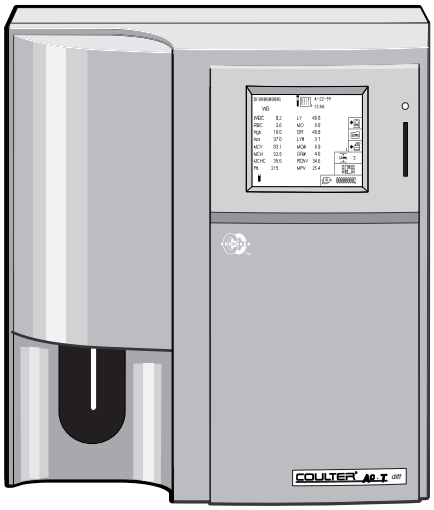
COULTER® AC•T diff™ Analyzer

Operator's Guide



CE

PN 4237416DA (August 2010)

Beckman Coulter, Inc.
250 S. Kraemer Blvd.
Brea, CA 92821

BECKMAN COULTER

WARNINGS AND PRECAUTIONS

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

HAZARDS AND OPERATIONAL PRECAUTIONS AND LIMITATIONS

WARNINGS, CAUTIONS, and IMPORTANTS alert you as follows:

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

BECKMAN COULTER, INC. URGES ITS CUSTOMERS TO COMPLY WITH ALL NATIONAL HEALTH AND SAFETY STANDARDS SUCH AS THE USE OF BARRIER PROTECTION. THIS MAY INCLUDE, BUT IT IS NOT LIMITED TO, PROTECTIVE EYEWEAR, GLOVES, AND SUITABLE LABORATORY ATTIRE WHEN OPERATING OR MAINTAINING THIS OR ANY OTHER AUTOMATED LABORATORY ANALYZER.

WARNING Risk of operator injury if:

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

To avoid injury:

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

CAUTION System integrity might be compromised and operational failures might occur if:

- This equipment is used in a manner other than specified. Operate the instrument as instructed in the Product Manuals.
- You introduce software that is not authorized by Beckman Coulter into your computer. Only operate your system's computer with software authorized by Beckman Coulter.
- You install software that is not an original copyrighted version. Only use software that is an original copyrighted version to prevent virus contamination.

IMPORTANT If you purchased this product from anyone other than Beckman Coulter or an authorized Beckman Coulter distributor, and, if it is not presently under a Beckman Coulter service maintenance agreement, Beckman Coulter cannot guarantee that the product is fitted with the most current mandatory engineering revisions or that you will receive the most current information bulletins concerning the product. If you purchased this product from a third party and would like further information concerning this topic, call your Beckman Coulter Representative.

Initial Issue, 11/97
Software Version 1.03

Issue B, 12/97
Software Version 1.03
Table 6.1 was changed to reflect updated information for replacing diluent filters and peristaltic pump tubing. A procedure for cleaning the inside of the instrument was added to Additional Cleaning Procedures. The first paragraph of Headings 6.8 and 6.9 was changed. Pages changed: 6-2, 6-7, 6-25 and 6-29.

Issue C, 11/99
Software Version 1.06

Note: A black bar in the left margin indicates where a change was made from the previous version of the manual.

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Page	Change
cover	updated illustration
x	replaced Reference manual with Operator's Guide
xv	added the Cycle Counter icon
xvi	added the Patient Range icon
xvi	updated illustration
xvii	updated the Icon Tree Detail to reflect current software screens
2-1	changed Coulter to Beckman Coulter
2-2	added a new step
2-3	added cell control level indicators; added information about "A" not being for use when entering the lot number or expiration date; and rewrote step 6.
2-4	defined the six-digit expiration date format and added an example; updated step 8 to reflect the correct step numbers
2-7	added information about verifying that the information is correct
2-9	changed Coulter to Beckman Coulter
2-11	changed Coulter to Beckman Coulter
2-14	clarified the icon selection for printing control data; defined IQAP; and changed Coulter to Beckman Coulter
2-16	updated the icon name; removed the requirement of sending a printed control report to IQAP department
2-18	clarified the icon selection for printing control summaries
3-1	added information about using the Predilute Mode if the specimen collection cannot be directly aspirated in a whole-blood mode; changed Coulter to Beckman Coulter

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

Page	Change
3-2	added a step for selecting the Patient Range
3-3	updated illustration
3-4	updated illustration and added information about flags; added a note about results printing based on the range selected when the sample was run: and moved the flag information to another step
3-5	added information about using the Predilute Mode if the specimen collection cannot be directly aspirated in a whole-blood mode; and changed Coulter to Beckman Coulter
3-6	added a step for selecting the Patient Range; and updated illustration
3-7	updated illustration
3-8	updated illustration and added flag information
4-1	updated chapter information and illustration
4-2	updated icon name
5-1	changed Coulter to Beckman Coulter
5-3	added information about using the Predilute Mode if the specimen collection cannot be directly aspirated in a whole-blood mode
5-5	added information about non-numeric results
5-6	updated the report and added a note about parameter limits
5-8	updated step reference
5-9	added a note about parameter limits and what to do if carryover fails
5-11	added information about printing old calibration factors
5-14	updated step reference
5-15	updated printing information
5-16	added calibration report illustrations and added information about verifying calibration
6-1	changed Coulter to Beckman Coulter and updated Startup screen
6-7	updated illustration
6-18	changed Coulter to Beckman Coulter
6-35	updated icon name
6-44	added a note about needle-nose pliers not being provided with the instrument
6-49	removed the Sample Results screen
6-50	added the setting units and range
6-51 - 6-58	added information about replacing syringe assemblies
6-63	changed Coulter to Beckman Coulter
6-63	updated illustration
6-64	added information about the diff A^{C}•T Pak reagent
6-68	changed Coulter to Beckman Coulter
6-70	updated the screen
6-71	added Cycle Counter icon and changed Coulter to Beckman Coulter
6-75	changed Coulter to Beckman Coulter
6-78	changed Coulter to Beckman Coulter
6-80	updated information about 35 fL count interference

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6-84 - 6-86	changed Coulter to Beckman Coulter
A-3	changed Coulter to Beckman Coulter
A-4	changed Coulter to Beckman Coulter
Trademarks	changed Coulter to Beckman Coulter

Issue D, 6/03
Changes were made to,

- comply with the EU IVD Directive (98/79/EC).
- change the company name from Coulter Corporation to Beckman Coulter Inc.

Issue DA, 8/10
Software Version 1.06.

Updates were made to the company corporate address.

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

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

REVISION STATUS

CONTENTS

ILLUSTRATION

TABLES

This introductory section contains the following topics:

- How to use your COULTER® A^{C}•T diff™ Analyzer Manuals
- About this Manual
- Conventions
- Graphics
- Symbols
- Installation Procedures
- Touch Screen Icons
- Icon Tree Overview
- Icon Tree Detail

HOW TO USE YOUR COULTER® A^{C}•T DIFF™ ANALYZER MANUALS

Use the **Reference** manual for in-depth information about:

- What the instrument does
- What special requirements the instrument has (for example, space, accessibility, power)
- What methods it uses
- What the instrument specifications are
- How to interface your A^{C}•T diff analyzer to your laboratory's host computer
- How to safely use the instrument.

Use the **Operator's Guide** for:

- Getting started
- Running your instrument day to day
- Reviewing unusual results, including how to read a result report and what flags mean
- Performing special procedures such as cleaning, replacing, or adjusting a component of the instrument
- Troubleshooting problems with your instrument.

Use the **Operating Summary** for:

- Running your instrument using a quick reference set of procedures
- Verifying screen icon definitions

Use the **Ticket Printer User's Guide** for:

- Understanding the printer's control panel
- Installing and setting up the printer
- Performing a printer self-test.

Use the **Roll Printer User's Guide** for:

- Understanding the printer's control panel
- Installing and setting up the printer
- Performing a printer self-test.

Use the **Graphic Printer User's Guide** for:

- Understanding the printer's control panel
- Installing and setting up the printer
- Performing a printer self-test.

ABOUT THIS MANUAL

Your COULTER A^{C}•T diff Analyzer **Operator's Guide** provides information on how to operate the instrument.

This information is organized as follows:

- Chapter 1, Routine Procedures
  Contains the startup and shutdown procedures.
- Chapter 2, Cell Controls
  Contains information on 4C® PLUS cell control and A^{C}•T Tron™ cell control, including how to use them with the instrument.
- Chapter 3, Running Samples
  Contains information on how to run whole blood and prediluted blood samples.
- Chapter 4, Reviewing Results
  Contains information on how to review current and stored sample results.
- Chapter 5, Calibration
  Contains the procedures for reproducibility, carryover, and auto-calibration. Also includes precalibration checks.
- Chapter 6, Service and Maintenance
  Contains information on the special procedures and troubleshooting procedures for the instrument. Covers topics such as cleaning, calibration, replacement and adjustment procedures, as well as defining flags and codes.
- Appendix A, Manual Calibration
  Contains the procedures for manual calibration when S-CAL® calibrator is not available.
- This manual also includes a Glossary, Abbreviations list, recommended References, and an Index.

CONVENTIONS

This manual uses the following conventions:

Bold font indicates A^{C}•T diff analyzer manual titles.

Bold indicates a screen icon.

Italics font indicates screen text displayed by the instrument.

Instrument refers to the A^{C}•T diff analyzer.

A Note contains information that is important to remember or helpful in performing a procedure.

GRAPHICS

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

SYMBOLS

Safety Symbols

Safety symbols alert you to potentially dangerous conditions. These symbols, together with text, apply to specific procedures and appear as needed throughout this manual.

Symbol	Warning Condition	Action
	**Biohazard**.Consider all materials (specimens, reagents, controls, and calibrators, and so forth) as being potentially infectious.	Wear standard laboratory attire and follow safe laboratory procedures when handling any material in the laboratory.
	**Probe hazard.** The probe is sharp and may contain biohazardous materials, including controls and calibrators.	Avoid any unnecessary contact with the probe and probe area.
	**Electrical shock hazard**. Possibility of electrical shock when instrument is plugged in to the power source.	Before continuing, unplug the A^{C}•T diff analyzer from the electrical outlet.

Procedure Symbols

Procedure symbols give direction.

Symbol	Definition	Action
	**Go to step number**.	Go to the step number that appears after the icon.
	**Special Procedures and Troubleshooting**	See Special Procedures and Troubleshooting in this manual for additional information.

INSTALLATION PROCEDURES

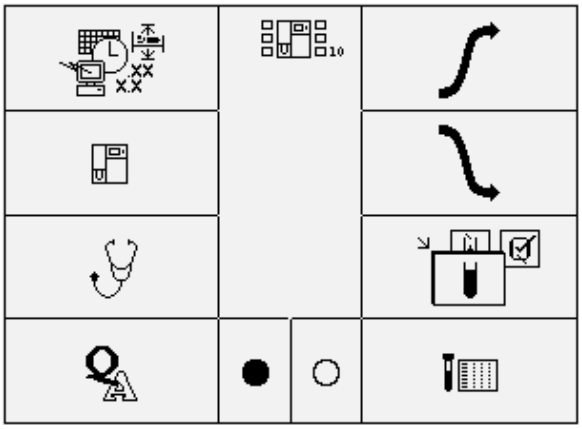
See the Installation and Training Guide for installation procedures.

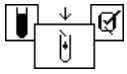
TOUCH SCREEN ICONS

Screen Numbers

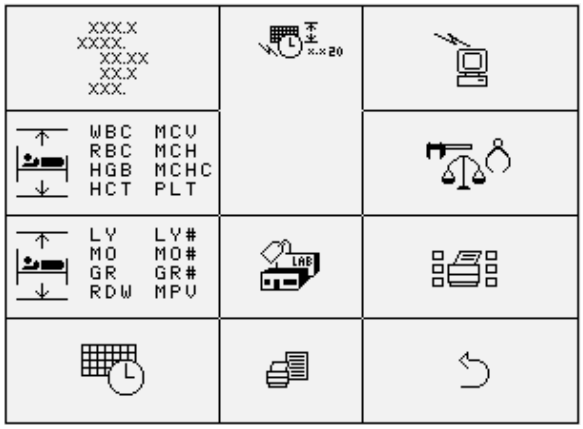
A number appears next to the title icon on a screen. The number is unique to that screen and is significant only as a screen identifier; the number does not print on any reports.

Main Screen Icons



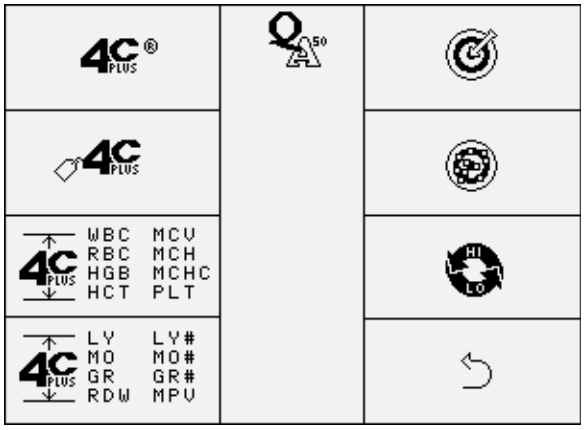
 Setup	 Startup
 Diluter Functions	 Shutdown
 Diagnostics	 Analyzing Mode
 Quality Assurance	 Whole Blood Mode
 Darken Screen	 Predilute Mode
 Lighten Screen	 A^{C}•T Tron Mode
	 Sample Results Screen

Setup Screen Icons



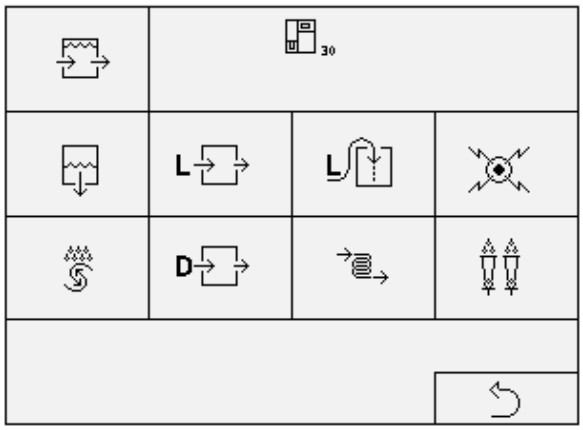
Units	Transmission
Patient Limits	Calibration Factors
Date/Time	Printers/Profiles
Laboratory ID	Exit
Print Setup Report	

QA Screen Icons



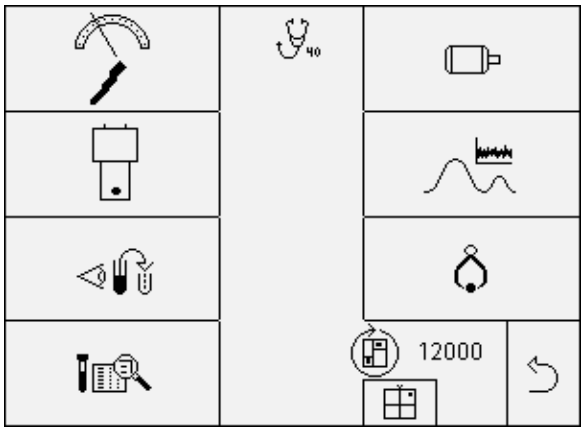
4C PLUS Cell Control Run	Calibration
4C PLUS Management	Reproducibility
4C PLUS Limits	Carryover
	Exit

Diluter Functions Screen Icons



Wet Prime	Dispense Lytic Reagent
Drain Baths	Prime Sweepflow
Rinse + Mix	Zap Apertures
Dry Prime Lytic Reagent	Clean Baths
Dry Prime Diluent	Exit

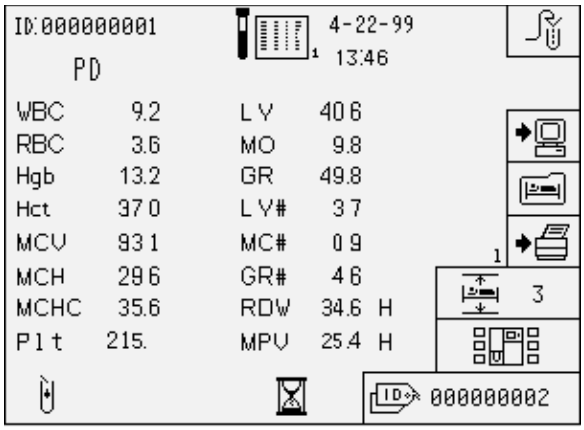
Diagnostic Functions Screen Icons



Voltages/Sensors	Motors†
Solenoids	Pulse Test
Verify Predilute	Latex Calibration
Sample Details	Prepare to Ship
Cycle Counter	Exit

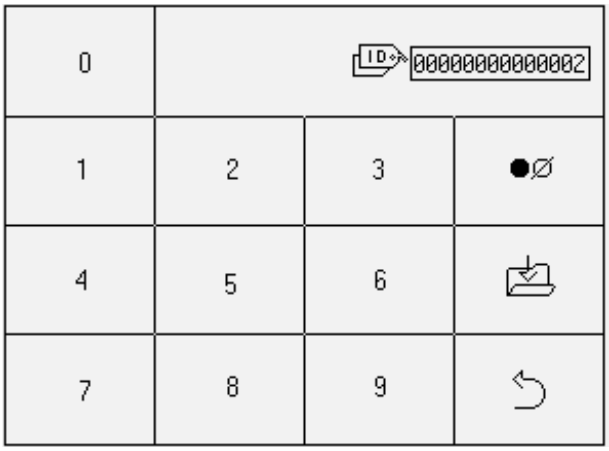
† Do not use this function without proper instruction from your Beckman Coulter Representative.

Sample Results Screen Icons



Dispense Diluent	Go to Main Menu
Resend to Host	Enter Patient ID
Retrieve Stored Data	In Progress
Print Sample Results	Patient Range

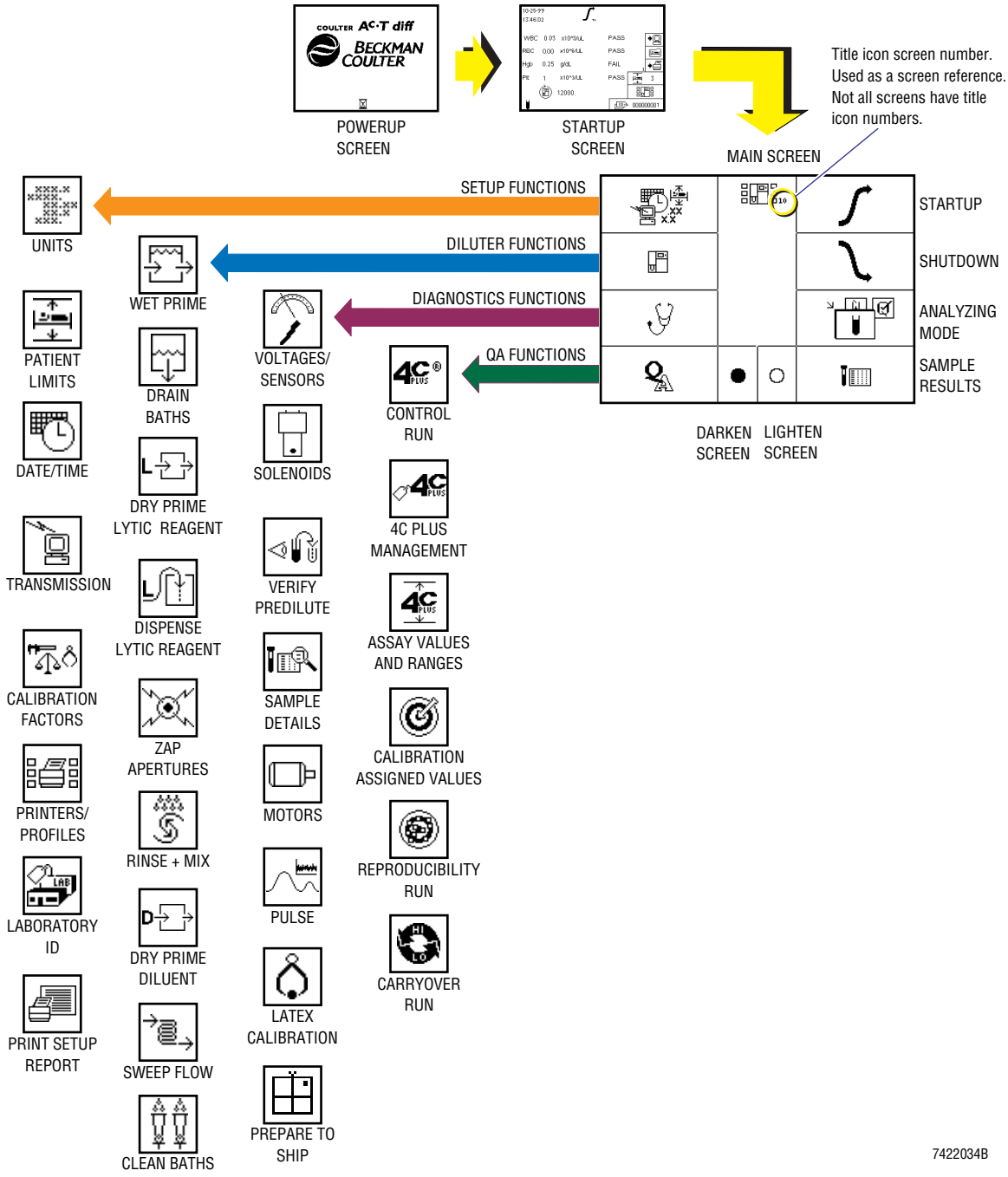
Sample ID Screen Icons



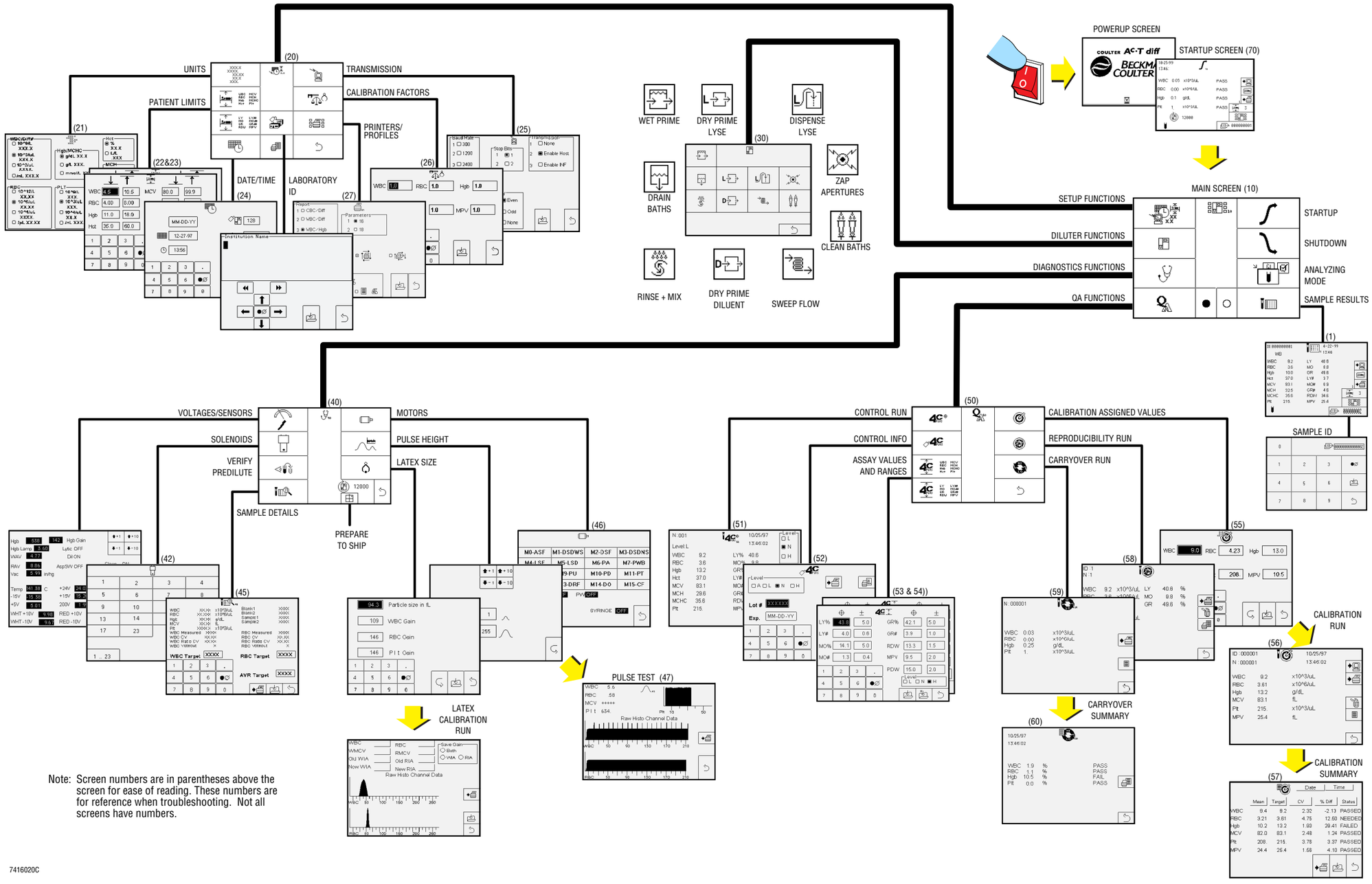
Auto ID	Save and Exit
Delete	Exit

ICON TREE OVERVIEW

Here is an overview of the icon tree. For additional information, see Touch Screen Icons and Icon Tree Detail.



ICON TREE DETAIL



Note: Screen numbers are in parentheses above the screen for ease of reading. These numbers are for reference when troubleshooting. Not all screens have numbers.

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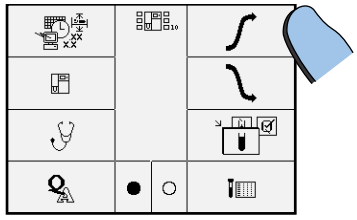
1.1 STARTUP

When you turn on the instrument, it automatically performs the startup procedure.

If you want to have the instrument do the startup procedure again when the instrument is on, follow this procedure.

---

1 At the Main screen, touch the **Startup** icon.



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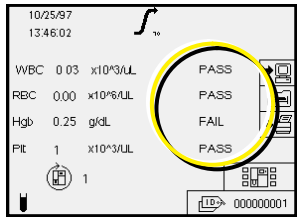
2 The instrument performs the startup routine and reports a *PASS* or *FAIL* for the WBC, RBC, Hgb, and Plt parameters.

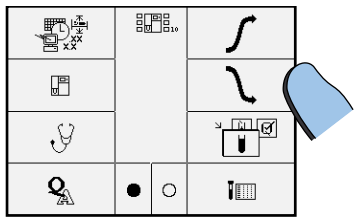


1.2 SHUTDOWN

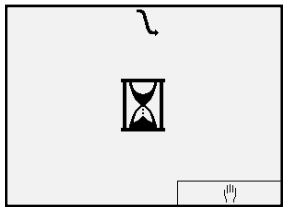
Before you turn the instrument off, do this shutdown procedure.

---

1 At the Main screen, touch the **Shutdown** icon.



2 When this screen appears, you can turn off the instrument.



2.1 ENTERING CELL CONTROL INFORMATION

Before running controls, the values from the TABLE OF EXPECTED RESULTS in the assay sheet must be entered and saved into the instrument for each lot of controls.

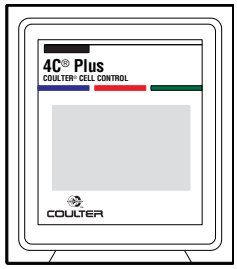
When operating this instrument outside the optimal temperature range (20° - 25°C), control results may exceed the expected limits. One of the suggested corrective actions is to establish your own mean values that are appropriate for your laboratory's environment. These values should be entered and saved in the instrument. The mean value you establish should not exceed the expected range limits determined for the control material at optimal temperature. If this occurs, contact your Beckman Coulter Representative.

IMPORTANT Risk of existing data in the database not being flagged using new values or ranges. If the Expected Values or Range is edited and saved when the control database is not empty, samples run after the change will be flagged according to the edited values; however, the data already in the database will not be reflagged based on the new values or ranges. The new values will be printed with the control summary data. Be sure to edit/save Expected Values or Ranges only when the control database is empty.

Entering the Lot Number

1 Are you using 4C PLUS cell control?

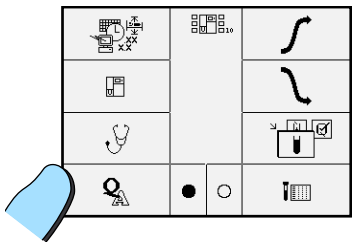
- If no, skip this procedure.
- If yes, go to step 2.



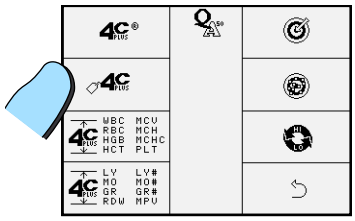
2 Prior to entering new cell control information:

- Be sure previous control data has been downloaded for IQAP as instructed in Heading 2.3, DOWNLOADING 4C PLUS CELL CONTROL RESULTS FOR IQAP.
- Be sure to keep a copy of the previous control data (summary or graph) currently in the system.
- If entering new lot information, delete the previous control data as instructed in Heading 2.4, DELETING 4C PLUS CELL CONTROL FILES.

