Critical	
		WBC	2.9 - 3.6	3.0 - 3.5	
		MCV	70 - 101		
		RDW	9.9 – 11.1	9.7 – 11.3	
		PLT	49 - 101		
7	Choose the	Definitive	Messages tab,	select the chec	kboxes 🔽 for:
1	Leukopenia, Neutrophilia%, Lymphocytosis#.				
Note 3	The Definit	ive Messag	ges reflect the v	values entered f	or Action Limits.
8	Select the 3+ Gradie The numbe action limit	(Help Monthead (Help	ode) button and ield. Single-clic tered is what is r a 3+ gradient	I move the curs ck with the left added to or sul range.	For to any 2+ or mouse button. practed from the
	Refer to the Action Limits you entered for MCV in Step 7.				
9	On the Definitive Messages window, select the reckbox for				
	Micro.				
10	For and MCV of 65.0, enter 5 for 2+ microcytosis.				
10	For an MCV of 60.0, enter 10 for 3+ microcytosis.				
11	On the Def Macro.	initive Me	ssages window	, select the \mathbb{M} of	checkbox for
10	For an MCV of 108.0, enter 7 for 2+ macrocytosis.				
12	For an MCV of 113.0, enter 12 for 3+ macrocytosis.				
13	Select 🕖	to save yo	ur new set of F	lagging Limits.	

Diff Flagging Preferences

Step	Action
1	At the Workstation, go to HELP \rightarrow Search \rightarrow type Flagging Preferences \rightarrow click on List Topics \rightarrow double-click on Flagging Preferences from the list.
2	Read this topic and become familiar with the Flagging Preferences procedure.
3	DO NOT change the Flagging Preferences on your instrument. Changes should only be made after a flagging study, i.e. Truth Table Analysis is performed.

Save/Restore Configuration

Step	Action		
1	From HELP, select the Index tab, type saving , select the topic "saving configuration". Display and review this topic.		
Note 1	Although the Help procedure only mentions using a floppy diskette, you may also cloose to use a formatted CD-R or a flash drive.		
2	Obtain removable media (CD, flash drive).		
Note 2	In the future, once all your Workstation setups are complete in your own lab, you should save the data configurations entered as a backup for use if the need arises (e.g. if data has been deleted or erased due to software upgrade).		
3	Insert your removable media into the appropriate drive.		
4	Open System Setup.		
5	Click on Save/Restore Configuration on the Menu Bar.		
6	Select Save and then select Next.		
7	Check both the Save Registry and Save Database Component(s) checkboxes and then select Next. Click on Browse.		
8	To use a CD or flash drive, select cancel when the "Insert disk in drive "A" window appears.		

9	When the "Save as" window appears, double click on My Computer.
10	Select the appropriate drive for your removable media and choose Open.
11	Type the filename in the format as shown XXXMMDDYY (i.e. For April 12, 2015 with software version 2D3 the filename would be 2D3041215 with no extension). Click Save.
12	The filename should display with .RGS after it. Click on Next> and then Browse.
13	To use a CD or flash drive, select cancel when the "Insert disk in drive "A" window appears.
14	When the "Save as" window appears, double click on My Computer.
15	Select the appropriate drive for your removable media and then choose Open.
16	Type the same filename again with no extension. Click Save.
17	The filename should display with .DBS after it. Click Next>.
18	Check all checkboxes: Patient Setup , Physician , Location and QA Setup .
19	Click on Finish . When done, the window will close automatically.
20	From the Workstation desktop, double-click My Computer.
21	Click on the appropriate removable media drive.
22	In the right pane of the window, there should be seven files. Two have the name you entered earlier with different extensions and five stain protocol files with .STP extensions. Remove your media.

Restore Configuration from Removable Media

Step	Action		
Note	Read these steps. DO NOT perform this procedure at this time.		
1	Insert your removable media in the appropriate drive. Open System Setup.		
2	Click on Save/Restore Configuration on the Menu Bar.		
3	Select Restore and then click on Next> .		

4	Check both the Restore Registry and Restore Database Component(s) checkboxes and then click on Next>. Click on Browse.
5	To use CD or flash drive, select cancel when the "Insert disk in drive "A" window appears.
6	When the next window appears, double click on My Computer.
7	Select the drive for your media and choose Open.
8	Select the filename you created earlier which is in the format XXXMMDDYY (i.e. For April 12, 2015 with software version 2D3 the filename would be 2D3041215) with the extension of .RGS. Click Open.
9	The filename displays with .RGS after it. Click Next> . Click on Browse .
10	To use the CD or flash drive, select cancel when the "Insert disk in drive "A" window appears.
11	When the next window appears, double click on My Computer.
12	Select the drive for your media and choose Open.
13	Select the same filename again with the extension of .DBS . Click Open .
14	The filename displays with .DBS after it. Click Next >.
15	Check all checkboxes: Patient Setup , Physician , Location and QA Setup . Click on Finish .
16	A window appears with the message "The system will be restarted now to reinitialize with the new settings."
17	Click OK . The system shuts down Windows. Another window appears with the message, "It is now safe to turn off your computer".
18	Remove your media. Press the Power OFF button on the computer tower. Wait one minute and then Power On.
19	Log on to the Workstation. When it is completely up, reset the analyzer.

All System Configurations are restored including Decision Rules and Stain Protocols. Patient results and Control runs are not restored with this procedure.

DECISION RULES

IMPORTANT

- Flagging is evaluated when the sample is analyzed.
- Flagging is <u>reevaluated</u> 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. Decision rules and Delta checks 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 limits (aH/aL), critical limits (cH/cL), definitive messages, suspect messages, 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.

Practice – Decision Rule (Reflex Manager)

Note: to perform this task requires Lab Administrator (Level 3) security access.

Follow these steps to set up the following Decision rule: "If WBC is ≤ 2.0 or ≥ 20.0 , perform a manual diff.

Step	Action			
1	From the Command Center, select and then select Patient to			
2	Decision Rules & Criteria tab to display any existing rules. System Setup - [Patterk] Flagging Preferences Decision Rules & Criteria Last Modified 7/25/2001 By Labhdmin Mode Type Mode of the type Intervention Rules & Criteria Last Modified 7/25/2001 By Labhdmin By Labhdmin By Labhdmin Intervention Rules & Criteria Intervention Rules & Criteria Last Modified 7/25/2001 By Labhdmin By Labhdmin Intervention Rules & Criteria Intervention Rules &			

	Select from the Decision Rules and Crite	ria tab to	o set up the
	messages for the decision rule, e.g. "Review t results".	to enter the slide	" or "Call
	Rule Configuration	Last Modifie By	d 7/25/2001
	Existing Reflex Manager Messages	Date Setup	Setup By 🔺
		7/11/2001	LabAdmin
	2 call the floor	7/25/2001	LabAdmin
	4 repeat sample	7/25/2001	LabAdmin
3	5 mix well and repeat	7/25/2001	LabAdmin 🗾
	Add New Message: Up to 64 Charactere	ula aritaria mat	
		 Review Folde Reflex Manag 	r r jer Folder
	Delta Check Time Limit Patient Specific Identifier To Bays Patient ID Select this to message to th	ule criteria met, j ? Review Fold ? Delta Check SAVE YOUI ne list.	Poost sample to: er Folder NCW
4	In the "Add New Message" box, type the message you want to appear on the report when a sample matches a rule that uses this message as an action. The message can be up to 64 characters in length. Type in " perform a manual diff " and then select the save icon.		
5	After selecting the save icon to save your message, select or return to the Decision Rules & Criteria tab.		

	Select to create a new rule. The Define Rule screen displays.			
	Define Rule			
	Rule Name © Reflex Manager Rule Description C Delta Check			
	Location: [None] Physician: [None]			
	Type Item Bel Op / Flag Value [None] Image: Comparison of the second seco			
6	Part 2 Type Item Bel Op / Flag Value Join [None]			
	Part 3- Type Item Bel Op / Flag Value Join [None]			
	Part 4 Type Item Bel Op / Flag Value [None) V V V			
	Action Text Message [(None) Make Automatic Slide			
Note 1	Use the Help Mode button for information on each selection on this screen. The basic steps to begin are to type in a Rule Name, specify the Type you are creating (Decision Rules = Reflex Manager), type a Rule Description (just use the Rule Name) and then build the rule.			
7	Type "WBC Rule" in Rule Name, choose Reflex Manager as Type and type WBC in Rule Description.			
	In Part 1 do the following steps:			
	a) Open the drop-down box for Type and select " Parameter ".			
8	b)Open the drop-down box for Item and select "WBC".			
	c)Open the Rel OP/Flag drop-down box and choose "<=".			
	d)Enter 2.0 in the Value box.			
	e)Open the Join drop-down box and choose "OR".			

	In Part 2 do the following:		
	a) Open the drop-down box for Type and select " Parameter ".		
9	b)Open the drop-down box for Item and select " WBC ".		
	c)Open the Rel OP/Flag drop-down box and choose " \geq =".		
	d)Enter 20.0 in the Value box.		
10	After entering 15.0 in the Value box, go to the Action area near the bottom of the screen. Open the drop-down box for Text Message and select "perform manual diff". This is where the entries from Rule Configuration reside.		
Note 2	Let's say you have gotten this far in creating a rule and when you open the drop-down box you realize that the message you want has not been entered. All you have to do is select		
11	Select the checkbox to Make Automatic Slide, if you have an LH SlideMaker.		
12	Select Se		
13	You should see your rule in the list. Notice the column "Enabled". New rules are always enabled. By clicking the check box you may disable a rule. Let's look at the other functions associated with rules:		
Delete Highlight a then delete	Import Saved Rules From a File HCT1 Reflex Manager Import Saved Rules MCIIC 3 Reflex M Copy Ball Reflex M Use to copy an Ball Rule Formula Use to copy an Ball Ball Ball Ball		

Note 3	In Run Configuration, make sure the Decision Criteria checkbox is enabled. Select the radio button to print All Samples. If you have an LH SlideMaker / LH SlideStainer, make sure that both checkboxes are enabled as well.
14	Run a sample and after the sample is processed and results are printed, check that the statement "Perform manual diff" appears on the Patient Results screen in the Rule Messages field, on the Demographics tab and in the Comments field on a printout.

Reference Information

Now that you have been introduced to the Decision Rules area, you may want to review and print the following topics from HELP:

- Setting up rules for Flagging Sample Results
- Setting Up the Rule Environment
- Defining Reflex Manager Criteria Use the Search feature in Help
- Prioritizing Decision Rules

IMPORTANT NOTES

- You may create an unlimited number of rules. However, the maximum number of rules that may be invoked on a <u>single sample</u> result is 20. This is the reason prioritizing the rules is important.
- 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 you include in your Report Profile.

Practice – Save Decision Rules to Removable Media

Save Decision Rules

Step	Action	
Note	Use a formatted CD-R from the previous exercise or a flash drive. This feature of the software allows you to save all your decision rules to removable media. The removable media can then be used to reload the rules, if there is a problem, or, if you have more than one LH 700 Series, create the rules at one and then just copy into the other(s).	
1	Insert your removable media and select the Export Rules to a File button on the Decision Rules and Criteria screen.	
2	When the "Please insert a disk in drive A" window appears, select Cancel. When the "Save As window" opens, double click on My Computer.	
3	Double click on the appropriate drive. Type in a file name and then click Save and then remove your media.	
4	Now test the CD. Delete <u>only</u> the decision rule you created for this exercise in the Workstation. <u>Do not delete any other rules that are</u> in use on your instrument.	
5	Insert your removable media into the appropriate drive.	
6	Select the Import Saved Rules From a File button on the Decision Rules and Criteria screen.	
7	When the "Please insert a disk in drive A" window appears, select Cancel.	
8	When the Open window appears, double click on My Computer \rightarrow double click on your drive \rightarrow double click on your file name.	
9	A warning message window appears, with the following message: "X" number of rules could not be imported because existing rules has the same keys. "X" number of rules were imported successfully. Please check that the desired rules have been imported successfully. Choose OK. Your new rule should now appear on the screen. Remove your media.	

CALIBRATION

The S-CAL calibration for CBC parameters must be performed by your laboratory after installation. Thereafter, you must follow your own laboratory, local or national regulations as to frequency of calibration.

Sometimes components involving dilution characteristics or primary measurements need to be replaced. After the replacement of any component that involves dilution characteristics (such as a BSV) or primary measurement (such as an aperture), your service engineer will perform a "rough" calibration afterward using your current controls to allow instrument operation to continue. Keep in mind that a new component should be given several days to "break-in" or settle before performing the verification. An S-CAL verification should be performed within several days to a week to verify cal factors.

Calibrate or Verify Calibration?

Step	Action
1	From the CALIBRATION screen, select ? on the Common Toolbar.
2	Click on the Index tab and type calibration .
3	From the list on the left, select the topic: Calibration Overview.
4	Review the information about When to Calibrate.

Calibrating CBC Parameters with S-CAL Calibrator

Use the on-line HELP system to find the topic, "**Calibrating CBC Parameters** with S-CAL Calibrator". You will see that there are nine main steps to complete calibration on the instrument. Note that each of the nine steps are linked via hypertexts to the details for that step.

Read and familiarize yourself with each of these steps before proceeding.

1. Ensure the Apertures are Clean

2. Ensure the Instrument Functions Properly

3. Prepare Instrument for Calibration

Step	Action
1	Allow the S-CAL Calibrator to warm up at room temperature for 15 minutes before using. (See Instructions for Use for details. IFUs can be found on the BCI website).
2	Ensure the blood detectors are enabled (on) by checking the lower left corner of the Analyzer CRT screen. If they are disabled (Off) Choose Main Menu (VIII), then System Configuration (II) and next Blood Detectors (III). Press the button to turn the blood detectors On.
Note	Forgetting to do step 2 is a very common error. If you forget to enable the blood detectors, <u>all</u> calibrator runs transmit as aspiration errors. No data is calculated and the runs can <u>not</u> be recovered.
3	Ensure the Default Type is set to C.
4	Set the number of aspirations per tube to 1.
5	On the Workstation Command Center, ensure the Process Type is set to AUTO ANALYSIS.
6	Cycle a sample of normal whole blood in automatic aspiration mode as a prime.
7	Change the number of aspirations per tube to 11.

4. Calibration Set Up at the Workstation

Step	Action	
1	Go to Solution on the Command Center then select (CBC Calibration) on the Common Toolbar.	
2	At the INSTRUMENT Workstation Command Center, select CALIBRATION in the Process Type drop-down box.	
3	The background color of the Calibration window changes to the same background color as the Command Center when you change Process Type to CALIBRATION.	
Note 1	Forgetting to do this is a very common error. If you forget to change the process type to CALIBRATION, all S-CAL runs will be analyzed as patient samples and there will be NO data in the calibration table.	
4	If necessary, select (Clear table) to clear old calibration runs from the database. The values on the table change to 0.00 except for Old Cal Factor.	
5	On the specific toolbar, select (Calibration Setup) to display the Instrument Calibration Setup window.	
6	Select Cload S-Cal values). Scan the 2D-barcode for your instrument (LH 750 or LH 780) on the S-CAL assay sheet to load the reference values, lot number and expiration date. Ensure that you select the assay values for the reagents on your instrument.	
7	Print the Instrument Calibration Setup window.	
8	Select <i>o</i> on the Instrument Calibration Setup window.	
9	On the CALIBRATION screen, check the Lot # box (on the left side of the screen) for the Lot # you just set up. If the Lot # is incorrect, use the drop-down box to select the correct Lot #. The Lot# is the 4 digit number on the S-Cal vial.	
Note 2	Calibration runs will be rejected if the calibrator information has not been set up, or if the calibrator is expired. If expired, the Expiration field will be backlit in RED with the message "Calibrator expired. No statistics will be calculated." appears in the task bar.	

5. Run S-CAL Calibrator

IMPORTANT

Misleading results could occur if you fail to perform the calibration procedure within 1 hour of opening the S-CAL calibrator vials. Follow the instructions in the S-CAL calibrator Instructions for Use.

Step	Action	
1	Prepare the S-CAL calibrator vial according to the Instructions for Use. (Two sets of 8x8x8, just like the 5C Cell Control). It is very important to follow the mixing directions carefully.	
2	Verify the number of aspirations is 11. (One vial of S-CAL is sufficient for 11 aspirations.)	
3	At this point, ensure that the blood dectectors are enabled, CALIBRATION is chosen in the Process Type box on the Command Center and the current S-CAL lot # is in the drop down box on the calibration table window.	
4	Place the S-CAL vial into a cassette, and place the cassette in the right loading bay on the Diluter.	
5	Automatic processing of the cassette begins. The Workstation automatically deselects the results from the first run because those results are used as a prime.	

6. Review Results On The Calibration Window

- On the CALIBRATION screen, inspect the calibration results table for trending. The parameter results must not show a trend.
- If the results show trending, there could be an instrument problem; call your Beckman Coulter representative. **Do not continue**.
- With the following in mind, use the calibration statistics to determine if you should transmit **new** calibration factors to the Analyzer.

IMPORTANT

Misleading results could occur if you transmit calibration factors that are outside the established limits. If results are outside the limits, call your Beckman Coulter representative.

- The Workstation checks the results for precision (%CV within the established limits; the same limits as used for Reproducibility.)
- The Workstation flags results outside the limits with a **RED** background (%CV, FAC % Diff and Delta Diff).
- <u>If you choose to transmit calibration factors other than those selected by</u> <u>the Workstation</u> – either outside the limits or factors that have verified – a message appears indicating a "Calibration Criteria Violation". You must confirm that you want to transmit the calibration factors. Once you confirm the transmission, the Workstation transmits the calibration factors and posts a message to the Calibration history log.

IMPORTANT

Misleading results could occur if you calibrate MCV when the RBC FAC% Diff is out of range because MCV depends on RBC. <u>Do not calibrate</u> MCV if the RBC FAC% Diff is out of range.

CALIBRATION CRITERIA TABLE

(This table is provided for your information only. The workstation makes these calculations and decisions for you).