3 At the Main screen, touch the **QA** icon.



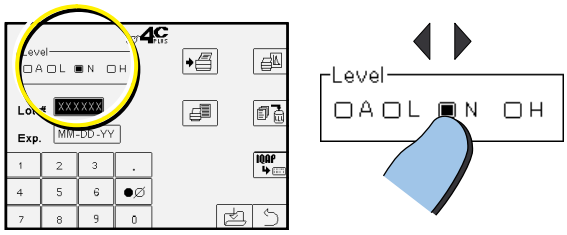
4 At the QA screen, touch the **4C Management** icon.



5 Select the cell control level (**L**, **N**, or **H**) by touching the level indicator.

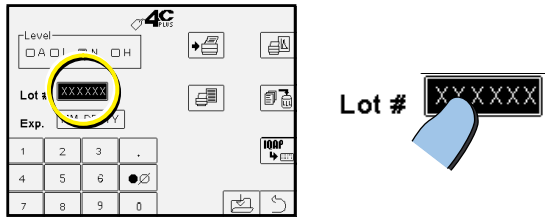
- **A** = all (Not for use when entering the lot number or expiration date.)
- **L** = low
- **N** = normal
- **H** = high

The square darkens next to your selection.

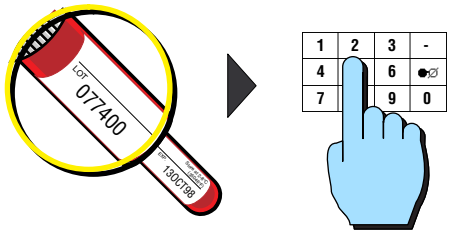


6 Enter the lot number:

a. Touch the Lot# field.

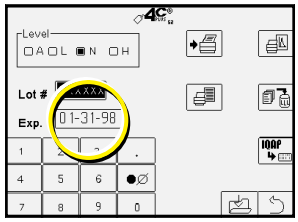


b. Enter the lot number located on the vial (up to 6 digits); include zeros.



7 Enter the expiration date:

a. Touch the Exp. field.

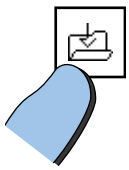


b. Enter the expiration date (up to 6 digits) in MMDDYY format. Use a dash to separate the month from the day and the day from the year.

For example, to enter October 13, 1998, you would press 10-13-98 at the keypad.

8 Repeat steps 5 through 7 for each additional level of control.

9 Save the information by touching the **Save and Exit** icon.



10 Do Entering Values.

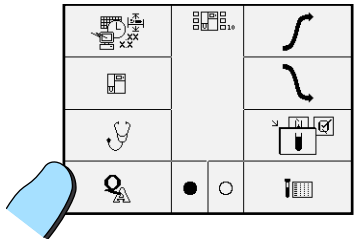
Entering Values

IMPORTANT Risk of misleading results if improper values are entered. If you are not using 4C PLUS cell control, DO NOT do this procedure.

If you are using A^{C}•T Tron cell control, skip this procedure.

---

1 At the Main screen, touch the **QA** icon.



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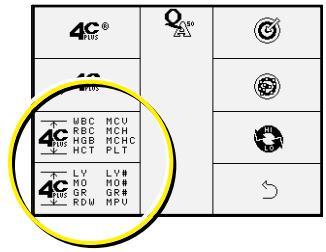
2 At the QA screen, touch one of the **4C Parameter** icons.



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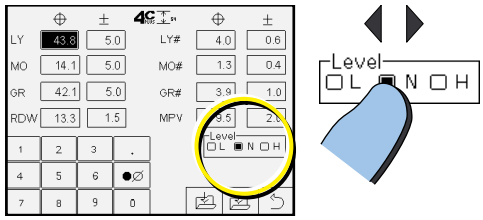
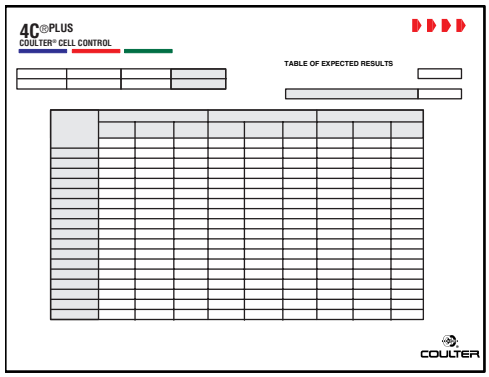
3 Select the control level:

- **L** = low
- **N** = normal, or
- **H** = high.

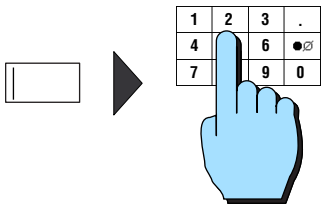
The square darkens next to your selection.



4 Refer to the TABLE OF EXPECTED RESULTS supplied with your control material.

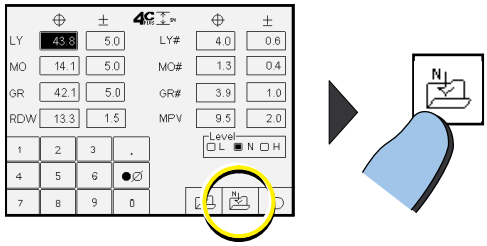


5 On the screen, touch the field where you want to enter the assay values of each parameter and the corresponding expected range from the TABLE OF EXPECTED RESULTS.

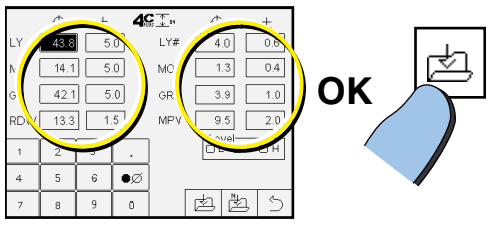


6 To save the data you enter while remaining at the current screen, touch the middle icon at the bottom right of the screen. (L, N, or H appears above the **Save** icon to reflect the control level.)

Note: This is recommended if your laboratory experiences electrical fluctuations or brownouts.

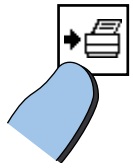


7 When you are ready to save and exit this screen, touch the **Save and Exit** icon.



8 Repeat steps 1 through 7 until target values are entered for all levels.

9 Print the information you entered by touching the **Print** icon, and verify that the information is correct.



2.2 RUNNING CONTROLS

The two controls for the A^C•T diff analyzer are 4C PLUS cell control and A^C•T Tron cell control. A^C•T Tron cell control monitors the performance of the CBC parameters only and is not available in the USA.

When operating this instrument outside the optimal temperature range (20° - 25°C), control results may exceed the expected limits. One of the suggested corrective actions is to establish your own mean values that are appropriate for your laboratory's environment. These values should be entered and saved in the instrument. The mean value you establish should not exceed the expected range limits determined for the control material at optimal temperature. If this occurs, contact your Beckman Coulter Representative.

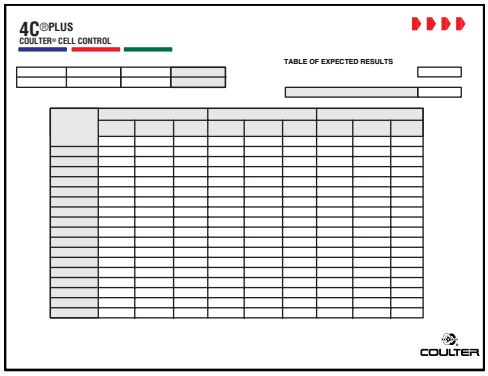
Running COULTER 4C® PLUS Cell Control

IMPORTANT Risk of misleading results. Misleading results will occur if you run 4C PLUS cell control in the A^C•T Tron mode. Do not run 4C PLUS cell control in the A^C•T Tron mode.

---

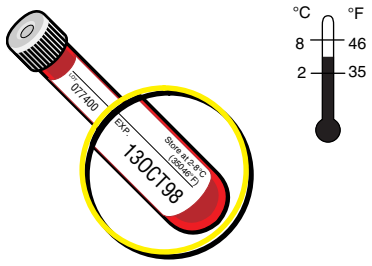
1 Be sure the 4C PLUS cell control information and values have been correctly entered from the TABLE OF EXPECTED RESULTS in the assay sheet.

For information on how to enter the values, see Entering Values for 4C PLUS Cell Control in this chapter.



---

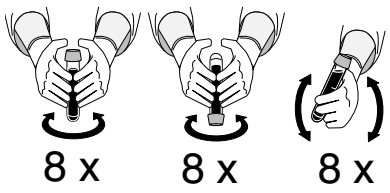
2 Ensure that 4C PLUS cell control is not past its expiration date and that it is at the correct storage temperature.



3

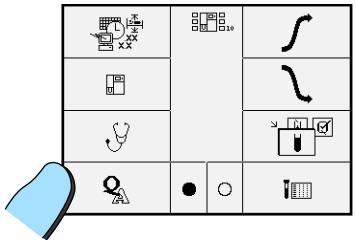
After warming at room temperature, mix each control gently according to instructions in the cell control package insert.

Inspect the vial contents to ensure that all cells are uniformly distributed; if not, repeat this step.



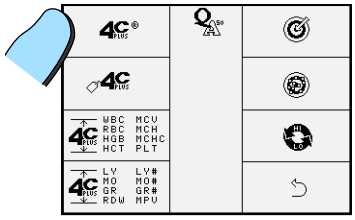
4

At the Main screen, touch the **QA** icon.



5

At the QA screen, touch the **4C PLUS Run** icon.

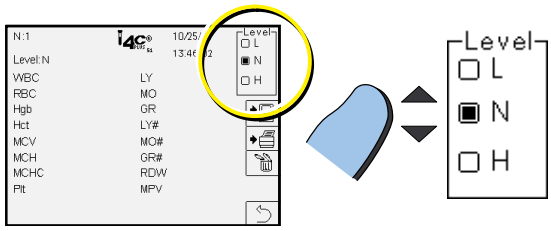


6

Select the correct control level:

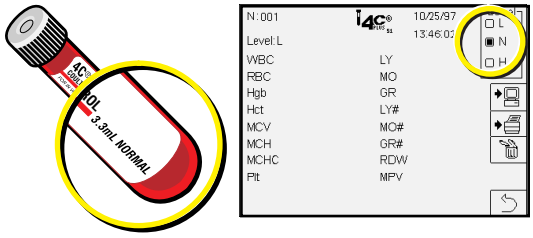
L - for low
N - for normal
H - for high

The square darkens next to your selection.

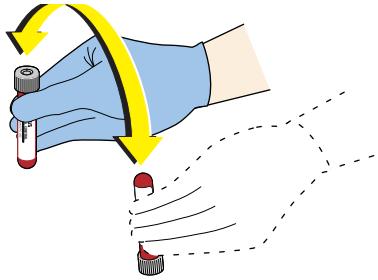


If the selected control level has expired, the **Control Expired** icon appears in the lower left corner of the screen.

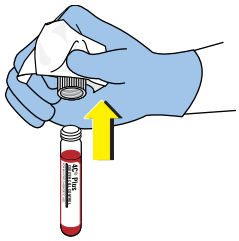
7 Make sure that the level of control you are testing matches the one selected (**L**, **N**, or **H**).



8 Invert the tube once or twice prior to cycling.

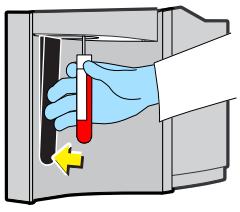


9 Cover the top of the control vial with lint-free tissue and remove the cap.



10 Present the 4C PLUS cell control vial to the probe so the tip is well into the vial, and press the aspirate switch.

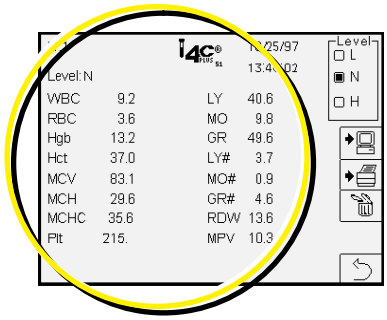
When you hear the beep, remove the 4C PLUS cell control vial, replace the cap, and return the vial to the refrigerator.



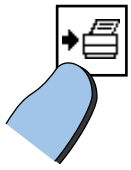
11

Results appear on the screen.

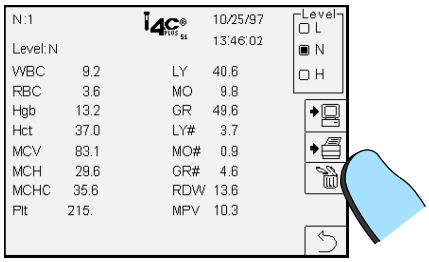
- Unless non-numeric results occur for one or more parameters, the control results are automatically stored.



- If Autoprint is off, you can manually print the results.



- To manually reject these results, touch the **Trash** icon.
- See Special Procedures and Troubleshooting in the Operator's Guide for information on reviewing flagged results.
- If results are not within the expected range, rerun the control starting at step 7.
- If results are still out of range, see the Special Procedures and Troubleshooting in the Operator's Guide.



12

Repeat steps 6 through 11 for each required control level.

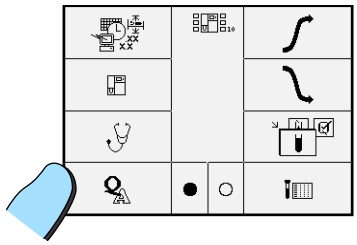
13

If the results are within the expected range, you are finished running controls.

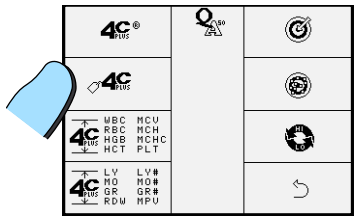
If you do all of the above steps and the results still do not meet your performance expectations, call your local Beckman Coulter Representative.

Printing Stored 4C PLUS Cell Control Results

1 At the Main screen, touch the **QA** icon.



2 At the QA screen, touch the **4C PLUS Management** icon.

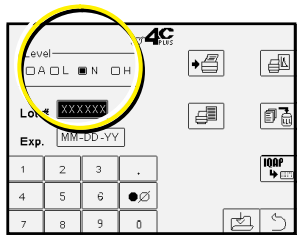


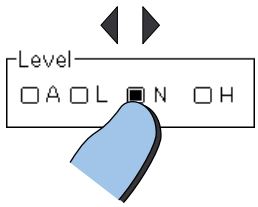
3 Select the control level you want to print:

- **A** = all
- **L** = low
- **N** = normal
- **H** = high

The square darkens next to your selection.

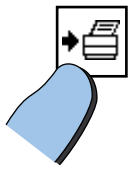
Note: If you are using a ticket printer, you cannot select level **A**.



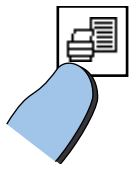


4 Touch the appropriate print icon to print the data you want:

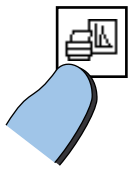
- Touch the **Print Assay** icon to print the assay values currently in the system.



- Touch the **Print Summary** icon to print a summary of the control data.



- If you have a graphic printer, touch the **Graph** icon to print a Levey-Jennings® graph of the control data.



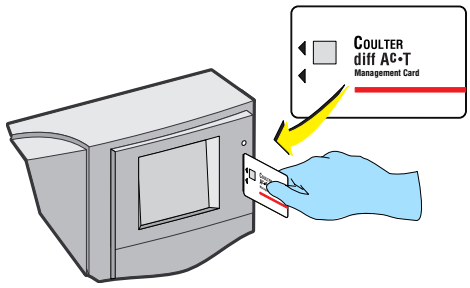
2.3 DOWNLOADING 4C PLUS CELL CONTROL RESULTS FOR IQAP

Stored control results can be returned to Beckman Coulter for inclusion in the Interlaboratory Quality Assurance Program (IQAP). Submit your IQAP data to Beckman Coulter each month after completing your last set of controls. For additional information on the IQAP program, see the Reference manual.

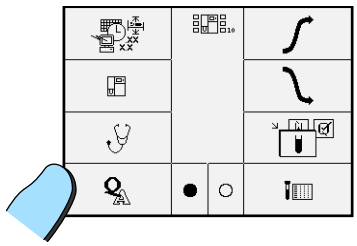
Save old reagent management cards to use for this procedure. The card is old if you see this warning on your instrument

Apply the IQAP identification label to an old reagent management card, using care not to cover up the microchip (gold square).

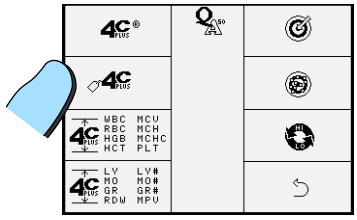
1 Remove the current A^{C}•T diff reagent management card and insert a used reagent management card into the instrument.



2 At the Main screen, touch the **QA** icon.



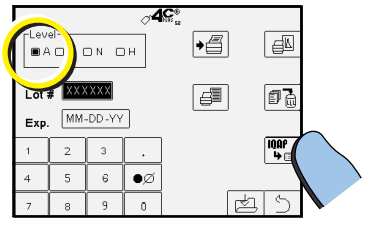
3 At the QA screen, touch the **4C PLUS Management** icon.



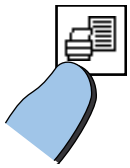
4 At the 4C Management screen:

a. Select **A** for all levels of control.

b. Touch the **IQAP** icon to download (send) the data to the card.



5 Touch the **Print Summary** icon to print the control summaries. Keep a copy of the control file data, if possible, for your records.



Note: If you are unable to download the data, submit your control data using a form approved by Beckman Coulter's IQAP department.

6 Place the reagent card with stored control data and attached label into the mailer; return the mailer to the Beckman Coulter IQAP department.

Note: At the time of enrollment in Beckman Coulter's IQAP program, you were supplied with pre-addressed mailers and self-adhesive return labels with your IQAP number.

2.4 DELETING 4C PLUS CELL CONTROL FILES

 indicates that one or more of your 4C PLUS cell control files are full and the instrument cannot store any additional control information. If you want to delete existing control files, follow this procedure.

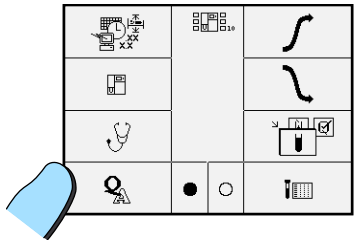
Once deleted, the control files cannot be recovered. Therefore, be sure that you have all the control information you need before deleting anything.

1

- If your laboratory is an IQAP participant, download all the control data before proceeding to step 2. See Heading 2.3 for details.
- If your laboratory is not an IQAP participant, go to step 2 below.

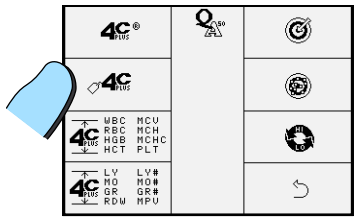
2

At the Main screen, touch the **QA** icon.



3

At the QA screen, touch the **4C PLUS Management** icon.

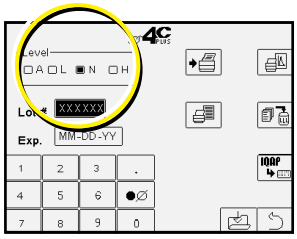


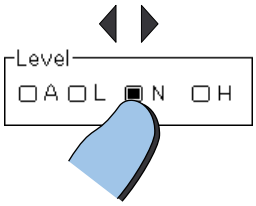
4

Select the control level you want to print.

- **A** = all
- **L** = low
- **N** = normal
- **H** = high

The square darkens next to your selection.

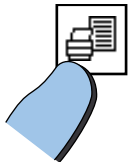




5

Touch the appropriate print icon to print control summaries or graphs for your records:

- Touch the **Print Summary** icon to print a summary of the control data.



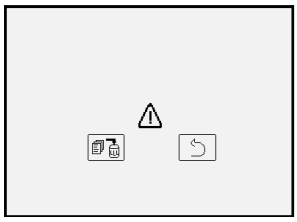
- If you have a graphic printer, touch the **Graph** icon to print a Levey-Jennings® graph of the control data.

6

Touch the **Trash** icon to delete the control files for the level of control you selected in step 4.

7 The Delete Confirmation screen appears.

- Touch the **Trash** icon to delete
- Touch the **Return** icon to return to the previous screen without deleting.



2.5 RUNNING A^{C}•T TRON™ CELL CONTROL (A^{C}•T Tron Mode Only)

This section contains an overview of the procedure. For complete instructions, see the procedure in the A^{C}•T Tron cell control package insert.

Note: A^{C}•T Tron cell control is not available in the USA.

IMPORTANT Only run A^{C}•T Tron cell control in the A^{C}•T Tron mode. Running A^{C}•T Tron in an incorrect analyzing mode will cause wrong results.

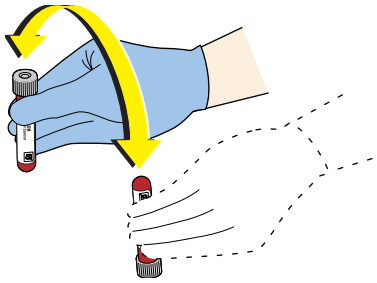
Risk of low results. Removal of the cap from the vial before warming and mixing prevents uniform resuspension of the cells. Do not remove the cap from the vial before warming and mixing.

Risk of high results. Aspiration of the control from the same vial more than 31 times might cause high results. Do not aspirate more than 31 times from a single vial.

1 Remove A^{C}•T Tron cell control tubes from the refrigerator and warm at ambient temperature for 15 minutes.

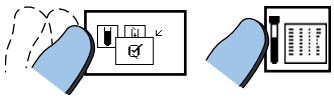
2 Before opening a new tube for the first time, mix 50 times by inversion within 1 minute.

After the first time, mix 30 times by inversion.



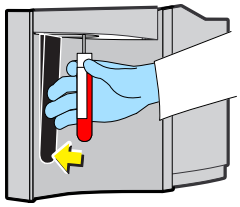
3 Inspect the tube contents to determine if all cells have been uniformly distributed. If not, repeat steps 2 and 3.

4 At the Main screen, select the A^{C}•T Tron mode and touch the **Sample Results** icon.



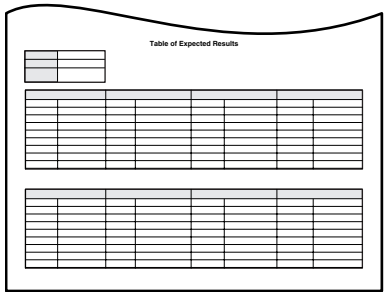
5 Present the well-mixed A^{C}•T Tron cell control vial to the probe so that the tip is well into the tube; press the aspirate bar.

When the instrument beeps, remove the tube.



6 Compare the results on the screen with those in the A^{C}•T Tron cell control TABLE OF EXPECTED RESULTS corresponding to your laboratory operating range.

See Table 6.11 for information on reviewing results.



7 Return the control vial to the refrigerator in the original package. Store horizontally.

3.1 GENERAL

If it is your laboratory's procedure to collect specimens for hematology via capillary collection into a microcollection device, you may run the specimen in the Whole Blood mode. However, the Predilute mode should be used if the specimen collected cannot be directly aspirated in a whole blood mode.

When you have set the A^C•T diff analyzer to the correct analyzing mode (Whole Blood or Predilute) and have verified the sample ID, you are ready to run samples.

To ensure that the blood specimen is analyzed correctly, you must set the instrument to the correct analyzing mode (Whole Blood or Predilute). Note: A^C•T Tron mode is used only for A^C•T Tron cell control, **not** for patient samples.

When storing samples:

- Do not refrigerate samples for Platelet and differential counts.
- If you do not need Platelet or differential results, you can store whole-blood specimens drawn in a salt of EDTA at 2 to 8°C.
- Warm samples to room temperature before you cycle them.

To record the sample results correctly, you must ensure that the ID number is correct.

IMPORTANT Risk of misleading results. Running a blood sample in an incorrect analyzing mode can cause wrong results. Only run a whole blood sample in the Whole Blood mode.

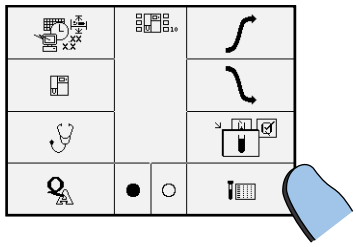
Beckman Coulter suggests that:

- You analyze a whole blood sample within 24 hours of collection.
- You analyze samples at the system's operating temperature (16-35°C).
- You warm samples to room temperature before you analyze them.
- If flags appear for a sample, you refer to Table 6.4.

3.2 RUNNING WHOLE BLOOD SAMPLES

1 At the Main screen, select the **Whole Blood** mode.

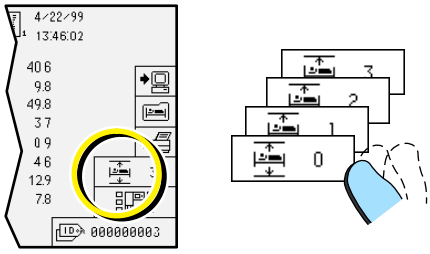
2 Touch the **Sample Results Screen** icon.



3 **IMPORTANT** Risk of misleading results if you process a sample with an incorrect range. If you run a sample with the incorrect range, you must rerun the sample using the appropriate range.

Touch the **Patient Range** icon until the desired range (**1**, **2**, or **3**) appears.

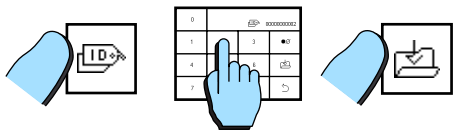
Note: **0** is not a patient range; it is the instrument's linearity range.



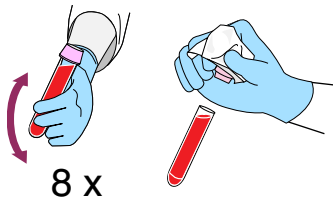
4 Verify that the sample ID is correct:

- If autosequencing is on, the sample ID number automatically increments by 1.
- If autosequencing is off, manually enter the sample ID and touch the **Save** icon. Be careful not to duplicate an existing sample ID number that may have been previously autoincremented.

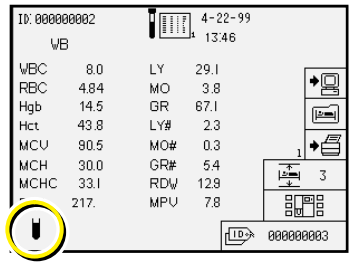
  Note: If autosequencing is off, the probe does not descend until you manually enter and save the next ID.



5 Mix the sample according to your laboratory's protocol, and place a lint-free tissue over the top and remove the cap.

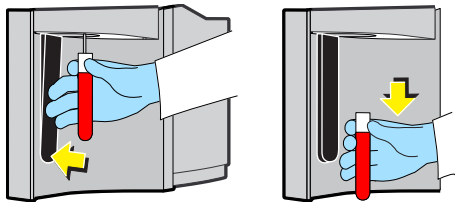


6 Be sure you are in the **Whole Blood** mode.



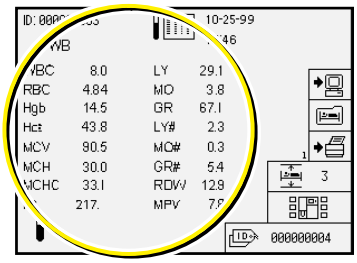
7 Present the well-mixed sample to the probe so that the tip is well into the tube, and press the aspirate switch.

When you hear the beep, remove the sample, and put the cap back on the tube.

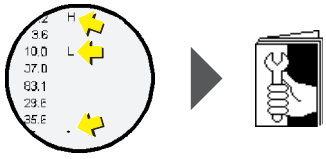


8

The sample results are automatically saved by the instrument and the results appear on the screen.



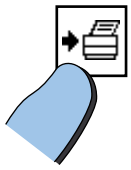
If flags appear, see Special Procedures and Troubleshooting in this manual.



9

Print the results:

- If Autoprint is on, the results print automatically.
- If Autoprint is off, touch the **Print** icon.



If the printout is illegible, unclear, or incomplete, correct the printer problem and reprint.

Note: Results print based on the patient range selected when the sample was run.

10

If autosequence is on, the instrument is ready to run the next sample.

If autosequence is off, you must manually enter an ID number before the probe descends for the next sample.

3.3 RUNNING PREDILUTED BLOOD SAMPLES

If it is your laboratory's procedure to collect specimens for hematology via capillary collection into a microcollection device, you may run the specimen in the Whole Blood mode. However, the Predilute mode should be used if the specimen collected cannot be directly aspirated in a whole blood mode. Predilute mode dispenses 1580 µL of diluent into an empty tube or receptacle where 20 µL of capillary blood will be added, thereby diluting it, to create an adequate amount of sample volume for the instrument to aspirate for analysis.

IMPORTANT Risk of misleading results. Running a blood sample in an incorrect analyzing mode can cause wrong results. Only run prediluted blood in the Predilute mode.