Parameter	Precision	Acceptable	Cal if	Cal if
L		Tac /oDill	1 ac /0D11113	Delta Dill 13
WBC	CV ≤2.5%	≤5.0%	>1.25% BUT ≤5.0%	>0.1 BUT ≤0.4
RBC	CV ≤0.8%	≤2.0%	>0.7% BUT ≤2.0%	>0.03 BUT ≤0.09
Hgb	CV ≤0.8%	≤3.0%	>0.78% BUT ≤3.0%	>0.1 BUT ≤0.4
MCV	CV ≤0.8%	≤2.5%	>1.18% BUT ≤2.5%	>1.0 BUT ≤2.0
Plt	CV ≤3.2%	≤9.0%	>2.70% BUT ≤9.0%	>6.0 BUT ≤20.0
MPV	CV ≤5.0%	≤20.0%	>5.0% BUT ≤20.0%	>0.5 BUT ≤2.0

- Are <u>all</u> parameters <u>within limits</u>? Are any boxes checked \square ?
- If No, then no further action is necessary. <u>Calibration is verified</u>.

7. Adjust Calibration Factors As Needed

Step	Action		
1	Are any boxes checked $\mathbf{\overline{C}}$? If Yes, then <u>parameter(s) need to be</u> <u>calibrated</u> .		
2	 Make sure you perform the next steps in the order listed. Go to the Analyzer CRT screen: Press MAIN MENU (VIII) Press ANALYZER FUNCTIONS (I) Press CALIBRATION (I) Press RECEIVE AVERAGE CALIBRATION FACTORS (III) 		
3	On the Workstation CALIBRATION screen, select (Adjust Calibration) on the Specific Toolbar. The Adjust Calibration button is active only after the Workstation receives ten (10) valid calibration results. After calibration factors have been adjusted, the Adjust Calibration button is grayed out.		
4	Once the Analyzer receives the calibration factors, return to the System Run Screen on the Analyzer CRT.		

5	Make sure that you clear the screen to prevent recalculation of calibration factors that were changed. This happens when you exit this screen and come back to it at a later time.
6	On the Command Center, set Process Type back to Auto Analysis and at the Analyzer CRT screen set #aspirations/tube back to 1 .
7	If you run S-CAL calibrator and change at least one parameter to a new cal factor, you have calibrated that parameter. You verify by running 5C Cell Controls. If you run S-CAL calibrator and make no changes to any cal factors, you have verified the current cal factors. No other verification is necessary.

Now that you have completed the calibration process, take a look at the summarized procedure in the Easy Reference Guide.

This provides a short summary of the steps of calibration without all the details. You may use this summary in your lab. Remember that you may always refer back to the online HELP procedure or to this module for the details.

HISTORY LOGS

Step	Action	
1	From the Command Center, go to 🖳 (History Logs).	
Note	Each History Log has its own tab. The Event Log has general instrument messages. Other Logs such as Instrument, Daily Checks, Control Data, etc. contain more specific information. Messages are listed with the most recent first on the list. Each log may have 2500 entries, then it "rolls over" (First in, First out).	
2	From the History Logs window, select HELP.	
3	Find and read the topic, Working with Electronic History Logbooks, as well as the data from the "add comments to a logbook" (hyperlink).	

Practice

Adding a Comment

Step	Action
1	Select any History Log , using the tab. Which tab did you choose?
2	Click on the date of the entry for which you want to make a comment.
3	Click on the (Add/Edit Comment) button.
4	Type a comment in the field provided (up to 256 characters).
5	Select O . The comment is stored and displayed with the selected message.

Accessing Descriptions and Corrective Actions

Step	Action
1	Select the Instrument History Log.
2	Use the Help Mode button to go to a specific error message.
4	Click on the actual message not the date and time.
5	If you will be printing History Logs in your laboratory, then print the HELP message.

Printing from a History Log

Step	Action		
1	Select the Calibration History Log.		
2	Select the Print button.	Print Logs	
3	Choose Selected Category.	© All Categories	
4	Choose By Date:	By Date:	
	Enter the date two months ago in	To: 77	
5	the From box and today's date		
	in the To box.	 	
6	Select 🕢 .		

Deleting

NoteIt is not necessary to delete to make room in the history log. Each tab
in the history log holds 2500 entries, then it "rolls" over. The oldest
entry is deleted and the most recent is added (first in, first out).
It is not recommended to delete any entries in the history log as the
information in this section may help when troubleshooting.

Archiving

Archive Using Removable Media (CD-ROM or Flash Drive)

Step	Action		
1	Select any History Log.	chive Logs	
2	Select the [Archive Result(s)]	© Selected Category ⊽ By Date:	
	button.	From: //	
	Choose the Selected Category radio		
3	button. You can specify by date if you		
	wish. Click on the OK button.		
4	A Save As box appears with the message "A:/ is not accessible. The folder was moved or removed". Click on Okay.		
5	Another Save As box appears. Place your removable media into the appropriate drive.		
6	In the Save As box, specify the drive where you want to archive the information.		
7	Type in the file name or use the suggested name which is the current date and then click on Save. Close the History Logs Viewer window		
8	If using using a CD-ROM, press the eject button on the CD drive on the Workstation computer. A "Drag-to-Disc" dialog box with the message "Failed to Rename disc" appears. Choose OK.		
9	A "Drag-to- Disc Eject Options" dialog box opens. Select "This disc will be used on other computers or devices." Keep enabled the "Always show this dialog when ejecting a disc." Then choose the Eject button.		
10	Another "Drag-to-Disc" box with a progress bar opens. Wait for it to become 100% complete. The CD drive will eject the CD. Save your archive for the skill check.		
SAMPLE FLOW - DILUTER

Be sure to wear full-face protection (either a full-face shield OR protective eyewear with a facemask) along with labcoat and gloves. This exercise is for observation only.

WARNING

Keep the lower door of the LH 700 Analyzer closed when you use the Automatic mode. You <u>CANNOT</u> operate the instrument with the lower door open.

Step	Action
1	Open HELP and select LH 750 or LH 780 Analyzer \rightarrow Reference Information \rightarrow Operation Principles.
2	Read the different sections to familiarize yourself with these principles.
3	Remove the Diluter center panel by pulling it toward you.
4	Remove the two gray side panels from the left and right diluter, pull at top and lift out.
5	Open the lower door in front of the Diluter center panel by pulling toward you and then opening outward.
6	Refer to the Easy Reference Guide \rightarrow LH 700 Series and familiarize yourself with the various parts referenced on the Diluter Front Panel and under the Diluter Front Cover.
Note	Locate the parts only by visual observation.

TROUBLESHOOTING - DILUTER

Basic Troubleshooting Techniques

How to Recognize an Instrument Issue		
Sta	rt with the data generated:	
	Error messages generated	
	 Error messages with corrective actions are listed in HELP 	
	 Whenever a message appears on the Workstation, read it and 	
	double-click if necessary for more information	
	 Use the History Logs to see if certain messages are occurring very 	
	often	
	Daily Checks	
	Control runs	
	Sample data	
	IQAP reports	
	Abnormalities in sample flow	
Steps to More Efficient Troubleshooting		
1	Become familiar with <u>normal</u> operation.	
	Startup, Sample Analysis, Shut down	
	Normal Sample Flow	
	Know what should happen during each part of the cycle	
	 Be familiar with normal sounds of operation 	
	 Review the Operation Principles in HELP 	
2	Use a logical approach to obtain a clear symptom and isolate the	
_	components involved.	
	• Use the error message information as a starting point	
	Use your knowledge of sample flow	
3	Acquire the knowledge and skills necessary to locate and correct issues.	
	• Use HELP	
	• Use the training modules	
	Observe the instrument	
	When necessary, call your Beckman Coulter representative	

Solenoid Functions and Diluter Functiions

Diluter and Solenoid functions are tools that can be used to help troubleshoot the instrument. During this module we will be utilizing some of these functions.

Diluter Functions are used to perform specific tasks on the instrument. The Functions are available by using the F-Key on the Diluter control keypad. To access the F-Key function, press F, the number of the option and Enter. For most functions you press Enter again to repeat the function. Press the Stop key to exit the function.

Solenoids are switches or controls for mechanical devices such as valves. See <u>Solenoid Functions</u> in HELP to determine what each solenoid does. You can <u>activate solenoids</u> to check the functioning of the instrument. Pressing F05 on the keypad, allows activation of individual solenoids. The solenoid then returns to its original position or state. Pressing STOP exits the routine for the selected solenoid. Press STOP again to exit this function.

TROUBLESHOOTING BY INSTRUMENT SUBSYSTEMS

There are three instrument subsystems:	
1	Electronic
2	Fluidic
	Pneumatics (pressures and vacuums)
	• Hydraulics (liquids)
3	Reagent

Electronic Subsystem

If there is no power:		
	• Check to see if the <u>Power</u> indicator light is On or Off.	
	 Look at the Analyzer Numeric Keypad. 	
	► Look at the Power Supply (PS).	
	 Check all plug connections. 	
	 If all plugs are in and Main Power (PS) is On, check fuses 	
	using the HELP procedure.	
	If both the Analyzer and the Power Supply are turned off, turning on	
Note	the Power Supply does not turn on the Analyzer. In order for the Power	
Note	Supply read-outs to light up, you must press the power on button on the	
	Analyzer keypad.	
If there is a message that Hgb Voltage is low:		
	Check the Hemoglobin Lamp:	
	 Try adjusting the Hgb Lamp Voltage, using Hemoglobin Lamp 	
	Adjust from theAnalyzer CRT buttons: Main Menu>>Analyzer	
	Functions>>Hgb Lamp Adjust. DO NOT THIS NOW.	
	 If you cannot adjust, call your Beckman Coulter representative. 	

Fluidic Subsystem

The <u>key components</u> of the fluidic subsystem are the Tubing, Pinch Valves, Pumps and Solenoids.

Pneumatics

	There are two main pneumatic supplies, vacuum and pressure:	
1	Vacuum has two measured levels: High Vacuum and Low Vacuum.	
	a High vacuum is equivalent to 17-28 inches of mercury.	
	• Aspiration, refilling diaphragm pumps and draining aperture baths use high vacuum	
	It is not operator adjustable	
	An error message alerts the operator of an issue	
	• If out of range on the Low side (<17), check the vacuum trap for the presence of liquid (normally it should be dry) and clean as needed. Use Search in Help to find the procedure - Cleaning the Vacuum Trap.	
	• If the vacuum trap is not the problem, call your Beckman Coulter representative for assistance.	
	b Low Vacuum is equivalent to 6 inches of mercury.	
	Derived from the high vacuum	
	 Also known as Aperture Vacuum 	
	• Pulls the dilutions through the RBC and WBC apertures and the sweep flow diluent behind the RBC aperture.	
	• Operator adjustable	
	• An error message alerts operator of a problem	
	• Refer to HELP for the Monitoring Low Vacuum procedure (or you	
	may use the printout saved from the TS1 module). Locate the Low	
	Vacuum regulator wheel but DO NOT adjust at this time.	
	 If the Low Vacuum has been adjusted and it doesn't stay 	
	adjusted, check the Vacuum Trap and clean it if necessary.	
	 Also check the WBC/RBC Vacuum Isolator Chambers (full) and VL11A and VL10 for holes in the tubing or disconnected 	
	tubing.	

2	Pressure has three measured levels: 60 psi, 30 psi and 5 psi:	
	а	60 psi
		• Generated by the compressor in the pneumatic power supply.
		• This is the source of the 30 psi and 5 psi.
		• Operator adjustable.
		• An error message alerts operator of an issue. If this occurs, call your Beckman Coulter representative.
		• <u>Locate</u> the 60 psi regulator knob on the left side of the Power Supply.
	b	30 psi
		• Dispenses reagents from pumps, opens pinch valves and moves air cylinder shafts.
		 Controlled through solenoids. Check solenoid function by
		accessing <f05> from the Analyzer Control Keypad.</f05>
		DO THIS NOW and perform the following procedure to
		verify the Diff Mixing motor. Open the Diluter lower door,
		check the function of Solenoid 73 (Mixer-Diff). When
		Inished, press Stop until you return to READY.
		• Operator adjustable
		• An error message alerts operator of an issue
		• Refer to HELP for the Adjust 30 PSI Pressure procedure. <u>Locate</u> the 30 psi regulator knob on the left side of the Power Supply.
	С	5 psi
		Used for Sheath pressure and mixing bubbles
		Operator adjustable
		• An error message alerts operator of an issue. Call your Beckman Coulter representative before making this adjustment.
		• <u>Locate</u> the 5 psi regulator knob on the left side of the Power Supply,
		but DO NOT adjust at this time.
		• Remove the Diluter Center Panel and open the cover for the baths.
		Press <f03> and observe mixing bubbles entering the two baths.</f03>
		There should be 10 mixing bubbles.

Hydraulics

Check tubing connections and routing. Look for leaks or disconnects. Refer to HELP for tubing replacement, etc.	
• At the reagent container	
• At the input manifold on the back of the Analyzer	
• Throughout the diluter.	

• Check associated pumps, pinch valves and solenoids.

Reagent Subsystem

Level Sensing

Reagent level sensing uses float sensors in either the reservoirs or the	
reagent container (Diluent)	
• When you see any of the error messages for reagent out you must	
replace the empty reagent container indicated.	
• Always check the indicated container to see if it is low. If it is low,	
replace it. If it is not low, you have a false reagent out message and	
may need to call your Beckman Coulter representative.	
 Try priming the reagent first. 	
• If it is Diluent, verify that the sensor near the container is plugged	
III. If it is any other reagant turn never OFF then go to the healy of the	
instrument and open the right panels.	
■ Locate the reservoir for the reagent and find the associated blue-	
striped I-beam tubing.	
Use a red transit clip to open the pinch valve.	
Move the tubing back and forth and check for a pinch. Massage	
the tubing to release pinch or replace the tubing.	
Close panels and turn power ON.	
• <u>Locate</u> the reagent reservoirs and associated tubings. Refer to the	
Easy Reference Guide, Common Troubleshooting Fixes, Level	
Sense Message for a graphic of the reagent reservoirs. DO THIS	
NOW.	
Call your Beckman Coulter representative.	
• The instrument will not operate until the issue is resolved.	
• Refer to HELP for the Reagent Replacement procedure.	
Waste container level sensing uses a float sensor (only applies if you use	
a waste container)	
• When you see the error message Waste Full , you must replace or	
empty the waste container.	
• If the waste is not full, check the float sensor, it may be stuck in the up	
position.	
• The instrument will not operate until an empty container is present.	
• Refer to HELP for the Waste Container Replacement Procedure.	

Reagent Related Issues

High background counts	
• Handle reagents properly to avoid accidentally introducing dust or powder. If you suspect the reagent may have become contaminated with any of these particles, replace the reagent.	
• Dried reagent spills or leaks can form salt deposits that create background electrical noise. To avoid salt deposits, clean all spills and leaks immediately.	
Expired reagent	
• Be sure to update the reagent replacement screen with the correct dates.	
Rotate stock to avoid accidental use of expired reagent.	
Frozen reagent	
• A reagent that was frozen and thawed could have separated chemical components.	
 One symptom could be increased MCVs, due to diluent now being non-isotonic. 	
• If there is a possibility of having frozen /thawed reagent (e.g. cold climates):	
 If a reagent is still frozen: allow to thaw completely at room temperature. 	
 Mix by inversion as per package labeling. 	

Troubleshooting Through Sample Flow

To successfully troubleshoot this instrument:	
• Become familiar with normal sample flow.	
• Know what should be happening during each part of the cycle	
This type of knowledge is gained mostly through experience. To increase your	
comfort level with the normal sample flow of this instrument, periodically	
review the Operation Principles in HELP.	

Automatic Mode Transport

Error messages alert the operator of issues with the rocker bed, sensors, cassette jams.	
• Double-click on the error message to get more information and follow the directions.	
• Press <stop> twice to release the stripper plate and allow cassette to be moved to the left.</stop>	
 Cassette problems can be related to buildup of debris or crystals in and on the cassette. Refer to HELP for the Cassette Handling procedure. Fluid or debris buildup on the underside of the rockerbed belt or on the suface of the rockerbed under the belt may also cause cassette problems. 	
 After checking that there is nothing obstructing the belt movement and that the belt is dry, do the following to check the belt movement: Activate Solenoid 36 – Belt Advance (Press < F05 > first in order to activate the solenoid functions, then press < 3 > and < 6 > and < ENTER >). When finished, press < STOP > several times to return to READY. DO THIS NOW. This is a very small, short movement. Watch carefully; the belt does not make a continuous movement. 	

VLS FUNCTION, CALIBRATION AND TROUBLESHOOTING

VLS Function

On an LH 700, the needle-vent line for the Analytical Station is also the aspiration line for the LH SlideMaker, if present. The vent-line sensing (VLS) function is used when the Analytical Station is operating in the Automatic mode to confirm the needle-vent/aspiration line is rinsed and dried correctly at the end of each cycle.

Note: The VLS function is used whether the LH SlideMaker is present or not. It is used for all test modes (CBC/DIFF/RETIC, CBC/DIFF, CBC ONLY, CBC/RETIC, and RETIC ONLY), but only in the Automatic aspiration mode.

Blood detector BD3 is the detector used for the VLS function. BD3 is located on the interface bracket installed near the BSV module.

VLS Diluent Error

During the vent-line backwashing process, BD3 is used to detect the presence of diluent. If diluent is not detected, a **VLS Diluent** error is generated, and the Automatic mode is disabled because insufficient rinsing of the vent line can lead to carryover problems.

A VLS Diluent error indicates an issue in the vent-line backwashing process that requires further troubleshooting.

VLS Air Error

During the vent-line drying process, BD3 is used to detect the presence of air. If air is not detected, a **VLS Air** error is generated, and the Automatic mode is disabled because inadequate drying of the vent line can lead to dilution of the specimen in the tube.

A VLS Air error indicates a problem in the vent-line vacuum drying process that requires further troubleshooting.