Beckman Coulter suggests that:

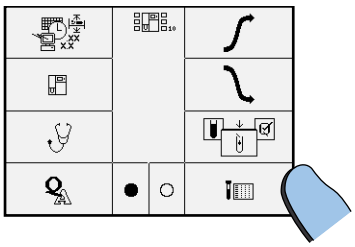
- You analyze prediluted specimens for CBC within 4 hours of collection/preparation.
- You analyze prediluted specimens for diff within 1 hour of collection/preparation.
- You allow a prediluted sample to stabilize in the predispensed diluent for at least 5 minutes.
- If flags appear, you refer to Special Procedures and Troubleshooting in this manual.
- You analyze at ambient operating temperature (16-35°C).
- Each laboratory evaluate predilute stability based on their sample population and specimen collection techniques or methods.

---

1 At the Main screen, select the **Predilute** mode.

---

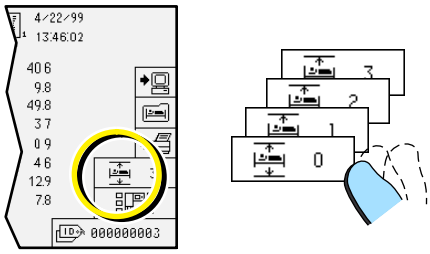
2 Touch the **Sample Results Screen** icon.



3 **IMPORTANT** Risk of misleading results if you process a sample with an incorrect range. If you run a sample with the incorrect range, you must rerun the sample using the appropriate range.

Touch the **Patient Range** icon until the desired range (**1**, **2**, or **3**) appears.

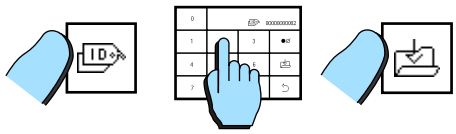
Note: **0** is not a patient range; it is the instrument's linearity range.



4 Verify that the sample ID is correct:

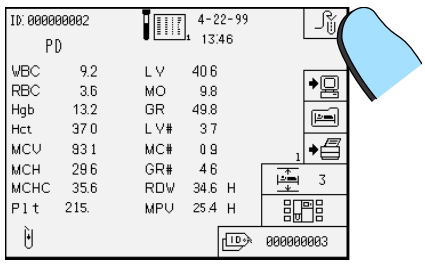
- If autosequencing is on, the sample ID number automatically increments by 1.
- If autosequencing is off, manually enter the sample ID and touch the **Save** icon. Be careful not to duplicate an existing sample ID number that may have been previously autoincremented.

  Note: If autosequencing is off, the probe does not descend until you manually enter and save the next ID.



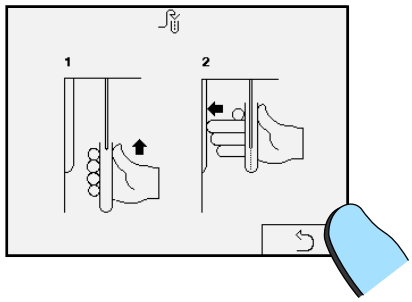
5 Touch the **Dispense Diluent** icon.

The aspiration probe then retracts into the instrument and descends again.



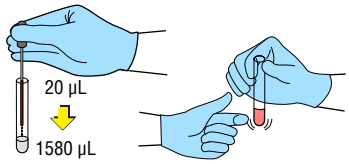
6 Present an empty tube to the probe and press the aspirate switch to dispense 1580 µL of diluent into the empty tube.

When all your samples are prepared, touch the **Exit** icon to return to the Sample Results Screen.

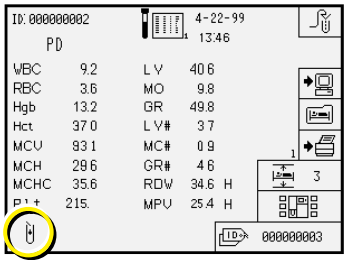


7 Prepare the sample for analysis:

a. Add 20 µL of blood specimen to the diluent in the tube.
b. Mix the sample according to your laboratory's protocol.
c. Wait at least 5 minutes before running the sample.

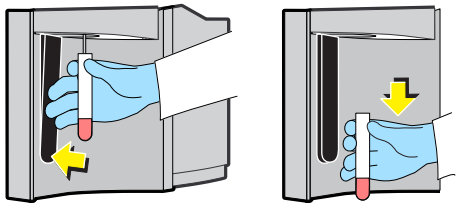


8 Be sure you are in the **Predilute** mode.

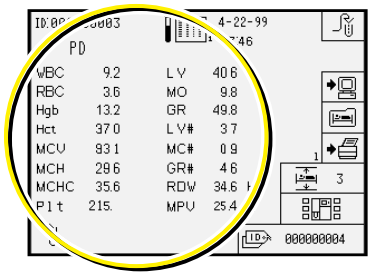


9 Present the well-mixed, prediluted sample to the probe and press the aspirate switch.

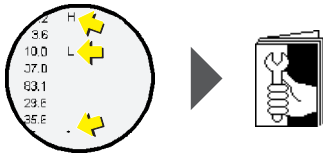
When you hear the beep, remove the sample.



10 The A^{C}•T diff analyzer displays the sample results on the screen and automatically saves them.

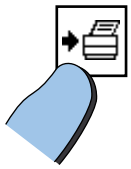


If flags appear, see Special Procedures and Troubleshooting in this manual.



11 Print the results:

- If Autoprint is on, the results print automatically.
- If Autoprint is off, touch the **Print** icon.



Note: Results print based on the patient range selected when the sample was run.

12 If autosequence is on, the instrument is ready to run the next sample.

If autosequence is off, you must manually enter an ID number before the probe descends for the next sample.

4.1 PRINTING STORED SAMPLE RESULTS FOR VIEWING

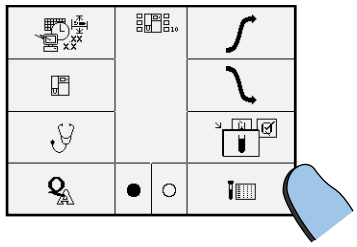
As mentioned in Chapter 3, RUNNING SAMPLES, the instrument automatically saves (or stores) the patient results once the sample is analyzed. There may be times when you need to review certain patient results that were saved. This procedure explains how to do that.

This function is available for use with the graphic printer only.

Note: Results print based on the patient range selected when the sample was run.

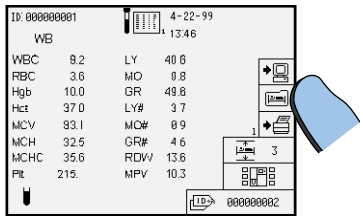
---

1 At the Main screen, touch the **Sample Results Screen** icon.

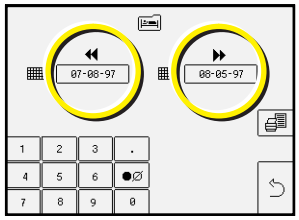


---

2 At the Sample Results Screen, touch the **Retrieve Stored Data** icon.

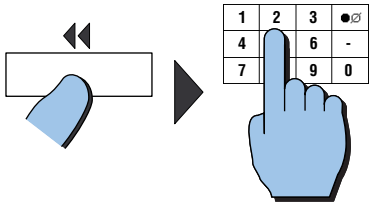


A screen with date fields appears. The date field on the left is the “from” date field, and the date field on the right is the “to” date field.

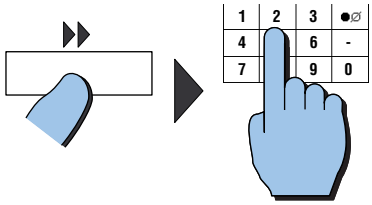


3 Enter the date range of the samples you want to review.

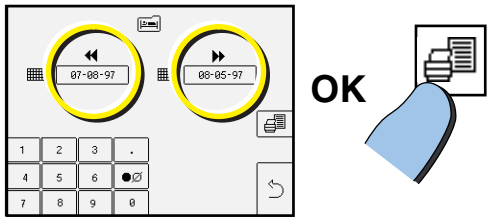
a. Enter the beginning date of the sample results you want.



b. Enter the ending date of the sample results you want.

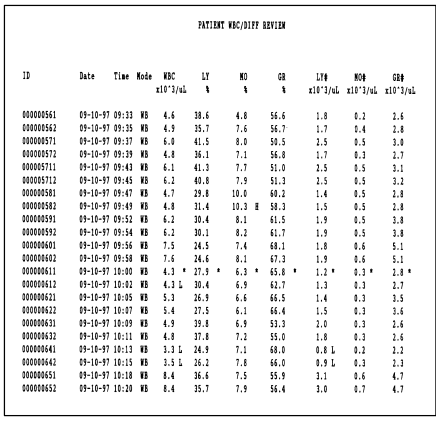


4 Touch the **Print Summary** icon to print the results. The **In Progress** icon appears on the screen during printing.



A report prints out similar to that shown here. The report reflects only the sample data saved for only the date range that you entered.

Note: In case of multiple samples with the same sample ID#, use the date and time to differentiate the runs.



PATIENT WBC/DIFF REVIEW

ID	Date	Time	Mode	WBC x10^3/uL	LY %	MO %	GR %	LY# x10^3/uL	MO# x10^3/uL	GR# x10^3/uL
00000561	09-10-97	09:33	WB	4.6	38.6	4.8	56.6	1.8	0.2	2.6
00000562	09-10-97	09:35	WB	4.9	35.7	7.6	56.7	1.7	0.4	2.8
00000571	09-10-97	09:37	WB	6.0	41.5	8.0	50.5	2.5	0.5	3.0
00000572	09-10-97	09:39	WB	4.8	36.1	7.1	56.8	1.7	0.3	2.7
00000711	09-10-97	09:43	WB	6.1	41.3	7.7	51.0	2.5	0.5	3.1
00000712	09-10-97	09:45	WB	6.2	40.8	7.9	51.3	2.5	0.5	3.2
00000581	09-10-97	09:47	WB	4.7	29.8	10.0	60.2	1.4	0.5	2.8
00000582	09-10-97	09:49	WB	4.8	31.4	10.3 H	58.3	1.5	0.5	2.8
00000591	09-10-97	09:52	WB	6.2	30.4	8.1	61.5	1.9	0.5	3.8
00000592	09-10-97	09:54	WB	6.2	30.1	8.2	61.7	1.9	0.5	3.8
00000601	09-10-97	09:56	WB	7.5	24.5	7.4	68.1	1.8	0.6	5.1
00000602	09-10-97	09:58	WB	7.6	24.6	8.1	67.3	1.9	0.6	5.1
00000611	09-10-97	10:00	WB	4.3 *	27.9 *	6.3 *	65.8 *	1.2 *	0.3 *	2.8 *
00000612	09-10-97	10:02	WB	4.3 L	30.4	6.9	62.7	1.3	0.3	2.7
00000621	09-10-97	10:05	WB	5.3	26.9	6.6	66.5	1.4	0.3	3.5
00000622	09-10-97	10:07	WB	5.4	27.5	6.1	66.4	1.5	0.3	3.6
00000631	09-10-97	10:09	WB	4.9	39.8	6.9	53.3	2.0	0.3	2.6
00000632	09-10-97	10:11	WB	4.8	37.8	7.2	55.0	1.8	0.3	2.6
00000641	09-10-97	10:13	WB	3.3 L	24.9	7.1	68.0	0.8 L	0.2	2.2
00000642	09-10-97	10:15	WB	3.5 L	26.2	7.8	66.0	0.9 L	0.3	2.3
00000651	09-10-97	10:18	WB	8.4	36.6	7.5	55.9	3.1	0.6	4.7
00000652	09-10-97	10:20	WB	8.4	35.7	7.9	56.4	3.0	0.7	4.7

5.1 OVERVIEW

Beckman Coulter calibrates the A^C•T diff analyzer at the factory before shipment. You may need to perform calibration procedures when you replace any instrument component that involves the primary measurement characteristics (such as an aperture).

Because the instrument is electronically stable, it should not require frequent recalibration when you operate it and maintain it according to the recommendations in this manual. Make the decision to recalibrate based on the performance of your quality control program.

Beckman Coulter recommends that you calibrate your instrument according to the regulations required by your inspecting agency.

Your laboratory's quality control program should continually monitor and confirm instrument calibration. Review your control results periodically. Keep a written record of this review. To confirm calibration of the A^C•T diff analyzer:

1. Verify that 95% of control results are within their ranges as listed in the TABLE OF EXPECTED RESULTS.
2. Verify that there are no unexplained shifts or trends in the data.

If recalibration appears necessary, but you have not replaced a component affecting calibration, do **NOT** recalibrate the instrument.

1. First, thoroughly clean your analyzer following the Clean the Baths procedure in Chapter 6 of this manual.
2. Then reanalyze a new vial of control material.
   - If the control results are still outside of the expected ranges, refer to Table 6.10 and Heading 6.21 in this manual.
   - If the results remain outside the expected ranges, call your Beckman Coulter Representative before recalibrating.

When necessary, perform calibration by following the procedures given in this section.

Before you begin calibration, be sure you have enough reagents to perform the complete procedure. If you run out of reagents during calibration, you must start over and perform a complete calibration.

Recommended Calibrator

Beckman Coulter recommends using S-CAL calibrator for automated calibration. If S-CAL calibrator is not available, manual calibration can be done after Reproducibility and Carryover are completed. See Appendix A for the manual calibration procedure.

You can calibrate either automatically or manually, using S-CAL calibrator.

5.2 BEFORE CALIBRATING

Before calibrating, you must first prepare the instrument:

1. Do precalibration checks.
2. Do Reproducibility.
3. Do Carryover.

Precalibration Checks

1 Be sure that all required maintenance (including replacement of parts) has been performed on the instrument. See Special Procedures and Troubleshooting in this manual.

2 Do the Clean the Baths procedure in Chapter 6 of this manual.

3 Calibrate only when the ambient temperature is within the system's operating range (16-35° C).

4 Check that you have a sufficient supply of reagents to complete this procedure.

5 Perform Startup in heading 1.1 of this manual.

5.3 REPRODUCIBILITY

The A^{C}•T diff analyzer includes a Reproducibility function that automatically performs calculations on the samples you run.

Reproducibility is a check to ensure that the instrument measures blood parameters consistently and precisely. After you run the sample N times consecutively, the instrument:

- Calculates the SD of N-1 results of the sample.
- Calculates the mean coefficient of variation (%CV) and standard deviation (SD) for the parameters
- Prints *PASS* or *FAIL* message for the reproducibility test.

You can run reproducibility in any of the following modes:

- Whole Blood
- Predilute
- QC Check

It is recommended that you run Reproducibility in the Whole Blood mode using either whole blood or a cell control with a known range of values, such as 4C PLUS cell control.

If it is your laboratory's procedure to collect specimens for hematology via capillary collection into a microcollection device, you may run the specimen in the Whole Blood mode. However, the Predilute mode should be used if the specimen collected cannot be directly aspirated in a whole blood mode.

To perform statistics, the instrument requires three acceptable samples. If a result is not acceptable, the instrument automatically rejects the result. You can also reject a result by touching the **Reject** icon.

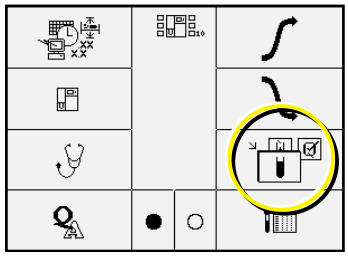
There is a summary screen for Reproducibility. Autoprint, if turned ON, prints a sample report upon completion of each run. Autoprint is not an option for printing the summary report; you must manually select the print summary icon. You can print a summary report beginning with the third sample all the way to the thirty-first sample, if you choose to run that many samples.

When doing Reproducibility, Carryover, or Calibration, do not leave the screen until you finish analyzing the required number of samples. Leaving the screen without finishing the required analysis will delete your data, which means that you must restart the test.

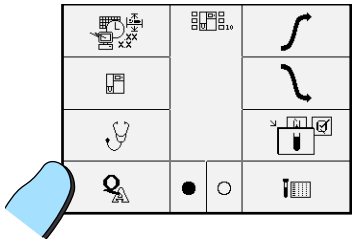
1 Select a sample that meets these parameter criteria:

WBC at 6.0 - 15.0 x 10^3 cells/µL
RBC at 3.00 - 6.00 x 10^6 cells/µL
Hgb at 12.0 - 18.0 g/dL
MCV at 80.0 - 100.0 fL
Plt at 200 - 500 x 10^3 cells/µL

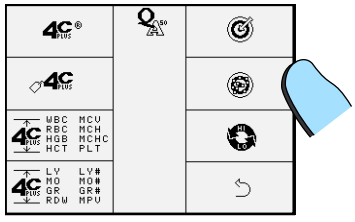
2 At the Main screen, select **Whole Blood** mode to run normal whole blood samples or 4C PLUS cell control.



3 At the Main screen, touch the **QA** icon.

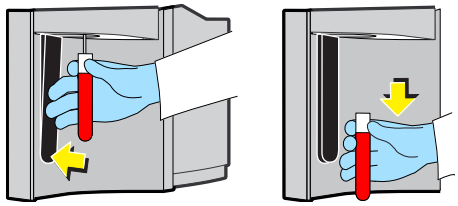


4 At the QA screen, touch the **Reproducibility** icon.

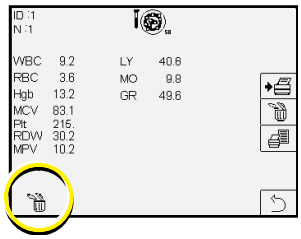


5 Present the well-mixed sample to the probe so that the tip is well into the tube, and press the aspirate switch.

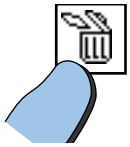
When you hear the beep, remove the sample.



If a non-numeric result is obtained or if you manually reject the sample, the **Trash** icon appears in the lower left corner of the screen.



6 When the sample result is displayed, touch the **Trash** icon to manually delete the first (prime) sample.

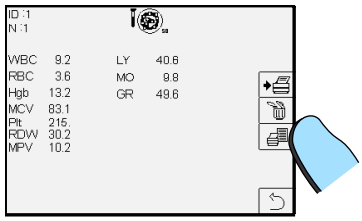


7 Repeat step 5 until an N of 11 is achieved. Look at the upper left corner of the screen for the N#.

After the instrument accepts the data, the Reproducibility results are stored.

Note: Up to 31 samples can be run as part of the statistical calculations.

8 If you are using a graphic printer, touch the **Print Summary** icon.



The Reproducibility Summary Report prints similar to that shown below. Keep a copy for your records.

	PLT	RDW	MPV
9	209.9	13.28	8.45
5	198.0	12.53	8.45
3	213.8	13.22	8.65
5	202.2	12.87	8.84
9	199.0	13.16	8.65
7	206.6	13.10	8.65
7	198.1	12.75	8.45
9	199.3	13.21	8.55
4	212.3	12.60	8.45
5	203.3	12.84	8.45
9	217.1	13.05	8.65
5	205.0	12.93	8.58
5	7.1	0.25	0.13
2	3.47	1.95	1.53
0	PASSED	PASSED	PASSED

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Note: For information on parameter limits, refer to PERFORMANCE SPECIFICATIONS in the Reference manual.

If Reproducibility fails, contact your local Beckman Coulter Representative.

9 Do Heading 5.4, Carryover.

5.4 CARRYOVER

Carryover is a check to make sure that no part of a sample is carried over to the next sample, thus affecting the next sample's results. Carryover:

- determines if there is carryover from the sample, and
- Prints *PASS* or *FAIL* message for the carryover test.

Note: You may use 4C PLUS cell control as an alternative to normal whole-blood samples.

The instrument determines what is acceptable for carryover.

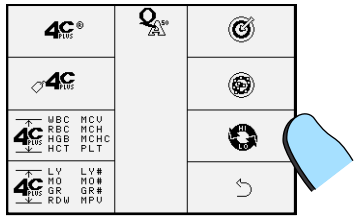
When doing Reproducibility, Carryover, or Calibration, do not leave the screen until you finish analyzing the required number of samples. Leaving the screen without finishing the required analysis will delete your data, which means that you must restart the test.

---

1 Be sure that you completed Reproducibility.

---

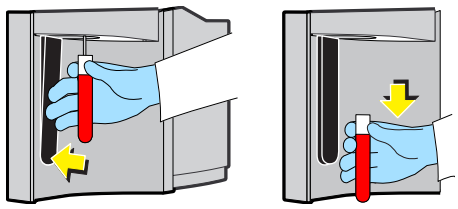
2 Touch the **Carryover** icon.



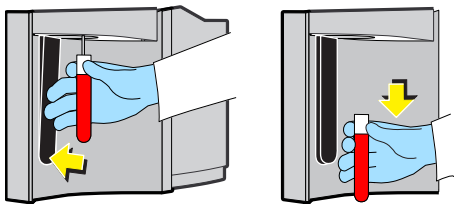
---

3 Present the well-mixed sample to the probe so that the tip is well into the tube, and press the aspirate switch.

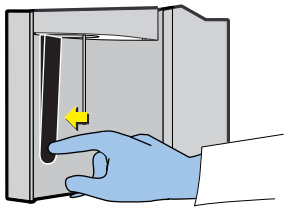
When you hear the beep, remove the sample.



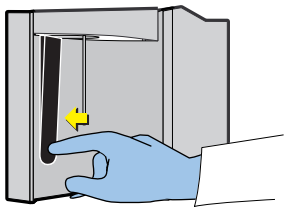
4 Repeat step 3 for the second sample.



5 Run a blank sample (air) by pressing the aspirate switch.



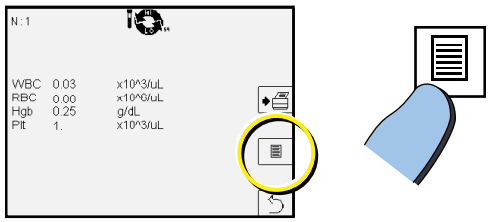
6 Repeat step 5 twice for a total of three blank samples.



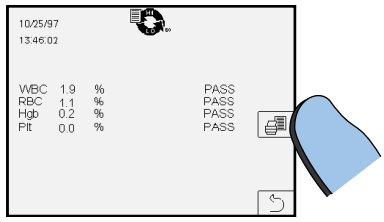
7 After the last blank sample is run, the probe retracts and the **Summary** icon appears.

Touch the **Summary** icon to view the summary screen.

Note: The N# on the screen indicates the numbers of acceptable runs.



8 Touch the **Print Summary** icon to print a summary report for your records.



This is an example of a Carryover Summary Report.

Note: For information on parameter limits, refer to PERFORMANCE SPECIFICATIONS in the Reference manual.

If Carryover fails, contact your local Beckman Coulter Representative.

CARRYOVER

Date: 08-27-97 Time: 09:52

CARRYOVER RESULTS

N	WBC	RBC	HGB	PLT
1	9.0	4.60	13.1	236.
2	9.1	4.71	13.3	251.
3	0.1	0.00	0.0	0.
4	0.1	0.00	0.0	0.
5	0.1	0.00	0.0	0.

Carryover%

0.0	0.0	0.0	0.0

Status

PASSED	PASSED	PASSED	PASSED

9 Do Heading 5.5, Auto-Calibration.

5.5 AUTO-CALIBRATION

Calibration standardizes the instrument by determining its deviation from calibration references and adjusting calibration factors as needed.

The S-CAL calibration kit helps you determine whether the calibration factors of the instrument need to be changed. Assigned values are provided in the S-CAL calibration kit package insert. **Only the package inserts provided with the S-CAL calibration kit provide the correct assigned values for the calibrator**.

For automated calibration, you simply cycle the S-CAL calibrator. After you enter the ASSIGNED VALUES from the S-CAL calibrator package insert, calculations and comparisons to assigned values are done automatically by the instrument. You can save the calibration data.

After calibration is completed, a *PASSED, NEEDED* or *FAILED* message appears for each parameter.

When doing Reproducibility, Carryover, or Calibration, do not leave the screen until you finish analyzing the required number of samples. Leaving the screen without finishing the required analysis will delete your data, which means that you must restart the test.

---

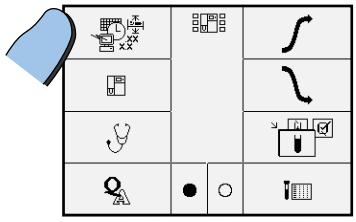
1 Be sure that you completed the Reproducibility and Carryover procedures.

---

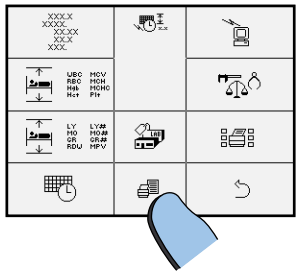
2 Verify that one vial of the S-CAL calibrator is at room temperature.

3

a. At the Main screen, touch the **Setup** icon.



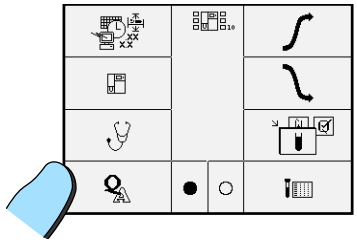
b. At the Setup screen, touch the **Setup Report** icon to print the old calibration factors.



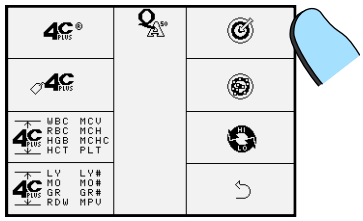
c. After the calibration setup report prints, touch the **Exit** icon.

4

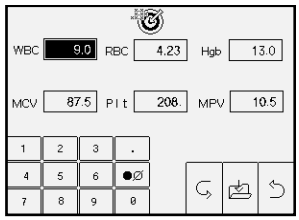
At the Main screen, touch the **QA** icon.



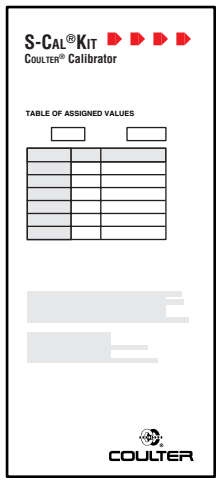
5 At the QA screen, touch the **Calibration** icon.



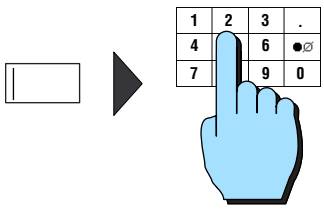
The calibration assay screen appears.



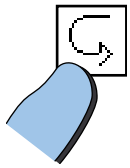
6 Refer to the TABLE OF ASSIGNED VALUES on the S-CAL calibrator package insert.



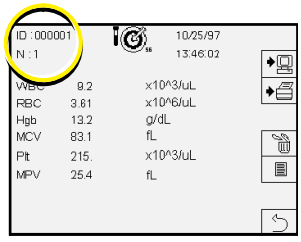
7 On the screen, touch the field where you want to enter values, and enter the values from the TABLE OF ASSIGNED VALUES using the keypad.



8 Save the values you entered by touching the **Continue** icon.



The run screen appears.

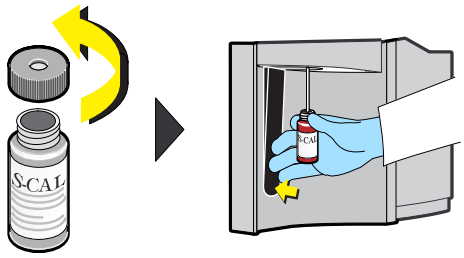


The ID# refers to the number of runs done under this calibration procedure.

The N# refers to the actual number of accepted samples for this test.

9 Mix the S-CAL calibrator according to the package insert.

10 Remove the cap from the S-CAL calibrator vial, and present S-CAL calibrator to the probe so the tip is well into the vial, and press the aspirate switch.

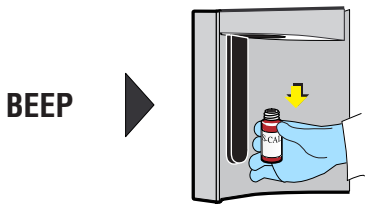


11

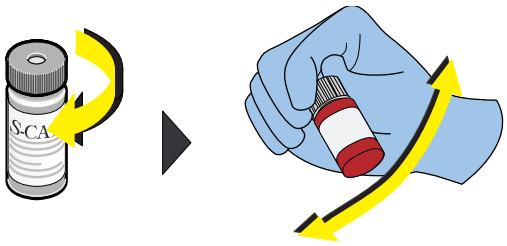
When the instrument beeps, remove the calibrator from the probe.

a. Put the cap back on the calibrator and mix gently between each cycle.

b. After analysis is complete, the results of sample #1 appear.



If an Aperture Alert message or any non-numeric result (XXXXX, - - - - -, •••••, +++++) occurs, the results will be displayed but the instrument automatically rejects them.

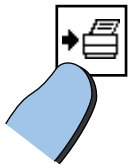


- If a result is rejected by the instrument, the N# does not increment.
- If you choose to reject the result for the last sample run, the N# automatically decrements by 1. (You can only reject the last sample analyzed.)

12

Print the results:

- If Autoprint is on, the results print automatically.
- If Autoprint is off, touch the **Print** icon.



13

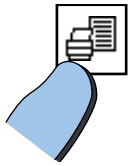
Repeat steps 9 through 12 for each of the 11 calibration samples.

- Note: The instrument does not use results for the first replicate. It performs statistics on replicates 2 through 11 for a total of 10.

The instrument automatically saves the results.

14 After 11 acceptable sample results, the **Summary** icon appears; touch the icon to view the summary screen.

- If Autoprint is ON and you are using a graphic printer, a summary report prints automatically.
- If Autoprint is OFF, you can print a report summary by pressing the **Summary** icon.



This is an example of a Calibration Summary Report.

CALIBRATION

Date: 08-27-97 Time: 09:18

N	WBC	RBC	HGB	MCV	PLT	MPV
1	9.13	4.713	13.28	90.89	245.4	10.12
2	8.97	4.634	13.22	90.88	234.8	10.22
3	8.89	4.731	13.36	90.93	251.9	10.22
4	9.02	4.714	13.40	90.49	254.6	10.32
5	9.03	4.676	13.36	90.74	247.1	10.32
6	9.04	4.705	13.29	90.55	249.5	10.22
7	9.19	4.764	13.49	90.52	247.5	10.12
8	9.05	4.692	13.27	90.48	239.3	10.02
9	9.13	4.716	13.41	90.46	247.4	10.22
10	9.10	4.706	13.34	90.59	237.2	10.02
11	9.00	4.635	13.13	90.44	240.6	10.12
MEAN	9.04	4.697	13.33	90.61	245.0	10.18
TARGET	9.2	4.71	13.3	91.0	246.	10.0
CV	0.93	0.86	0.77	0.20	2.70	1.06
%DIFF	1.74	0.28	0.23	0.43	0.41	1.80
STATUS	PASSED	PASSED	PASSED	PASSED	PASSED	PASSED

Note: The first sample is not used in the calculations

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15 Review the status of each result.

- If *PASSED* appears for all the parameters, calibration adjustments are not required. Touch the **Return** icon.
  Note: Touching the **Return** icon **does not** update the calibration factors.

CALIBRATION

Date: 08-27-99 Time: 12:04

N	WBC	RBC	HGB	MCV	PLT
1	8.73	4.205	12.88	86.80	205.7
2	8.55	4.199	12.82	87.03	200.1
3	8.78	4.268	13.04	86.71	208.3
4	8.61	4.255	12.89	86.62	206.0
5	8.58	4.187	12.81	86.80	210.3
6	8.52	4.206	12.80	86.76	207.5
7	8.78	4.208	12.76	86.50	211.2
8	8.49	4.123	12.67	86.46	201.7
9	8.70	4.208	12.77	86.38	206.0
10	8.73	4.279	13.16	86.59	214.9
11	8.51	4.150	12.72	86.48	207.6
MEAN	8.63	4.208	12.84	86.63	207.4
TARGET	8.6	4.23	12.8	87.6	210.
CV	1.31				2.09
%DIFF		0.52	0.31	1.11	
STAT	PASSED	PASSED	PASSED	PASSED	PASSED

- If *NEEDED* appears for any of the parameters, calibration adjustments are required.

  Press the **Save and Exit** icon to automatically replace the *NEEDED* calibration factor with the new calibration factor. This automatically updates the instrument's calibration parameters.

  Print the new calibration factors and place them in your log book.

  Verify calibration by analyzing one replicate for each level of control.

CALIBRATION

Date: 08-27-99 Time: 11:38

N	WBC	RBC	HGB	MCV	PLT
1	8.34	4.223	12.42	85.19	207.4
2	8.29	4.129	12.36	86.25	199.2
3	8.53	4.128	12.44	86.30	208.3
4	8.61	4.154	12.52	85.19	201.4
5	8.55	4.200	12.45	84.86	200.2
6	8.52	4.163	12.47	84.84	195.9
7	8.50	4.108	12.60	84.84	200.3
8	8.52	4.165	12.57	85.01	208.2
9	8.51	4.086	12.61	84.85	198.2
10	8.61	4.088	12.55	85.10	190.4
11	8.71	4.335	12.70	84.31	206.9
MEAN	8.54	4.156	12.53	85.16	200.9
TARGET	8.6	4.23	12.8	87.6	210.
CV	1.26	1.75	0.7	0.75	2.83
%DIFF	0.70	1.75	2.11	2.79	4.33
STATUS	PASSED	PASSED	NEEDED	NEEDED	PASSED

- If *FAILED* appears, the % diff value and/or CV% exceeds the high acceptable limit.

  You cannot save *FAILED* calibration results. Call your local Beckman Coulter Service Representative for assistance.

CALIBRATION

Date: 08-27-99 Time: 11:38

N	WBC	RBC	HGB	MCV	PLT
1	8.34	4.223	12.42	85.19	207.4
2	8.29	4.129	12.36	86.25	199.2
3	8.53	4.128	12.44	86.30	208.3
4	8.61	4.154	12.52	85.19	201.4
5	8.55	4.200	12.45	84.86	200.2
6	8.52	4.163	12.47	84.84	195.9
7	8.50	4.108	12.60	84.84	200.3
8	8.52	4.165	12.57	85.01	208.2
9	8.51	4.086	12.61	84.85	198.2
10	8.61	4.088	12.55	85.10	190.4
11	8.71	4.335	12.70	84.31	206.9
MEAN	8.54	4.156	12.53	85.16	200.9
TARGET	8.6	4.23	12.8	87.6	210.
CV	1.26	1.75	0.79	0.7	2.83
%DIFF	0.70	1.75	2.11	2.79	4.33
STATUS	PASSED	PASSED	NEEDED	FAILED	PASSED

16 Verify calibration by running 4C PLUS cell control. See Running COULTER 4C® PLUS Cell Control under Heading 2.2, RUNNING CONTROLS for instructions.

6.1 GENERAL MAINTENANCE

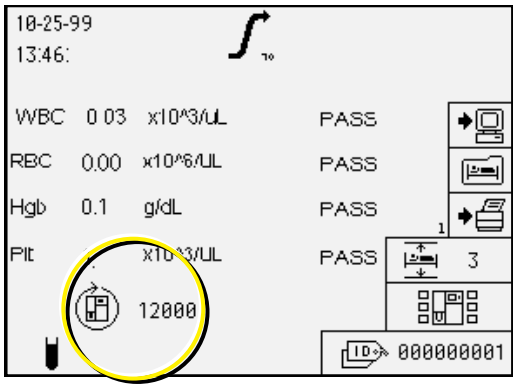
This chapter details the A^{C}•T diff analyzer maintenance procedures that are your responsibility. It also includes a troubleshooting guide to help you solve instrument problems.

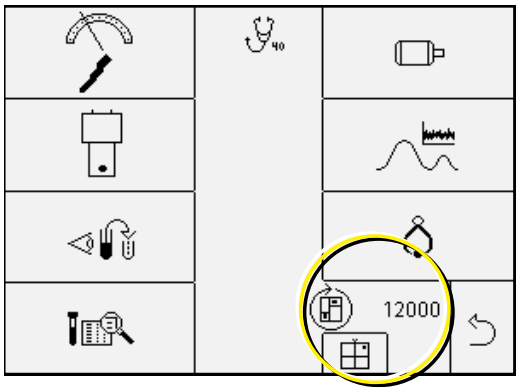
You perform maintenance procedures either on a time schedule or on an instrument cycle schedule. Keep a calendar marked with dates for maintenance and check the Startup results screen for the number of cycles performed.

CAUTION Incorrectly performed maintenance procedures can damage the A^{C}•T diff analyzer. Do not attempt any procedures that are not included in this manual or in the instrument replacement cards. Call your Beckman Coulter Representative for service and maintenance beyond the scope of Beckman Coulter documentation.

Cycle Counter

The cycle counter appears on the Startup results screen and on the Diagnostics screen. The cycle number prints on the Startup report.





6.2 MAINTENANCE SCHEDULE

Table 6.1 Maintenance Schedule

Maintenance Procedure	Frequency	Situation
Startup 	Daily	• Coming out of Shutdown (you touch the **Continue** icon on the screen). • Automatically occurs when powering up after turning the power off during a cycle or after a power interruption during a cycle. • Automatically occurs when powering on more than 2 hours after the previous sample was run.
Shutdown 	Daily	You run Shutdown to clean the instrument. If you consistently run less than 5 samples per day, you may perform Shutdown every other day.

Table 6.1 Maintenance Schedule *(Continued)*

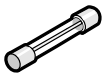
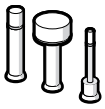
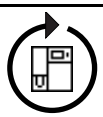
Maintenance Procedure	Frequency	Situation
Clean the baths 	When necessary	• Before any type of calibration. • Increased voteouts. • Decreased cell counts. • Increased MCV values. • Failure to recover control values. • Erratic MCV, RBC and WBC counts.
Calibration 	When necessary or as required by your regulatory agency	• After replacing major component parts such as an aperture bath assembly. • When control values are consistently out of expected assay range.
Replace check valve 	When defective	Clogged or lets liquid or air flow both ways.
Replace fuses 	When blown	• No power. Green power LED is not lit. • Instrument is plugged in but does not run.
Replace diluent filters 	When necessary	• When you get excessive diluent empty messages. • When you replace peristaltic pump tubing. • When a filter is clogged.
Replace peristaltic pump tubing 	When necessary	• When you get excessive diluent empty messages. • When you replace diluent filters. • Tubing is worn to the extent that it looks almost worn through.
Replace syringe pistons and seals 	 **12,000**	• Excessive fluid leaks. • If you see fluid leaking.
Replace probe wipe block 	When defective or plugged.	Fluid drips from probe wipe but vacuum is good and instrument works.
Replace tubing 	Every 3 years	When cracked, leaking or has lost resilience.

Table 6.1 Maintenance Schedule *(Continued)*

Maintenance Procedure	Frequency	Situation
Replace vacuum isolator chamber 	When defective	• When you cannot get it clean. • When it is cracked or damaged or creating a vacuum leak. • If there is buildup under the top, causing Plt and WBC noise problems.
Replace reagents	When empty	When instrument reports empty and the container is empty.

6.3 CLEANING PROCEDURES

These are not routine procedures. Use them only if necessary for troubleshooting or before calibrating.

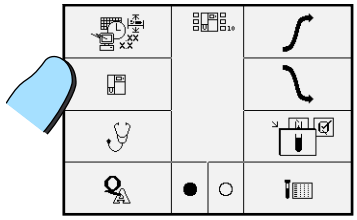
Zap Aperture

Zap the aperture when the instrument:

- Produces increased Aperture Alerts.
- Produces increased voteouts.
- Produces decreased cell counts.
- Produces increased MCV values.
- Fails to recover control values.
- Produces erratic MCV, RBC and WBC counts.

---

1 At the Main screen, touch the **Diluter Functions** icon.



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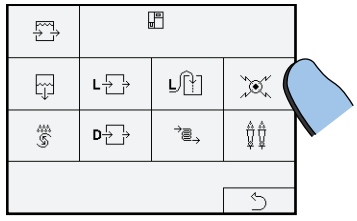
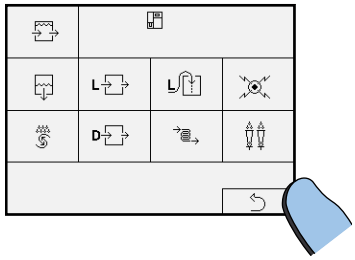
2 At the Diluter Functions, touch the **Zap Aperture** icon.



3 At the Setup screen, touch the **Exit** icon.

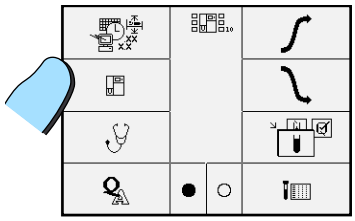


Clean the Baths

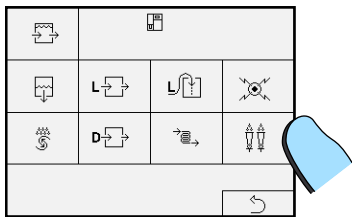
Bleaching removes any clog or debris that restricts proper sample flow. Occasionally, you must do this procedure for troubleshooting.

1 Fill a tube (from which the A^{C}•T diff analyzer can aspirate) with more than 1 mL of high quality, fragrance-free bleach (5% sodium hypochlorite - available chlorine).

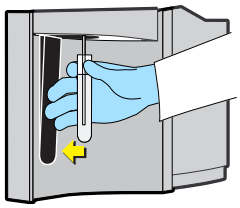
2 At the Main screen, touch the **Diluter Functions** icon



3 At the Diluter Functions screen, touch the **Clean Baths** icon.



4 Present the tube to the probe so that the tip is well into the bleach, and press the aspirate switch.

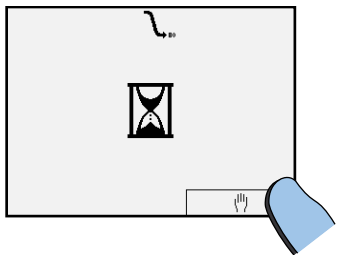


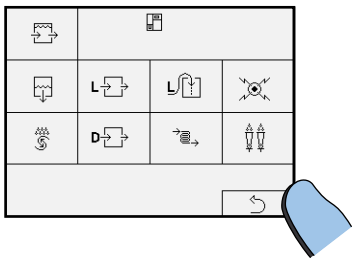
5 The instrument cleans the baths.

6 The cleaning procedure takes approximately 15 minutes to be completed.

> **Note**: If you want to cancel the cleaning procedure before the 15 minute cleaning period ends, touch the **Stop** icon.

When the procedure is completed, the Diluter Functions screen reappears.





Additional Cleaning Procedures

Clean the outside of the instrument with a damp cloth and distilled water. This prevents the buildup of corrosive deposits. Clean up spills promptly. Pay particular attention to the probe wipe housing.

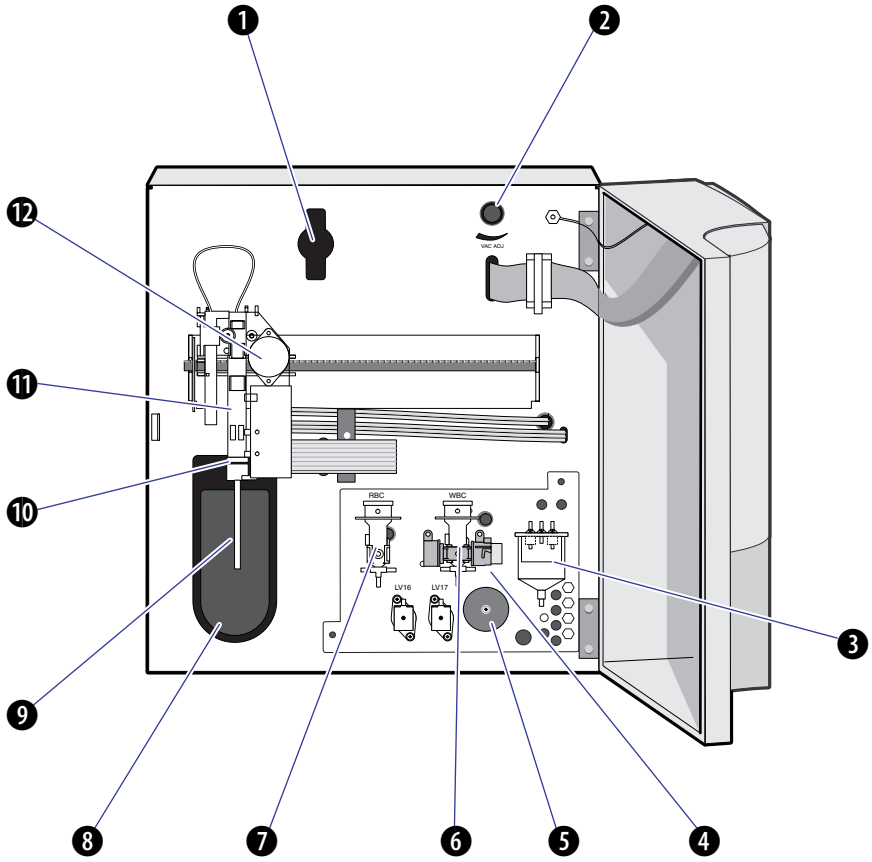
Clean the inside of the instrument (behind the front door and beneath the bath shield) with a damp cloth and distilled water if obvious evidence of corrosive deposits exists. Be careful not to wipe contaminants into the bath. Utilize appropriate barrier protection, as these areas may contain biohazardous material.

6.4 CALIBRATION PROCEDURES

See Chapter 5, Calibration.

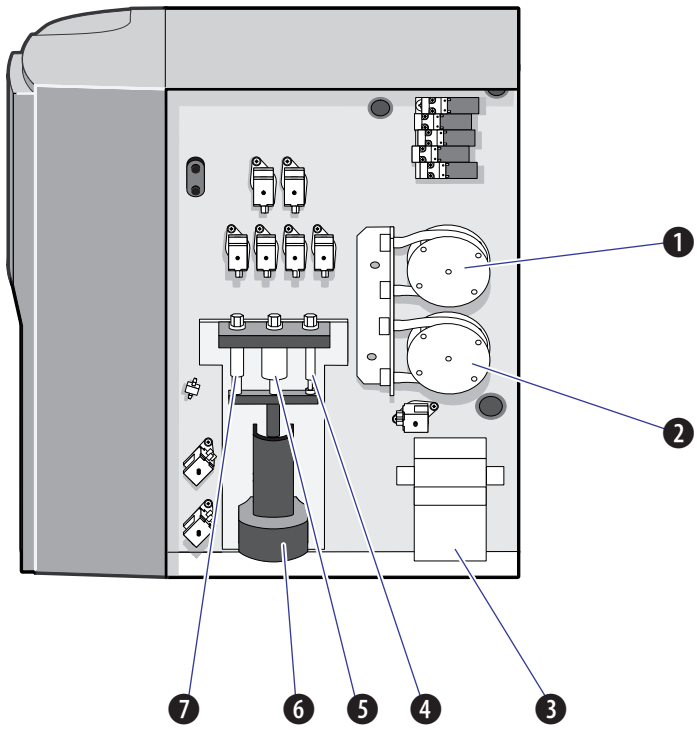
6.5 A^{C}•T diff ANALYZER COMPONENT LOCATIONS

Inside Front



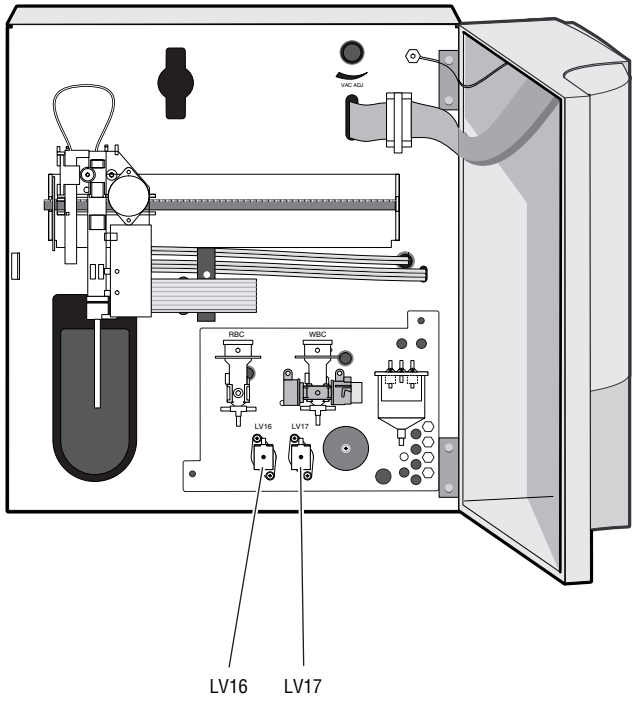
1. Software Card Slot
2. Vacuum Adjust
3. Vacuum Isolator Chamber
4. Hgb Lamp
5. Sweepflow Spool
6. WBC Bath
7. RBC Bath
8. Aspirate Switch
9. Probe
10. Probe Wipe Block
11. Horizontal Traverse Assembly
12. Horizontal Traverse Motor

Inside Right



1. Waste/Rinse Pump
2. Diluent Pump
3. Diluent Reservoir
4. Aspiration Syringe (0.25 mL)
5. Diluent Syringe (5 mL)
6. Syringe Module
7. Lytic Reagent Syringe (1 mL)

Valves, Inside Front

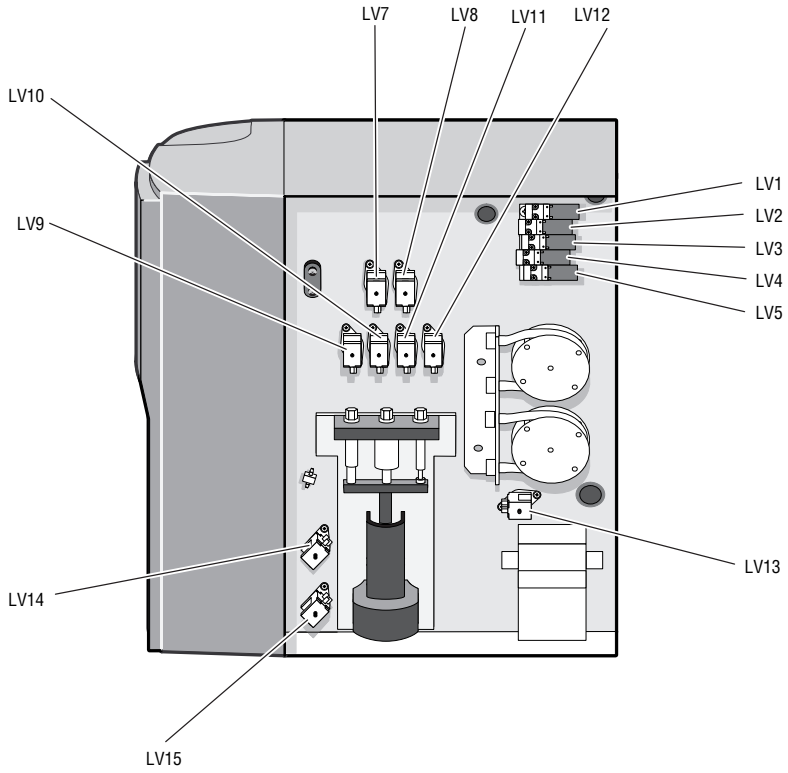


LV16 On = Opens count path from RBC bath.

OFF = Closes count path from RBC bath.

LV17 ON = Opens count path from WBC bath.
OFF = Closes count path from WBC bath.

Valves, Inside Right



LV1 Open top of Vacuum Isolator Chamber to vent.

LV2 ON = High vacuum.
OFF = Low vacuum.

LV3 ON = Sends mixing bubbles to the WBC bath.
OFF = Sends mixing bubbles to the RBC bath.

LV4 ON = side of WBC bath.
OFF = bottom of WBC bath.

LV5 ON = Vacuum pump vent sending mixing bubbles.

OFF = Vacuum pump venting to atmosphere.

LV7 ON = Prefill to RBC bath.
OFF = Prefill to WBC bath.

LV8 ON = Opens probe wash drain to vacuum isolator chamber.
OFF = closes probe wash drain to vacuum isolator chamber.

LV9 ON = Lytic reagent syringe connected to bath.
OFF = Lytic reagent syringe connected to lytic reagent source.

LV10 ON = Diluent pump goes to the probe wash.
OFF = Diluent pump goes to the diluent reservoir.

LV11 ON = Diluent from the syringe goes to LV7 (bath prefill).
OFF = Probe connected to syringes for aspirate or diluent dispense.

LV12 ON = Diluent syringe connected to aspirate syringe.

OFF = Diluent syringe connected to diluent reservoir.

LV13 ON = Waste pump inputs from cleaner.
OFF = Waste pump outputs to waste.

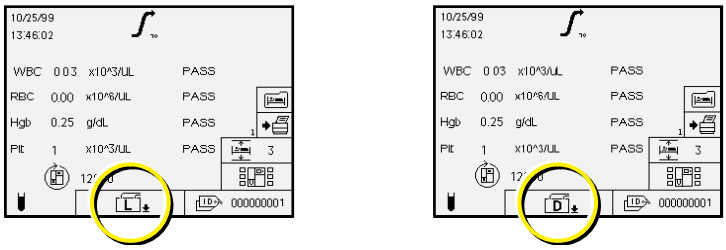
LV14 ON = Drains WBC bath.
OFF = Drains RBC bath.

LV15 ON = Drains vacuum isolator chamber.
OFF = Drains bath specified by LV14.

6.6 REPLACING REAGENTS

For information on connecting the reagents the first time, see the Installation and Training Guide.

Change the reagent container when you see one of these symbols:



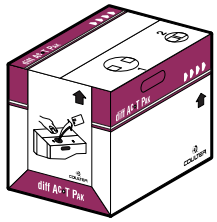
Replacing the diff A^{C}•T Pak™ Reagent

Periodically check the expiration date on the reagent container. Do not use an expired reagent. Replace the reagent if the existing reagent is expired or empty.

---

1 Be sure your reagent is the diff A^{C}•T Pak reagent.

If you have the diff A^{C}•T Tainer reagent, do the Replacing the diff AC•T Tainer™ Reagent procedure.



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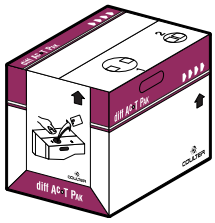
2 Check to see if the reagent container is empty.

- If the container is not empty, touch the **Reagent** icon on the screen to prime.
- If the container is empty, go to step 3.

3 Remove the diff A^{C}•T Pak reagent management card from the instrument.

Note: Keep the card for use with IQAP if your laboratory is a participant in Beckman Coulter's IQAP program.

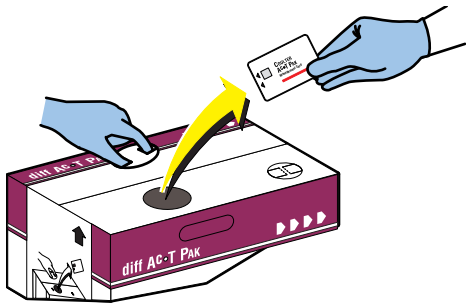
4 Get a new diff A^{C}•T Pak reagent container.



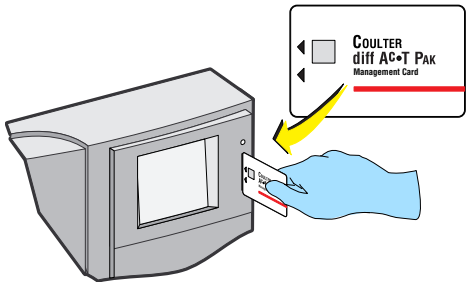
5 Remove the diff A^{C}•T Pak reagent management card from the reagent container box:

a. Pull the perforated cardboard from the reagent container box.

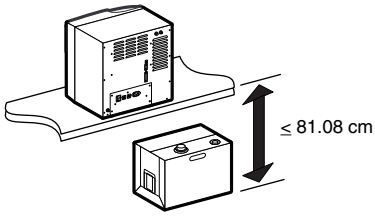
b. Remove the management card.



c. At the front of the instrument, insert the management card from the reagent container into the slot, with the writing facing the touch screen.

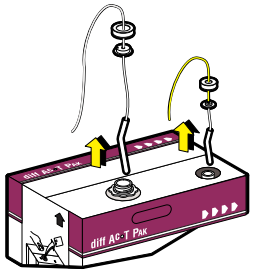


6 Place the reagent container on the floor or on a shelf no more than 32 in. (81 cm) below the A^{C}•T diff analyzer.



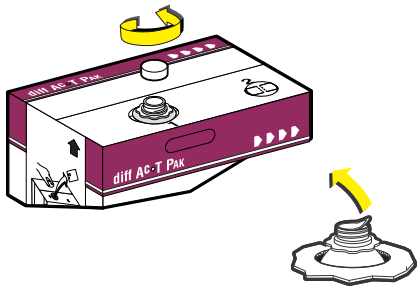
7 Remove the pickup tubes from the used reagent container:

a. Unscrew the cap.
b. Pull the reagent tube from the container.



8 Prepare to connect reagent pickup tube 1 to the reagent container.

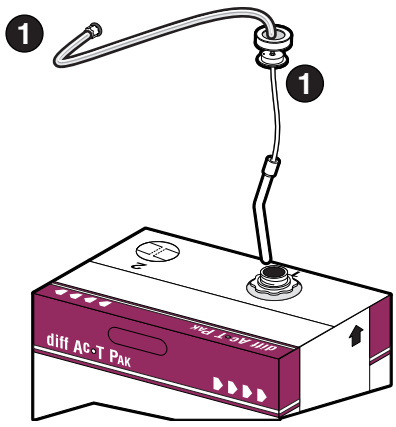
a. Unscrew the cap from 1 on the new reagent container box.
b. Remove the seal to expose the opening.



9 Connect pickup tube 1 to the reagent container box:

a. Insert the cap end of pickup tube 1 into opening 1 of the reagent container.

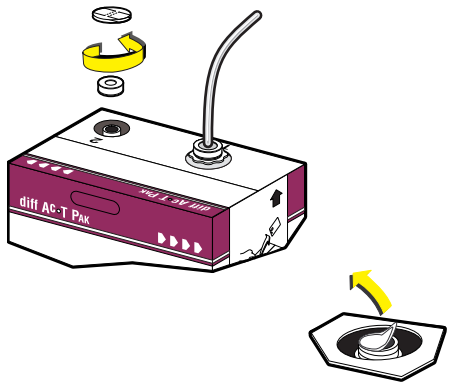
b. Screw the cap to the box.