Calibration

BD3 is calibrated automatically whenever the LH 700 System is powered up or reset. You can also initiate a calibration of BD3 by using the F79 function on the Diluter numeric keypad. The software routine for the automatic calibration and for calibration using F79 is the same, so you can use F79 as a troubleshooting function in the event of a VLS failure.

• Diluent Prime and Calibration

Diluent is dispensed from the backwash tank to prime the needle vent-line for 3 seconds. At the completion of the priming process, BD3 is automatically calibrated on the diluent.

• Diluent and Air Checking

After the calibration routine, the vent line is primed with diluent for an additional 2.5 seconds during which BD3 is checked for diluent. The check is considered successful if the diluent value is between 70% and 100% of the calibration value. Immediately after the diluent check, vacuum dries the vent line for 9.5 seconds during which BD3 is checked for air. The check is considered successful if the air value is between 30% and 50% of the calibration value.

• Calibration and Diluent and Air Checking Retry

If the diluent or air checking routine fails, the System performs the calibration routine a second time. If the system fails to recover the correct diluent or air value a second time, a **VLS Diluent** or **VLS Air** error is generated and the Automatic mode for the System is disabled. The manual aspiration mode remains enabled.

Troubleshooting

ATTENTION: You must reset the LH 700 System to return it to the Automatic mode after a VLS error. However, F79 can be done continually. Most VLS errors are usually caused by tubing kinks at the feed-thru or Y-fittings in the needle-vent/aspiration line. Under normal conditions, the diluent rinse flows very rapidly through the vent line, followed by a very rapid air dry.

If unable to find the cause and clear the VLS error, call your Beckman Coulter representative. In the interim, use the Manual aspiration mode.

Aspiration

Aspiration error messages alert the operator of aspiration issues.

- The front and rear optical blood detectors determine if the aspirated blood meets the criteria for a proper aspiration. If not, an <u>aspiration error</u> <u>message</u> appears. All sample results flag with a **P**.
- In addition, on the **Results & Graphics** Screen in the **Common Area** under Status it will state **"Part Asp"**.

Aspiration Errors



Aspiration Error Messages

Message	Summary
Acceleration O	• Immediately before automatic mode aspiration, both blood detectors check for similar optical readings, ensuring that the last blood was backwashed and the pathway is clear of
Aspiration-C	blood.
CARRYOVER	• If the optical difference between the two detectors is
	blood, the instrument displays an Aspiration-C error.
	• Immediately after automatic mode aspiration, the front blood detector is read to ensure the optical reading is below
Aspiration-N	a specified limit, indicating that aspiration did take place (blood is present)
NO BLOOD	 If the optical reading does not reach the specified limit in a
	predetermined time (no blood or diluted blood is present), the instrument displays an Aspiration-N error.
Aspiration-B	• Until the BSV rotates, the front blood detector is monitored
BUBBLES	 If any optical changes occur (such as a bubble), the instrument displays an Aspiration-B error

Aspiration-P	• After the BSV rotates, the front and rear blood detectors are compared to ensure similar optical reading at both detectors.
PARTIAL ASPIRATION	• If the optical difference between the two detectors is greater than a specified limit (blood in one blood detector, but not in the other), the instrument displays an Aspiration-P error.

What May Be The Cause(s) Of An Aspiration Error?

Aspiration-C			
• The last sample did not backwash			
• No diluent (air) in aspiration pathway at start of cycle			
Aspiration-N			
• Short sample or clot in tube preventing blood from being aspirated			
Obstruction in the aspiration pathway			
• Diluted blood or non-blood sample (diluent)			
• Low Hgb (approx. ≤ 4 g/L)			
Aspiration-B			
• Short sample, clot or bubble in tube that prevented even aspiration			
Obstruction in the aspiration pathway			
• Bubble is detected by the front blood detector, triggering the error			
Aspiration-P			
• Short sample or clot in tube that prevented full aspiration			
Obstruction in the aspiration pathway			
• BSV did not rotate or did not rotate fully			
Blood detectors turned OFF			
Diff or Retic Shear Valves did not move correctly			

What Can You Do?

	If one sample only:
•	Check sample tube for clots and sufficient sample volume
•	Repeat sample in manual mode
	If multiple samples:
•	Ensure aspiration pathway is being backwashed (no blood remains in aspiration tubing at end of cycle)
•	Clean needle, remove and replace if necessary
•	Inspect/Clean BSV and ensure it is not leaking
•	Inspect/Clean outside of Diff or Retic Shear Valves with DI water and lint free tissue. In HELP, use the Search tab to find the topic "Cleaning the Shear Valve." DO THIS NOW.
•	Inspect tubing at the needle, the pinch valves (VL 9A) and (VL 9B), and the aspirate pump for leaks or crimps
•	Inspect pinch valves (VL 9A) and (VL 9B) for proper operation and proper tubing placement
•	As a last resort, replace the needle using the HELP procedure.
•	The BSV may not be rotating properly due to crystalline buildup. Refer to HELP for the Clean BSV (Outside Sections) and the Releasing BSV procedures DO THIS NOW .

ASPIRATION NEEDLE ASSEMBLY



Component Function Checks

Check the Needle and Aspiration Pathway	 Power Off the Analyzer and then the Power Supply. Open the Diluter front door. Check the needle position, check for kinked or leaking tubing (vent and aspiration lines). If necessary, remove the needle from its holder using the safety clip, and check the attached tubing. Check the vent line sheath tubing position. Reseat the needle assembly. Power On the Power Supply, then the Analyzer.
--	--

Sample Delivery

If the baths do not drain or do not drain completely, the next sample will be over diluted. When overflow is detected in the overflow tank, an error message appears to alert the operator.

• Check the drain lines at the bottom of each aperture bath. Be sure they are not pinched. Check for holes in the drain tubing and possible fluid accumulation. Use a red clip to open the pinch valve (VL 12A or 12B) and move the blue-striped I-beam tubing back and forth.

If the RBC and WBC dispensers are leaking due to cracks or to leaky tubing, not enough diluent is delivered to the baths. This causes all counts to be too high.

• Check the dispensers and tubing for leaks. Look for micro-bubbles in the dispenser. Replace tubing if necessary. Call your Beckman Coulter representative if a dispenser is leaking.

If the CBC lytic reagent pump or associated tubing leaks, then not enough lytic reagent is delivered to the WBC bath. This causes the WBC and the Hgb to be grossly elevated.

• Observe sample flow for leaks and watch for the color change from cloudy red to clear red in the WBC bath. Verify tubing connections at the pinch valve and at the pump. Replace tubing if necessary. Call your Beckman Coulter representative if a pump is leaking.

If the mixing bubbles are missing from either bath, erratic results and increased voteouts may occur.

- Check for the presence of bubbles by observing sample flow or by activating F03. **DO THIS NOW.** There will be only 10 mixing bubbles.
- Verify the mixing bubble check valves are not leaking or plugged. Replace if necessary.

CBC Sensing

If the Aperture Vacuum (or Low Vacuum) is out of range, an error message alerts the operator of the issue.

▶ Perform <F92> and try to adjust reading to 6.000 ± .010.

Refer to Low Vacuum section; page for more info.

If the apertures become clogged or partially clogged, there could be Total Voteouts (-----) of the measured parameters.

- If this happens on just one sample, repeat it.
- ▶ If sporadic, try < CLEAR APERT >,or < F01 >.
- If this happens on most or all samples, try F09, Zapping the Apertures. Refer to the HELP procedure Zapping Apertures. **DO THIS NOW**.

• Aperture Zap may be done more than once..

• If you continue to experience voteouts, you can try the Bleach Apertures procedure, Refer to HELP for this procedure. Note that this procedure should only be done as a last resort.

If the Hemoglobin Lamp voltage is too low, an error message alerts the operator.

Refer to the Hemoglobin Lamp Adjust procedure. If this fails, call your Beckman Coulter representative.

Diff or Retic Sensing

Message / Flag	Summary	
	An issue was detected in the flow cell during analysis, accompanied by one of the following flags displayed on the Dataplot	
	 PC1 (partial clog 1) PC2 (partial clog 2) FC (full clog) 	
	Can mean there is a partial obstruction of the sample line from the diff mixing chamber or retic clearing chamber to the flow cell	
PC1 Partial Clog 1	A partial flow cell obstruction	
	Flow cell sample or sheath pressure errors (This generates the specific pressure error message at the instrument and Workstation)	
	Insufficient Diff or Retic reagent delivery	
PC2 Partial Clog 2	Patient chemistry imbalance (common with sample issues such as improper sample collection/mixing or abnormal sample problems)	
	Full alog of the flow cell. The instrument tries Areta description	
FC Full clog of the flow cell. The instrument tries Autoclear the flow cell, but if unsuccessful, the system stops.		

Note: The presence of the above codes <u>does not always</u> mean that there is a <u>clogged</u> flow cell. You can use COULTER[®] LATRON Primer and Control to help differentiate the issue.

Component Functions Checks

Component(s)	Action			
LATRON Primer and	Use Latron as a troubleshooting tool. Use F57 D & R			
Control		Diff	Retic	
Take note of what		Result	Result	
your normal daily	Primer, if normal	0 – 500	0 – 500	
Primer results are	Control, as a Primer	8192	8192	
running. To run the	The above results are e	xpected with a	clear flow cell.	
Drimor proge the CLEAR	If this is what you are r	running, then the	he problem is	
Primer, press the	probably not a flow cel	l clog. Run yo	ur Latron	
key on the Analyzer	Control the correct way	and examine	your results. If	
Control keypad.	there is a VCS problem	n, call your Bee	ckman Coulter	
	Representative.			
	Deimensentt	Diff Result	Retic Result	
NOTE:	Primer result	0 - 3	0 - 3	
The Primer results	The share manufactor of	0-5	0192	
used in the	heing blocked. Call you	leative of the I	oultor	
examples at the	Dening Diocked. Call yo	ui beckinan C	ouner	
right are estimates	Representative.	Diff Booult	Potio Pocult	
consider these	Primer result			
examples as	Control as Primer	8192	0 - 5	
absolute. You must	The above result is indicative of the Retic sample line			
relate the numbers	being blocked Call vo	ur Beckman C	oulter	
you get to your	Representative.			
usual results.		Diff Result	Retic Result	
Review the data in	Primer result	0 – 3	0 – 3	
your Latron folder.	Control, as Primer	0 – 3	0 – 3	
	The above result is indi	icative of the H	Flow Cell being	
	blocked or the commor	n line to the Flo	ow Cell being	
	blocked. If still clogged	d after trying F	44, F45, F46	
	[the instrument should	remain idle fo	r 30 minutes	
	after pressing F46], the	n call your Be	ckman Coulter	
	Representative.	1 1 2	11 1. 1	
	If you have a partially clogged flow cell or line, then			
	you may recover Contr	rol as Primer v	alues of < 8000 .	
	In this case, try F44/F45 and it not successful, call			
	your Beckman Coulter	Representativ	t.	
	11 your Latron results a	ire good with t	au sample	
	results, it is indicative of reagent delivery problems.			

F14/F15	• Prime Diff Lytic reagent/Prime Diff Preservative reagent, check for leaks at pumps and tubings,			
	replace if necessary.			
	Prime Retic stain reagent/Prime Retic clear			
F18/F19	reagent, during prime cycle check for leaks at			
	pumps and tubings, replace if necessary.			
	• At the end of this cycle, you may watch for the			
	rotation of the mixing chambers. If they are not			
	rotating, call your Beckman Coulter			
	Representative.			
Not all flow cell issues a	re clogs. They may be related to an individual sample.			
• From the Analyzer	Control Keypad try F44. Use F44 again, if you still see			
FLOW CELL CLO	GGED on the Analyzer. DO THIS NOW .			
• If still no results (:::	::), try F45, up to three times			
• If still no results (:::	::), try running Latron.			
 Run the Latron 	Primer as usual, if OK proceed to next step.			
 Run the Latron 	Control as if it were the <u>Primer</u>			
➢ If the Flow 0	Cell is clear, you should recover the number 8192 for			
both Diff an	both Diff and Retic. DO THIS NOW. Most likely the flow cell is			
not clogged	. (see next step).			
If you recover a very low number, on one or the other, then either				
the Diff sample line or Retic sample line has a clog.				
If you recover a low number on both, then either the Flow Cell or				
the common line is clogged. Try F46.				
Refer to the procedure "	Clearing Clogged Flow Cell" in HELP.			
If the flow cell is not clo	gged, then it could be a VCS Technology issue, a			
chemistry issue or a mix	ing issue.			
 VCS Technology is 	sue:			
 Run Latron Con 	ntrol the correct way. If all values recover within			
limits, go to ne	xt step. If not, call your Beckman Coulter			
representative.				
Chemistry issue:				
► If the sample is very lipemic, do the diff manually.				
If the issue appears on many samples, consider the LH Series Pak				
reagents or the LH Retic Pak reagents.				
➢ Be sure the	y are not expired.			
Check the r	espective reagent pumps and tubing for leaks. Use the			
Prime funct	ions to help look for problems.			
Replace rea	gent, if necessary.			
• Mixing issue:				
• Observe the mi	xing chamber rotation during sample flow. If the			
chamber is not	rotating, call your Beckman Coulter representative.			

SAMPLE FLOW – LH SLIDEMAKER

Be sure to wear full-face protection (either a full-face shield OR protective eyewear with a facemask) along with labcoat and gloves. This exercise is for observation only.

WARNING

Keep the LH 700 Analyzer and the LH SlideMaker doors closed when you use the Automatic mode. You <u>CANNOT</u> operate the instrument with the LH Analyzer lower door and the LH SlideMaker door open.

Summary

The LH SlideMaker sample acquisiton system:

- 1. First aspirates a portion of blood from the specimen tube for the Diluter side, then a second aspiration of blood occurs through the vent side of the needle for the SlideMaker.
- 2. Transfers the sample to one of two reservoirs.
- 3. Holds and mixes the sample.
- 4. Transfers the sample from the reservoir to the dispense probe, priming the dispense line with a portion of the sample.
- 5. Dispenses a measured drop of the blood sample onto a slide for processing.
- 6. Rinses and dries the aspiration and dispense lines between samples to limit dilution and carryover.

The three modules involved with these functions are the Sample Access and Reservoir module (located under the front cover of the diluter on the left) and the Dispense module (located in the LH SlideMaker on the front right). Refer to your Easy Reference Guide for labeled diagrams to use during this exercise.

Conditions When The LH SlideMaker Never Makes A Smear

- 1. SlideMaker is disabled in Run Configuration.
- 2. In Retic only mode of operation (slides are never made if Retic only is used).
- 3. Blood detectors are disabled.
- 4. Aspiration error conditions from Analyzer.
- 5. Any Process Type **except** Auto Analysis.
- 6. When running bar-coded COULTER[®] 5C[®] and Retic-C Controls.
- 7. Samples run in Manual mode.
- 8. When the SlideMaker is set to make slides based on Decision Rules Only and the samples run do not meet Decision Rule criteria (in other words, normal samples).

Conditions When The LH SlideMaker <u>Always</u> Makes a Smear

1. If no response from workstation within about 20 seconds, then makes a slide with "Auto Slide" label.

Step	Action	
1	Open HELP and select LH SlideMaker \rightarrow Reference Information \rightarrow Operation Principles.	
2	Read the different sections to familiarize yourself with these principles.	
3	Open the lower door in front of the Diluter center panel by pulling toward you and then opening outward.	
4	Lift the front door of the LH SlideMaker up.	
6	Refer to the Easy Reference Guide \rightarrow LH SLIDEMAKER and familiarize yourself with the various parts referenced for the LH SlideMaker.	
Note	Locate the parts only by visual observation.	

TROUBLESHOOTING - LH SLIDEMAKER & LH SLIDESTAINER

LH SLIDEMAKER TROUBLESHOOTING

VLS FUNCTION AND CALIBRATION

VLS Function

On an LH 700 with an LH SlideMaker, the needle-vent line for the Analytical Station is also the aspiration line for the LH SlideMaker. The vent-line sensing (VLS) function is used when the Analytical Station is operating in the Automatic mode to confirm the needle-vent/aspiration line is rinsed and dried correctly at the end of each cycle. Note: The VLS function is used whether the LH SlideMaker is on or off. It is used for all test modes (CBC/DIFF/RETIC, CBC/DIFF, CBC ONLY, CBC/RETIC, and RETIC ONLY), but only in the Automatic aspiration mode. Blood detector BD3 is the detector used for the VLS function. BD3 is located on the interface bracket installed near the BSV module.

VLS Diluent Error

During the vent-line backwashing process, BD3 is used to detect the presence of diluent. If diluent is not detected, a **VLS Diluent** error is generated, and the Automatic mode is disabled because insufficient rinsing of the vent line can lead to carryover issues. A **VLS Diluent** error indicates an issue in the vent-line backwashing process that requires further troubleshooting.

VLS Air Error

During the vent-line drying process, BD3 is used to detect the presence of air. If air is not detected, a **VLS Air** error is generated, and the Automatic mode is disabled because inadequate drying of the vent line can lead to dilution of the specimen in the tube. A **VLS Air** error indicates an issue in the vent-line vacuum drying process that requires further troubleshooting.

Calibration

BD3 is calibrated automatically whenever the LH 700 System is powered up or reset. You can also initiate a calibration of BD3 by using the F79 function on the Diluter numeric keypad. The software routine for the automatic calibration and for calibration using F79 is the same, so you can use F79 as a troubleshooting function in the event of a VLS failure.

• Diluent Prime and Calibration

Diluent is dispensed from the backwash tank to prime the needle vent-line for 3 seconds. At the completion of the priming process, BD3 is automatically calibrated on the diluent.

• Diluent and Air Checking

After the calibration routine, the vent line is primed with diluent for an additional 2.5 seconds during which BD3 is checked for diluent. The check is considered successful if the diluent value is between 70% and 100% of the calibration value. Immediately after the diluent check, vacuum dries the vent line for 9.5 seconds during which BD3 is checked for air. The check is considered successful if the air value is between 30% and 50% of the calibration value.