10 Prepare to connect reagent pickup tube 2 to the reagent container

a. Unscrew the cap from 2 on the new reagent container box.

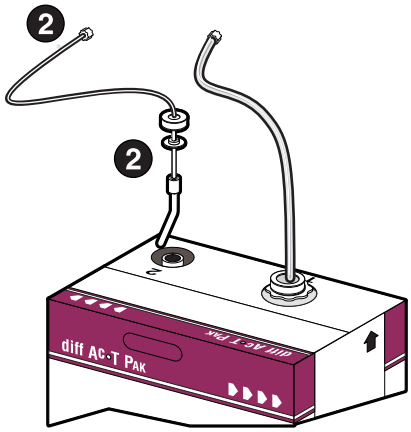
b. Remove the seal to expose the opening.



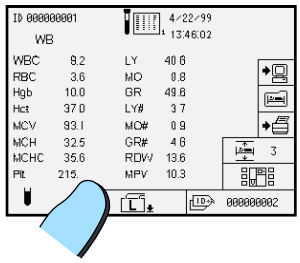
11 Connect pickup tube 2 to the reagent container box:

a. Insert the cap end of pickup tube 2 into opening 2 of the reagent container.

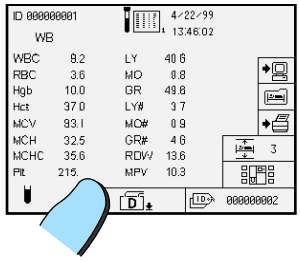
b. Screw the cap to the box.



12 Touch the **Lyse Prime** icon, if displayed.



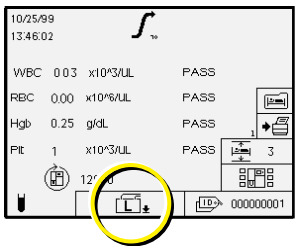
13 Touch the **Diluent Prime** icon, if displayed.

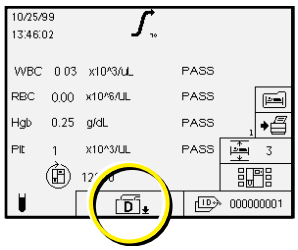


14 In your laboratory log book, record the reagent lot number and expiration date from the new diff A^{C}•T Pak reagent.

Replacing the diff A^{C}•T Tainer™ Reagent

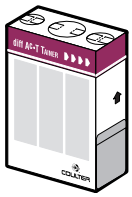
Change the reagent container when you see one of these symbols:





---

1 Be sure your reagent is the diff A^{C}•T Tainer reagent.



If you have the diff A^{C}•T Pak reagent, do Replacing the diff A^{C}•T Pak Reagent in this chapter.

---

2 Check to see if the reagent container is empty.

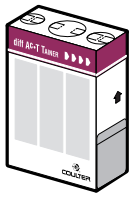
- If the container is not empty, touch the **Reagent** icon on the screen to prime.
- If the container is empty, go to step 3.

---

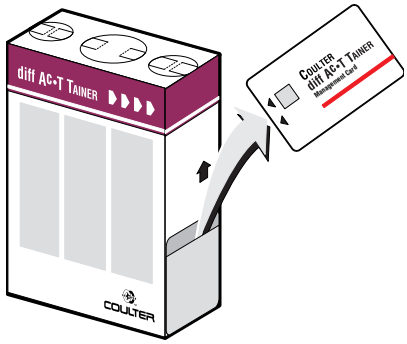
3 Remove the diff A^{C}•T Tainer reagent management card from the instrument.

Note: Keep the card for use with IQAP if your laboratory is a participant in Beckman Coulter's IQAP program.

4 Get a new diff A^{C}•T Tainer reagent container.

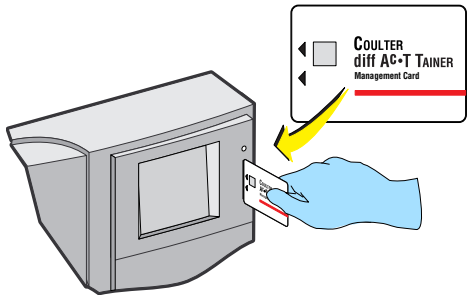


5 Remove the new reagent management card from the sleeve on the reagent container.

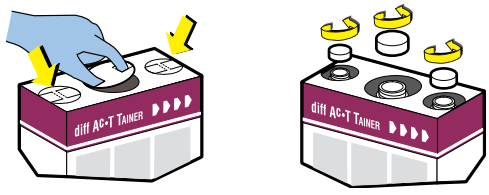


6 Insert the diff A^{C}•T Tainer reagent management card from the new reagent container into the slot at the front of the instrument.

Be sure the writing is up and facing the touch screen.

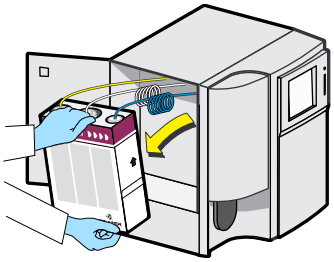


7 Unscrew the three white plastic caps from the container.



8 Remove the seals to expose each opening.

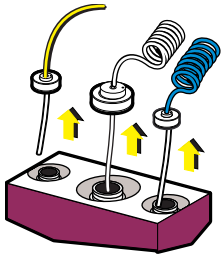
9 Open the reagent compartment door and remove the empty diff A^{C}•T Tainer reagent.



10 Remove the pickup tubes from the reagent container:

a. Unscrew the caps.

b. Pull the reagent tubes from the container.



11 Connect pickup tubes 1, 2, and 3 to the new reagent container box:

a. Insert the cap end of pickup tube 1 into opening 1 of the reagent container.

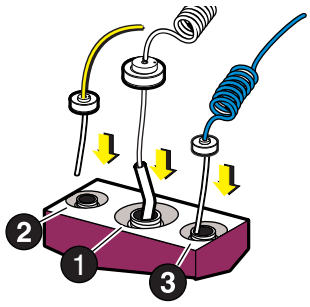
b. Screw the cap to the container.

c. Insert the cap end of pickup tube 2 into opening 2 of the reagent container.

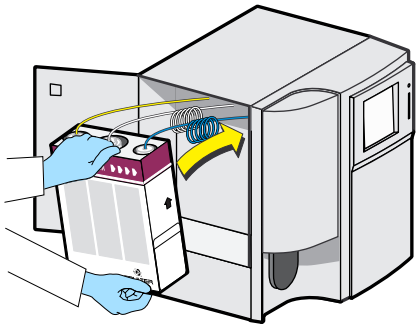
d. Screw the cap to the container.

e. Insert the cap end of pickup tube 3 into opening 3 of the reagent container.

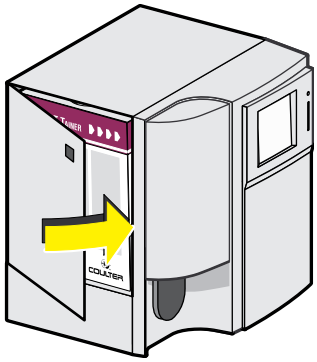
f. Screw the cap to the container.



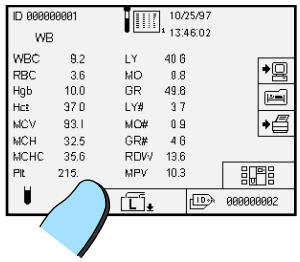
12 Place the container, with tubes attached, in the reagent compartment.



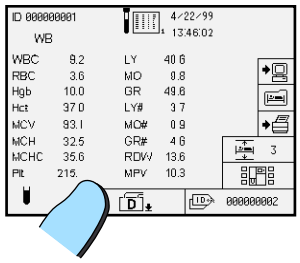
13 Close the reagent compartment door.



14 Touch the **Lyse Prime** icon, if displayed.



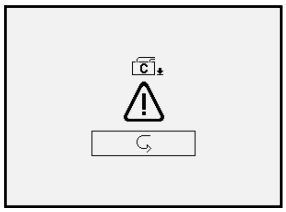
15 Touch the **Diluent Prime** icon, if displayed.



16 In your laboratory log book, record the reagent lot number and expiration date from the new diff A^{C}•T Tainer reagent.

Replacing the A^{C} •T Rinse™ Shutdown Diluent

Replace the A^{C}•T Rinse shutdown diluent container when you see:



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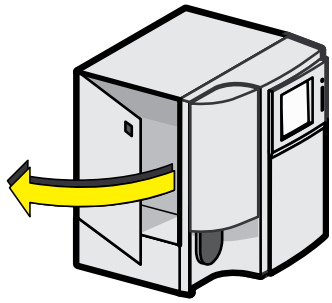
1 Check to see if the A^{C}•T Rinse shutdown diluent container is empty.

- If it is not empty, touch the **Continue** icon to prime the rinse lines.
- If it is empty, go to step 2.

---

2 Open the reagent compartment door and remove the rinse container (with tubing still attached.)

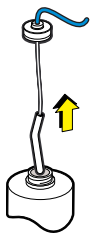


---

3 Remove pickup tube from the rinse container:

a. Unscrew the cap.

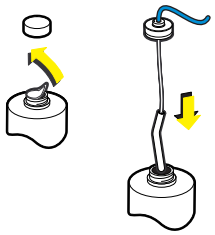
b. Pull the tube from the container.



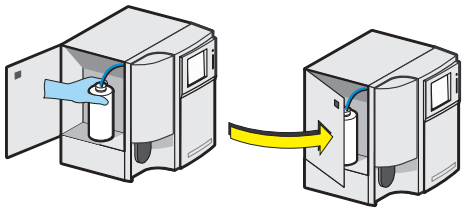
4 Connect pickup tubes to the new diluent container:

a. Insert the cap end of pickup tube into the rinse container.

b. Screw the cap to the box.



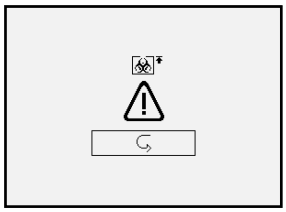
5 Place the new rinse container into the reagent management compartment and close the door.



6 Touch the **Continue** icon.

6.7 REPLACING THE WASTE CONTAINER

Replace the waste container when you see:

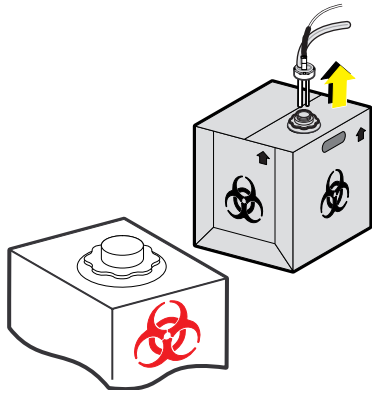


WARNING Waste can include biohazardous material that could cause contamination. Handle and dispose of according to acceptable laboratory standards.

Do not operate the instrument if the waste sensor level is disconnected.

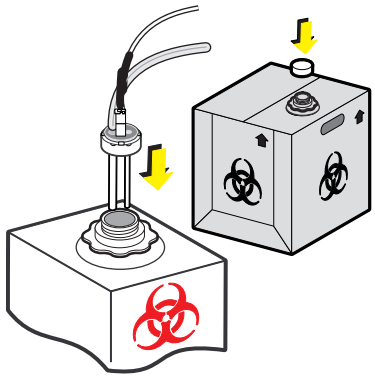
---

1 Remove the tubing from the full waste container.



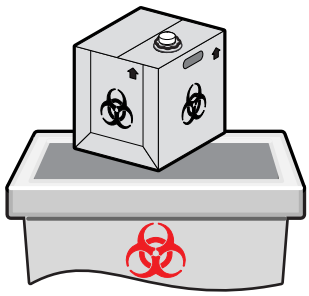
---

2 Insert the tubing into the new waste container, securing the cap by turning clockwise.



3 Touch the **Continue** icon.

4 Place a cap on the full waste container and dispose of properly.



6.8 REPLACING DILUENT FILTERS

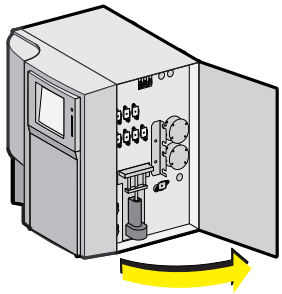
To optimize instrument performance, replace the diluent filters when you replace the peristaltic pump tubing.

Note: If the vacuum fluid barrier filter becomes plugged, replace it with the following method.

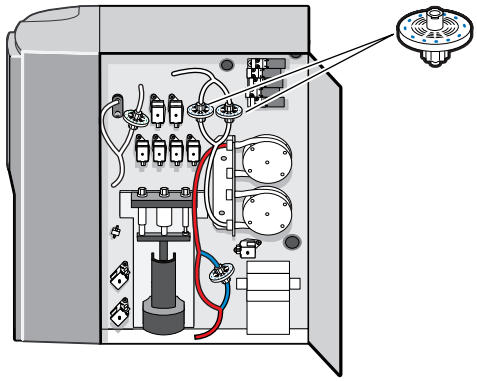
WARNING Possible injury to hands. The peristaltic pumps rotate at various intervals during a normal run. To avoid injury, do not put your hands in the area while the instrument is on.

1 Turn instrument off.

2 Open the right compartment door.



3 Locate the diluent filters.



4 Remove the diluent filter from the tubing:

a. Twist the connector until completely loosened from fitting.

b. Pull tubing from diluent filter.

5 Repeat steps 4 at other end, twisting filter counterclockwise to remove.

6 Properly dispose of diluent filter.

7 Connect a new diluent filter to the tubing by inserting tubing end into filter and turning the connector until secure.

8 Repeat step 7 to connect the other end of the diluent filter.

9 Close the right compartment door.

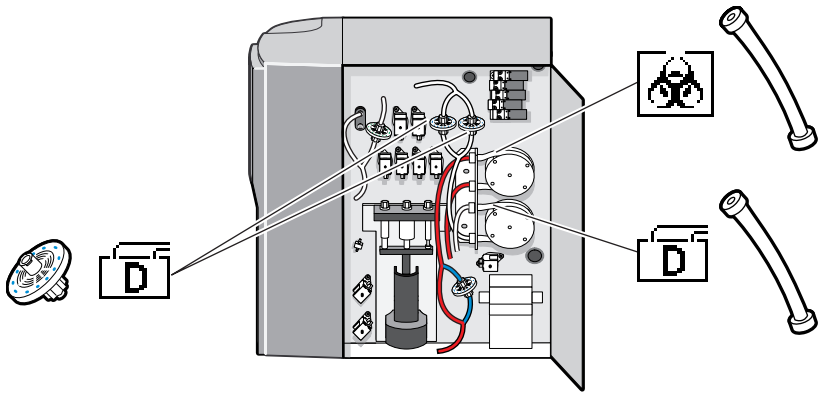
10 Turn the instrument on.

11 Cycle a sample with known results to verify instrument performance.

12 If you are doing this procedure as part of the REPLACING PERISTALTIC PUMP TUBING procedure, go to step 16 of that procedure to continue.

6.9 REPLACING PERISTALTIC PUMP TUBING

To optimize instrument performance, replace the peristaltic pump tubing when you get excessive diluent empty messages. At the same time, replace the diluent filters (see Heading 6.8). Also, check periodically for defects or twists in the tubing or for pump rollers that are not rotating properly as these things may cause the tubing to wear more quickly.



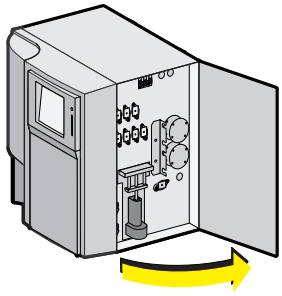
WARNING Possible injury to hands. The peristaltic pumps rotate at various intervals during a normal run. To avoid injury, do not put your hands in the area while the instrument is cycling

---

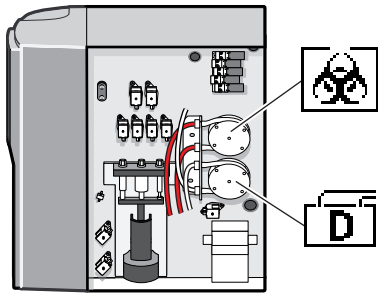
1 Turn the instrument off.

WARNING The waste pump tubing can contain biohazardous material that can cause contamination if not handled properly. Handle these components according to acceptable laboratory practices.

2 Open the right compartment door.



3 Locate the biohazardous waste pump and the diluent/rinse pump.



4 Pull the tubing from the top groove and stretch the tubing over the pump.

5 Disconnect the pump tubing by pulling it apart.

6 Pull the tubing from the bottom groove.

7 Disconnect the tubing.

8 Properly dispose of used tubing.

9 Connect the new pump tubing to the tubing for the bottom connector.

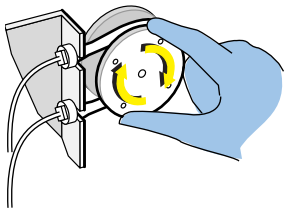
10 Place newly connecting tubing in bottom groove.

11 Stretch tubing around pump, using care not to twist or crimp tubing.

Insert tubing into top groove.

12 Connect the tubing to the top connector of the pump tubing.

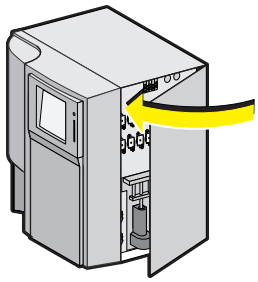
13 Rotate the pump clockwise four times.



14 Repeat steps 3 through 13 for the remaining pump.

15 Do Heading 6.8, Replacing Diluent Filters.

16 After you have installed new tubing for both pumps, close the right compartment door.

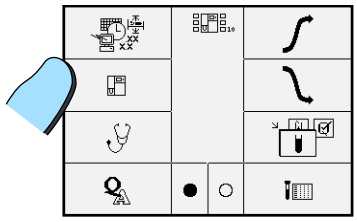


17 Turn the instrument on.

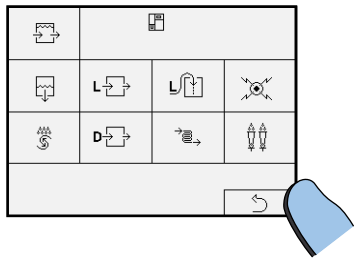
18 Prime the diluent lines:

a. At the Main screen, touch the **Diluter Functions** icon.

b. At the Diluter Functions screen, touch the **Wet Prime** icon.



19 When the instrument is finished priming, touch the **Exit** icon.



20 Cycle a sample with known results to verify instrument performance.

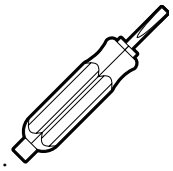
6.10 REPLACING CHECK VALVES

Check valves allow liquid or air to flow through in one direction only.

Replace a check valve if:

- It is clogged.
- It lets liquid or air flow both ways.

A regular, flathead screwdriver is needed for this procedure.



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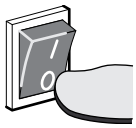
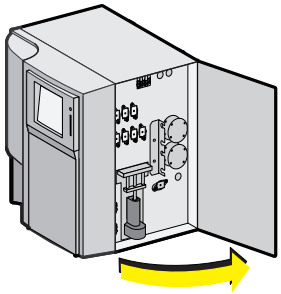
1 Turn the instrument off.

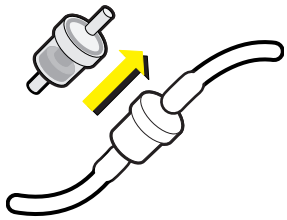


---

2 Open the right compartment door.

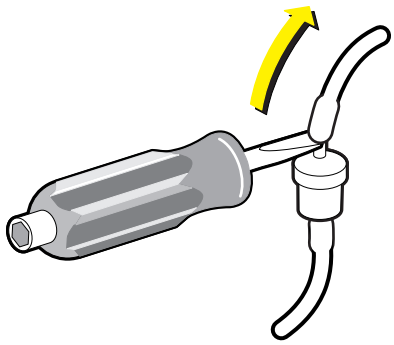


3 **Note** the direction that the check valve is pointing before you remove it.

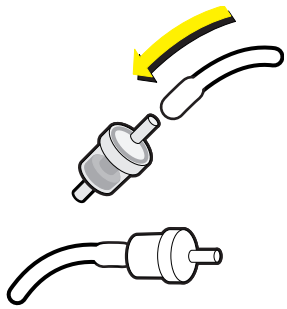


WARNING Biohazardous material might be contained in the check valves and associated tubing and could cause contamination unless handled with care. Wear protective gear. Avoid skin contact. Clean up spills immediately. Dispose of valve and tubing according to acceptable laboratory procedures for biohazardous materials.

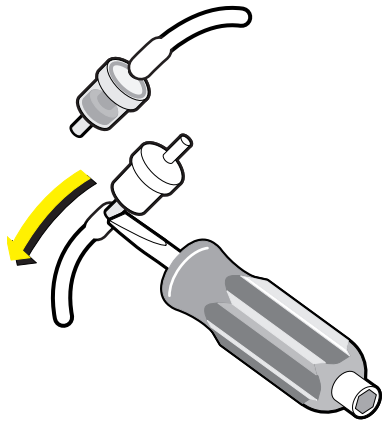
4 Use a screwdriver to pry the tubing from the top of the check valve.



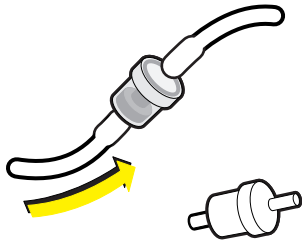
5 Connect the tubing to the top of the new check valve.



6 Use a screwdriver to pry the tubing from the bottom of the old check valve.

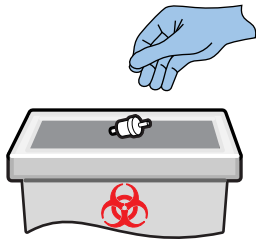


7 Connect the tubing to the bottom of the new check valve.

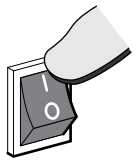


IMPORTANT To avoid obtaining misleading results, make sure the new valve is in the same position as the old one.

8 Properly dispose of used check valve.



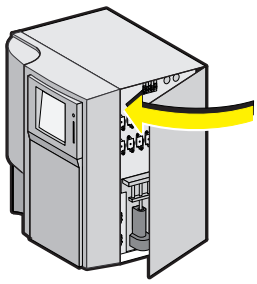
9 Turn the instrument on.



10 Cycle a sample with known results to verify instrument performance.

Watch the sample and ensure that the check valve is working properly and does not leak.

11 After you verify that the check valve is not leaking, close the right compartment door.



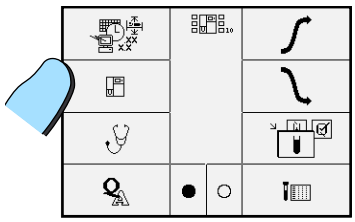
6.11 REPLACING TUBING

Replace tubing if it is cracked, leaking or has lost resilience.

Scissors are needed for this procedure.

---

1 At the main menu screen, touch the **Diluter Functions** icon.



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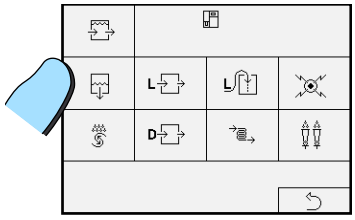
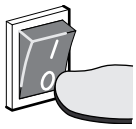
2 At the Diluter Functions screen, touch the **Drain Baths** icon.



---

3 Turn the instrument off.



---

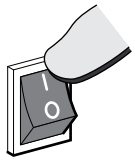
4 Remove the tubing section from the two components it connects.

5 Measure the new tubing of the same material, color code and bore size of the old tubing you just removed.

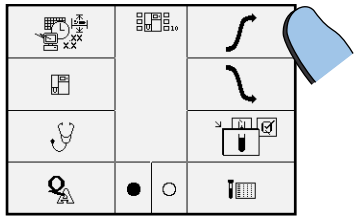
6 Cut the new tubing with scissors at the desired length.

7 Push new tubing onto the two components it is to connect.

8 Turn the instrument on.



9 At the Main screen, touch the **Startup** icon.



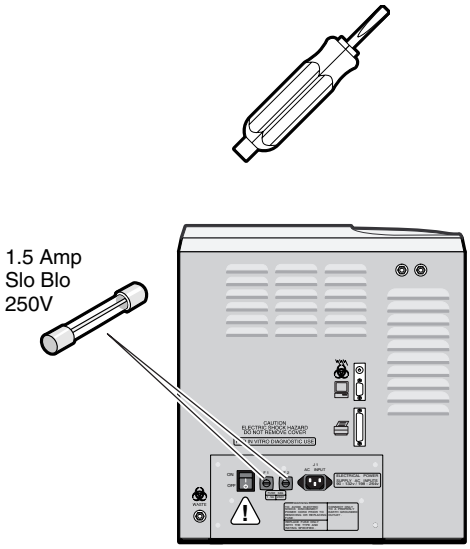
10 Run a sample with known results to verify instrument performance.

Note: Make sure that the new tubing is correctly connected and does not leak.

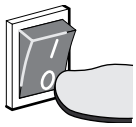
6.12 REPLACING FUSES

Replace fuses as needed.

A regular, flathead screwdriver is needed for this procedure.

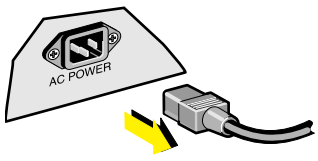


1 Turn the instrument off.

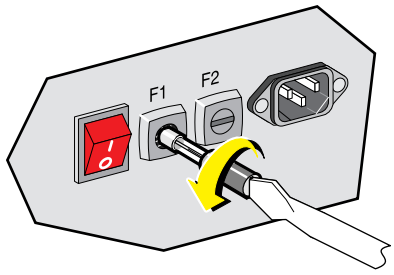


CAUTION Risk of electrical shock. Avoid electrical shock by unplugging the instrument's power cord.

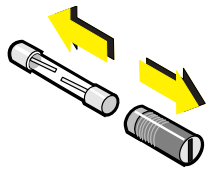
2 Unplug the power cord from the back of the instrument where AC INPUT is marked.



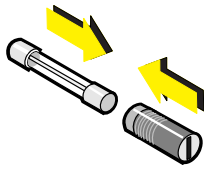
3 Unscrew the fuse holder from the back of the instrument, where F1 is marked.



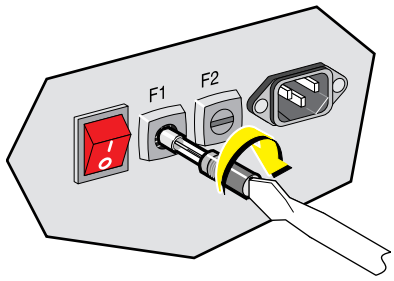
4 Pull the fuse out of the holder.



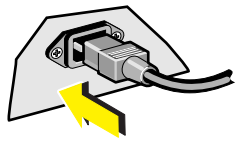
5 Insert the new fuse into the holder.



6 Screw the fuse holder back into the instrument at F1.



7 Plug the power cord back into the instrument at AC INPUT.



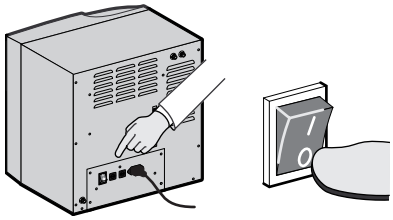
8 Turn the instrument on.

6.13 REPLACING VACUUM ISOLATOR CHAMBER

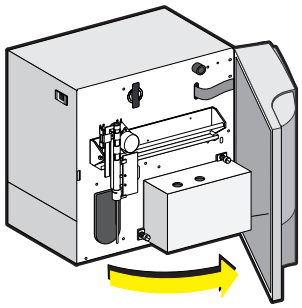
Replace the Vacuum Isolator Chamber (VIC) when it is defective. See Table 6.1 for defective situations.

Needle-nose pliers are needed for this procedure; they are not provided with the instrument.

1 Turn the instrument off.

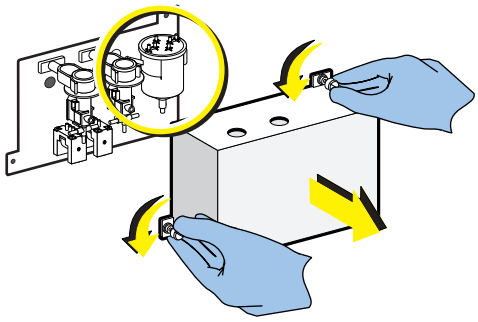


2 Open the front door.



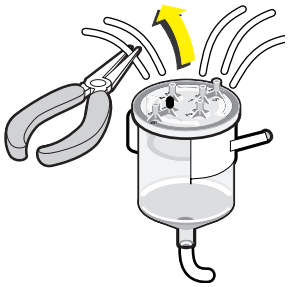
WARNING The waste pump tubing can contain biohazardous material that could cause contamination if not handled properly. Handle these components according to acceptable laboratory practices.

3 Remove the metal cover and locate the VIC.



4 Use the pliers to remove the numbered tubing from the top of the VIC.

Note: If tubing to the VIC is worn or cracked, replace it with new tubing from your accessory kit.



5 Remove the VIC from its holder.

6 Use the pliers to remove the tubing from the bottom of the VIC.

7 Properly dispose of the used VIC.

8 Connect the tubing to the bottom of the new VIC.

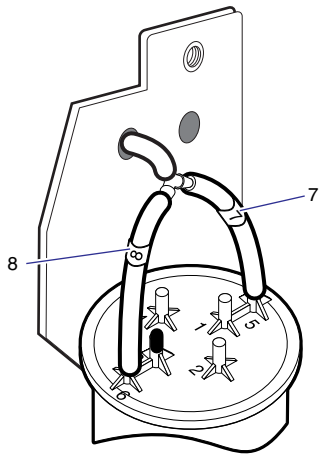
9 Insert the new VIC into the holder.

10 Connect the tubing:

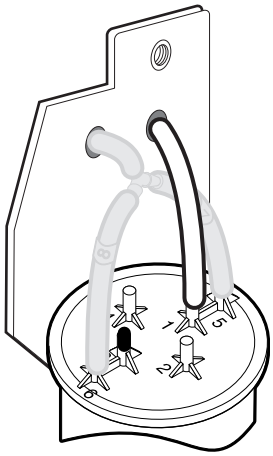
a. Connect tubing number 8 to fitting number 6 on the VIC.

b. Connect tubing number 7 to fitting number 5 on the VIC.

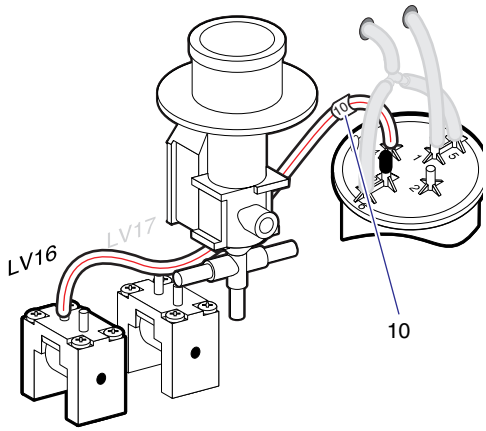
Note: The tubing and the VIC fittings are not numbered the same due to the quantity of fittings throughout the entire instrument.



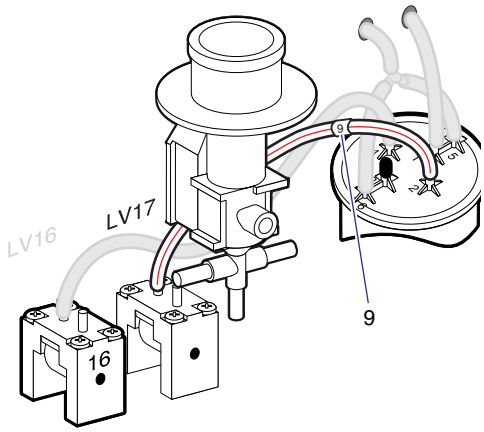
11 Connect tubing number 6 to fitting number 1 on the VIC.



12 Connect tubing number 10 from LV16 to fitting number 4 on the VIC, feeding the tubing as shown.



13 Connect tubing number 9 from LV17 to fitting number 2 on the VIC.

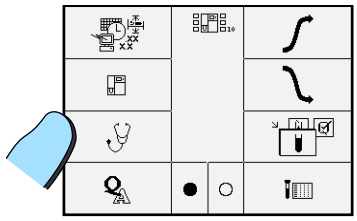


14 Replace the metal cover and secure.

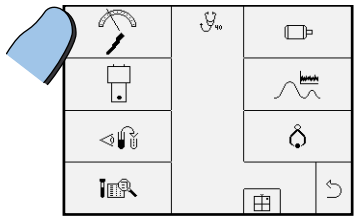
15 Close the front door.

16 Turn the instrument on.

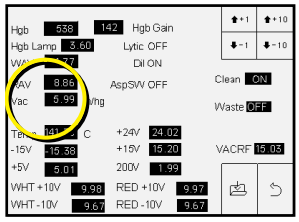
17 At the Main screen, touch the **Diagnostics** icon.



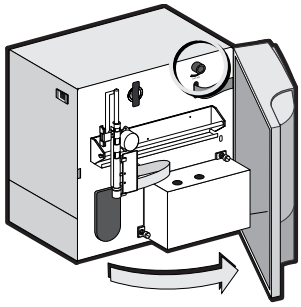
18 At the Diagnostics screen, touch the **Voltages/Sensors** icon.



19 Locate the vacuum setting indicator.

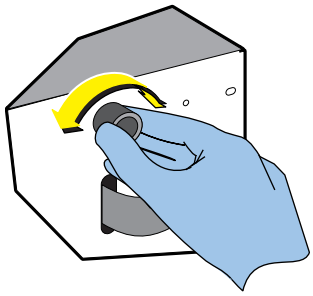


20 Open the front door and locate the vacuum adjustment knob.

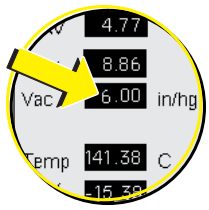


21 Adjust the setting:

a. Turn the knob to adjust the setting to 6.00 (±0.02) in/hg.



b. Verify that the setting is acceptable.



22 Cycle a sample with known results to verify instrument's performance.

6.14 REPLACING SYRINGE PISTONS AND SYRINGE ASSEMBLIES

To optimize instrument performance, replace the syringe pistons or syringe assemblies every 12,000 cycles. (See Heading 6.1 for instructions on how to determine the cycle count.) When replacing more than one syringe piston, be sure to replace them one at-a-time to ensure that you do not misplace the plungers. (See Heading 6.1 for how to determine the cycle count.)

Also, periodically check to see if excessive amounts of liquid appear to be leaking from any of the syringes. If there are, clean the syringe and perform a reproducibility test (Heading 5.3).

- If the reproducibility test passes, the suspected syringe is not defective.
- If the reproducibility test fails, then replace the syringe piston.

Note: It is normal for a small amount of fluid to escape between the seal and the glass barrel. The fluid is a lubricant that helps extend the life of the syringe.

There are two styles of diluent and sample syringes – the original sytle (without covers) and the modified style (equipped with a flexible, protective covers.

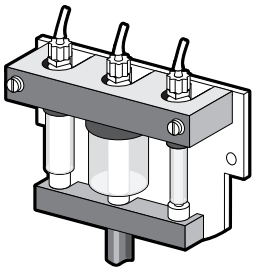


Figure 6.1 Syringe Assembly Without Covers

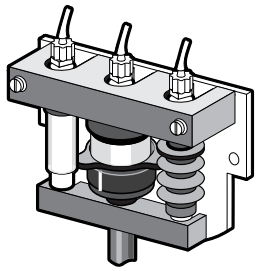
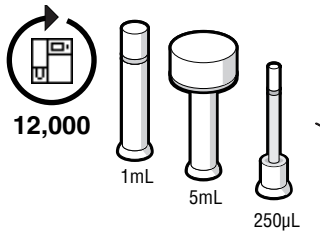
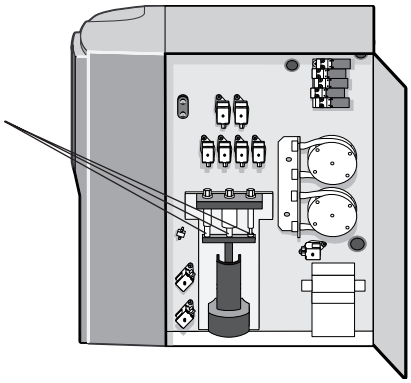
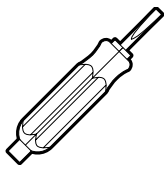


Figure 6.2 Syringe Assembly With Covers





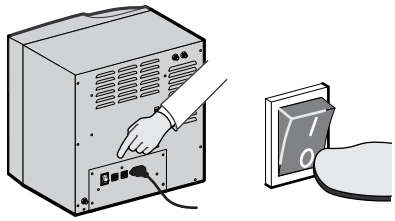
A regular, flathead screwdriver is needed for this procedure.



Note: This procedure illustrates the modified style of diluent and sample syringes. Your instrument may be different from what is shown here.

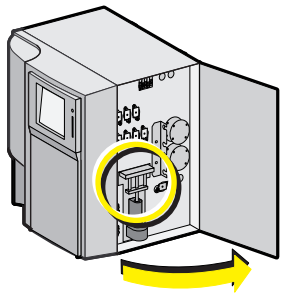
---

1 Turn the instrument off.



---

2 Open the right compartment door and locate the syringes.

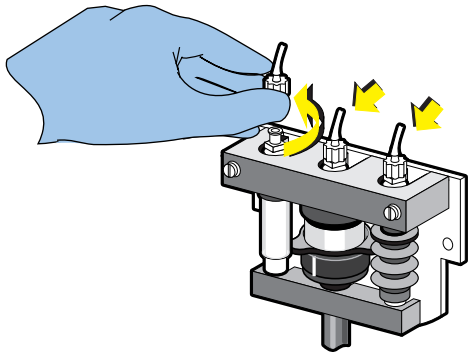


---

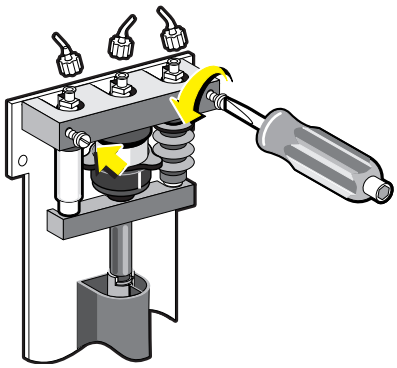
3 Remove the connectors from the syringes:

a. Turn the connectors counterclockwise until loosened.

b. Pull the connector from the syringe fitting.



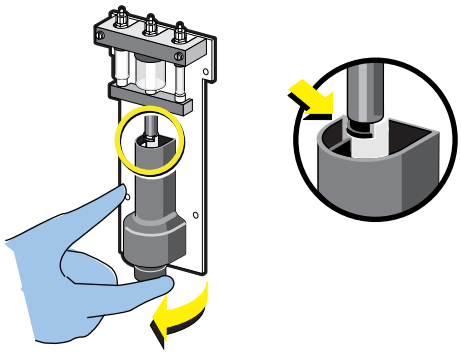
4 Unfasten the screws securing the top bracket.



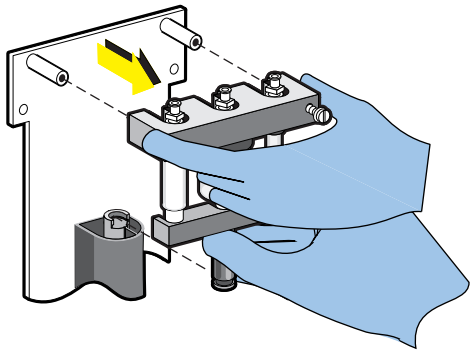
5 Raise the pistons until the motor shaft coupling is visible:

a. Locate the knob on the bottom of the motor.

b. Turn the knob clockwise until the motor shaft coupling is visible.

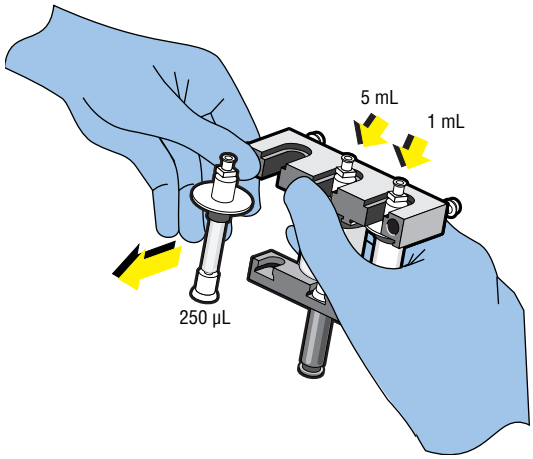


6 Remove the syringe assembly.

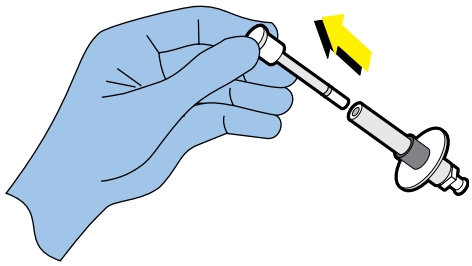


7 Remove the syringe from the bracket.

- If the replacement syringe has a flexible, protective cover, go to step 11.
- If the replacement syringe does not have a flexible, protective cover, continue to step 8.



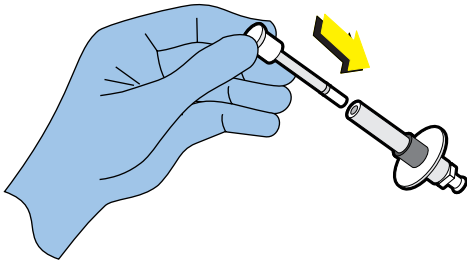
8 Remove the piston from the barrel.



9 **Note**: Do not dispose of the barrel.

Properly dispose of only the old **piston**.

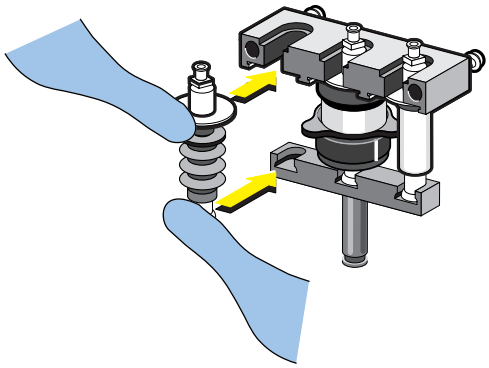
10 Insert the new piston into the barrel.



11 Insert the replacement syringe into the bracket:

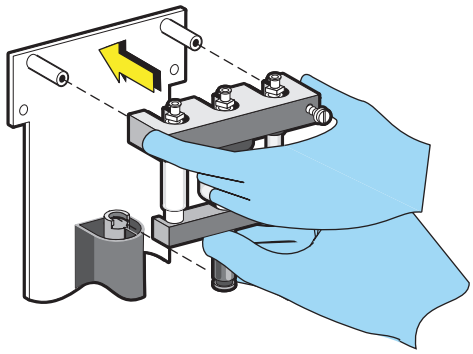
a. Insert the flange into the groove.

b. Slide the syringe all the way into the bracket.

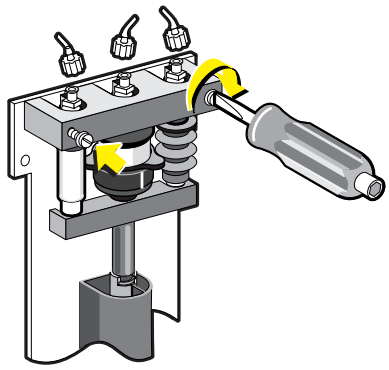


12 Repeat steps 7 through 11 as needed for the other syringes.

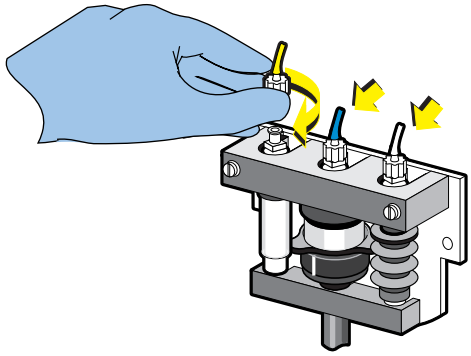
13 Slide the syringe assembly onto the screw posts and the motor shaft.



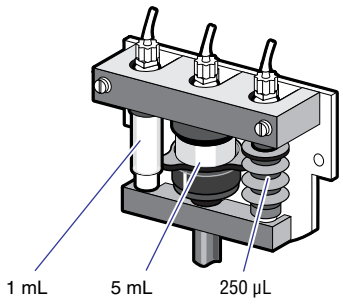
14 Secure the bracket onto the posts using the screws you unfastened in step 4.



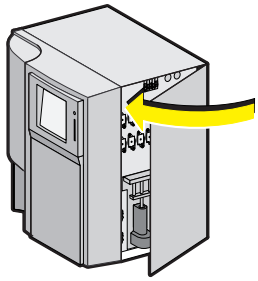
15 Reattach the connectors to the fittings and firmly tighten the connectors.



16 Be sure that the syringes are in the bracket as shown.

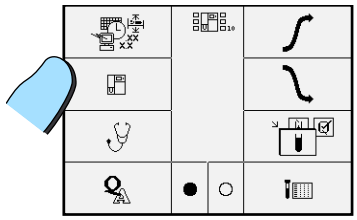


17 Close the right compartment door.

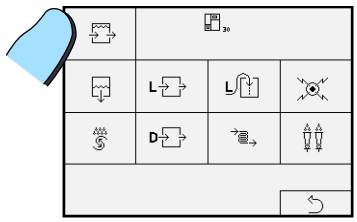


18 Turn the instrument on.

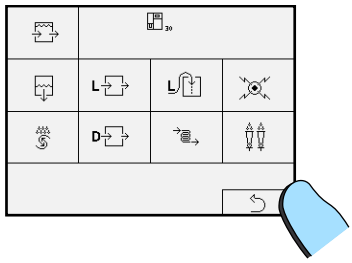
19 At the Main screen, touch the **Diluter Functions** icon.



20 At the Diluter Functions screen, touch the **Wet Prime** icon.



21 After the instrument finishes the wet prime, touch the **Exit** icon.

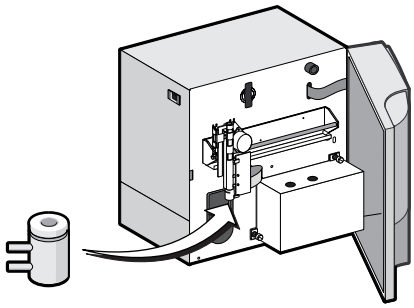


22 Cycle a sample with known results to verify instrument's performance.

6.15 REPLACING THE PROBE WIPE

Replace the probe wipe when it is defective or plugged. If fluid drips from the probe wipe but vacuum is good and the instrument works, then the probe wipe is probably defective and you should replace it.

Do not attempt to run the instrument if the probe is bent or loose.

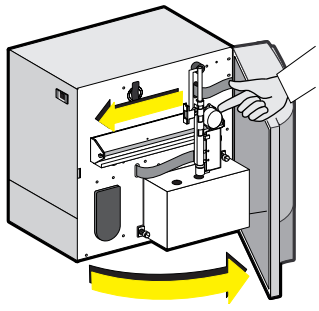


---

1 Turn the instrument off.

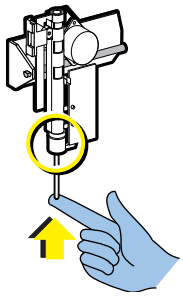
---

2 Open the front door and slide the probe assembly to the left.

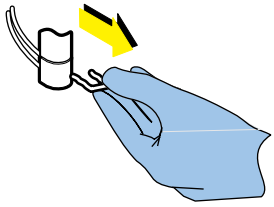


WARNING To avoid being exposed to biohazardous material, adhere to standard laboratory safety procedures.

3 Push the aspiration probe up into the probe assembly.



4 Remove the metal clip that holds the probe wipe in the probe assembly.

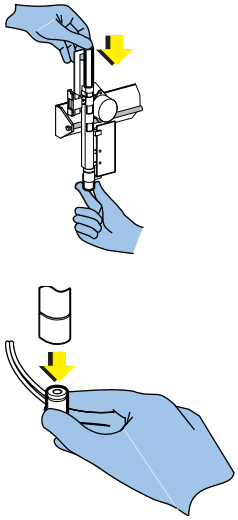


5 Remove the probe wipe from the assembly:

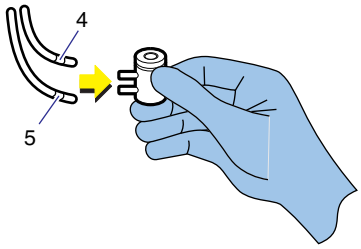
a. Using your left hand, grasp the vertical bar.

b. Using your right hand, reach behind the bottom of the probe assembly and grasp the tubing.

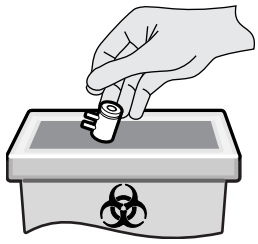
c. Simultaneously, pull the bar up with your left hand and pull the probe wipe tubing down with your right hand.



6 Remove the tubing from the probe wipe.



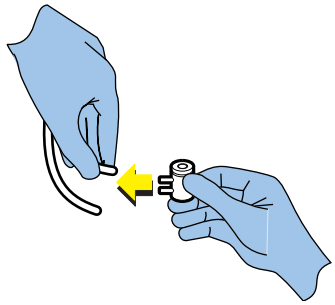
7 Properly dispose of the probe wipe.



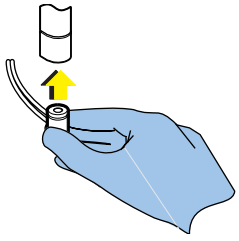
8 Connect the tubing to the new probe wipe:

a. Connect tubing number 4 to the top fitting.

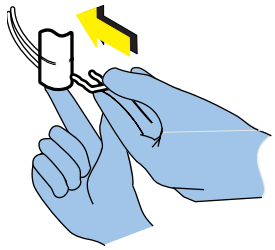
b. Connect tubing number 5 to the bottom fitting.



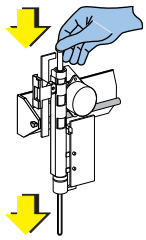
9 Insert the probe wipe into the assembly, with the groove at the top of the wipe.



10 Slide the clip into the groove of the probe assembly to secure the probe wipe.



11 Push the vertical bar all the way down so the aspiration probe is fully descended.



12 Close the front door.

13 Turn the instrument on.

14 Cycle a sample with known results to verify instrument's performance.

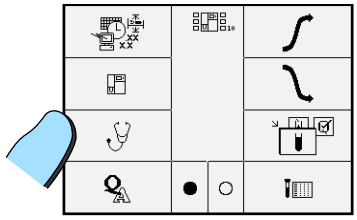
6.16 PREPARING TO SHIP THE INSTRUMENT

When you have done all the troubleshooting and still cannot fix the problem, call your Beckman Coulter Representative. **If directed to**, follow the authorization procedures and prepare the instrument for shipment as follows.

Two containers, bleach, distilled water, and paper towels are needed for this procedure.

---

1 At the Main screen, touch the **Diagnostics** icon.



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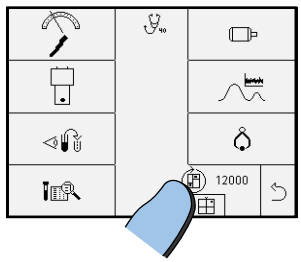
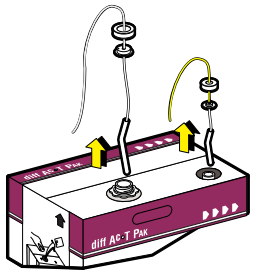
2 At the Diagnostics screen, touch the **Prepare to Ship** icon.



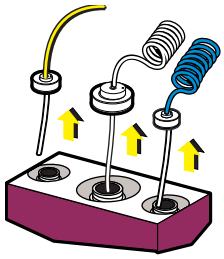
WARNING Instrument tubing can contain biohazardous material that can cause contamination if not handled properly. Handle these components according to acceptable laboratory practices.

3 Remove the diluent and lytic reagent pickup tubes from the reagent containers.

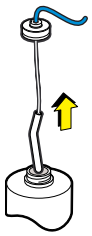
- For diff A^{C}•T Pak reagent, remove both pickup tubes



- For diff A^{C}•T Tainer reagent, remove all three pickup tubes

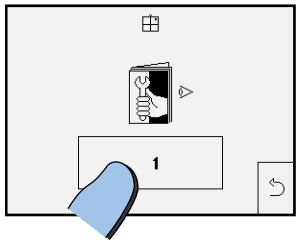


4 Remove the pickup tubes from the A^{C}•T Rinse shutdown diluent container, if using the diff A^{C}•T Pak reagent.

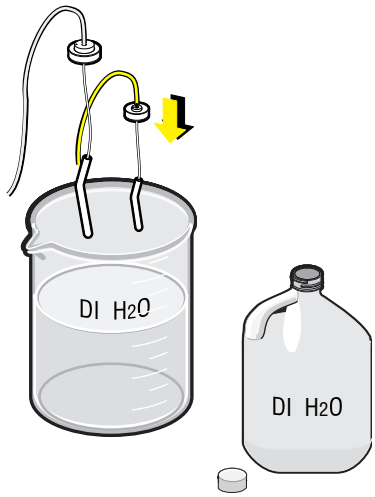


5 Touch the **1** to continue.

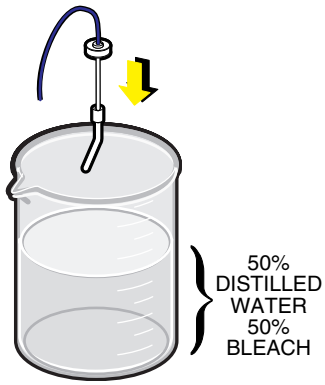
This process takes approximately 2 minutes.



6 Place the diluent and lytic reagent tubes upright in a deep container filled with distilled water.

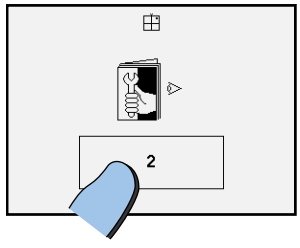


7 Place the rinse tube upright in a deep container filled with a 50% bleach-50% distilled water solution.



8 Touch the **2** to continue.

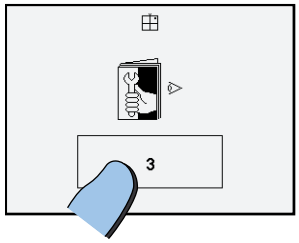
This process takes approximately 15 minutes.



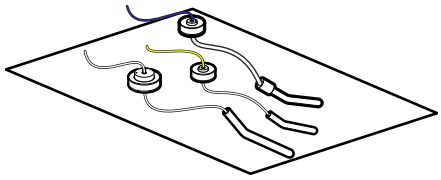
9 Remove the A^{C}•T Rinse shutdown diluent pickup tube from the bleach and place it with the others in distilled water.

10 Touch the **3** to continue.

This process takes approximately 2 minutes.

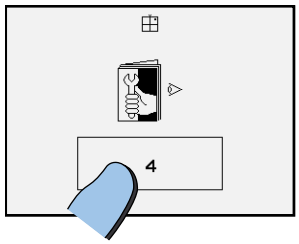


11 Remove the tubes from their respective solutions and place them on a paper towel to dry.

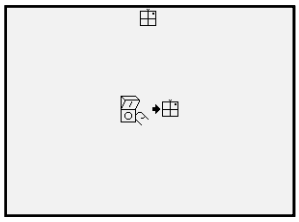


12 Touch the **4** to continue.

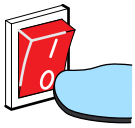
This process takes approximately 4 minutes, 15 seconds.



13 When the Ready to Ship screen appears, the instrument is cleaned out and decontaminated.



14 Turn the instrument off.



15 Prepare to dispose of the waste tubes and sensor:

a. Remove the waste tubes and sensor from the waste container.

b. Squirt the waste tubes with a bleach solution to decontaminate.

16 Disconnect the reagent and rinse pickup tubes from the instrument and pack them with the instrument.

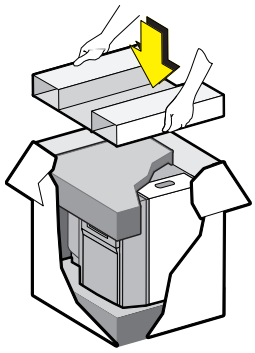
17 Tightly seal all reagent containers.

18 Remove reagent management card from instrument and put back into the card slot on the reagent container box.

19 Disconnect all cables (power, printer) from the instrument.

Pack them with the instrument.

20 Pack the instrument in its original box.



21 Ship the instrument to the address obtained from your Beckman Coulter Representative.

6.17 TROUBLESHOOTING

Troubleshooting Tools

Knowing what your A^{C}•T diff analyzer does, how it sounds when operating properly, and what normal results look like are the keys to troubleshooting problems. Study the Normal Sample Flow. Then watch and listen while the instrument goes through its cycles.

If you later find that your A^{C}•T diff analyzer is not operating properly, you can begin to isolate the problem by studying irregular results (Table 6.10) and watching the instrument cycle a sample.