• Calibration and Diluent and Air Checking Retry

If the diluent or air checking routine fails, the System performs the calibration routine a second time. If the system fails to recover the correct diluent or air value a second time, a **VLS Diluent Or VLS Air** error is generated and the Automatic mode for the System is disabled. Only the Manual aspiration mode is allowed.

Troubleshooting

ATTENTION: You must reset the LH 700 System to return it to the Automatic mode after a VLS error. However, F79 can be done continually. Most VLS errors are usually caused by tubing kinks at the feed-thru or Y-fittings in the needle-vent/aspiration line. Under normal conditions, the diluent rinse flows very rapidly through the vent line, followed by a very rapid air dry. If unable to find the cause and clear the VLS error, call your Beckman Coulter representative. In the interim, use the Manual aspiration mode.

Fluid Detectors

The fluid detectors for the LH SlideMaker are located in the Sample Access and Reservoir module and the Dispense module. The LH SlideMaker uses information from the fluid detectors, in conjunction with regulated vacuum or pressure, to determine the volume and positioning of the blood sample. The LH SlideMaker also uses fluid detectors to detect and confirm rinsing and drying of the blood sample lines. The fluid detectors are designed to detect three distinct fluids: diluent, air and blood. The fluid detectors are calibrated with diluent. To confirm the presence of a particular fluid, blood, air or diluent, several readings are taken at defined intervals.

Fluid Detector Function Summary

FD	Functions	Module
FD1	 Identifies blood in the aspiration line during aspiration to ensure the minimum volume is acquired. 	Sample Access and Reservoir
	 Identifies diluent and air in the aspiration line during rinsing and drying of the aspiration lines. 	(outside module, near needle)
	• Identifies the leading edge of the aspirated sample for RES1, determining when to stop aspiration.	
FD2	• Detects the presence of blood during mixing in RES1, determining when to stop the left-to-right movement.	Sample Access and Reservoir
	• Confirms the presence of diluent and air during the rinsing and drying of RES1 and the aspiration lines.	
	• Controls the positioning of blood in RES1.	
FD3	• Detects the presence of blood during mixing in RES1, determining when to stop the right-to-left movement.	Dispense
	• Confirms the presence of diluent and air during the rinsing and drying of RES1 and the aspiration lines.	
FD4	• Identifies the leading edge of the aspirated sample for RES2, determining when to stop aspiration.	
	• Detects the presence of blood during mixing in RES2, determining when to stop the left-to-right movement.	Sample Access and Reservoir
	• Confirms the presence of diluent and air during the rinsing and drying of RES2 and the aspiration lines.	
	• Controls the positioning of blood in RES2.	
FD5	• Detects the presence of blood during mixing in RES2, determining when to stop the right-to-left movement.	Dispense
	• Confirms the presence of diluent and air during the rinsing and drying of RES2 and the aspiration lines.	
FD6	• Detects the trailing edge of the blood during the dispensing of the prime sample, determining when to stop dispensing sample.	Dispense
	• Confirms the presence of diluent and air during the rinsing and drying of the dispense line.	
FD7	• Detects diluent and air during the backwashing and drying of the aspiration lines.	Sample Access and Reservoir

FD8	•	Detects diluent and air during the rinsing and drying of the reservoirs and the dispense line. Confirms the presence of air during the drying of the aspiration lines.	Dispense
BD3	•	Identifies diluent and air in the aspiration line during the rinsing and drying of the aspiration lines. Note: While FD1 only checks the aspiration line for diluent and air if the LH SlideMaker is on, BD3 checks this line whether the LH SlideMaker is on or off. Since the aspiration line for the LH SlideMaker is also the needle-vent line for the Analytical Station, it is important to verify that this line is cleaned and dried during LH 700 System operation.	Sample Access and Reservoir (outside module, near needle)

FD/BD3 Error Conditions

If fluid detectors FD1 through FD6 sense an issue while aspirating or dispensing the blood sample, the LH SlideMaker discards the sample and warns the operator. If the same issue occurs three times in a row, the LH SlideMaker generates an error message and stops.

If fluid detectors FD1 through FD8 sense an issue while rinsing or drying the lines, the LH SlideMaker generates an error message and stops.

If blood detector BD3 senses an issue while rinsing or drying the needle-vent line, the LH 700 generates a VLS error and disables the Automatic mode.

If an error message occurs for any of the fluid detectors, FD1 through FD8, refer to the table above.

Error Recovery

- At the Workstation, go to HELP
 Contents → LH SlideMaker → Messages → SlideMaker Message List
- 2. To add this topic to your Favorites, select the Favorites tab and select Add.
- 3. Next select Contents \rightarrow LH SlideMaker \rightarrow Troubleshooting \rightarrow Overview and Add this topic to your Favorites.
- 4. The LH SlideMaker messages are listed in alphabetical order. Use the letters at the top of the page to access your particular message. Both the SlideMaker Message List and the Troubleshooting Overview contain <u>hypertext links</u> that take you to Help topics that have troubleshooting tips related to the error condition as well as steps to take to resolve the issue. There are many videos included to show the area and what to do.

LH SlideMaker Messages and Error Recovery

The following are some of the most common errors encountered on the LH SlideMaker. When the Workstation receives an error message for the LH SlideMaker, <u>do not</u> acknowledge (i.e., click the green checkmark) until you finish all troubleshooting. Acknowledging the error prior to troubleshooting causes the LH SlideMaker to automatically reset and the same error may happen again.

Message	Why This Message Occurs	What To Do	
	a) A jam prevented completion of the slide basket transfer	Press any key on SM screen to silence the alarm, wait until dryer belt stops moving.	
	b) When you turned the SM	Remove any jammed baskets or any other visible obstruction, such as slides.	
Paakat	(SlideMaker) on, a basket was in a	Acknowledge error at the Workstation to reset the SM.	
Dasket (Did Not Transfer Between Belts)	a belt position sensor.	If the issue continues, turn SM power off.	
	c) One of the sensors failed (extension or retraction).	Open cover and remove slides from dryer, pusher bars and platen area and place them in a slide basket for staining.	
		Call your Beckman Coulter Representative.	
	a) Jam prevented movement.	Press any key on SM screen to silence alarm.	
	b) Profile sensor failure	Remove jammed slide basket.	
Basket (Move Position)		Acknowledge error screen at Workstation to reset the SM.	
,		If message persists turn SM power off.	
		Close cover; call your Beckman Coulter Representative.	

Message	Why This Message Occurs	What To Do
	a) Truck lift sensor failure.	Press any key on SM screen to silence alarm.
	b) Slides may be problematic	Wait until last slide in dryer is deposited in a basket.
Truck (Vacuum, Sensor 3)		Acknowledge error at Workstation to reset SM.
		If you suspect a vacuum issue, debris may exist on the truck or on the slide. Use a lint-free tissue moistened with distilled water to wipe the truck and and its o-ring to remove any debris.
		Change/replace slides.
	a) Dispense probe is stuck.	Press any key on the SM screen to silence the alarm.
	b) Mechanism that pushes dispense probe down is not receiving sufficient	Wait until the last slide in the dryer has deposited in a slide basket.
		Open the cover, if a slide is on the shuttle or has fallen, remove it.
Dispense (Probe Not Down, Sen 12)	pressure. c) SEN12 failed.	Inspect the area below the smear truck for fallen slides and retrieve the slides if possible.
	d) Dispense probe or rinse block is dirty	Clean dispense probe and/or rinse block.
	unty.	Close cover and acknowledge error on Workstation to reset the SM.
		If the issue continues, call your Beckman Coulter Representative.

Message	Why This Message Occurs	What To Do
	 a) Failure to detect vacuum when passing a slide from smear truck to shuttle indicating an improperly placed slide or debris on shuttle prevents the necessary seal. b) Shuttle vacuum sensor is defective. c) Shuttle vacuum supply solenoid defective. 	Stop alarm, wait for last slide to be deposited.
		Open cover, if a slide is on the shuttle, remove it (if labeled, save for staining).
Shuttle (Vacuum, Sensor 4)		Carefully wipe shuttle (area with orange oval o-ring) with lint-free tissue moistened with distilled water to remove any debris.
		Remove any fallen slides.
		Close cover and acknowledge error on Workstation.
Communication (PC Timeout) – SlideMaker to Workstation Timeout	a) The Workstation is not responding. Handshake signals are absort when	Ensure the Workstation is working properly. If it is, check if the dryer module belt is moving by placing a finger on the plastic conveyer belt of the dryer module in the SlideMaker. If the belt is moving at the Workstation
Communication (Analyzer CRC) –absen inforr requir b) Three conse	 absent when information is required. b) Three consecutive messages 	Command Center in Process Type, change from AUTO ANALYSIS to any of the other choices and then back to AUTO ANALYSIS.
	 between the SlideMaker and the Analytical Station were not acknowledged. c) SlideMaker is disabled. d) SlideMaker is powered off and/or disconnected from power source. 	Ensure the Analytical Station is working properly (at READY). Only if necessary, reset the Analyzer.
		Ensure SlideMaker is enabled in Run Configuration.
Communication Lost (CRC Check		Ensure SlideMaker is connected to power source and powered on.
Failed)		Reseat the cable at the port labeled HOST INTFC on the back panel below the power cord. Ensure the SM is powered off when reseating any cable.

Message	Why This Message Occurs	What To Do
	 a) Label printer detected a failure. b) Loose labels are trapped within the 	Stop alarm and wait for last slide to be deposited into a basket.
		Check for proper seating of label roll and ribbon roll and ensure rolls are seated properly on the printer spools.
Printer (Failure) label/ribbon pathway.	label/ribbon pathway.	To confirm proper routing and seating of the labels and ribbon, print a dummy label. From the SlideMaker main menu choose Special Cycles and then Print Label.
	Remove any stuck labels and clean the area with an alcohol prep.	
a) No slide cassette is available at	Press any key on the SlideMaker to reset the alarm.	
	 b) Sensor failure indicates no slide cassettes with slides when 	If the cassette input queue is empty, place a full slide cassette in the cassette input queue module and acknowledge error at Workstation.
Cassette (No Cassette)	one is present.	If a full slide cassette is in the cassette input queue wait until the last slide is deposited in the basket and unlock the cassette. At the Main Menu, select Routine Functions→Unlock Cassette to unlock the cassette
	Remove and reinstall the slide cassette that is in the slide ejector station.	
	Acknowledge the error at the Workstation to reset the SlideMaker.	

Message	Why This Message Occurs	What To Do
Ejector (Slide Not Ejected)	 a) The slide pusher is jammed. b) Slides within the cassette may be stuck together due to humidity c) A broken slide may prevent a slide from being dispensed. d) The slide pusher extended sensor, SEN24, is blocked or failed. 	Press any key on the SlideMaker to reset the alarm. Wait until the last slide in the Dryer module is deposited in a slide basket. At the Main Menu, select Routine Functions→Unlock Cassette to unlock the cassette. Remove the slide cassette that is in the slide ejector station and ensure no slides in the cassette are sticking together. Open the cover. Manually remove any slide from the slide ejector mechanism and close cover. Reinstall the slide cassette in the Cassette Input Queue module. Acknowledge the error at the Workstation to reset the SlideMaker. If the issue continues, call your Beckman Coulter Representative.

Message	Why This Message Occurs	What To Do
	a) The X-register is jammed.	Press any key on the SlideMaker to reset the alarm.
	b) The slide is broken and is too short to push the flag into the slide register sensor,	Wait until the last slide in the Dryer module is deposited in a slide basket.
		At the Main Menu, select Routine Functions→Unlock Cassette to unlock the cassette.
Ejector (Slide not X registered)	c) The slide register sensor,	Remove the slide cassette that is in the slide ejector station.Open the cover. Manually remove any slide from the slide ejector mechanism and close cover.
	SEN25, failed.	
		Reinstall the slide cassette in the Cassette Input Queue module.
		Acknowledge the error at the Workstation to reset the SlideMaker.
	a) Either fluid detector FD6 is defective or there is a	Press any key on the SlideMaker to reset the alarm.
		Acknowledge the error at the Workstation to reset the SlideMaker.
Fluidics (Detector 6)		Ensure the tubing to the fitting at FD6 is not kinked. You may need to remove the splashguard to get a good view of FD6.
	fluidics problem.	If the message persists, clean the dispense probe and replace the red- striped I-beam dispense line tubing at VL8.
		If the issue continues, call your Beckman Coulter Representative.

Workflow Scenarios for SlideMaker

- 1. You observe that no slides are being made on your LH SlideMaker. You have not received any errors on the Workstation.
- A. What are the first things you would check?
- Verify that the SlideMaker is powered on.
- Verify that the SlideMaker is enabled in Run Configuration (Enable System Function checkbox).
- Verify correct checkbox selected in Run Configuration SlideMaker tab. Verify SlideMaker keypad screen displays "Ready".
- B. What would you do to verify that the problem has been resolved?

Run blood samples. Observe operation to confirm that the SlideMaker is now making smears.

- 2. You observe that the labels on your slides are hanging off the edge of the slide and are not centered.
 - A. What would you do to try to resolve the problem?
 - Verify that the labels and ribbon are installed correctly. Check that the "cores" of the rolls are pushed all the way in on the spools.
- B. What would you check?
 - Check to ensure that no labels have gotten stuck within the pathway.
- C. What test would you perform to ensure that the placement of the labels on your slides is correct?

Print a test label by accessing Special Cycles→Print Label from the SlideMaker Main Menu.

- 3. You observe that your LH SlideMaker appears to be making slides, however, upon further investigation, you discover you are not getting a drop of blood on your slide to make the smear.
 - A. What would cause this situation?
 - Incomplete aspiration of sample to the SlideMaker due to a possible blood clog in the pathway from the vent line to the dispense probe.
- B. Where would you look?
 - Check the tubing through the fluid detectors for holes or kinks. Check the dispense probe.
- C. What could you do to resolve the issue?
 - Perform F-79 to calibrate the vent line. Observe the line through BD3 and FD1. Watch for the presence of liquid, then a change to air.

Remove kinks in any tubing that may be preventing proper sample flow.

- Replace any tubing that is visibly leaking.
- Clean dispense probe.

TIPS

- If the compressor has timed out and you place a sample cassette in the loading bay, <u>the LH SlideMaker will not automatically start</u>.
- Before placing a cassette in the loading bay, press <PRIME APERT> to place the system in a READY state.
- Once READY appears on the Analyzer Control Keypad display, place the cassette in the loading bay and process normally.

LH SLIDESTAINER TROUBLESHOOTING

Monitor Sensor Status

Step	Action	
1	In HELP, go to Contents \rightarrow LH SlideStainer \rightarrow Operating Procedures \rightarrow Operating – BASIC .	
2	Select and read the procedure Monitor Sensor Status. Close HELP.	
3	Open the Monitor Sensor Status 🛄 screen.	
	At the SlideStainer, place a basket in each of the following positions and observe changes on the Monitor Sensor Status window:	
4	• Output queue	
	► STAT IN position	
	Parking lot	
5	Remove the baskets from the SlideStainer.	

Input Queue Configuration

Step	Action
1	In HELP, go to Search and type Input Queue .
2	Click on List Topics.
3	On the list displayed, select Input Queue Configuration.
4	Select Display . Read this topic.
5	Select the SlideStainer Input Queue Status button from the SlideStainer setup screen and follow the printed procedure to reconfigure the Input Queue.
Note	To change the configutation, select the button with text (Parking or Empty). Do not deselect any input/output queue positions. Doing so disables that specific slide basket position.
8	Configure the empty basket area to seven spaces and the parking lot to five spaces.
9	Manually move the plastic divider to indicate the visual dividing line between parking and empty baskets to reflect the change made in step 7.
10	Now change the configuration so that both parking lot and empty basket areas have six spaces. Move the plastic divider as well.
11	Select 🖉 to save.

Reinitialize Arm

Step	Action
1	In HELP, go to Contents \rightarrow LH SlideStainer \rightarrow Operating Procedures \rightarrow Operating – BASIC .
2	Select topic: Reinitialize Arm and print the procedure.
3	If the arm is not in the "home" position at the rear of the LH SlideStainer, perform the procedure.
4	From the SlideStainer Status dialog box, practice opening and closing the gripper.

LH SLIDESTAINER TROUBLESHOOTING TIPS

1. At the Workstation, go to HELP **?**

$Contents \rightarrow \ LH \ SlideStainer \rightarrow Messages \ List \rightarrow ST \ Message \ List$

- 2. To add this topic to your Favorites, select the Favorites tab and select Add.
- 3. The SlideStainer messages are listed in alphabetical order. Use the letters at the top of the page to access your particular message. The **SlideStainer Message List** contains <u>hypertext links</u> that will take you to Help topics that have troubleshooting tips related to the error condition as well as steps to take to resolve the problem. There are many videos included to show the area and what to do.

<u>Use this now</u> by selecting any of the <u>hypertext links</u> and viewing the associated help suggestions for the topic you selected.

Message	Why This Message Occurs	What To Do
a) The waste filter	Clear error.	
	 is clogged. b) Metal drain tube in bath is clogged. 	Try to drain bath 1 again.
		Try to drain another bath.
		If neither bath drains, change the waste filter
Unable to Drain Bath 1 (also applies to baths 2-5)	 c) Fublig leak of tubing not in pinch valve. d) Drain pump 6 is defective. e) A pinch valve is defective. 	If the second bath drains, the problem is not the waste filter, but could be b) Metal drain tube in bath is clogged or c) Tubing leak or tubing not in pinch valve. If b), clean the metal drain tube with a syringe or a pipe cleaner. If c), change tubing or place tubing back into pinch valve.
		If d) Drain pump 6 is defective or e) A pinch valve is defective, call your Beckman Coulter representative.
	a) The reagent supply is empty.	Check the reagent supply and replace if necessary.
	b) The peristaltic	Clear error.
Unable to Fill	pump is problematic.	If issue persists, change the peristaltic pump.
Bath 1 (also applies to	Bath 1c) The reagent(also applies tofilter is clogged.	If issue persists, change the reagent filter.
baths 2- 4)	 d) The reagent pickup line is clogged. 	If issue persists, perform the Flushing Stain Baths and Tubing procedure from HELP. If unsuccessful, replace the line. If the issue persists, call your Beckman
		Coulter Representative.

LH SlideStainer Messages and Error Recovery

Message	Why This Message Occurs	What To Do	
	a) The reagent grade water supply is empty.	Check the reagent grade water supply and replace/refill if necessary.	
Unable to Fill Bath 5	b) Bath 5 reagent filter is clogged.		
	c) The membrane pump is problematic.		
		If possible, assess cause of jam and remove obstacle.	
Arm Mechanism Jam (X-Axis, Y- Axis, Z-Axis)		Clear error. If slide baskets are in the baths or dryer, you can abort the run or continue processing the baskets.	
	a) A jam.b) A hardware issue.	 If you choose to abort the run, the SlideStainer goes to Standby, and YOU MUST REMOVE ALL SLIDE BASKETS IN THE BATHS AND THE DRYER AND FROM BOTH POSITIONS OF THE TEMPORARY HOLD. If you choose to continue process, the SlideStainer tries to recover automatically and continue. 	
		If the SlideStainer fails to recover, turn the SlideStainer off and then on.	
		If the message persists, call your Beckman Coulter Representative.	
Message	Why This Message Occurs	What To Do	
--	--	---	--
		If possible, assess cause of jam and remove obstacle.	
		Clear error. If slide baskets are in the baths or dryer, you can abort the run or continue processing the baskets.	
Arm Initialization Error (X-Axis, Y- Axis, Z-Axis)	 a) The axis home or initialization position sensor is defective. b) The axis arm mechanism is jammed. 	 If you choose to abort the run, the SlideStainer goes to Standby, and you must remove any slide baskets in the baths and the dryer. If you choose to continue process, the SlideStainer tries to recover automatically and continue. 	
		If the SlideStainer fails to recover, turn the SlideStainer off and then on.	
		If the message persists, call your Beckman Coulter Representative.	

REPLACING COMPONENTS

<u>NOTE</u>: The section that follows is not meant to be all-inclusive as to every type or possible application of the parts and pieces covered. The main intent is to provide a familiarity with the different parts and an awareness of the differences that may exist.

TUBING

Types of Tubing

The general rule of thumb is to **replace a piece of tubing with the same type as what you remove**. Color-code stripes or printed part numbers identify the proper match. This is important because it ensures that the correct inner diameter of tubing is used.

- Silicon
 - I-beam
 - Always used in pinch valves through the normally closed part of a pinch valve.
 - > I-beam tubing must be threaded properly in the pinch valve tracks.
 - Color-code stripe Blue, Black, Red, No stripe.
 - Round
 - Almost always used in pinch valves through the normally open part of a pinch valve.
 - Color-code stripe–Blue, Black, Yellow, Red, Green, Brown.
- Pharmed
- A more chemically stable type of tubing (it has an opaque, cream color)
 - I-beam and round versions
 - Color-code stripe Blue, Black, No stripe
- Polyurethane
 - A harder type of tubing not easily pinched
 - Usually has a part number printed on the tubing
 - If no part number is printed, it will have a color stripe or stripes because it has a particular function, for example:

Green/black – used in 30 psi/vent lines White – used for diluent or cleaner lines

- Green used in 30 psi lines
- Special tubing
 - There is some tubing that comes precut, with or without molded ends. It is prepackaged individually and has a specific part number.

Tubing Lengths

Coulter LH 700 Series Training Guide Ver. 1.1 (April 2016)

The general rule of thumb is to **cut the replacement piece of tubing to the same length** as the faulty piece.

- Tubing designated as "critical length" is usually marked with a small red plastic ring that slides onto the tubing. However, **not all red rings are critical length markers**. Some rings are spacers to keep the ends of Cross, T or Y- fittings out of mini pinch valves. Critical length rings are approximately 1/16" wide and spacers are approximately ¹/₄" wide.
 - There is some critical length tubing that does not have any indicator, e.g. the aspiration tubing from the needle to the first blood detector.
 - There is some critical length tubing that is precut and may or may not have fitted ends attached. This precut tubing is packaged individually and has specific part numbers.

PINCH VALVES

- Double-action pinch valves are proprietary, patented valves that are designed specifically to work with I-beam tubing.
 - These pinch valves can be removed with a pinch valve wrench (removal tool) to make tubing replacement a little easier or to replace a broken pinch valve.
 - View the HELP topic: Remove Pinch Valve Tubing and Pinch Valve. Use a red transit clip to hold the pinch valve open when replacing I-beam tubing.
 - Remember that I-beam tubing must be threaded properly in the pinch valve tracks. One simple idea to make this easier is to use a two-inch piece of applicator stick, inserted into one end of the I-beam tubing. This makes threading the tubing easier and ensures the I-beam is in the tracks correctly.
- There are also mini pinch valves (single) and triple (six tube) pinch valves.

ANGAR VALVES

- This is a type of valve that performs a similar function to the pinch valve, but does not pinch any tubing as the tubing attaches to the outside of the valve only.
 - These valves switch one common fitting to one of two possible fittings internally.

CHECK VALVES

- Check valves allow liquid or air flow in only one direction.
- Since they allow flow in one direction only, the orientation of the valve in the line is important.
- There are three check valve sizes: small, medium and large.
 - Some medium check valves have a black stripe, indicating they have been tested to a certain specification. If a check valve you are replacing has a black stripe, be sure to replace it with a black striped check valve.
- When replacing a check valve, remove the tubing one end at a time from the old check valve and reconnect to the new check valve to ensure the direction of flow is correct.



Check Valves and Chokes (examples)

CHOKES

There are five types of chokes, color-coded by sizes, described below.

Metal

Metal chokes restrict the flow of the air in a pathway.

• Cylindrical metal chokes



- An arrow on the cylindrical metal choke represents the direction of flow and should be noted when replacing the choke.
- These chokes do not come with fittings on them. It is necessary to unscrew the fitting from the end of the old choke and screw it into the new choke. There is an o-ring on the fitting that must be in place to ensure no air leaks at the union point.
- Color coded Red, Black, Brown, Green, Blue, Gold Metal fittings with a built-in choke
 - Color-coded Blue, Green, Brown, Black, Red
- Variable Chokes
 - Allows adjustable restriction



Plastic

Plastic chokes restrict the flow of liquid or air in a pathway.

- There are two styles of plastic chokes.
- They also have direction indicators.
- Color-coded Black, Brown, Gray, Yellow, Blue

Restrictors

Tubing used to provide a certain amount of restriction to the flow of liquid or air.

FITTINGS

- Can be metal or plastic
- There are several styles including Y, T, Cross-, Feed-through, Union, Reducer.
- Connects tubing to components or tubing-to-tubing.
- Carefully push tubing straight onto a fitting.
 - Push tubing onto a fitting so that the end of the tubing is beyond the barb on the fitting.



NEVER use LH Series Cleaner or LH Series Diluent or CBC Lytic Reagent to moisten the end of a tubing for lubrication. Any residue may dry into a salt or gel and affect instrument operation. <u>You may use Reagent Grade water</u>.

You may also carefully stretch the end of a tubing using hemostats, or needlenose pliers or even a toothpick. It depends on the tubing. You must be careful not to create a hole in your new tubing.

Fittings (examples)



Needle Assembly

Always view the Needle Replacement video in HELP before beginning. This assembly consists of a cartridge holder, a plastic bellows and the needle.

- At the bottom of the assembly are three lines:
 - Aspiration line
 - Needle vent line
 - Waste line
 - It is very important when replacing a needle to reconnect the aspiration and vent lines to their correct ports as aspiration errors could occur.
 - If your instrument has an Advanced Bar-Code Reader, remember to lift and secure the Barcode Reader out of the way before you begin. Return the Barcode Reader to original position when done. See the following topic in HELP: Positioning the Advanced Bar-Code Reader.
 - A new needle assembly includes a new waste line already attached.
- Be sure the aspiration and vent lines are not twisted or kinked.
- The vent line has a "sheath" that protects the tubing. Ensure this sheath is pushed up onto the vent fitting at the bottom of the needle.
- Remember that the assembly is mounted at an angle, so when removing or replacing the assembly, it is important to apply the same angle.
- Use the supplied needle safety clip whenever handling the needle assembly.
- Always Power Off the Diluter and Power Supply and unplug the unit from the wall receptacle or from the UPS before touching the needle.
- After replacing a needle assembly and powering on, if you get a VLS error, it probably means that the protective sheath was not positioned correctly and the vent line is pinched. This is a very common error so be careful.



LH SLIDESTAINER COMPONENTS (if applicable)

Peristaltic Pump

- This is a type of pump that is used for filling Baths 1 4 in the LH SlideStainer.
- They are the four round devices located on the top front of the liquid module assembly. They are arranged the same as the baths, so the front pump, P1 corresponds to Bath 1 and the back pump corresponds to Bath 4.

Waste Filter

- This is a type of filter that is used in draining Baths 1 4 in the LH SlideStainer.
- It is mounted in the LH SlideStainer in the horizontal position.

Reagent Line Filter

- This is a type of filter that is used for filling Baths 1 4 in the LH SlideStainer.
- They are mounted in line from the supply to the rear of the LH SlideStainer.

Step	Action
1	Open HELP and use Index or Search to locate the procedures in the following steps.
2	Locate Replacing Tubing and read this topic. Locate Checking Pinch Valves and familiarize yourself with how I-beam tubing is threaded through a pinch valve.
4	Locate Replacing Check Valves and read this topic.
5	Locate Replacing Needle and read this topic. Ensure you read each hyperlink and watch the videos that are a part of the procedure.
6	LH SlideStainer : Locate Replacing a Peristaltic Pump and read this topic.
7	LH SlideStainer : Locate Replacing a Reagent Line Filter and read this topic.
8	LH SlideStainer : Locate Replacing the Waste Filter and read this topic.

Inspection Checklists for LH 700

Checklist for Leaky Tubing Replacement

- The I-beam tubing is the same type and length as the tubing being replaced.
- The tubing is threaded properly in the pinch valve.
- Both ends of the tubing are properly reconnected.
- Transit clip has been removed.

Checklist for Check Valve Replacement

- □ The correct size check valve was used.
- The check valve is in the proper orientation.

Checklist for Needle Assembly Replacement

- The vent and aspiration lines are reconnected to the correct ports.
- □ The protective sheath tubing for the vent line is pushed up onto the vent fitting on the bottom of the needle assembly.
- □ The waste line is reconnected to its fitting.
- □ The needle assembly is inserted properly in its holder.
- □ No lines are pinched or bent.

Inspection Checklists for SlideStainer

Checklist for Replacing a Peristaltic Pump

- □ The pump is oriented in its original direction and reconnected to the correct tubing.
- Both sides of the pump are snapped into place.
- □ No tubing is kinked or crimped.

Checklist for Replacing a Waste Filter

- □ The filter is oriented in the clamp with its arrow pointed toward the back of the LH SlideStainer and reconnected to the waste line tubing.
- □ No tubing is kinked or crimped.

Checklist for Replacing a Reagent Line Filter

□ The filter is reconnected with its arrow pointed up toward the LH SlideStainer and the tubing pinches are completely open.

AIR FILTERS

Analyzer Air Filters

Step	Action
1	At the Workstation, go to HELP $?$ \rightarrow Index \rightarrow type air.
2	Under the "air filter" entry, click on clean.
3	Click on Display . Read the procedure, Cleaning and Replacing Air Filters.

LH SlideMaker Air Filters

Step	Action
1	In HELP, locate Cleaning and Replacing Air Filter (SlideMaker) procedure.
2	Read and familiarize yourself with all the steps.

LH SlideStainer Air Filter

Step	Action
1	Go to HELP \rightarrow LH SlideStainer \rightarrow Replacement Procedures \rightarrow Replacing the Air Filter.
2	Read and familiarize yourself with all the steps.

REPRODUCIBILITY & CARRYOVER

Reproducibility (Precision)

A measure of the ability of the instrument to reproduce similar results when a sample is run repeatedly. Precision of the instrument is a CV (or an SD for differential results), based on at least 31 replicate determinations of the same sample. Precision shows the closeness of test results when repeated analyses of the same material are performed.

Note: Both the Reproducibility and Carryover procedures may be a requirement of regulatory agencies. These procedures may be used at any time to verify Diff and Retic performance, in addition to the CBC only that we will perform as part of this module. Refer to the Performance Specifications in HELP for the results criteria.

Step	Action
1	Go to $(\mathbf{Reproducibility}) \rightarrow \text{open HELP from the}$
•	Common Toolbar. Read this procedure.
2	Next, in HELP select the Index Tab, Type Repro, select the topic "donor requirements", and read this information.
2	At the Analyzer CRT ensure the blood detector is enabled .
3	At the Command Center , ensure that Default Type is set to C . You can perform reproducibility using other operating modes, however the procedure will take longer and use more reagents.
4	At the Analyzer CRT set the number of aspirations per tube to 1.
5	Select REPRODUCIBILITY as the Process Type on the Command Center.
6	<u>WARNING</u> The background color of the Reproducibility window changes to the same green background color as the Command Center when you change Process Type to REPRODUCIBILITY. Watch out for this relatively common error! Failure to perform this step will result in data going to the database instead of to the Reproducibility screen.
7	If necessary, select is on the Reproducibility window, Specific Toolbar, to clear previous old values from the results table.
8	Place the single EDTA tube into a cassette and place the cassette in the right-hand loading bay. This "prime" will automatically be omitted from the Reproducibility calculations.

	After running	the previous "prime	" sample set the n	umber of
9	aspirations per tube to 5. This is in preparation to run your $N = 10$.			
10	Mix the two sample tubes and place into a cassette.			
11	Place the cas	sette in the right-han	d loading bay.	
12	After the ten table and stat	results are received a istics.	at the Workstation r	eview the results
Note 1	The procedur stop processi	re begins with an N= ng. Otherwise, see N	10. If all parameters ote 2 below.	s pass, you may
13	Verify that the %CV (Coefficient of Variation) does not exceed the established limits.			
		Reproducibility	Limits for CBC	
		Parameter	CV%	
		WBC	≤ 1.7	
		RBC	≤ 0.8	
		Hgb	≤ 0.8	
		MCV	≤ 0.8	
		Plt	≤ 3.3	
Note		MPV	≤ 2.2	
2	Verify that the %CV does not exceed the established limits above. If limit is exceeded, repeat with two more tubes of blood, until at least 11 but not more than 31 whole blood samples have been analyzed. You may stop the analysis at any point between 11 and 31 runs if the reproducibility established limits have been met . If any instrument results exceed these limits, repeat with another donor sample. If you still have a failure, an instrument problem may exist. Call your Beckman Coulter Representative. (Note: the above limits are also available in HELP).			

Carryover

"Carryover is the discrete amount of analyte carried by the measuring system from one specimen reaction into subsequent specimen reactions, thereby erroneously affecting the apparent amounts in subsequent specimens" (NRSCL8-A 1998. Clinical Laboratory Standards Institute). It is conventionally expressed as a percentage of the concentration of the analyte in the first specimen which is carried into the subsequent specimen, as indicated by the specified limits listed above.

Step	Action
1	Go to \bigcirc (Carryover) \rightarrow open HELP from the
-	Common Toolbar. Read this procedure.
2	Ensure the blood detectors are Disabled at the Analyzer CRT screen. (Go to Main Menu \rightarrow System Configuration \rightarrow Blood Detectors).
•	<u>WARNING</u>
3	If blood detectors are not disabled, the carryover study is invalid. The diluent values will give a partial aspiration message.
4	Ensure the Default Type is set to C . You can perform carryover check using other operating modes, however the procedure will take longer and use more reagents.
5	Ensure the number of aspirations per tube is set to 1.
6	Select CARRYOVER as the Process Type on the Command Center.
7	The background color of the Carryover window changes to the same green background color as the Command Center when you change the Process Type to CARRYOVER.
8	If necessary, select \boxed{base} on the Carryover screen, Specific Tool bar, to clear the previous values that appear on the results table.
9	Collect your supplies: 2 EDTA tubes with blood (not necessarily from the same donor), 3 empty EDTA tubes.
10	At the Analyzer Control Keypad, press <f04> <enter> to dispense diluent through the Manual aspiration mode aspirator tip into each of the uncapped, empty EDTA tubes.</enter></f04>

11	The Analyzer Control Keypad displays DILUENT DISPENSE while the instrument performs this function. When the function completes, the Analyzer Control Keypad displays FUNCTION = 04. Press <enter> to perform this function again.</enter>			
12	Press <stop> to exit the function. The Analyzer Control Keypad displays READY.</stop>			
13	Ensure that the	blood samples are	well mixed.	
14	Place the tubes into consecutive positions in a cassette in this order: 2 blood tubes, 3 diluent tubes.			
15	Place the cassette in the right loading bay. The instrument begins processing the cassette automatically.			
16	Verify the carr	yover results.		
	Carryover Acce Carryover limi Carryover Not limits are exce	eptable indicates th ts. Acceptable indicate eded.	at all results meet these these that High-to-Low	ne High-to-Low 7 Carryover
17		High-to-Low Carryover Limits		
17		WBC	≤ 2.0%	
		RBC	≤ 1.0%	
		Hgb	≤ 2.0%	
		Plt	≤ 2.0%	
18	Carryover acce Beckman Coul	eptable? If YES , priter representative.	int results. If NO, c	all your
19	Ensure the blo	od detectors are En	abled at the Analyz	zer CRT screen.

LAB LIMITS & PATIENT CONTROL SET UP

Setting Up Lab Limits

Lab limits are used to replace the default expected range provided for control material by the manufacture. The expected range is determined using intrument precision along with intrument to intrument differences.

Why establish your own lab limits?