Diluter Functions

The Diluter Functions screen provides you with basic diluter functions to use in troubleshooting. Table 6.2 describes the diluter functions

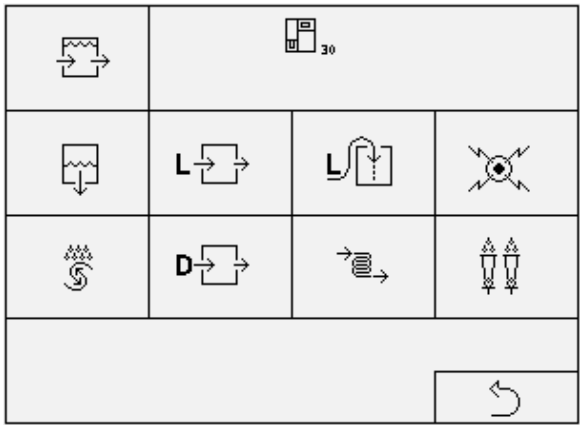


Table 6.2 Diluter Functions Screen

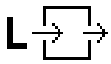
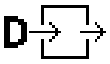
Icon	Description	Function
	Wet Prime	Primes the diluent fluidic path and baths. Dispenses lytic reagent to WBC bath. Removes air from diluent and lytic reagent lines.
	Sweepflow	Primes the fluidic path from the diluent reservoir through the sweepflow coil and the path between the RBC aperture and the vacuum isolator chamber.
	Automatically drains the baths then, after you aspirate bleach, cleans the baths.	Cleans the baths with a solution other than COULTER A^{C}•T Rinse cleaning agent (see Clean the Baths). If the zap aperture function does not work, this is the third attempt (after Shutdown) to clear a clogged aperture.
	Primes the lytic reagent system when the A^{C}•T diff analyzer is first installed or reinstalled after being drained.	Primes the lytic reagent path of the fluidics system. Fills the lytic reagent path completely even if it is empty.

Table 6.2 Diluter Functions Screen *(Continued)*

Icon	Description	Function
	Primes the diluent system.	Primes pickup tube and diluent reservoir. Fills the diluent path (between the diluent container and the diluent reservoir) completely, even if it is empty.
	Drains the baths and the vacuum isolator chamber.	Drains fluid before you remove the baths or the vacuum isolator chamber. Verifies the operation of the waste pump.
	Primes the diluent reservoir system and fills both baths with fresh diluent. Sends mixing bubbles to each bath in turn.	Verifies operation of the rinse pump. Helps detect a plugged filter. Checks the operation of the diluent pump if you use it enough times to force a refill of the reservoir. Verifies operation of air/mix system. Helps detect plugs or leaks in the fluid barrier.
	Performs an aperture burn or zap.	Attempts to clear a plugged aperture, perform several times.
	Dispenses lytic reagent into the WBC bath.	Manually primes the lytic reagent system. Checks for bubbles in the lytic reagent system. Verifies the operation of the lytic reagent pump.
	Exits from the Diluter Functions screen.	Returns to previous screen.

Diagnostic Functions

The Diagnostic Functions screen provides you with basic diagnostic functions to use in troubleshooting. Table 6.3 describes the diagnostic functions.

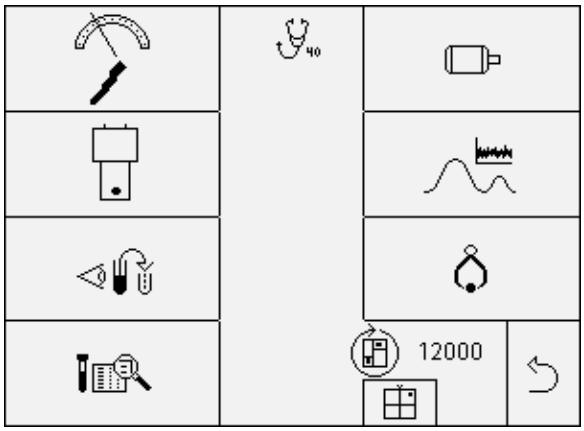
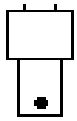


Table 6.3 Diagnostic Functions Screen

Icon	Description	Function
	Displays current state of digital sensors and current value of analog sensors and voltages.	Lets you adjust to 6.00 vacuum. Lets you verify correct sensor readings.
	Displays solenoids screen and allows you to change the state (ON or OFF) of each solenoid.	Lets you test solenoid functions.
	Displays verify predilute screen.	Lets you verify that the instrument is dispensing 1580 µL of diluent. Creates prediluted sample.
	Displays details of the last sample run screen.	Lets you troubleshoot aperture problems.
	Displays motors screen and allows you to interactively run each motor through its normal range of motion.	**CAUTION** Indiscriminate use of these functions can damage the instrument. Do not use the motors function without instruction from your Beckman Coulter Representative.
	Displays an in-progress screen and performs an electronics pulse test.	Lets you verify the electronic stability of the instrument for WBC and RBC apertures.
	Latex gain Calibration	Lets you set particle sizes for WBC, RBC, and Plt gains.
	Prepares the instrument for shipping.	Lets you drain and disinfect the instrument in preparation for shipping.
	Displays the cycle count.	Lets you view the cycle count.
	Exits the Diagnostic Functions screen.	Returns to previous screen.

6.18 PARAMETER CODES AND FLAGS

Analyze samples within 24 hours of collection.

Report results immediately if there are no flags and if the results are within your referenced ranges. Table 6.4 shows the parameter codes and flags that can appear with results. Also note:

- If any flag appears, review the results according to your laboratory's protocol.
- The cells of whole blood collected in EDTA undergo a process of equilibration. White blood cells of certain samples might take up to 30 minutes to reach this state of equilibration in the EDTA. Also, after 5 hours, cellular deterioration might start to occur. These samples might show increased flagging of differential parameters (1, 2, 3, M). If a sample that produces differential flags is less than 30 minutes old, reanalysis of the sample at a later time might eliminate the differential flags.

Whole blood samples processed between 30 minutes and 5 hours of collection provide the best differential performance for all sample types, collection devices, and collection variables.

Prediluted samples processed between 5 minutes and 1 hour of collection provide the best differential performance for all sample types, collection devices, and collection variables.

Hierarchy of Flags

There are two types of flags:

- Those that **replace** the parameter results, also known as codes, and
- Those that **appear next to** the parameter results. Up to two of these flags can be displayed for a parameter.

Replacement Flags (Codes)

For those flags that **replace** the parameter results, the hierarchy, in decreasing order of importance, is:

- - - - -

+++++

XXXXX

. . . . .

Non-Replacement Flags

For those flags that **appear next to** the parameter results, the hierarchy, in decreasing order of importance, is:

X

+

*****

1, 2, 3, 4, M (where M means multiple regions)
H or **L**

6.19 WHAT FLAGS AND CODES MEAN

Table 6.4 describes the flags and suggests actions you should perform when they appear.

Table 6.4 What Flags Mean

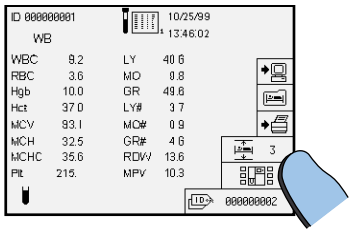
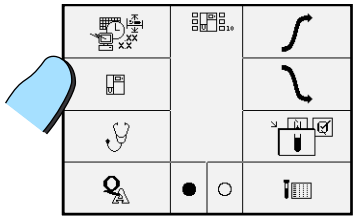
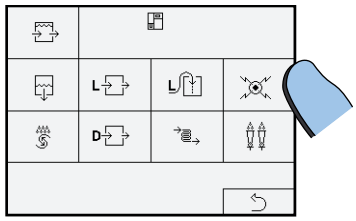
Flag/Code	Indication	Suggested Action
- - - - - (dashes)	Total Voteout. Replaces result when: • Two of the three count periods did not agree. • For WBC and RBC, the first count period votes out. You also see . . . . . for any parameter derived from a parameter replaced by - - - - -. If for WBC, also - - - - - for LY#, MO#, GR#, LY%, and * for MO%, and GR%. If for RBC, also . . . . . for Hct, MCH and MCHC, and * for MCV, RDW, Plt, MPV, (Pct and PDW). If for MCV, also . . . . . for Hct and MCHC, and * for RDW. If for Plt, also . . . . . for MPV (Pct and PDW). If for MPV, also * for Plt (Pct and PDW). If for PDW, also * for Plt, MPV (and Pct).	1. Thoroughly mix and rerun the sample. 2. If the voteout repeats, zap apertures: a.  b.  c. 

Table 6.4 What Flags Mean *(Continued)*

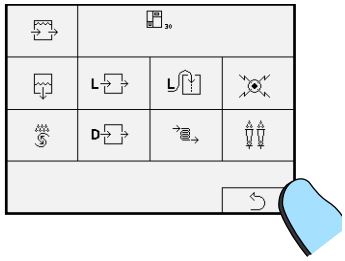
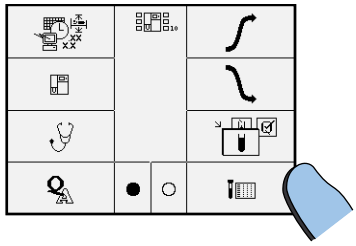
Flag/Code	Indication	Suggested Action
– – – – – *continued*		d.  e.  3. Thoroughly mix and rerun the sample. 4. If the voteout repeats, run a previously run sample with known values. 5. If the voteout repeats, clean the baths according to Clean the Baths in this chapter. 6. Thoroughly mix and rerun the sample. 7. If the voteout repeats, call your Beckman Coulter Representative.

Table 6.4 What Flags Mean *(Continued)*

Flag/Code	Indication	Suggested Action
+++++ (pluses)	If for Plt, also **. . . . .** for MPV (Pct and PDW), and ***** for WBC, LY#, MO#, GR#, Hgb, MCH, MCHC. If for Hgb, also **. . . . .** for MCH and MCHC. If for RBC, * for MCV, RDW, Plt, MPV (Pct and PDW) and Hct; also **. . . . .** for MCH and MCHC. If for WBC, also **. . . . .** for LY%, MO%, GR%, LY#, MO#, GR#; also ***** for RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, Plt, and MPV (Pct and PDW).	For WBC, RBC, Hgb or Plt: 1. Ensure that the bath shield is in place. 2. Make a dilution to determine the parameter result: a. Dilute 1 part thoroughly mixed sample with 1 part normal saline (0.85% NaCl) in a clean test tube. b. Mix then immediately run the dilution in whole blood mode. c. Multiply the parameter result by 2. Corrected result = (Dilution result x 2) d. Correct derived parameters if applicable. e. If result still gives **+++++**, increase dilution and repeat. For WBC and Hgb, if it occurs on multiple samples, verify correct delivery of lyse.
+++++	MCV <50 fL or >130 fL. • If for MCV <50, also ***** for RBC, MCH, RDW, Plt, MPV (Pct and PDW); also **. . . . .** for Hct and MCHC. • If for MCV >130, also ***** for RBC, MCH, RDW; also **. . . . .** for Hct and MCHC.	For MCV, verify results by alternative method, such as blood film review or spun Hct.
XXXXX	Aperture Alert. A problem was detected during counting that could compromise the integrity of the results. • If on WBC aperture, WBC and differential % and # show **XXXXX**. • If on RBC aperture, RBC, Hct, MCV, MCH, MCHC, RDW, Plt, MPV (Pct and PDW) show **XXXXX**.	1. Remove the stopper and gently mix the sample with a wooden applicator stick to check for fibrin strands or clots: • If fibrin strands or clots are found, collect and run a new sample. • If fibrin strands or clots are not found, thoroughly mix and rerun the sample.

Table 6.4 What Flags Mean *(Continued)*

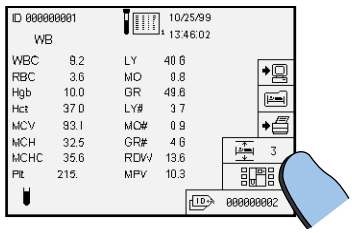
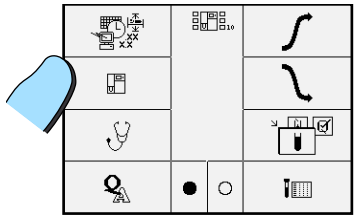
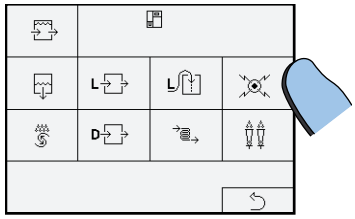
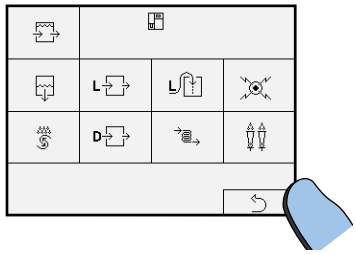
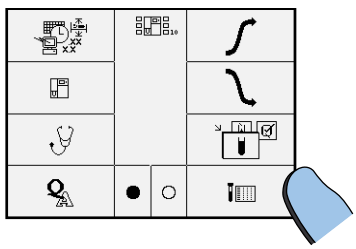
Flag/Code	Indication	Suggested Action
XXXXX *continued*		2. If the Aperture Alert repeats, run a previously run sample with known values. 3. If the Aperture Alert repeats, zap apertures: a.  b.  c.  d.  e.  4. Thoroughly mix and rerun the sample.

Table 6.4 What Flags Mean *(Continued)*

Flag/Code	Indication	Suggested Action
XXXXX *continued*		5. If the Aperture Alert repeats, clean the baths according to the Clean the Baths procedure in this chapter. 6. Thoroughly mix and rerun the sample. 7. If the Aperture Alert repeats, use an alternative method. 8. If the Aperture Alert repeats, call your Beckman Coulter Representative.
. . . . . (dots)	Incomplete calculation. Result cannot be calculated. System does not have enough information to compute a result.	See instructions for voteout (- - - - -).
	Parameter derived from parameter with a voteout (- - - - -).	
	If for Hgb, error was detected during Hgb measurement, also . . . . . for MCH and MCHC. The Hgb Blank and/or Hgb Read results do not correlate.	1. Thoroughly mix and rerun the sample. 2. If Hgb . . . . . repeats, call your Beckman Coulter Representative. If on all samples: 1. Verify that Hgb lamp is illuminated. • If not, call your Beckman Coulter Representative. • If it is illuminated, run startup to set Hgb lamp voltage. 2. If problem persists, call your Beckman Coulter Representative.
	If for Diff parameters: a. WBC <1.0 or >99.9 x 10^3/uL, b. WBC voteout (Diff # parameters only), or c. Result cannot be calculated.	If a): 1. Confirm results. 2. Do manual differential. If b), see instructions for voteout (- - - - -). If c): 1. Verify sample handling. 2. If this sample has been refrigerated, warm to room temperature then thoroughly mix and rerun sample. 3. Some samples require a longer than normal equilibration time. Wait 10 to 15 minutes, then thoroughly mix and rerun the sample. 4. If this sample is more than 5 hours old, collect a fresh sample or perform manual differential.

Table 6.4 What Flags Mean *(Continued)*

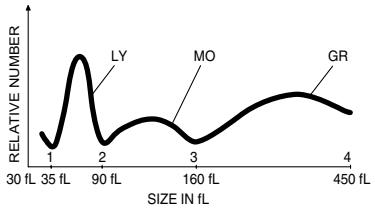
Flag/Code	Indication	Suggested Action
. . . . . (dots) *continued*	If for Hct, MCH and MCHC: a. RBC voteout (- - - - -), or b. RBC, Hgb, or MCV > Operating range (+++++), c. Hgb incomplete (error).	If a), see instructions for voteout (- - - - -). If b), see instructions for over operating range (+++++). If c), see Hgb above.
	If for MPV (Pct and PDW): a. Plt voteout. b. Plt over operating range.	If a), see instructions for voteout (- - - - -). If b), see instructions for over operating range (+++++).
	If for Hct and MCHC, MCV voteout.	See instructions for voteout (- - - - -).
+ (plus)	Overrange result. Indicates result is greater than linear range but less than operating range: WBC >99.9 <150 x 10^3/uL RBC >7.00 <8.00 x10^6/uL Hgb >25.0 <30.0 g/dL Plt >999 < 3000 x 10^3/uL	Verify results according to your laboratory's protocol. If any parameter is outside linearity limits, cycle diluent blank before proceeding with subsequent samples.
	If for WBC, also * for RBC, Hgb, MCV, Hct, MCH, MCHC, RDW, Plt, MPV (Pct and PDW), and . . . . . for LY#, MO#, GR#, LY%, MO%, and GR%.	
	If for RBC, also * for Hct, MCH MCHC, MCV, RDW, Plt, MPV, (Pct and PDW).	
	If for Plt, also * for MPV (Pct and PDW), WBC, LY#, MO#, GR#, Hgb, MCH, MCHC.	
	If for Hgb, also * for MCH and MCHC.	
1, 2, 3, 4, M	Differential parameters failed the internal regional size distributional criteria at one specific region (1, 2, 3 or 4) or multiple regions (M).  	Verify results according to your laboratory's protocol.
H	High result. For Patient samples, result is higher than the high patient sample limit. For Control samples, result is higher than the upper limit for that control sample.	Follow your laboratory's protocol.

Table 6.4 What Flags Mean *(Continued)*

Flag/Code	Indication	Suggested Action
L	Low result. For Patient samples, result is lower than the low patient sample limit. For Control samples, result is lower than the low limit for that control sample.	Follow your laboratory's protocol.
X	Review results. **X** flag indicates that one of the multiple Aperture Alert criteria was not met.	1. Thoroughly mix and rerun the sample. 2. If flag does not repeat, report result. 3. If flag repeats, clean the aperture as instructed in heading 6.3. 4. If after cleaning, problem persists, contact your Beckman Coulter Representative.
*	* occurs on parameters influenced by **+++++**, **+**, - - - - - as detailed above.	See instructions for **+++++**, **+**, or - - - - - .
	If (Hgb g/dL x 3)/Hct% is <0.8 or >1.2 then RBC, Hgb, MCV, Hct, MCH, MCHC, Plt, MPV (Pct and PDW) are flagged with *. Possible sample handling problem.	
	If on RDW only, RBC histogram failed internal asymmetry check. Possible dual RBC population.	
	If on WBC and Differential # only, 35 fL count interference check failed. Possible interference with WBC count.	
	If on Plt, MPV (Pct and PDW) only, Plt <20 $x10^3$/uL, or Platelet distribution failure Non-positive curve Mode <3 or >15 fL PDW >20 Voteout of fitted curve Sweepflow error	
	If MCHC <25.0 or >40.0 g/dL, then RBC Hgb, Hct, MCH, MCHC are flagged with *. Possible sample interference or instrument problem.	

6.20 WHAT WARNING MESSAGES MEAN

Table 6.5 describes the warning messages and suggested recovery action.

Table 6.5 Warning Messages

Warning	Description	Suggested Action
	Printer is disconnected. Printer is not turned on. Printer is offline or out of paper.	Turn printer on and touch **printer** icon on the Sample Results screen to print. If you have no printer, check to see that auto-print is turned off (Print Profiles screen). See Setting Autoprint in Chapter 2.
	Transmission incomplete	Sample transmission to host failed. Touch the **transmission** icon on the Sample Results screen to retry the transmission. If transmission still fails, check communications cable to host and make sure that the host is online. If failure still occurs, power instrument off and then on. **Note**: You lose the ability to transmit a sample result when you power off the instrument.
	Vacuum failure	Go to voltage screen and try to adjust vacuum to 6.00. If it does not adjust: • Make sure the pump is ON. • Is there a leak associated with the Vacuum Isolator Chamber and associated tubing? Check all green striped tubing, front and right side. Is tubing connected tightly? Are there leaks? • Is fluid barrier filter plugged? If yes, replace fluid barrier and adjust vacuum.
	Hgb voltage failure	Run a startup. Startup tries to adjust Hgb voltage. If it does not adjust: • Make sure Hgb lamp is ON. • Check for spillage around Hgb components on WBC bath. • Make sure there is no diluent leak. (The baths fill and there is no air in the large 5-mL diluent syringe). Proper fluid level must be in the WBC bath at all times.
	High Plt count	Plt channel overrange. • Acknowledge warning; instrument provides numeric results. Verify the results. • Check for proper sweepflow operation with no bubbles. • Check for sources of electrical interference. • Check to ensure that bath shield is on. • Check to ensure that Vacuum Isolator Chamber is clean and dry where the count drops appear.
	Time keeper failure	Reset the time and date. See Installing the Instrument in Chapter 2.

Table 6.5 Warning Messages *(Continued)*

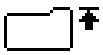
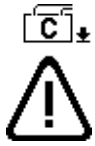
Warning	Description	Suggested Action
	Setup data corrupted	Check the setup values against your records. Correct the values, if necessary, and save. (See Customize Software in Chapter 2.) Print setup values. Run sample.
	Control file full	There is no more storage space available for your 4C PLUS control files. If your laboratory is an IQAP participant, save the control data to a depleted reagent management card. See Downloading 4C PLUS Cell Control Results for IQAP in Chapter 5. To make room for additional control file storage, you may want to delete some existing control files. See Deleting 4C PLUS Cell Control Results in Chapter 5.
	Control expired	Do not use this control; it has expired. Use a control that is not expired.
	Patient data or control data corrupted	If this appears during startup, print what is currently stored to determine what patient data, if any, are present. Depending on the type of error, one or possibly all patient samples previously stored may be gone.
	Check A^{C}•T diff Reagent Management card	Make sure card is in reader correctly. If problem persists, it may be time for new reagent with a new card. If problem occurs with a new card, there could be a problem with the card, card reader, card reader connection, or card reader controller (which is part of the display assembly).
	Waste full	1. Do Heading 6.7, Replacing the Waste Container. 2. Touch the **Continue** icon.
	Diluent empty	• If reagent container does not appear empty, try priming first. • If there appears to be reagent, but it does not fill properly, check for proper position of pickup tube, air leaks in tubing from cube to reservoir, worn peristaltic pump tubing, or a partially plugged blue filter to the diluent peristaltic pump PM2. • Also check for crimps or plugs in the tubing from the reagent pickup through the peristaltic tubing and filter, to the bottom of the reservoir. These could affect reservoir fill. • If reservoir is overfilled, replace peristaltic pump tubing (Heading 6.9) and diluent filters (Heading 6.8).

Table 6.5 Warning Messages *(Continued)*

Warning	Description	Suggested Action
	Lytic reagent empty	• If reagent container does not appear empty, try priming first. • If there is lytic reagent in the lytic reagent container, make sure reagent pickup tubing is in fluid and that tubing and fittings are not leaking between reagent pickup and lytic reagent sensor. The lytic reagent sensor is located in the lytic reagent tubing.
	A^{C}•T Rinse Shutdown Diluent (cleaner) empty	• If the cleaner container does not appear empty, try priming first. • If priming does not work, make sure there are no leaks in any blue stripe tubing, beginning at the cleaning reagent pickup. • Check the blue filter associated with peristaltic pump PM1, the tubing to LV13 and the tubing connections to the cleaning agent fluid sensor FS3.

6.21 FATAL ERRORS

Turn OFF the instrument, then turn it ON to see if the error is corrected. Table 6.6 offers some suggested actions. If these do not solve the problem, call your Beckman Coulter Representative.

Table 6.6 Fatal Errors

Number	Description	Probable Cause/Suggested Action
1	PCMCIA Error	Turn instrument OFF. Remove and reinstall software card. Turn instrument ON. If problem still exists, obtain new software card. If problem persists, call your Beckman Coulter Representative.
3	DVM Error	There is an instrument power supply failure or the power to the instrument is out of range. A temporary loss of power can also trigger the error. Try turning the instrument OFF/ON. Ensure that the power supply to instrument and power source are good. Ensure that fuses are good. If turning the instrument OFF/ON does not work, call your Beckman Coulter Representative.
4	Unexpected Software Condition	Turn instrument OFF. If this occurs, reseat the software card and turn ON the power. If the problem still persists, obtain a new software card. If problem persists, call your Beckman Coulter Representative.
6 7 8 9 10 11	Probe Did Not Reach Up Position Probe Did Not Reach Down Position Probe Did Not Reach Thief Position Probe Did Not Reach Aspirate Position Probe Did Not Reach WBC Position Probe Did Not Reach RBC Position	The Probe has 3 horizontal and 3 vertical probe positions. When the probe is sent to, but does not reach, a position, an error is generated describing the position that was not reached. Turn the power OFF and move the probe vertically and horizontally. Make sure there is no binding and there is nothing in the mechanism's path as it moves. Leave the probe in a central position horizontally and vertically. Turn the power ON. If the problem returns, check any probe movement that occurred. No attempt at movement indicates a motor or motor connection problem. Erratic motion could indicate a motor problem or a mechanism problem. Normal motion that seems to go into and past the proper position indicates a sensor or sensor connection problem. If problem persists, call your Beckman Coulter Representative.
12 13	Syringe Did Not Reach Up Position Syringe Did Not Leave Up Position	The one syringe sensor is at the top of the syringe motion. At the beginning and during a cycle, the syringe is sent to the top position. If if does not get to the top, an error is generated. When the syringe is sent down, the sensor is checked. If the syringe is still in the top position, an error is generated. If the syringe does not move at all, there is a motor problem, motor connection problem, or board problem. If the syringe moves erratically there may be a problem with the motor or the syringe mechanism: Binding or worn syringe pistons. Pistons pulled out of the syringe barrels. Turn instrument OFF then ON. If problem persists, call your Beckman Coulter Representative.

Table 6.6 Fatal Errors *(Continued)*

Number	Description	Probable Cause/Suggested Action
	Diluent Level Error During Power Up	During power up, the diluent reservoir is overfilled and drained enough to ensure that the sensor sees fluid and air. If both conditions cannot be sensed, this error is generated. Causes could be: Excess debris, bubbles, or buildup on the sensor. Insufficient diluent because of: • low diluent supply • leak in the diluent delivery system • worn peristaltic pump tubing on the diluent pump • plugged or partially plugged filter to the diluent pump. Turn instrument OFF then ON. If problem persists, call your Beckman Coulter Representative.
16	Internal Communication Failure	Each motor in the instrument has its own microprocessor to control it. A problem has occurred with communication between the main and motor processors. When problems occur with this communication process, this error is generated. All the components in question are found on the Analyzer card. Turn instrument OFF then ON. If problem persists, call your Beckman Coulter Representative.
17	Steps Missing	During a normal cycle, the syringe makes many up and down movements before getting back to the top position. All the up movements and down movements are tracked. When the syringe returns to the sensor position, the amount of up movement should equal the amount of down movement or this error is generated. Turn instrument OFF then ON. If problem persists, call your Beckman Coulter Representative.
	Insufficient vacuum at beginning of cycle.	Leak or plug in vacuum system or problem with vacuum pump. Ensure that the vacuum pump is ON. Check the vacuum isolator system for leaks, plugs or fluid buildup. Ensure that there are no plugs near the vacuum source, such as a plug in the fluid barrier (green striped). Other problems may be with the pneumatic solenoids or vacuum sensor.Turn instrument OFF then ON. If problem persists, call your Beckman Coulter Representative.

6.22 TROUBLESHOOTING GUIDES

Tables 6.7 through 6.11 are troubleshooting guides. Each table details problems/situations, states the probable causes, and suggests actions for solving the situations.

Table 6.7 Power Problems

Situation	Probable Cause	Suggested Action
Screen is dark Power LED is lit.	A^{C}•T diff analyzer dims the screen if you do not use the instrument for 15 minutes and also requires a prime if you do not use it for 2 hours.	Touch the screen to brighten it. If the **Continue** icon appears in the status field, touch it to prime the system.
Power will not turn on.	Power cord loose or not securely connected to wall or instrument. Turn power OFF. No voltage or wrong voltage at laboratory power outlet. Defective power switch. Instrument malfunction.	Make sure power cord is securely connected to instrument and wall. Turn power ON. Make sure voltage is on and outlet is 90-264 Vac. Check fuses, replace if necessary. Call your Beckman Coulter Representative. Call your Beckman Coulter Representative.

Table 6.8 Aspiration Problems

Situation	Probable Cause	Suggested Action
No aspiration takes place	1. Tubing Problem. Plug or leak in tubing from aspirate probe to aspirate syringe. 2. Problem with connection to syringe module. 3. Problem with LV11. This valve is in the aspiration path and a plug or incorrect position would stop aspiration.	1. Inspect tubing for leaks, kinks or plugs. Also inspect tubing to LV11 and LV12. See Heading 6.10. 2. Check to see that the connector on top of the 250 µL syringe module is tight and there is no air in the tubing or syringe. See Heading 6.13. 3. The small brown knob on top of the solenoid valves will move when the valve energizes. Check that this moves during a cycle.
Incomplete aspiration	It is very difficult to tell an incomplete aspiration when you are aspirating only 12 µL. This conclusion can only be arrived at by analyzing the results. WBC, RBC, Hgb and Plt would have to be low, with MCV normal.	Check for the same problems as above. They will be partial leaks or plugs instead of pulled-off tubes or total plugs. Also, LV12 may “steal” some of the aspirate volume if it does not completely block its connection to the syringe during aspiration.

Table 6.8 Aspiration Problems *(Continued)*

Situation	Probable Cause	Suggested Action
Sample drips from probe after aspiration.	1. Fluid drips from inside the probe.	1. This is a leak in the aspiration pathway. Check the same tubing and components as above for leaks.
	2. Fluid drips outside the probe.	2. The probe wipe is not working. Check for leaks in the tubing to the probe wipe, a plug in the lower waste port of the probe wipe, a plug in the tubing between the lower probe wipe port and the Vacuum Isolator Chamber, a vacuum leak at the Vacuum Isolator Chamber, or no vacuum. Check to ensure that the vacuum pump is turned on and is working. (Vacuum pump is under left side door.)
Bubbles in aspirator tubing between tip and aspirator pump.	1. Leak from syringe to aspirate tip.	1. If air is in these lines, check the components and tubing for partial or no aspiration.
	2. Leak between diluent reservoir and syringe assembly.	2. A leak from the reservoir to the syringe assembly will cause air to be in the aspirate and diluent syringe and in the line to the aspirate probe. This would involve the tubing, LV11 and LV12. Also check for leaks at the diluent or aspirate syringe.