- Some regulatory agencies reguire it
- Good QC practice
 - Allows the lab to tighten up their own intralaboratory range
 - This should be based on at least six months of QC data
 - Could use printed monthly data or IQAP reports
- Once established, lab limits do not change from lot to lot
- To calculate the lab limits for your instrument refer to the Hematology Perfomance Verification Manual

Step	Action
1	At the LH Workstation, from the Command Center, go to (System Set Up) \rightarrow Quality Assurance (Quality Assurance Set Up) \rightarrow select Controls
2	Use the line select button to highlight a control folder.
3	Select Setup Lab Limits) button.
4	Enter the lab limits your laboratory has established.
5	Click on \bigcirc (OK) to save.
6	Click on <i>o</i> again to close the System Setup [Quality Assurance] window.

7	Select Se	E E E E E E E E E E E E E E E E E E E
8	On the screen to the left of the cumu Mean => Lab Target Lets you replace the manufacturer values with the means of your own control runs.	Ilative results are two buttons: Restore Assigned Values Lets you restore the assigned values and expected ranges from the control package insert.
Note	If the buttons are grayed out, verify that there are at least five runs in the file (this is the minimum required before the buttons become active), if there are at least five runs and the buttons are still inactive then log off the Workstation and log on again.	
9	Toggle these buttons now to see how points on the thumbnail (and full-pa take place.	v they work. Also notice that the ge) graphs move as the changes

Setting Up A Patient Control Folder

Step	Action
1	Select Systen Setup QA setup QA setup .
	After you select (New Control Folder) button, choose the following:
2	 Source: Other Type: CBC (You may choose any Type in your lab) Level: Normal (You may choose any Level in your lab)
3	Select (Setup Lab Limits) button.

4	<u>If lab limits are already established by your lab</u> , DO NOT change <u>them</u> . If they have not yet been established, review this screen to be familiar with the values required for entry.
5	Select 🖉 to save.
	Select 🚫 (Setup New Lot). Cursor is in Lot Number field.
6	Use the hand-held bar code scanner to scan the bar code label on a patient sample tube.
7	Set the expiration date to tomorrow's date .
8	Select Use as Default (checkbox below expiration date).
9	Select ⊘ to save.
	Select p to close.
10	A warning appears; "One or more fields have not been completed. Do you wish to continue?" Select Yes, then select it to exit Control Set Up.
	At the Workstation Command Center
11	➢ Set Default Type to "C".
10	Set Process type to Auto Analysis
12	At the Analyzer CRT, set # Aspirations/tube to 2.
13	Place the EDTA tube in a cassette in right-hand loading bay. At the Workstation go to Quality Assurance , Quality Control .
14	Expand the Control Tree to find the Other / CBC folder you set up.

Note	The Assigned Value and Expected Range lines are blank, therefore when you process your first run of the Patient Control, no results are out-of-limits.	
15	The Mean => Lab Target button becomes active as soon as one run is in the control folder.	
16	After the one run is in the folder, select the Mean => Lab Target button. After the second run is in the folder, you may select the button again.	
17	The assigned value line changes to Target and is the mean value of the run(s). The Lab Limits are in the former Expected Range line.	
18	When done, change # aspirations/tube back to 1.	

What Do I Do On The Next Day Or Shift?

Step	Action	
1	On the next day or shift, select a different patient sample. Bar code the tube. Go to $\$, $\$ and in the Patient Control Folder, select button.	
2	Select the radio button Only Table Run Data. Then select 🧭.	
3	 After deleting Table Run Data you can enter a new Patient Control Lot # and Expiration Date in System Set Up, Quality Assurance Set Up, Controls tab. > Highlight the folder then select (Edit Control Values) > Highlight the lot number field > Scan new barcode label > Change the expiration date 	
4	Run the patient control.	
5	Select Mean => Lab Target. You have a new Target value for the current day or shift.	

QC DATA REVIEW

Editing Control Information

This is for your information only. DO <u>NOT</u> perform these steps now.

One special editing situation that you may find useful applies to the LATRON control folder. One characteristic of LATRON control is that the assigned values and expected ranges do not usually change from lot number to lot number. When you set up a new LATRON control lot number, you do not have to type in the assigned values and expected ranges each time if you follow this procedure. After printing old LATRON control lot number values, delete "**Table Run Data**". This deletes all the runs in the file, but does not delete the Setup Table.



Deleting Control Folder Data

For this exercise just observe the data deletion options available. Please <u>DO NOT</u> delete any control data at this time.	
Step	Action
1	At the Workstation, access any control folder containing data from QA, QC.
2	Click on the Delete) button on the Specific Toolbar.
3	 The screen gives you three different levels of severity for deletion: All Data for Control Lot Number(s), including Setup Table Only Table Run Data – just the runs and statistical information not the Setup Table Only Selected Runs Within Table
4	Refer to "Control Data—DELETION REQUESTED Window" in HELP, if you need further clarification of these options. Control Data - DELETION REQUESTED CAUCION YOU HAVE ELECTED TO DELETE ONE OR MORE CONTROL RECORD(S) FROM THE DATABASE. PLEASE SPECIFY THE SEVERITY OF THE DELETION All Data For Control Lot Number(s), Including Setup Table Only Table Run Data Only Selected Runs Within Table
5	If you select on the above screen, you have a chance to reconsider your decision before selecting again.

IQAP Download Procedure

Step	Action
1	In HELP go to Index \rightarrow type IQAP \rightarrow click on the topic participating to display Participating in IQAP .
2	Follow the IQAP Download Procedure using removable media.
3	After the download dialog box closes, press the eject button on the CD drive on the Workstation computer. A "Drag-to-Disc Eject Options" dialog box opens. Select "This disc will be used on other computers or devices." Keep enabled the "Always show this dialog when ejecting a disc." Then choose the Eject button.
4	Another "Drag-to-Disc" box with a progress bar opens. Wait for it to become 100% complete. The CD drive will eject the CD.
5	If there is a problem downloading QC data to your chosen removable media, refer to Troubleshooting in the above HELP topic.

IQAP Submission - eIQAP

- Electronic uploading of your IQAP control data files from multiple media types via the internet is now possible using eIQAP.
- You must have an IQAP account set up first. Then you will be asked if you want to use eIQAP. To enroll in eIQAP, go to www. beckmancoulter.com/qap/index.jsp and select the Hematology tab and follow the instructions for registering and enrolling. If you have an IQAP participant ID, have that handy when you register. If you are not already enrolled in IQAP, it can be done as part of the eIQAP enrollment process.
- Once you have the removable media from the previous exercise, you will log in to the internet site for eIQAP and follow screen instructions to upload your data.
- The advantage to the internet upload is that you will have access to the pool data as soon as the minimum number of pool participants has been reached. You will access and print your own reports via a .pdf format. The internet site provides access to the download for Adobe[®] Acrobat[®] ReaderTM if you do not have it already.
- Once you enroll all eligible hematology instruments in your laboratory, you access your data through your eIQAP account. Also, each institution can have multiple users each with either user or administrator access rights. The first user to enroll the institution will be given administrator access, but other users can also be administrators. Each institution must have at least one administrator.

One of the features of the control file area is the Shift Clock, which allows data review by shift. If you do have multiple shifts set up, then you need to think about how you want to receive your IQAP reports.

• If you want to receive three separate reports, one for each shift, do nothing. Your current setup will provide that.

Note: Check your regulatory requirements to verify that this archiving method is an acceptable way to store and retrieve data.

- If you want to receive one overall report, then you need to change the system setup, **before** you download:
 - Go to System Setup, Quality Assurance Setup, select the Shifts tab.
 - Deselect the Multiple Shifts checkbox (you will see the shift times disappear). Select OK to save.
 - Now do your IQAP download as described in the section above.
 - After the download, go back to System Setup, Quality Assurance Setup, Shifts tab and select the Multiple Shifts checkbox. The shift times will reappear. Select OK to save.
- The 5C Cell Control requires monthly downloads as soon after the expiration date as possible or when you have stopped running it. Remember that if there are fewer than 10 runs, you will receive a report, but your data is not included in the pool. This may affect some shifts more than others.
- In general, Retic-C is not run as often as 5C and may run into the problem of not enough data, especially if submitted by shift.

Archiving Control Results



-		
4	When the "Save as" window appears, double click on My Computer.	
5	Select the drive for your removable media. Type in a file name or use the suggested name. Select Open and then select Save.	
6	Wait until the "Archive Complete" window appears, click OK.	
7	After the download dialog box closes, press the eject button on the CD drive on the Workstation computer. A "Drag-to-Disc Eject Options" dialog box opens. Select "This disc will be used on other computers or devices." Keep enabled the "Always show this dialog when ejecting a disc." Then choose the Eject button.	
8	Another "Drag-to-Disc" box with a progress bar opens. Wait for it to become 100% complete. The CD drive will eject the CD.	
9	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.	
Note 2	You can retrieve the archived data later on a personal computer (not the LH Workstation computer) by using a spreadsheet application, such as the Microsoft [®] Excel. For information about how to retrieve this data, refer to your spreadsheet application's documentation.	
10	Choose the "Deselect All" button on the specific toolbar.	
Note 3	The archived files are in .csv format. In a spreadsheet program you can save the files in the standard format for the program that you are using. Archive only for statistical review purposes. The Levey-Jennings graphs are not archived.	
	The control files in the Workstation remain unchanged after the archiving process.	

SECURITY ACCESS

Step	Action
Note	In order to complete this exercise you must be logged on as a Level 3 user.
1	In HELP, go to Index \rightarrow type security \rightarrow Setting Up User Access Levels.
2	Follow the procedure to create Level 1 and Level 2 users.
3	Select a user name and password for a Level 1 user. User name Password
4	Select a user name and password for a Level 2 user. User name Password
5	Log off the Workstation.
6	Log on to the Workstation with the Level 1 user name and password.
	Based on what you know about Level 3 (Labadmin) security access, look at the following areas and note the differences. Refer to the next pages for information.
7	(Note: The term Labadmin is not a job but a user level).
	Patient Results toolbars (all applications) Quality Assurance toolbars (all applications)
	System Set Up
8	Repeat steps 5 through 7 using the Level 2 user name and password.
9	Log off the Workstation and log on again as a Level 3 user. Delete all users that you set up for this practice exercise.
10	Log off the Workstation and log on again at your access level for your lab.

USER PRIVILEGES FOR LEVEL 1, 2, AND 3 OPERATORS

All Levels have access to <u>everything</u> on the Command Center, Run Configuration screen and to all HELP screens.	
Level 1 Operators (Operator)	
Patient Re	sults Screens - Results & Graphics View, DB/ToDo View
CAN:	Manually Transmit & Print, Use Database Explorer, Validate, Add Request to ToDo List, View 3-D Dataplots, Access DB/ToDo area, Use Navigation, View Save List, View History, Select/Deselect All, Access all Display modes Lock/Unlock screen, Increment slides made
CANNOT:	Archive, Store Permanently, Edit, Delete,
Qu	ality Assurance Screens – Daily Checks, QC, XB
CAN:	Manually Transmit & Print, Access QC, XB and Background Graphics, Access Daily Check Details, View History, Remove/Restore runs from statistics, Change control file status, Select/Deselect All, View by shift, Add Comments, View XB/XM Batches, Remove/Restore XB/XM runs, Add comments to XB/XM.
CANNOT:	Archive, Access Reproducibility, Carryover, Calibration or Workload Recording, Delete from Daily Checks History, Archive or Delete QC, Delete runs from QC, XB or XM, Clear Tables, Download IQAP
	History Logs
CAN:	Print, Add Comments
CANNOT:	Delete Entries, Archive
	System Setup
CAN:	General Settings – access all QA – access reagent tab Location & Physician – access all Password – can change own password SlideMaker/Stainer - access Stainer tab only, changes state, drain and fill baths, access status, drain reagent lines, monitor sensor status
CANNOT:	Access Patient, Institution, Communications, Database Preferences, Security Access or Control Panel QA – set up controls, setup XB, set up shifts SlideMaker/Stainer – access SM tab(includes smear dispense mode, slide label definition, and automatically advance basket), create stain protocol, delete stain protocol, save stain protocol, download stain protocol

Level 2 Operators (Advanced Operator)			
Patient	Results Screens – Results & Graphics View, DB/ToDo		
CAN:	Perform all Level 1 functions plus: Store Permanently, Delete, Edit, Increment slides made		
CANNOT:	Archive		
Quality Assurance Screens – Daily Checks, QC, XB			
CAN:	Perform all Level 1 functions plus: Archive, Access Reproducibilty, Carryover, Calibration and Workload Recording, Delete from Daily Checks History, Delete QC runs, Download IQAP, Clear table, Delete XB runs		
	History Logs		
CAN:	Perform all Level 1 functions plus Archive		
CANNOT:	Delete Entries		
System Setup			
CAN:	General Settings – access all QA – access all Location & Physician – access all Password – can change own password Control Panel – access to basic functions		
CANNOT:	Access Patient, Institution, Communications, Database Preferences or Security Access SlideMaker/Stainer – same as Level 1		

	Level 3 Operators (Lab Administrator)
CAN:	Perform all Level 1 and 2 functions plus: Archive patient results, Delete History Log entries, Set up Patient Area, Institution, Communications, Database Preferences and Security Access, Use all features of SlideMaker / SlideStainer

XB ANALYSIS

What is $\overline{\mathbf{X}}_{_{\mathrm{B}}}$ Analysis?

"Weighted Moving Average" of patient sample results

- Originally created by Dr. Brian S. Bull
- Uses RBC indices (MCV, MCH, MCHC)
- Small batches of samples (20 samples)
- Compares batch results to lab "target values" automatically
- Batch results are "in control' if batch mean is within 3% of the target value
- An ongoing method of monitoring automated hematology instruments
- No additional cost (uses patient sample results)

Why Use The RBC Indices?

- MCV, MCH and MCHC are fairly stable parameters
- Stable for individual patient from day to day
- Stable for "patient population" over time
- "Target values" or mean vales can be established for your patient population

What Is A Target Value?

- An average value, for each parameter, calculated from large numbers of patient results
- Target values should reflect the entire patient population of the laboratory
- Include all ages and disease states

Dr. Bull's Target Values

	MCV = 89.0	
	MCH = 30.5	
	MCHC = 34.0	
•	Suggested starting values to use until laboratory values are established	
•	Based on general population across the nation	

What Does an "Out of Control" Batch Indicate?

"Out of C	"Out of Control" batches may indicate:	
•	An instrument problem	
•	A reagent problem	
•	A sample handling problem	
•	A calibration problem	
•	A change in the patient population	

Establishing Laboratory "Target Values"

Ensure the following:		
•	Instrument is clean	
►	Instrument is calibrated	
•	There are no instrument problems	
•	Sufficient data collected	

How Do You Get Started?

Start with Dr. Bull's default values already in the Workstation			
•	Enable XB on the Run Configuration screen		
٠	Run samples to collect batches of patient samples		
٠	Save printouts		
٠	Collect data to reflect entire patient population (all ages and disease states)		
•	Results from at least 250, but ideally 1000 blood samples should be collected to find your laboratory's target values		
	 Include all types of patients (oncology, presurgical, OB, dialysis, outpatients and so forth) 		

After Data is Collected

Collect printouts of XB batches

- Calculate the mean and %CV for each of the XB parameters
- Verify the lab's means do not exceed Bull's target values by more than 3%
- Verify the %CV is less than 1.5%
- Use the calculated means as the new target values
- Enter the new values in the Workstation setup

What Makes a Batch "Out of Control"?

- Instrument problem
- Change in patient population
 - One or more types of patients added or removed from mix of patient population
- Non-random patient sampling
- Batch of patients is biased by several abnormal patients of a certain type (oncology, neonatal and so forth)

Non-Random Sampling

- Batch may go outside the $\pm 3\%$ limits, because the batch is biased
- Each subsequent batch should move closer to the target and be back "in control" within 3 to 4 batches
- Make a note that the "batch was out due to non-random sampling" by adding a comment in the Batch Mean Table.

Batch Results Go "Out" and Stay Out:

There is a change in the patient population

- One or more new type of patient is added to the patient population
- One or more types of patient is no longer a part of the patient population
 - Seasonal changes of the patient population (hospitals or clinics in resort areas)

Instrument problem

- Can be a gradual change that may indicate a part going bad over time or a calibration drift
 - ➢ Will go back "in control" after calibration
 - > Will go back "in control" after part is replaced
- Can be a sudden change that indicates an instrument problem
 Will go back "in control" after problem is fixed

Troubleshooting When a Batch is "Out"

Know which parameter is out				
•	 Look at the batch results "Out" parameters are flagged with H or L 			
Know	Know where the parameter comes from			
►	MCV:	Derived from the RBC Histogram		
•	MCH:	Hgb x 10 RBC		
•	MCHC	<u>Hgb x 100</u> Hct		
	where the Hct	$x = \frac{\text{RBC x MCV}}{10}$		
• As you can see, two of the XB parameters are calculated using other RBC results				
• Troubleshoot those things that can affect the parameters used in the calculations				

What to Look for When XB Parameters are "Out"

	MCV LOW	MCV HIGH	MCH LOW	MCH HIGH	MCHC LOW	MCHC HIGH
MCV	dec	inc			inc	dec
RBC			inc	dec	inc	dec
Hgb			dec	inc	dec	inc
Hct	dec	inc			inc	dec

Practice

Step	Action				
1	At the LH Workstation, select HELP \rightarrow Search \rightarrow type Setting Up XB Analysis \rightarrow select the List Topics button \rightarrow double-click on Setting Up XB Analysis from the list.				
2	Read this HELP topic to become familiar with the procedure.				
3	Go to System Set Up \rightarrow Quality Assurance \rightarrow XB				
3	At the LH Workstation, using "Reviewing $\overline{\mathbf{X}}_{\mathbf{B}}$ Results" go to Quality Assurance, $\overline{\mathbf{X}}_{\mathbf{B}}$				
	Review the $\overline{\mathbf{X}}_{\mathbf{B}}$ data in the Workstation:				
4	a)	Look at the current batch as well as the previous and last batches.			
	b)	Look at the batch mean summary table.			
	c)	Examine the Levey-Jennings graphs for trending or shifts.			

INTRODUCTION TO TRUTH TABLES

Introduction

One of the most important tasks to accomplish during the Implementation of any automated differential analyzer is to establish/verify an effective flagging protocol. **The purpose of the flagging protocol is to identify those samples which require a slide review so that significant morphology detail can be added to the automated report**. The extent to which an analyzer can effectively screen "normal" vs "abnormal" is defined as the instrument's clinical sensitivity. The Truth Table is an effective tool for evaluation of the instruments's clinical sensitivity.

The first step in establishing an effective flagging protocol is to clearly define those findings that are considered clinically significant. A significant finding would be considered some detail that could add value to the report and ultimately affect/improve patient care.

The next step is to identify ways to flag for these findings. Some flags and codes are already built into the analyzer and are generated when the analyzer detects an unusual or unexpected distribution of particles. Additional flags can be set up by the operator to reflect the laboratory's review requirements and to support the screening process.

Specimens determined to be abnormal by the automated system should be evaluated according to the laboratory's protocols. Specimens determined to be normal by the automated system could be released without further review (autovalidation). The evaluation of the instrument's clinical sensitivity is critical because over-flagging may lead to unnecessary differential review, while underflagging may miss abnormal samples.

The manual differential is used as a reference method to assess whether the instrument's flagging is appropriate. The lab determines the flagging limits which separate normal results from abnormal results, classifying each sample as a True Negative, True Positive, False Negative or False Positive. Reviewing and possibly adjusting the operator definable flags may further improve the efficiency of the automated differential system.
IMPORTANT NOTE

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

Beckman Coulter Inc. does not claim to identify every abnormality in all samples. All Truth Tables and associated recommendations reflect the extent to which your workflow may be managed efficiently but are limited to the sample data submitted for evaluation. Accepting any of the suggested recommended changes to the current review criteria would require appropriate changes to action limits and/or lab protocol that were in place at the time of this evaluation. Finally, all observations are recommendations and subject to your review and discretion in the formation of your Laboratory's review and flagging protocols."

AUTOMATED VS MANUAL DIFF DATA COLLECTION

When comparing the automated differential to the manual differential, ensure that the inherent variations of slide preparation are minimized by:

- Making quality smears.
- Staining with quality stain.
- Using optically clean microscopes.
- Having qualified technologists review the smear(s).

Specimens are identified by lab number on both printouts and microscopic slides for future reference.

CLSI (H20)³ recommends that two technologists each perform a 200 cell manual differential on two different slides (total of 400 cells analyzed by each technologist). More cells counted results in a more precise and accurate reference against which to judge the accuracy of the automated method. Automated differential systems analyze thousands of cells. The following Rumke Binomial Distribution Table⁴, published by C.L. Rumke in 1978, illustrates that the statistical uncertainty of reference values is a direct function of the number of cells counted. The imprecision of the manual differential is especially pronounced with low numbers (e.g., monocyte, eosinophil and basophil percent).

TRUTH TABLE DATA COLLECTION

- The ideal truth table would include a minimum of 100 samples with 50% having an abnormal slide review. Specimens should be collected into K2 or K3 EDTA. For optimum performance, all specimens should be analyzed within time limits recommended by the manufacturer(s). Analyze the same specimen within 2 hour on all instruments for accurate comparison. Refer to CLSI Standard for Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; H20-A2 or current revision.
- In addition, a complete manual differential should be performed. A complete manual differential includes WBC differential, RBC and Plt morphology and WBC and Plt estimate. Results of other test procedures, i.e. manual Plt count, should be also noted.
- Poor statistics could be obtained because of the imprecision of the manual differential. This will be especially pronounced in cell populations with lower numbers.
- The statistical error of the manual differential can be reduced by performing several 200-cell differentials. Differential counts by several technologists are preferred. The CLSI protocol (H20) recommends two (2) technologists each doing a 200-cell differential for each sample. If you choose to have multiple technologists perform manual differentials, average them and submit the average differential counts.
- Ensure a random sampling of the population. Specimens analyzed should therefore represent your a general hospital population. Results should span as much of the clinical range of the instrument as possible. Check your instrument specifications.
- Random sampling should include:
 - ▶ specimens with normal values.
 - abnormal specimens representing various types of leukocyte (WBC) disorders including but not limited to:

leukemias	lymphocytosis	Lymphopenia
granulopenia	granulocytosis	
eosiniphilia	basophilia	

• abnormal specimens representing various types of erythrocyte (RBC) disorders including but not limited to:

hemoglobinopathy	
polycythemia	
microcytic anemias	macrocytic anemias

 abnormal specimens representing various types of platelet (Plt) disorders, including but not limited to:

thrombocytosis	thrombocytopenia		
morphological platelet disorders			

- If vote-outs, incomplete computation, partial aspirations or results with System Messages are observed for any specimen, repeat the analysis of that specimen on the evaluation instrument. Submit both the original and repeated values.
- Printed results for all specimens analyzed on all instruments should be obtained and labeled appropriately. For each specimen, collect the following data:
 - Printout from the Evaluation instrument(s)
 - Printout from the reference instrument
 - Manual differential results, note the total number of cells counted
 - Any confirmatory results
 - If instrument has archive feature, archive specimen results to appropriate external media, such as a CD or a flash drive and include with the printed results

Define Review Limits and Review Protocol

To establish review limits and a review protocol for your laboratory's patient population and specific needs:

Step	Action
1	Define and record a Test instrument review protocol on the Differential Review Limit and Protocol Worksheet provided.
	a. Record the instrument-generated flags that require further action.
	b. Define the high and low limits your laboratory uses to take slide review action on an automated differential result.
	c. Be specific, define less than and greater than with "or equal to" if applicable; e.g. if >10 % is your limit for Eosinophils, then 10 % is normal or negative and 11 % is abnormal or positive. Depending upon your protocol, results falling outside these abnormal limits require either a smear scan or a full manual differential.

DIFFERENTIAL REVIEW LIMIT AND PROTOCOL WORKSHEET

- 1. Define Test Instrument Review Protocol (Abnormal Limits)
 - a. All instrument generated flags will be used. List exceptions below.

	Instrument Review Limits		
	Low	High	
WBC			
RBC			
Hgb			
HCT			
MCV			
MCH			
MCHC			
RDW CV			
RDW SD			
Plt			
MPV			
Ne %			
Ly %			
Mo %			
Eo %			
Ba %			
NRBC %			
Ne #			
Ly #			
Mo #			
Eo #			
Ba #			
NRBC #			

b. Operator Defined Flags

2. Define Reference Manual Differential Abnormal Limits

Segmented Neutrophils	Metamyelocytes
Band Neutrophils	Myelocytes
Lymphocytes	Promyelocytes
Variant Lymphocytes	Blasts
Monocytes	NRBCs
Eosinophils	RBC morphology
Basophils	Plt morphology
Other (specify)	WBC morphology

How to Establish a Truth Table

The automated differential's sensitivity, specificity and efficiency in distinguishing normal and abnormal specimens are determined using Truth Table analysis. The manual differential is used as a reference to assess whether the instrument has correctly classified the specimen as normal (released without further review-autovalidation) or abnormal (requiring review).

To perform a Truth Table Analysis:

Step	Action
1	For each specimen analyzed on the Beckman Coulter Analyzer:
	a. Classify the instrument results as Normal ("negative") if no flags or messages are present.
	b. Classify the instrument results as Abnormal ("positive") if flags or messages are present.
2	Perform a manual differential on all samples evaluated in Step 1.
	a. Classify as Abnormal ("positive") any morphological or distributional abnormality observed.
	b. Classify as Normal ("negative") any manual differential count in which all cell types are normal and within your established limits.
3	Categorize each specimen as one of the following four categories and record the results on the differential Truth Table Worksheet:
	 True Negative (TN): Normal (negative) by both test (new instrument) and reference (manual diff) methods.
	 True Positive (TP): Abnormal (positive) by both test (new instrument) and reference (manual diff) methods.
	 False Negative (FN): Normal (negative) by test method (new instrument) and abnormal (positive) by reference (manual diff) method.
	 False Positive (FP): Abnormal (positive) by test method (new instrument) and normal (negative) by reference method (manual diff).
4	Calculate and record on the Differential Truth Table Worksheet the following:
	 a. True Negative: the percentage of specimens considered normal (negative) by both the test method (new instrument) and the reference method (manual diff). % TN = (# True Negatives / total number of specimens) x 100
	 b. True Positive: the percentage of specimens considered abnormal (positive) by both the test method (new instrument) and the reference method (manual diff). % TP = (# True Positives / total number of specimens) x 100

 c. False Negative: the percentage of specimens considered normal by the test method (new instrument) and abnormal by the reference method (manual diff). Galen/Gambino
% FN = (# False Negatives / total number of specimens) x 100
CLSI
% FN = (# True Negative / (True Negative+False Positives) x 100
 d. False Positive: the percentage of specimens considered abnormal by the test method (new instrument) and normal by the reference method (manual diff). Galen/Gambino
% FP = (# False Positives / total number of specimens) x 100
<u>CLSI</u>
% FP = (False Positive/(False Positive+TN)) X 100
e. Specificity : the percentage of manual differential normals that were also normal on the instrument.
Specificity = # True Negatives ÷ # (True Negative+False Positives) x 100
f. Sensitivity : the percentage of manual differential abnormals that were also abnormal on the instrument.
Sensitivity = # True Positives ÷ # (True Positives+False Negatives) x 100
g. Predictive Value of a Negative Test (PVN): the percentage of
specimens that were normal on both the instrument and the manual differential.
PVN = # True Negatives ÷ # (True Negatives + False Negatives) x 100
h. Predictive Value of a Positive Test (PVP) : the percentage of specimens that were abnormal on both the instrument and the manual differential.
PVP = # True Positives ÷ # (True Positives + False Positives) x 100
i. Agreement : the percentage of specimens correctly categorized by the automated differential.
[# (True Positives + True Negatives) ÷ total number of specimens] x 100

IMPORTANT

The Truth Table format can be used for a variety of purposes. It is important to understand that the statistics reflect the patient mix that is used during the study. The focus of an Implementation Truth Table is to optimize Sensitivity. Focus on the False Negative Samples. Evaluate if there is a particular flag that could be added or modified so that these same samples would be flagged. Determine what is an acceptable balance between False Negative (missed significant findings) and False Positive samples (increased review rate). The responsibility to determine acceptable performance of above data lies with the evaluating laboratory.

DIFFERENTIAL TRUTH TABLE WORKSHEET – EXAMPLE ONLY

	REFERENCE (Manual Differential)			
	Normal Abnormal Tota (Negative) (Positive)			
TEST	Normal (Negative)	(TN)	(FP)	
(new instrument)	Abnormal (Positive)	(FN)	(TP)	
	Total			

1. Classify differentials into one of four categories and total each column.

2. Calculate the following parameters.

PARAMETER	CALCULATION	RESULT (%)
% TN	Number of TN/Total	
% TP	Number of TP/Total	
% FN	Number of FN/Total	
% FP	Number of FP/Total	
Specificity	[# TN/ # (TN + FP)] x 100	
Sensitivity	[# TP/ # (TP + FN)] x 100	
Predictive Value of a Negative Test	[# TN/ # (TN + FN)] x 100	
Predictive Value of Positive Test	[# TP/ # (TP + FP)] x 100	
Agreement	[(# TP + # TN)/Total] x 100	

3. Reviewed by _____

Date

Practice

Note: This practice may not be exactly the way you would perform in your own lab. Many times a first pass using instrument generated flags only is evaluated first. The data is reevaluated adding in laboratory defined limits.

Step	Action			
1	There are 11 examples of LH 700 results on the following pages. The laboratory doing this Truth Table Study, uses the following Review Criteria:			
	• Any parameter or instrument generated flag is a positive. (i.e., suspect, definitive, action, critical, high, low, etc).			
	 The example manual differential criteria are from this "lab" are: (an abnormal condition exists if any of the values below are found to be present) 			
	Atypical Lymph: > 6			
	$\frac{\text{NRBC.} > 2}{\text{Bands:} \ge 12}$			
	Meta: ≥ 1			
	Myelo: ≥ 1			
	Blast: ≥ 1			
2	Work through the data in the eleven examples keeping this Lab's Criteria in mind. Decide whether each is a True Positive, True Negative, False Positive, False Negative. You have the right to exclude from the study any data which you think might misrepresent or skew the conclusions.			
3	Collate your decisions and enter the totals for each category on the worksheet below.			

DIFFERENTIAL TRUTH TABLE WORKSHEET

	TEST (LH 700)			
		Normal (Negative)	Abnormal (Positive)	Total
REFERENCE (Manual Differential)	Normal (Negative)	True Negative	False Positive	
	Abnormal (Positive)	False Negative	True Positive	
	Total			

Check your answers using the answer key at the end of this exercise.

PARAMETER	CALCULATION	RESULT (%)
% TN	Number of TN/Total	
% TP	Number of TP/Total	
% FN	Number of FN/Total	
% FP	Number of FP/Total	
Specificity	[# TN / # (TN + FP)] x 100	
Sensitivity	[# TP / # (TP + FN)] x 100	
Predictive Value of a Negative Test	[# TN / # (TN + FN)] x 100	
Predictive Value of a Positive Test	[# TP / # (TP + FP)] x 100	
Agreement	[(# TP + # TN) / Total] x 100	

1. Using the data from the Truth Table Worksheet, calculate the following parameters.

Thought Questions

1	If your flagging limits are set correctly, which two categories on the Truth Table should contain most of your samples?
2	If a laboratory's False Positive rate is around 40%, what corrective action do you think the laboratory should take?
3	If a laboratory's False Negative is around 35%, what corrective action do you think the laboratory should take?
4	If agreement is around 40%, what does this mean to the laboratory?

Rumke Binomial Distribution Table

a	n = 100	n = 200	n = 700	n = 1000
0	0 - 2	0 - 2	0 - 1	0 - 1
1	0 - 6	0 - 4	0 - 3	0 - 2
2	0 - 8	0 - 6	0 - 4	1 - 4
3	0 - 9	1 - 7	1 - 5	2 - 5
4	1 - 10	1 - 8	2 - 7	2 - 6
5	1 - 12	2 - 10	3 - 8	3 - 7
6	2 - 13	3 - 11	4 - 9	4 - 8
7	2 - 14	3 - 12	4 - 10	5 - 9
8	3 - 16	4 - 13	5 - 11	6 - 10
9	4 - 17	5 - 14	6 - 12	7 - 11
10	4 - 18	6 - 16	7 - 13	8 - 13
15	8 - 24	10 - 21	11 - 19	12 - 18
20	12 - 30	14 - 27	16 - 24	17 - 23
25	16 - 35	19 - 32	21 - 30	22 - 28
30	21 - 40	23 - 37	26 - 35	27 - 33
35	25 - 46	28 - 43	30 - 40	32 - 39
40	30 - 51	33 - 48	35 - 45	36 - 44
45	35 - 56	37 - 53	40 - 50	41 - 49
50	39 - 61	42 - 58	45 - 55	46 - 54
60	49 - 70	52 - 67	55 - 65	56 - 64
70	60 - 79	63 - 77	65 - 74	67 - 73
75	65 - 84	68 - 81	70 - 79	72 - 78
80	70 - 88	73 - 86	76 - 84	77 - 83
90	82 - 96	84 - 94	87 - 93	87 - 92
100	96 - 100	98 - 100	99 - 100	99 - 100

95 % Confidence Limits for various percentages of blood cells of a given type as determined by differential counts.

a the observed percentage of cells of a given type

n the total number of cells counted

Rumke, CL. The statistically expected variability in differential leukocyte counting. College of American Pathologists CAP Conference, Aspen, CO, 1977; 39-45

<u>LH 700 Results:</u> Tost **B**osy

Test Res	ult Flag	Test
WBC:	23.0	аH
NE%:	87.3	aH
LY%:	5.4	
MO%:	6.4	
EO%:	0.8	
BA%:	0.1	
NRBC%:	0.0	
NE#:	20.0	
LY#:	1.2	
MO#:	1.5	
EO#:	0.2	
BA#:	0.0	
NRBC#:	0.0	

TRUTH TABLE EXAMPLE # 001

Result Fla	g 1	ſest	Resu	lt Fla
RBC:	2.56			
HGB:	8.0			
HCT:	22.6			
MCV:	88.1			
MCH:	31.3			
MCHC:	35.5			
RDW:	15.8	ć	аH	
RET%	1.92			
RET#:	.0064			
IRF:	0.33			
MRV	100.7			

ıg		
PLT:	854	аH
MPV:	7.3	

LH 700 Generated Messages:

Suspect/Definitive WBC: Suspect/Definitive RBC:

Suspect/Definitive PLT:

NE Blast	1+ Anisocytosis	Thrombocytosis
Imm.NE2 & Imm.NE1		
Leukocytosis		
Neutrophilia		

Comments / Decision Rule Generated:

[Perform a Manual diff] (Due to the presence of NE Blast & Imm. NE 2 flags)

<u>LH 700 Out-Come</u>: (Place a '+' or '-' in the boxes below.)

Any flag / message indicates an 'instrument positive' out-come.

-	WBC:	RBC:	PLI	F:	
CBC (+ / -)					
DIFF $(+/-)$					

<u>Manual Differential</u>

Neut	71		Atyp Lym			Morphology (RBC & PLT):
Lymph	6		Bands	13		Slight Aniso
Mono	7		Meta	1		Increased Plts
Eos	1		Myelo	1		
Baso	0		ProMyelo			
NRBC			Blast			
Manual Differential Out Come: Circle below (+/-) with comments.						
(+):						
(-):						

		LH 700 Result		COMMENTS:
Reference:		NEG	POS	
Manual	NEG	TN	FP	
Diff	POS	FN	ТР	

Test	Result	Flag
WBC:	12.8	
NE%:	76.6	
LY%:	12.9	
MO%:	8.5	
EO%:	1.7	
BA%:	0.3	
NRBC%:	0.0	
NE#:	9.8	
LY#:	1.7	
MO#:	1.1	
EO#:	0.2	
BA#:	0.0	
NRBC#:	0.0	

TRUTH TABLE EXAMPLE # 002

Т	est Result	Flag	Test
	RBC:	3.50	
	HGB:	10.1	
	HCT:	29.3	
	MCV:	83.6	
	MCH:	28.9	
	MCHC:	34.6	
	RDW:	14.3	
	RET%	1.60	
	RET#:	.0609	
	IRF:	0.35	
	MRV	100.1	

Result F	Result Flag								
PLT:	490								
MPV:	7.5								

LH 700 Generated Messages:

Suspect/Definitive WB	C: Suspect/Defini	tive RBC: Suspect/D	efinitive PLT:

Comments / Decision Rule Generated:

<u>LH 700 Out-Come</u>: (Place a '+' or '-' in the boxes below.)