Table 6.9 Background Problems

Situation	Probable Cause	Suggested Action
WBC, RBC and Plt exceed limits. Hgb may also be high in noted instances.	1. Contaminated diluent.	1. Replace diluent. Do a prime and startup. If you suspect biological contamination, perform the Prepare to Ship procedure. This allows you to cycle bleach through all appropriate tubing and components.
	2. Contaminated baths. This can be caused by a cleaning solution left in the baths for an extended period of time.	2. Run several startups to remove any contamination. Perform a Clean the Baths procedure (see Heading 6.3).
	3. Many bubbles in both baths. If not enough bubbles are dissipated by the end of the WBC count, they could affect the light path and give a high Hgb result.	3. Check the system for bubbles, starting with the fluid reservoir and moving on to the syringe assembly. Remove the bath shield and run a cycle, observing the fluid in the baths if necessary. Repair any leaks that have caused the bubbles, whether tubing, fitting, or component.
	4. Blood in the aspiration path before the background aspiration. The instrument guards against this and any problem that circumvents the system would usually cause some other error on the previous cycle.	4. Do high/low carryover checks (see Heading 6.4). Backgrounds should pass or be very close on the first blank. If they are high and then fall on subsequent cycles, there could be blood left over from the previous cycle.
	5. Electrical interference. This will usually affect only the counts, not Hgb	5. Ensure that the bath shield is on the plate that the baths are mounted to, including the bath shield, is not connected to the main instrument. Ensure no electrical connection is made, including salt buildup that could connect the shield or plate to the main instrument chassis. Ensure there are no fluid spills in and around the bath area. Ensure that no electrical equipment, especially motorized equipment, is operating near the instrument. Check the power source. Check that no motorized piece of equipment is plugged into the same power circuit.

Table 6.9 Background Problems *(Continued)*

Situation	Probable Cause	Suggested Action
Only WBC results exceed background specifications.	1. Contamination to a smaller degree than above. 2. Bubbles in bath. Since only WBC is affected, the source is either incorrect mixing bubbles to the WBC bath or air in the lytic reagent system. 3. Electrical interference. This generally affects WBC and/or Plt first, since they normally produce smaller count pulses than the RBC.	1. Redo startup. Proceed as above if problem persists. 2. Check the bath during count for excessive mixing bubbles. Check the lytic reagent (yellow tubing) system for leaks, air bubbles. The lytic reagent sensor is located in the line just after it enters the instrument; therefore it will not detect bubbles in the instrument, only incoming bubbles. 3. See above. Problem could also be with WBC bath/aperture assembly, connection to the Analyzer card, or the Analyzer card itself.
Only Plt results exceed background specifications	1. Plts are the smallest pulses measured. Any problem that affects all the other count parameters will affect Plts first. Depending how bad the problem is, only Plts may be affected. This includes contamination, bubbles, sweepflow problems, and electrical interference.	1. See above.

Table 6.10 Irregular Sample Results

Situation	Probable Cause	Suggested Action
All counted parameters are consistently lower than normal. MCV is normal.	1. Short sample. 2. Poor bath drain. 3. Diluted sample.	1. See aspiration problems in Table 6.8. 2. Leaks or plugs are in drain path, LV14 or LV15 has a problem, plugged check valve is near LV13, waste pump peristaltic pump tubing has a problem. 3. Check that probe wipe is working and not dripping into sample. See aspiration problems in Table 6.8.
All counted parameters are consistently higher than normal. MCV is normal.	1. Incomplete probe wipe. 2. Insufficient diluent for dilution.	1. Check for signs of blood left on probe at end of cycle. Check for blood left at lower probe wipe fitting when probe has just retracted. 2. Check for air in diluent path from syringe, to probe and to side fitting at bottom of bath. Check for diluent leaks at bottom of WBC bath.
All counted parameters are consistently higher than normal.	1. Contamination 2. Electrical interference	1. See high backgrounds in Table 6.9. 2. See high backgrounds in Table 6.9.
WBC and Plt are too high or low, Hgb and RBC are opposite, too low or high.	Sample was not mixed adequately before aspiration.	Remix sample and cycle again.
Parameters generally erratic with no specific high/low trend.	Poor or no mix bubbles in bath.	Check green striped tubing at bottom of baths for leaks or plugs. Inspect or replace the check valves in these lines. LV3 and LV4 may have problems. They are at the other end of the green striped tubing.
Samples run in Predilute mode have erratic parameters.	Incorrect or contaminated predilute dilution.	Verify predilution. Make a dilution using larger volumes or use the **Verify Predilute** icon in the Diagnostics Function screen.
WBC results are higher than normal.	1. Insufficient lytic reagent. 2. Insufficient mix bubbles to WBC dilution. 3. Electrical interference. 4. Cracked aperture. This will generally cause WBC Aperture Alerts before the affect to results is noticeable.	1. Air bubbles or leak in lytic reagent system. Check reagent lines as above. 2. Check for mixing bubbles after lytic reagent has been added. These bubbles enter lower right side port of WBC bath. Check the green stripe tubing, the check valve in this tubing, and LV4. 3. See electrical interference and backgrounds in Table 6.9. Do a background and see if it passes. 4. Replace WBC aperture bath assembly.
WBC and Hgb results are higher than normal.	Insufficient lytic reagent in dilution. More severe case than above. Will get WBC voteouts or Aperture Alerts frequently.	Check for insufficient lytic reagent as above.

Table 6.10 Irregular Sample Results *(Continued)*

Situation	Probable Cause	Suggested Action
WBC results are lower than normal.	1. Protein buildup on aperture.	1. Perform several zap aperture functions from the Diluter Functions screen. If this is not sufficient, bleach the apertures and baths using the **clean baths** icon from the Diluter Functions screen (in the Diluter Functions section of this chapter).
	2. Problem with vacuum draw to aperture. This will cause an Aperture Alert before the results are noticeably low.	2. Check the red stripe tubing leaving the rear of the bath, going to LV17, and going from LV17 to the VIC. A plug in LV17 or in the fitting entering the VIC is also a possibility.
Hgb results are erratic.	1. Fluid in optical path outside of bath.	1. Check for fluid and salt deposits on outside of bath and Hgb components. Remove, clean and dry, if necessary. If there is fluid, find the source and repair if necessary.
	2. Bubbles in blank rinses. Blanks are taken on the rinse that is in the bath before aspiration takes place and the rinse that occurs just after the WBC/Hgb dilution is drained. The latter rinse will be more suspect.	2. The diluent rinse comes from the diluent syringe. Correct any leaks and air in this system.
	3. Abnormal sample interfering with Hgb.	3. Run several other samples to see if problem is unique to original sample.
RBC, MCV and Plt are affected.	1. Inadequate mixing or bubbles remaining during count.	1. Check for mixing bubble problems or leaks in the diluent path from the syringe to the bath and probe. See above.
	2. Sweepflow problem.	2. Perform the Sweepflow function from the Diluter Functions screen (see Table 6.2). Ensure that fluid moves in the sweepflow system and that all bubbles have been removed.
RBC, Plt incorrect	1. Dilution problem.	1. Air in diluent, possible leak. See above.
	2. Aspiration problem.	2. Air in aspiration path after sample delivered to WBC bath, causing aspiration problems for RBC aspiration. RBC dilution aspirates fluid from WBC bath after initial delivery and mix. If level in bath is too low, or probe barely reaches level, results are low.
	3. Aperture sampling problem.	3. Partial plug or leak in aperture area, red tube from rear of bath to Vacuum Isolator Chamber (VIC), LV16, or tubing port on VIC. A severe blockage or leak could cause an Aperture Alert.

Table 6.10 Irregular Sample Results *(Continued)*

Situation	Probable Cause	Suggested Action
MCV only incorrect.	1. Protein buildup on aperture, causing elevated MCV. If this problem gets worse, Plts and RBCs are affected. A high frequency of RBC Aperture Alerts occurs.	1. Perform the **Clean Baths** function from the Diluter Functions screen (see Heading 6.3, Clean the Baths).
	2. Cracked aperture resulting in low MCV. If the crack is bad, RBC Aperture Alerts will occur. Also the RBC and Plt counts will increase.	2. If this is the problem, you must replace the RBC aperture bath. Call your Beckman Coulter Representative.
Plt only incorrect	1. Electrical interference. Since Plts produce the smallest pulses analyzed by the system, low level electrical interference affects Plts only.	1. See electrical interference under background problems, Table 6.9.
	2. Contamination by small particles could also affect Plts only. This is unlikely, since contamination usually involves a wide size range of particles.	2. Change diluent. If the instrument is badly contaminated, especially with biological growth, run the Prepare to Ship procedure from the Diagnostic Functions screen.
	3. Fluid in sweepflow, but sweepflow is not moving. This could be a plug or an air lock that low vacuum cannot break.	3. Perform the Sweepflow prime from the Diluter Functions screen. This function primes the sweepflow with high vacuum. Make sure that fluid is moving. If not, a plug or a leak in the sweepflow check valve could be the problem.
Whole blood results similar to pattern below: WBC 2.0 x 10^3 cells/µL RBC **+++++** x 10^6 cells/µL Hgb **+++++** g/dL Hct **+++++** % MCV **+++++** fL MCH 25 pg MCHC 10 g/dL Plt 0 x 10^3 cells/µL	Whole blood was analyzed in the A^C•T **Tron** mode.	Select **Whole Blood** mode and rerun the patient sample.

Table 6.10 Irregular Sample Results *(Continued)*

Situation	Probable Cause	Suggested Action
Whole blood results similar to pattern below: WBC - - - - - x 10^3 cells/µL RBC **+++++** x 10^6 cells/µL Hgb **+++++** g/dL Hct **+++++** % MCV **+++++** fL MCH 40 pg MCHC 15 g/dL Plt 0 x 10^3 cells/µL	Undiluted whole blood was analyzed in the **Predilute** mode.	Select **Whole Blood** mode and rerun the patient sample.

Table 6.11 A^{C}•T Tron Cell Control Results

Situation	Probable Cause	Suggested Action
All results are within the assay ranges listed in the TABLE OF EXPECTED RESULTS.	The A^{C}•T System is operating properly.	Analyze patient samples.
Upon initial use, the Hgb results are low outside of the assay ranges listed in the TABLE OF EXPECTED RESULTS.	Possible damage due to prolonged exposure to high temperature.	1. Thoroughly mix a new control vial from a different package or shipment. 2. Rerun the control. 3. If the problem persists, call your Beckman Coulter Representative.
Upon initial use, the WBC, RBC and Plt results are low outside of the assay range listed in the TABLE OF EXPECTED RESULTS.	• Improper handling of the control. • The cap was removed before mixing the control. • Insufficient mixing. • Control not stored horizontally.	1. Thoroughly mix a new control vial before opening. 2. Rerun control. 3. If problem persists, see Table 6.10, Irregular Sample Results, for possible instrument problem.
Upon continued use, the WBC, RBC and Plt results are low outside of the assay range listed in the TABLE OF EXPECTED RESULTS.	• Improper handling of the control. • The cap was removed before mixing the control. • Insufficient mixing. • Control not stored horizontally.	1. Thoroughly mix a new control vial before opening. 2. Rerun control. 3. If problem persists, see Table 6.10, Irregular Sample Results, for possible instrument problem.
WBC, RBC and Plt results are high after 31 aspirations.	• More than 31 aspirations. • Insufficient volume of supernatant to mix the cells.	1. Thoroughly mix a new control vial. 2. Rerun control. 3. If problem persists, see Table 6.10, Irregular Sample Results, for possible instrument problem.
Sudden upward shift in Hgb recoveries of approximately 1 gram. WBC results may also shift upward.	• Not a control problem. • Possible instrument problem.	See Table 6.10, Irregular Sample Results, for possible instrument problem.
WBC, RBC, Hgb and Plt results are all above the assay range.	• Not a control problem. • Possible instrument problem.	See Table 6.10, Irregular Sample Results, for possible instrument problem
WBC, RBC and Plt results trend upward.	• Increase in laboratory temperature. • More than 31 aspirations.	1. Use TABLE OF EXPECTED RESULTS for your laboratory operating temperature. 2. Thoroughly mix a new control vial. 3. Rerun control. If problem persists, see Table 6.10 for possible instrument problem.
Increase in WBC, RBC, Plt without a significant change in Hgb.	Increase in laboratory temperature.	Use the corresponding TABLE OF EXPECTED RESULTS for your laboratory operating temperature.

Table 6.11 A^{C}•T Tron Cell Control Results *(Continued)*

Situation	Probable Cause	Suggested Action
An upward trend of 1 to 2 fL in MCV over the 3-month shelf life of the product.	MCV may show trending through the product shelf life. This is inherent to the control and is not an indication of instability. 95% of the control results should remain within the assay ranges found in the TABLE OF EXPECTED RESULTS.	No action, normal characteristic of aging RBCs.
Controls' results similar to pattern below: WBC 36 x 10^3 cells/µL RBC 0.04 x 10^6 cells/µL Hgb 2.0 g/dL Hct 0.3 % MCV 66.9 fL MCH **+++++** pg MCHC **+++++** g/dL Plt - - - - - x 10^3 cells/µL	A^{C}•T Tron cell control was analyzed in the **Whole Blood** mode.	Select the A^{C}•T **Tron** mode and rerun the control.
Controls' results similar to pattern below: WBC **+++++** x 10^3 cells/µL RBC 3.2 x 10^6 cells/µL Hgb **+++++** g/dL Hct 20 % MCV 64 fL MCH **+++++** pg MCHC **+++++** g/dL Plt 195 x 10^3 cells/µL	A^{C}•T Tron cell control was analyzed in the **Predilute** mode.	Select the A^{C}•T **Tron** mode and rerun the control.

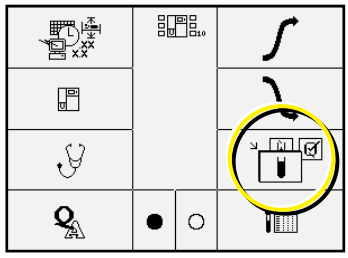
A.1 ANALYSIS PROCEDURE

Use a material with known reference values as your calibrator.

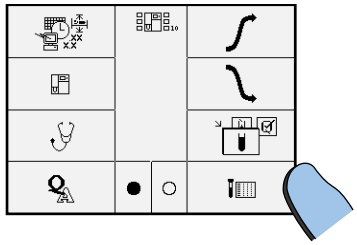
1 Be sure you have done Precalibration Checks, Reproducibility, and Carryover. See Chapter 5 for details.

2 Prepare your material as needed.

3 At the Main screen, select the **Whole Blood** mode.

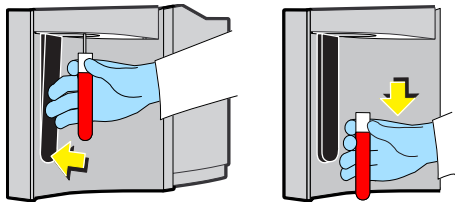


4 At the Main screen, touch the **Sample Results** icon.



5 Present the well-mixed material to the probe so that the tip is well into the tube, and press the aspirate switch.

When you hear the beep, remove the tube.



6 Record the results on the calibration worksheet.

CALIBRATION WORKSHEET

Sample Number	WBC	RBC	Hgb	MCV	Plt
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
TOTAL					
MEAN (A)					
ASSIGNED VALUE (B)					
ABSOLUTE DIFFERENCE (C)					
CALIBRATION REQUIRED					
CURRENT CALIBRATION FACTOR (D)					
NEW CALIBRATION FACTOR (E)					

C = B - A
E = (B / A) x D

7 Repeat steps 4 and 5 ten times, for a total of 11 runs.

8 Do the Calculations Procedure.

A.2 CALCULATIONS PROCEDURE

1 Calculate the mean for each parameter using samples 2 through 11 on the worksheet. Write this number into row A on the worksheet.

2 Copy your calibrator material's assigned value to the worksheet. Write this number into row B on the worksheet.

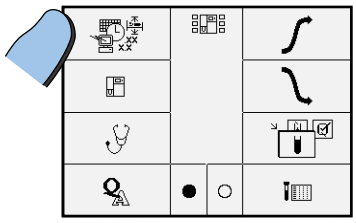
3 Calculate the absolute difference between the assigned value and the mean value calculated in step 1. Write this number into row C of the worksheet.

4 Determine if calibration is necessary by comparing the absolute difference from row C to your material's calibration criteria table.

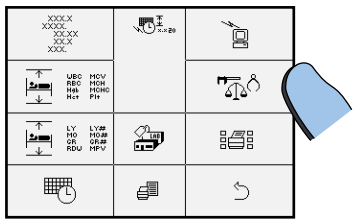
- If the absolute difference is less than the value in your material's calibration criteria table, no calibration is required.
- If the absolute difference is between the values found in your material's calibration criteria table, do Calculating New Calibration Factors.
- If the absolute difference is greater than the value found in your material's calibration criteria table, eliminate possible instrument problems and possible calibrator deterioration. If you determine calibration may be needed, call your Beckman Coulter Representative before calibrating.

A.3 CALCULATING NEW CALIBRATION FACTORS

1 At the Main screen, touch the **Setup** icon.



2 At the Setup screen, touch the **Calibration Factors** icon.



3 Record these factors into row D on the worksheet.

4 Calculate the new calibration factor using this formula:

$$\text{new calibration factor} = \frac{\text{assigned value (B)}}{\text{mean value (A)}} \times \text{current calibration factor}$$

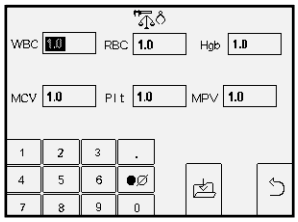
a. Divide the assigned value (row B) by the mean value (row A).

b. Multiply the derived number from step a by the current calibration factor (row D).

c. Record the new calibration factor into row E of the worksheet.

5 Enter the new values on the Calibration Factors screen.

Save the new values by touching the **Save** icon.



6 Verify that calibration is acceptable:

a. Analyze a material with known values, such as 4C PLUS cell control or A^{C}•T Tron cell control.

b. Be sure that the results fall within the expected ranges. If they do not, run one more sample.

c. If the results still do not fall within the expected ranges, call your Beckman Coulter Representative.

Calibration Worksheet

Sample Number	WBC	RBC	Hgb	MCV	Plt
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
TOTAL					
MEAN (A)					
ASSIGNED VALUE (B)					
ABSOLUTE DIFFERENCE (C)					
CALIBRATION REQUIRED					
CURRENT CALIBRATION FACTOR (D)					
NEW CALIBRATION FACTOR (E)					

A = samples 2 through 11
C = B - A
E = (B / A) x D

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GLOSSARY

Accuracy	Ability of the instrument to agree with a predetermined reference value at any point within the operating range; closeness of a result to the true (accepted) value.
Ambient	Surroundings or environment.
Assay	Procedure of repeat testing to determine the assigned value for a given lot and level of control.
Assay Values	Values of all parameters in a control established by extensive assay of that control.
Assigned Values	Values of all parameters in a calibrator established by extensive testing of that calibrator.
Aspirate-Verify Cycle	Aspirates 20 µL of whole blood.
Background Count	Measure of the amount of electrical or particle interference.
Background Cycle	Ensures that instrument is ready to run.
Baud	A rate defining how many data bits per second are transferred during communications between two pieces of equipment.
Blank Cycle	Runs diluent through the system to clean it out.
Calibration	A procedure to standardize the instrument by determining its deviation from calibration references and applying any necessary correction factors.
Calibration Factors	These are correction factors that the system uses to fine-tune instrument accuracy.
Calibrator	A substance traceable to a reference method for preparation or material used to calibrate, graduate, or adjust a measurement.
Carryover	The amount, in percent, of blood cells or Hgb remaining in diluent following the cycling of a blood sample.
Cell Control	A preparation made of human blood with stabilized cells and surrogate material. It is used for daily instrument quality control.
Clean Baths Cycle	You present bleach at the sample probe for aspiration into the baths; alternative to Shutdown.
Cleanup Cycle	Cleans up the system during powerup.
Codes	On printouts, symbols such as +++++, -----, ..., +, * that appear **in place of** sample results. See Heading 9.18, WHAT FLAGS AND CODES MEAN for additional information.
Coefficient of Variation	An expression, in percent, of data (SD) spread as related to the mean. %CV = (SD / mean) 100
Coincidence	More than one cell within aperture sensing boundaries at the same time. The system senses these as one large cell rather than as two distinct cells, so it generates one large pulse.
Control	A substance used for monitoring the performance of an analytical process or instrument.
Coulter Histogram Differential (CHD)	How the computer computes absolute numbers for each population of LY, MO, and GR.
Coulter Principle	W.H. Coulter's method for counting and sizing cells and particles.
Conventions	Standard style or format used in a particular manual.
CV	(see Coefficient of Variation)
Data Bit	Computer code used to transfer each character of information.
Defaults	Original settings in the instrument. You can change these to tailor operation to your situation.
Diluter	Prepares the proper dilutions for sample analysis.
Dispense Diluent Cycle	Provides the proper amount of diluent for preparation of a prediluted sample.
Dispense Lyse Cycle	Dispenses lyse into the WBC bath.

Dispense-Verify Cycle	Dispenses proper volume of diluent for preparation of a prediluted sample with 20 µL of whole blood aspirated by the aspirate-verify cycle.
Drain Cycle	Drains the RBC bath, WBC bath, and the vacuum isolator chamber.
Dry Prime Diluent Cycle	Primes the pickup tube and diluent reservoir. Fills the diluent path between the diluent container and the diluent reservoir, even if empty; it does not fill the diluent path between the diluent reservoir and the baths.
Dry Prime Lyse Cycle	Primes the lyse path of the fluidics system; fills the lyse path completely, even if empty.
Expiration Date	The last day when you can use that lot number of reagent, control or calibrator.
fL	Abbreviation for femtoliters.
femtoliters	One quadrillionth (10^{-15}) of a liter.
Field	Area on a screen for entering data.
Flags	On printouts, letters (H, L, *, +) that appear **next to** parameter results to indicate specific conditions. See Heading 9.18, WHAT FLAGS AND CODES MEAN for additional information.
Hemoglobinometry	Measurement of hemoglobin in the blood. In COULTER instruments, this is done by comparing the amount of light that passes through a diluted lysed sample in which the released Hgb has been chemically converted, with the amount of light that passes through a blank.
Icon	Pictorial representation for commands or options on an instrument.
IQAP (Interlaboratory Quality Assurance Program)	Beckman Coulter provides this program which statistically compares your 4C PLUS cell control data to a group of other laboratories' control recovery data.
Linearity	The ability of an instrument to recover expected results (reference values or calculated values) for such parameters as WBC, RBC, Hgb and Plt at varying levels of concentration of these parameters within specified limits.
Lot Number	A manufacturer's code that identifies when the reagent was manufactured.
Mean	Arithmetic average of a group of data.
Operating range	Range of results over which the instrument displays, prints, and transmits data.
Outlier	Control result that falls outside the expected range.
Parameters	Components of blood that the instrument measures and reports.
Parity	Method of detecting errors in data handling. The computer generates a parity bit such that the sum of the data bits and the parity bit are odd or even for each data word.
Performance characteristics	Actual performance of the instrument.
Performance specifications	Targeted performance of the instrument based on established ranges and parameters.
Powerup Cycle	Performs appropriate checks to ensure system is functioning correctly and prepares the instrument for running. This cycle is part of the entire powerup procedure and cannot be directly selected.
Precision	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 diff parameters, 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. A measure of reproducibility.

Predilute	The process of preparing a minimal amount of blood specimen for analysis by dispensing diluent to an empty tube then adding the blood specimen.A prediluted sample is different than a whole-blood sample. *See* whole blood.
Predilute Cycle	Executes “request sample analysis” using the prediluted specimen.
Prime Sweepflow Cycle	Primes the fluidics path from the diluent reservoir through the sweepflow coil and the path between the RBC aperture and the vacuum isolator chamber.
Prime Timeout Cycle	Prepares the Diluter to run samples if Diluter has been idle for 2 hours or more.
Quality Check Cycle	Executes “Request Sample Analysis” using non-labile control as the specimen.
QC (Quality Control)	A comprehensive set of procedures your laboratory sets up to ensure that the instrument is working accurately and precisely.
Reagent Management Card	A program card that manages your reagent usage.
Reproducibility	This procedure checks that the system gives similar results (within established limits) every time it measures the same sample. Also called precision.
Rinse and Mix Cycle	Drains the baths, supplies the rinse, and provides the air for mixing.
SD (Standard Deviation)	A measure of variation within a group of samples or a population.
Shift	Consecutive values that abruptly move from one side of the mean to the other then maintain a constant level.
Shutdown Cycle	Cleans the fluidic lines and apertures to help prevent residue buildup, and turns off Hgb lamp.
Software Card	A program card that contains instructions to run the instrument.
Standard Deviation (SD)	A measure of variation within a group of samples or a population.
Startup Cycle	Ensures that the instrument is ready to run; includes turning on Hgb lamp and performing background test.
Stop Bit	A computer code that indicates the end of a character.
Sweep Flow	A steady stream of diluent that flows behind the RBC aperture during sensing periods to keep RBCs from swirling back into the sensing zone.
TABLE OF EXPECTED RESULTS	Assigned values for a control material used for quality control parameters. Usually reported on a package insert shipped with the control material; can be a separate assay sheet.
Trend	Values that continue to increase or decrease gradually over a period of time.
Verification	Procedure to analyze cell controls or whole blood with known values to determine if your control results are within expected range.
Verify Predilute	Procedure that performs the aspirate-verify cycle followed by the dispense-verify cycle.
Voting	In COULTER hematology instruments, the system compares the three counts for RBC, WBC, Plt. Unless at least two counts agree, the system does not accept the count. It displays a code (-----) to indicate a voteout.
Wet Prime Cycle	Primes the fluidics path of the Diluter and baths with diluent and removes small amounts of air that may have leaked into the diluent lines.
Whole Blood	Non-diluted blood; blood and anticoagulant only.
Whole Blood Cycle	Executes “Request Sample Analysis” using whole blood as a specimen.
Zap Aperture Cycle	Clears the aperture using the zap current circuit.

ABBREVIATIONS

Abbreviation	Explanation
µL	microliter
µm	micrometer
A	ampere
AIM	aperture integrity monitor
ANSI	American National Standards Institute
ASCII	American Standard Code for Information Interchange
ASTM	American Society for Testing and Materials
AWG	American Wire Gauge
bps	bits per second
CBC	complete blood count
CDC	Centers for Disease Control and Prevention
CEE	Commission for Electrical Equipment
CHD	Coulter Histogram Differential
cm	centimeter
CSA	Canadian Standards Association
CV	coefficient of variation
diff	differential
dL	deciliter
EDTA	ethylenediaminetetraacetic acid
FDA	Food and Drug Administration
fL	femtoliter
ft	foot or feet
g	gram
gal	gallon
GR	granulocyte
Hct	hematocrit
Hgb	hemoglobin
Hz	hertz
IEC	International Electrical Commission
IQAP	Interlaboratory Quality Assurance Program
L	liter
LY	lymphocyte
m	meter
MCH	mean corpuscular hemoglobin
MCHC	mean corpuscular hemoglobin concentration
MCV	mean corpuscular volume

Abbreviation	Explanation
mL	milliliter
mm	millimeter
MO	mononuclear
MPV	mean platelet volume
MSDS	material safety data sheets
mW	milliwatt
n	number
NCCLS	National Committee for Clinical Laboratory Standards
NEMA	National Electrical Manufacturers Association
nm	nanometer
pg	picogram
Plt	platelet
psi	pounds per square inch
QA	quality assurance
RBC	red blood cell
RDW	red cell distribution width
SD	standard deviation
UL	Underwriters Laboratory
Vac	volts of alternating current
Vdc	volts of direct current
VIC	vacuum isolator chamber
VRM	Volts Root Mean Square
WBC	white blood cell

Symbols

Numerics

A

B

C

D

E

F

G

H

I

L

M

N

O

P

Q

R

S

T

U

V

W

Z

TRADEMARKS

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▪ Reference PN 4237422	Use and Function • Installation • Operation Principles • Specifications/Characteristics • Precautions/Hazards • Host Transmission Specifications • Log Sheets • References • Glossary • Abbreviations • Index
▪ Operator's Guide PN 4237416	Routine Procedures • Cell Controls • Running Samples • Reviewing Results • Calibration • Service and Maintenance • References • Glossary • Abbreviations • Index
▪ Operating Summary PN 4237420	Overview of daily procedures and screen icons.
▪ Installation and Training Guide diff A^{C}•T Tainer PN 4237417	Installing the A^{C}•T diff Analyzer • Learning About the A^{C}•T diff Analyzer • Questions and Answers • Component Locations • Installation Checklist
▪ Installation and Training Guide diff A^{C}•T Pak PN 4237421	Installing the A^{C}•T diff Analyzer • Learning About the A^{C}•T diff Analyzer • Questions and Answers • Component Locations • Installation Checklist

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