Any flag / message indicates an 'instrument positive' out-come.

	WBC:	RBC:	PLT:
CBC (+/-)			
DIFF (+ / -)			

Manual Differential

Neut	80		Atyp Lym			Morphology (RBC & PLT):
Lymph	12		Bands			
Mono	5		Meta			
Eos	2		Myelo			
Baso	1		ProMyelo			
NRBC			Blast			
Manual Different	ential	Out Come: Circ	le below $(+/$	-) w	ith comments.	
(+):						
(-):						

		LH 700 <u>Result</u>		COMMENTS:
Reference:		NEG	POS	
Manual	NEG	TN	FP	
Diff	POS	FN	ТР	

Test	Result	Flag
WBC:	10.0	aН
NE%:	45.9	
LY%:	50.0	aH
MO%:	1.8	
EO%:	1.5	
BA%:	0.3	
NRBC%:	0.0	
NE#:	4.6	
LY#:	5.1	
MO#:	0.2	
EO#:	0.2	
BA#:	0.0	
NRBC#:	0.0	

TRUTH TABLE EXAMPLE # 003

Test

Т	est Re	sult Flag	g
	RBC:	3.17	
	HGB:	10.1	
	HCT:	30.1	
	MCV:	91.6	
	MCH:	31.9	
	MCHC:	34.8	
	RDW:	12.9	
	RET%	1.71	
	RET#:	.0696	
	IRF:	0.54	
	MRV	105.2	

Result	Flag	
PLT:	213	
MPV:	7.3	

LH 700 Generated Messages:

Suspect/Definitive WBC:	Suspect/Definitive RBC:	Suspect/Definitive PLT:	
Variant Lymph			

Comments / Decision Rule Generated:

[Perform a diff scan for variant forms]

<u>LH 700 Out-Come</u>: (Place a '+' or '-' in the boxes below.)

Any flag / message indicates an 'instrument positive' out-come.

	WBC:	RBC:	PLT:
CBC (+ / -)			
DIFF (+ / -)			

Manual Differential

Neut	17		Atyp Lym	4		Morphology (RBC & PLT):
Lymph	73		Bands			
Mono	5		Meta			
Eos	1		Myelo			
Baso	0		ProMyelo			
NRBC	0		Blast			
Manual Differe	ential (Out Come: Circl	le below $(+/$	-) wi	th comments.	
(+):						
(-).						

		LH700	Result	COMMENTS:
Reference:		NEG	POS	
Manual	NEG	TN	FP	
Diff	POS	FN	ТР	

TRUTH TABLE EXAMPLE # 004

LH 700 Results:

Test	Result Fl	ag T	`est
WBC:	11.3		1
NE%:	76.6		
LY%:	15.1		
MO%:	6.4		
EO%:	1.5		
BA%:	0.3		
NRBC%:	0.0		
NE#:	8.7		
LY#:	1.7		
MO#:	0.7		
EO#:	0.2		
BA#:	0.0		
NRBC#:	0.0		

Result	Flag	Test
RBC:	3.48	
HGB:	10.9	
HCT:	32.0	
MCV:	92.0	
MCH:	31.3	
MCHC:	34.0	
RDW:	14.1	
RET%	0.47	
RET#:	.0123	
IRF:	0.52	
MRV	114.3	

Result	Flag		
	PLT:	223	
	MPV:	8.6	
_			
_			
_			
_			
_			

LH 700 Generated Messages:

Suspect/Definitive WBC: Suspect/Definitive RBC: Suspect/Definitive PLT:

Comments / Decision Rule Generated:

<u>LH 700 Out-Come</u>: (Place a '+' or '-' in the boxes below.)

Any flag / message indicates an 'instrument positive' out-come.

	WBC:	RBC:	PLT:
CBC (+ / -)			
DIFF $(+/-)$			

<u>Manual Differential</u>

Neut	80	Atyp Lym		Morphology (RBC & PLT):
Lymph	14	Bands		
Mono	3	Meta	1	
Eos	2	Myelo		
Baso	0	ProMyelo		
NRBC		Blast		

Manual Differential Out Come: Circle below (+/-) with comments.

(+):	
(-):	

LH 700_Result		Result	COMMENTS:	
Reference:		NEG	POS	
Manual	NEG	TN	FP	
Diff	POS	FN	TP	

Test	Result F	lag
WBC:	0.4	cL
NE%:	15.8	R
LY%:	60.5	RaH
MO%:	5.3	R
EO%:	18.4	R
BA%:	0.0	R
NRBC%:	0.0	R
NE#:	0.1	R
LY#:	0.2	R
MO#:	0.0	R
EO#:	0.1	R
BA#:	0.0	R
NRBC#	0.0	R

TRUTH TABLE EXAMPLE # 005

Т	est Res	ult Flag	5
	RBC:	2.99	
	HGB:	9.3	
	HCT:	26.2	
	MCV:	87.3	
	MCH:	31.0	
	MCHC:	35.5	
	RDW:	16.3	аH
	RET%	3.38	
	RET#:	.1058	
	IRF:	0.42	
	MRV	105.4	

Test	Result	Flag	
	PLT:	4	cL
	MPV:	6.0	

LH 700 Generated Messages:

Suspect/Definitive WBC:	Suspect/Definitive RBC:	Suspect/Definitive PLT:
Low Event #	1+ Anisocytosis	Thrombocytopenia
Leukopenia		
Lymphocytosis		
Eosinophilia		

Comments / Decision Rule Generated:

[Perform a manual diff] (due to the presence of the 'R' flag on diff count)

<u>LH 700 Out-Come</u>: (Place a '+' or '-' in the boxes below.)

Any flag / message indicates an 'instrument positive' out-come.

	WBC:	RBC:	PLT:
CBC (+ / -)			
DIFF $(+/-)$			

Manual Differential

Neut	10		Atyp Lym			Morphology (RBC & PLT):
Lymph	60		Bands			
Mono	10		Meta			
Eos	20		Myelo			NOTE: Only 10 cells were
Baso			ProMyelo			counted on the manual diff.
NRBC			Blast			
Manual Differe	ntial (<u> Out Come</u> : Circl	e below $(+/)$	-) wi	ith comments.	
(+):						
(-):						

		LH 700	Result	COMMENTS:
Reference:		NEG	POS	
Manual	NEG	TN	FP	
Diff	POS	FN	ТР	

TRUTH TABLE EXAMPLE # 006

LH 700 Results:

Test	Resul	t Flag	z	Test
WBC:		9.3		
NE%:		66.5		
LY%:		24.1		
MO%:		6.8		
EO%:		2.5		
BA%:		0.1		
NRBC%	ó:	2.0		
NE#:		6.2		
LY#:		2.2		
MO#:		0.6		
EO#:		0.2		
BA#:		0.0		
NRBC	ŧ٠	0.2		

Result	Flag	Test
RBC:	5.17	
HGB:	13.8	
HCT:	40.3	
MCV:	78.0	
MCH:	26.6	
MCHC:	34.1	
RDW:	14.3	
RET%	0.82	
RET#:	.0376	
IRF:	0.26	
MRV	113.5	

Result F	Flag	
PLT:	257	
MPV:	9.2	

LH 700 Generated Messages:

Suspect/Definitive	WBC: Susp	ect/Definitive RBC:	Suspect/I	Definitive PLT:

Comments / Decision Rule Generated:

<u>LH 700 Out-Come</u>: (Place a '+' or '-' in the boxes below.)

Any flag / message indicates an 'instrument positive' out-come.

	WBC:	RBC:	PLT:	
CBC (+ / -)				
DIFF (+ / -)				

Manual Differential

Neut	62	Atyp Lym		Morphology (RBC & PLT):		
Lymph	24	Bands	5	Slight Aniso		
Mono	7	Meta				
Eos	2	Myelo				
Baso	0	ProMyelo				
NRBC	2	Blast				
Manual Differential Out Come: Circle below (+/-) with comments.						
(+):						
(-)						

		LH 700	Result	COMMENTS:
Reference:		NEG	POS	
Manual	NEG	TN	FP	
Diff	POS	FN	ТР	

Test	Result Flag
WBC:	6.8
NE%:	65.7
LY%:	26.0
MO%:	7.5
EO%:	0.5
BA%:	0.3
NRBC%:	0.0
NE#:	4.5
LY#:	1.8
MO#:	0.5
EO#:	0.0
BA#:	0.0
NRBC#:	0.0

TRUTH TABLE EXAMPLE # 007

Test

Т	est Re	sult Fla	g
	RBC:	4.06	
	HGB:	12.1	
	HCT:	35.4	
	MCV:	87.1	
	MCH:	29.9	
	MCHC:	34.3	
	RDW:	13.6	
	RET%	1.11	
	RET#:	.0449	
	IRF:	0.35	
	MRV	112.9	

Resul	t Flag	
PLT:	322	
MPV:	9.5	

LH 700 Generated Messages:

Suspect/Definitive WBC:	Suspect/Definitive RBC:	Suspect/Definitive PLT:

Comments / Decision Rule Generated:

<u>LH 700 Out-Come</u>: (Place a '+' or '-' in the boxes below.) Any flag / message indicates an 'instrument positive' out-come.

Any mag / message	e mulcates an instrument po	sitive out-come.	
	WBC:	RBC :	PLT:
CBC (+ / -)			
DIFF $(+/-)$			

Manual Differential

Neut	65		Atyp Lym	3		Morphology (RBC & PLT):
Lymph	21		Bands			
Mono	7		Meta			
Eos	3		Myelo			
Baso	1		ProMyelo			
NRBC	0		Blast			
Manual Differe	ential (Out Come: Circ	le below (+/	-) w	ith comments.	
(+):						
(-):						

		LH 700	Result	COMMENTS:
Reference:		NEG	POS	
Manual	NEG	TN	FP	
Diff	POS	FN	ТР	

Test Resu	ult Flag	Test
WBC:	6.7	
NE%:	75.0	
LY%:	13.3	
MO%:	6.7	
EO%:	4.9	
BA%:	0.1	
NRBC%:	0.0	
NE#:	5.0	
LY#:	0.9	
MO#:	0.4	
EO#:	0.3	
BA#:	0.0	
NRBC#:	0.0	

TRUTH TABLE EXAMPLE # 008

Result Flag	5	Гest
RBC:	2.97	
HGB:	10.1	
HCT:	27.8	
MCV:	93.6	
MCH:	33.9	
MCHC:	36.2	
RDW:	14.4	
RET%	2.63	
RET#:	.0906	
IRF:	0.40	
MRV	113.5	

Result	Flag		
	PLT:	129	
	MPV:	11.0	
_			
_			
_			
_			

LH 700 Generated Messages:

Suspect/Definitive WBC:	Suspect/Definitive RBC:	Suspect/Definitive PLT:
-------------------------	-------------------------	-------------------------

Imm. NE 1	

Comments / Decision Rule Generated:

[Perform a diff scan] (Scan for the presence of Bands)

<u>LH 700 Out-Come</u>: (Place a '+' or '-' in the boxes below.)

Any flag / message indicates an 'instrument positive' out-come.

	WBC:	RBC:	PLT:
CBC (+ / -)			
DIFF (+ / -)			

<u>Manual Differential</u>

Neut	72	Atyp Lym		Morphology (RBC & PLT):
Lymph	13	Bands	9	
Mono	4	Meta		
Eos	2	Myelo		
Baso	0	ProMyelo		
NRBC	0	Blast		

Manual Differential Out Come: Circle below (+/-) with comments.

(+):		
(-):		

		LH 700	Result	COMMENTS:
Reference:		NEG	POS	
Manual	NEG	TN	FP	
Diff	POS	FN	ТР	

Test Res	ult Flag	Test
WBC:	5.5	
NE%:	83.3	
LY%:	6.4	
MO%:	8.6	
EO%:	1.4	
BA%:	0.3	
NRBC%:	0.0	
NE#:	4.6	
LY#:	0.4	
MO#:	0.5	
EO#:	0.1	
BA#:	0.0	
NRBC#·	0.0	

TRUTH TABLE EXAMPLE # 009

Result Flag	Ş	Test]
RBC:	2.73		
HGB:	8.3		
HCT:	24.1		
MCV:	88.2		
MCH:	30.4		
MCHC:	34.4		
RDW:	14.8		
RET%	1.98		
RET#:	.0754		
IRF:	.036		
MRV	108.4		

Result	Flag		
	PLT:	300	
	MPV:	6.8	

LH 700 Generated Messages:

Suspect/Definitive WBC: Suspect/Definitive RBC:

Suspect/Definitive PLT:

Imm. NE1	
Imm. NE2	

Comments / Decision Rule Generated:

[Perform a manual diff] (review slide for immature cells)

<u>LH 700 Out-Come</u>: (Place a '+' or '-' in the boxes below.)

Any flag / message indicates an 'instrument positive' out-come.

	WBC:	RBC:	PLT:
CBC (+ / -)			
DIFF $(+/-)$			

Manual Differential

Neut	76	Atyp Lym		Morphology (RBC & PLT):
Lymph	4	Bands	15	
Mono	9	Meta		
Eos	0	Myelo		
Baso	0	ProMyelo		
NRBC	0	Blast		

Manual Differential Out Come: Circle below (+/-) with comments.

(+):			
(-):			

		LH 700	Result	COMMENTS:
Reference:		NEG	POS	
Manual	NEG	TN	FP	
Diff	POS	FN	ТР	

Test Res	ult Flag	Test
WBC:	5.9	
NE%:	40.3	
LY%:	48.7	aH
MO%:	6.2	
EO%:	4.1	
BA%:	0.7	
NRBC%:	0.0	
NE#:	2.4	
LY#:	2.9	
MO#:	0.4	
EO#:	0.2	
BA#:	0.0	
NRBC#:	0.0	

TRUTH TABLE EXAMPLE # 010

Result Flag	3	Test	Result	Flag
RBC:	4.60			
HGB:	12.8			
HCT:	37.4			
MCV:	81.3			
MCH:	27.9			
MCHC:	34.3			
RDW:	12.6			
RET%	1.16			
RET#:	.0533			
IRF:	0.25			
MRV	105.1			

PLT:	222	
MPV:	9.0	

LH 700 Generated Messages:

Suspect/Definitive WBC:	Suspect/Definitive RBC:	Suspect/Definitive PLT:

Variant Lymph	

Comments / Decision Rule Generated:

[Perform a manual diff] (review slide for the presence of atypical cells)

<u>LH 700 Out-Come</u>: (Place a '+' or '-' in the boxes below.)

Any flag / message indicates an 'instrument positive' out-come.

	WBC:	RBC:	PLT:
CBC (+ / -)			
DIFF (+ / -)			

<u>Manual Differential</u>

Neut	46	Atyp Lym	9	Morphology (RBC & PLT):
Lymph	37	Bands		
Mono	3	Meta		
Eos	4	Myelo		
Baso	1	ProMyelo		
NRBC	0	Blast		

Manual Differential Out Come: Circle below (+/-) with comments.

(+):	
(-):	

		LH 700	Result	COMMENTS:
Reference:		NEG	POS	
Manual	NEG	TN	FP	
Diff	POS	FN	ТР	

Test Res	ult Flag	Test
WBC:	14.4	
NE%:	79.1	
LY%:	14.7	
MO%:	5.8	
EO%:	0.2	
BA%:	0.2	
NRBC%:	0.0	
NE#:	11.4	
LY#:	2.1	
MO#:	0.8	
EO#:	0.0	
BA#:	0.0	
NRBC#:	0.0	

TRUTH TABLE EXAMPLE # 011

Result Flag	; Т	Test	Res
RBC:	3.77		
HGB:	11.1		
HCT:	32.2		
MCV:	85.6		
MCH:	29.4		
MCHC:	34.3		
RDW:	14.9		
RET%	1.64		
RET#:	.0767		
IRF:	0.33		
MRV	120.3		

esult	Fla	g		
		PLT:	190	
		MPV:	7.8	

LH 700 Generated Messages:

Suspect/Definitive WBC: Suspect/Definitive RBC:

Suspect/Definitive PLT:

Comments / Decision Rule Generated:

<u>LH 700 Out-Come</u>: (Place a '+' or '-' in the boxes below.)

Any flag / message indicates an 'instrument positive' out-come.

_	WBC:	RBC:	PLT:	
CBC (+ / -)				
DIFF $(+/-)$				

Manual Differential

Neut	76	Atyp Lym		Morphology (RBC & PLT):
Lymph	15	Bands		
Mono	8	Meta		
Eos	1	Myelo		
Baso	0	ProMyelo		
NRBC	0	Blast		

Manual Differential Out Come: Circle below (+/-) with comments.

(+):	
(-):	

		LH 700	Result	COMMENTS:
Reference:		NEG	POS	
Manual	NEG	TN	FP	
Diff	POS	FN	ТР	

Answer Key for Examples

Category	Number in Category	Example #
True Pos	3	1, 9, 10
True Neg	4	2, 6, 7, 11
False Pos	2	3, 8
False Neg	1	4

#5 was discarded due to low diff cells counted, but would be a FP.

%TN	4/10	40%
%TP	3/10	30%
%FN	1/10	10%
%FP	2/10	20%
Specificity	4/(4+2)	66.6%
Sensitivity	3/(3+1)	75%
Predictive Value of Neg. Test	4/(4+1)	80%
Predictive Value of Pos. Test	3/(3+2)	60%
Agreement	(3+4)/10	70%

If you used an n=10, then your calculations should be: