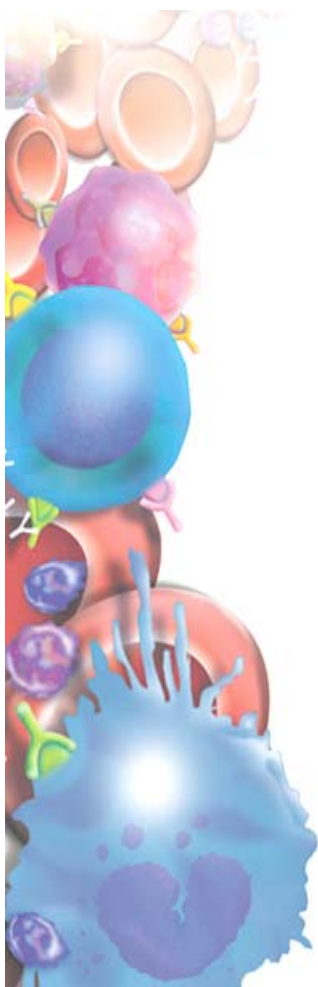




**BECKMAN
COULTER**



**COULTER[®] A^C•T diff[™]
COULTER[®] A^C•T diff 2[™]**

HEMATOLOGY ANALYZER

ROUTINE OPERATION

EASY REFERENCE GUIDE

INTRODUCTION

READ ALL PRODUCT MANUALS BEFORE ATTEMPTING TO OPERATE INSTRUMENT

This document is not intended to replace the information in your instrument Instructions for Use manual. Information in the Instructions for Use manual supersedes information in any other manual.

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

HAZARDS AND OPERATIONAL PRECAUTIONS AND LIMITATIONS

WARNINGS, CAUTIONS, and IMPORTANTS alert you as follows:

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

SAFETY SYMBOLS



Biohazard

Consider all materials (specimens, reagents, controls, etc.) 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 / A^C•T diff 2 analyzer from electrical outlet

SUMMARY OF ICONS

Before you begin, familiarize yourself with some of the instrument screen icons

	Closed Vial Whole Blood Mode		Diluter Functions
	Open Vial Whole Blood Mode		Continue
	Predilute Mode		Print
	Analyzing Mode		Exit
	In Progress		Next Sample ID
	Main Screen		Save and Exit
	Startup		Dispense Diluent
	Shutdown		Delete
	Sample Results		Darken Screen
	Diagnostics		Lighten Screen
	Setup		Retrieve Stored Data
	Quality Assurance		4C PLUS Run
	Reproducibility Run		Carryover Run
	Calibration Assigned Values		

TABLE OF CONTENTS

COULTER[®] A^C•T diff / A^C•T diff 2

Routine Operation

DAILY OPERATION

Startup	3
Running COULTER 4C Plus/4C-ES [®] Cell Control	4
Running Patient Samples / Whole Blood Mode	7
Shutdown	9

QUALITY CONTROL

Quality Control Review	10
Participating in IQAP	13
Quality Control Set Up	16

DATA REVIEW

Codes and Flags	19
Histograms	21

TABLE OF CONTENTS

GENERAL PROCEDURES

<u>POWER UP ANALYZER</u>	22
---------------------------------	----

<u>REPLACING REAGENTS</u>	24
----------------------------------	----

<u>GENERAL PROCEDURE SCHEDULE</u>	31
--	----

CLEANING

Zap Apertures	33
---------------	----

Cleaning (Bleaching) the baths	34
--------------------------------	----

Cleaning Dust Filter (A ^C •T diff 2)	35
---	----

REPLACING

Vacuum fluid barrier	36
----------------------	----

Peristaltic Pump Tubing (A ^C •T diff)	38
--	----

Diluent Filters (A ^C •T diff)	42
--	----

Replacing Syringe Pistons/Syringe Assemblies (A ^C •T diff)	44
---	----

Waste Filter (A ^C •T diff 2)	49
---	----

RBC Diluent Filters (A ^C •T diff 2)	52
--	----

Hydrophilic Diluent Filters	58
-----------------------------	----

CALIBRATION

Preparation for Calibration	62
-----------------------------	----

Reproducibility	63
-----------------	----

Carryover	64
-----------	----

Autocalibration with COULTER S-CAL [®] Calibrator	67
--	----

APPENDIX

Recognize the Products	72
------------------------	----

Parts List	73
------------	----

Revision Status	74
-----------------	----

Trademarks	75
------------	----

Notes	76
-------	----

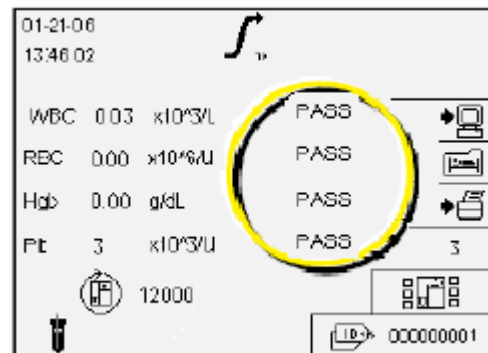
STARTUP

Do this procedure daily.

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



2. Review results on Startup screen.



3. If all parameters *PASS*, touch **Print** icon.



- Go to **Running 4C-ES[®] Cell Control** on page 4.
4. If any parameters *FAIL*, repeat Startup up to **two times**.
 - If Startup continues to fail, refer to A^C•T diff or A^C•T diff 2 *Operator's Guide, Service and Maintenance* chapter; *Troubleshooting*.

DAILY OPERATION / RUNNING CONTROLS

RUNNING COULTER® 4C PLUS/4C-ES® CELL CONTROLS

NOTE: You may use either "COULTER 4C-ES Cell Control" or "4C Plus Cell Control" on your AC•T diff /diff 2 analyzers. We will refer to all acceptable control material as **4C-cell control** throughout this document.



1. Remove control vials from refrigerator.

- Confirm that *lot numbers* and *expiration dates* on vial match information on the Table of Expected Results.
- Warm **at** room temperature **10 - 15 minutes**.



2. At Instrument Main screen

- Touch **QA** icon.

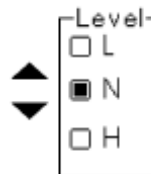


4C Run icon



- Select correct control level:

L - low
N - normal
H - high



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

DAILY OPERATION / RUNNING CONTROLS

3. Verify control cap is secure.

4. Mix each control vial **8 x 8 x 8** times according to package insert instructions.



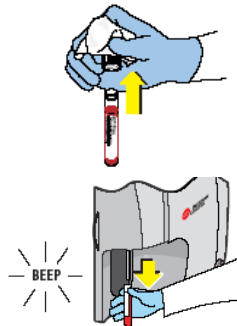
- Inspect vial contents to ensure uniform cell distribution. If contents are not well distributed, repeat this mixing procedure.

A^C•T diff

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

Place well-mixed vial under probe. Press the aspirate switch.

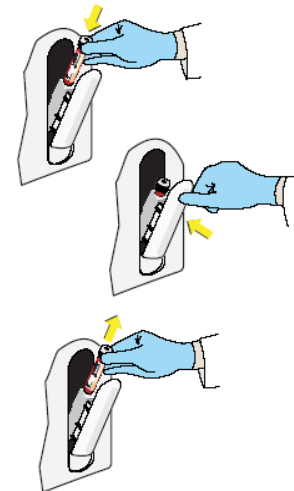
When you hear the **beep** remove the vial and recap it.



A^C•T diff 2

Place well-mixed vial in Cap Pierce tube holder and close door.

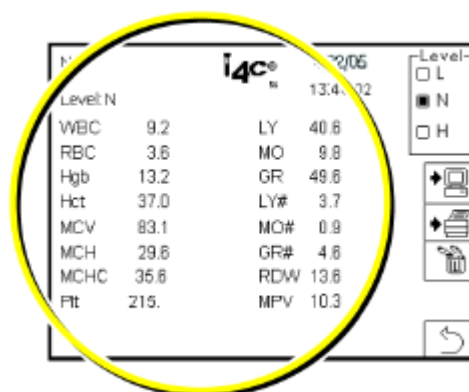
When tube holder door opens, remove vial.



DAILY OPERATION / RUNNING CONTROLS

5. Results appear on screen.

- Review control results.
 - Refer to **Quality Control** section for review procedures.
- To reject a result, touch **Trash** icon.
- Control results are automatically stored (unless results are non-numeric).
- If Autoprint is OFF, manually print results.



i4c [®]			
Level: N			13.4, 32
WBC	9.2	LY	40.6
RBC	3.6	MO	9.8
Hgb	13.2	GR	49.6
Hct	37.0	LY#	3.7
MCV	83.1	MC#	0.9
MCH	29.6	GR#	4.6
MCHC	35.6	RDW	13.6
Plt	215.	MPV	10.3

6. Repeat steps 3 through 5 for each required control level.
7. Return control vials to refrigerator within **30 minutes** of removing them.
8. Refer to **QUALITY CONTROL REVIEW** in this document.
9. Review out-of-limits control results according to your laboratory's protocol.

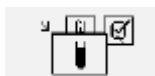
DAILY OPERATION / RUNNING SAMPLES

RUNNING PATIENT SAMPLES / WHOLE BLOOD MODE



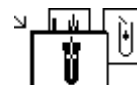
1. At Main screen select

A^C•T diff



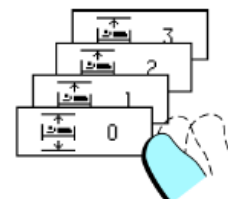
Whole Blood mode

A^C•T diff 2



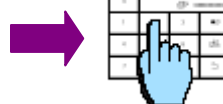
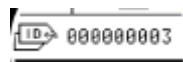
Closed Vial Whole Blood mode

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



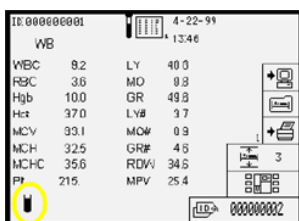
NOTE: 0 is not a patient range, it is the instrument's linearity limit.

- Enter *Sample ID*

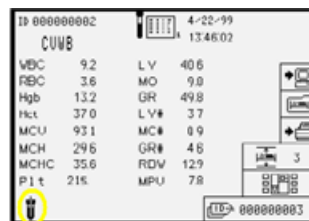


2. Mix sample **thoroughly** according to your laboratory's protocol.
3. Be sure you are in **Whole Blood** mode.

A^C•T diff



A^C•T diff 2



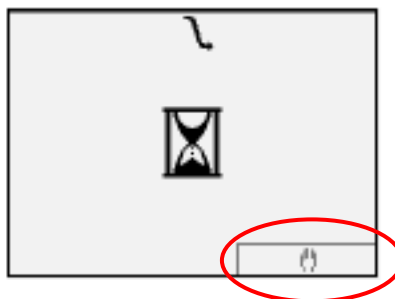
SHUTDOWN

Perform Shutdown daily.

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



2. To abort Shutdown cycle, press **Stop**  icon.



Allow A^c•T Rinse to remain in the instrument for 30 minutes.

At end of Shutdown cycle, you receive a screen prompt to perform Startup.

3. To perform Startup, touch **Continue** icon.



QUALITY CONTROL REVIEW

NOTE: Non-numeric control results are not stored.

If control results are within expected ranges, proceed to run the next control level.

Reviewing control results

1. Review control results as they are run.
2. Rerun any controls not within expected ranges.
 - If rerun control is still out of range, follow your laboratory's protocol for troubleshooting out-of-range controls
 - Reject the control, if necessary.
3. If a control is run in the **wrong** file
 - Delete it **immediately** or all control results for that file are invalid for IQAP reporting.
 - IQAP information must then be entered manually using eIQAP so that the invalid run can be excluded.
4. If no more storage space is available for one or more 4C-control files, **Control file full** icon  appears at bottom of screen.
5. If control is **expired**, do not use it.  icon appears at bottom of screen.

QUALITY CONTROL / REVIEW

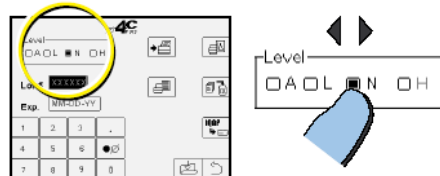
Deleting and Printing 4C Series cell control files

NOTE: Once deleted, control files cannot be recovered. Be sure you have all control information you need before deleting any files.

1. If your laboratory participates in IQAP, download all control data for IQAP before proceeding to step 2.
 - If your laboratory does not participate in IQAP, go to step 2.

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

3. Select control level for printing.



4. To print

- Summary: touch **Print Summary** icon. 
- Levy-Jennings: touch **Print Graph** icon. 

5. To delete control files for the level selected in step 4,

- Touch **Trash** icon.  Delete Confirmation screen appears.
- Touch **Trash** icon again.  **OR**
- Touch **Return** icon  to return to pervious screen without deleting.

QUALITY CONTROL / REVIEW

IMPORTANT INFORMATION ABOUT 4C-ES Cell Control

- 4C-ES cell control is an **Extended Stability** control. A set of lot numbers can be used for 90 days.
- **Open vial stability** defines the maximum # of events that can occur with a control vial.
- An event occurs each time a vial is taken out of the refrigerator, warmed and refrigerated again.
- 4C-ES cell control has a maximum of 20 allowable events within 35 days
- IQAP is a free program offered by Beckman Coulter that compares your laboratory's submitted control results to all other laboratories using the A^C•T diff or A^C•T diff 2 analyzer and the same 4C-ES cell control lot numbers. Your Beckman Coulter Representative can help you enroll into IQAP and provide you with information about eIQAP (electronic IQAP).

PARTICIPATING IN IQAP (INTERLABORATORY QUALITY ASSURANCE PROGRAM)

Stored 4C-Series cell control results can be returned for inclusion in the IQAP program. For additional information about the IQAP program, see the *IQAP Procedure Manual and Addendum for Beckman Coulter Instruments* assayed for 4C-ES- Cell Control or visit our website at www.BeckmanCoulter.com

Save used reagent management cards from your A^C•T diff Series reagent to use for this procedure.

NOTE: Only A^C•T diff reagent management cards should be used.

NOTE: Prior to downloading your data, ensure that your IQAP participant number has been entered into your instrument.

Without the IQAP participant number, your data cannot be automatically processed.

Attach the IQAP identification label to a used reagent management card, using care not to cover up the microchip (gold square).

-
1. Review the control summary printout that contains the individual control runs, mean, 2SD, N (number of runs). Ensure that:
 - The controls were analyzed in a correct file.
 - The control files contain the correct lot number.
 - The control files contain only one *month's* worth of data points.

If the control files meet these criteria, go to Step 2.

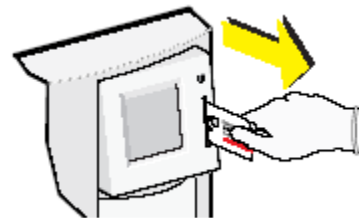
If the control files do not meet these criteria, do not continue this procedure because the control files cannot be processed from the IQAP download onto the reagent management card.

QUALITY CONTROL / SET UP

If you identify any erroneous data identified above, you will need to submit your data using the following.

- The Electronic Interlaboratory Quality Assurance Program (eIQAP); visit <http://www.beckman.com/eiqap>

2. Remove the current A^C•T diff reagent management card and insert a **used** reagent management card into the instrument.



3. At the Main screen

- Touch **QA icon**.



- Touch **4C Management icon**.



4. At the 4C Management screen:

- Select **A** (all levels of control).
- Touch **IQAP icon** to download the data to the card.



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



6. Place the reagent card with stored control data and attached label into the pre-addressed mailer, using care not to cover up the microchip (gold square)

Return the mailer to Beckman Coulter's IQAP department.

7. To submit your data electronically, visit <http://www.beckman.com/eiqap>.

8. After completing the IQAP download, delete the control files:

- Select (A) for **All** files.

- Touch  icon The Delete Confirmation screen appears.

- Touch  icon again to delete the files.

OR

- Touch  to return to the previous screen without deleting the files.

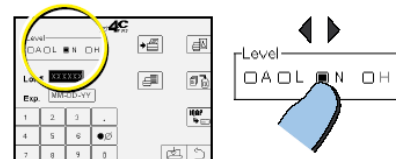
9. Enter your next set of controls by entering the new assigned values, expected ranges, lot numbers and expiration dates.

QUALITY CONTROL SET UP

ENTERING LOT NUMBER / EXPIRATION DATE

1. At Main screen, touch **QA** icon.  → **4C Management** icon. 

- Select control **Level** (L, N, or H)



- Touch **Lot #** field and enter lot number located on vial (up to 6 digits).

Example: 079600

- Touch **Exp.** field and enter expiration date (up to 6 digits) in MMDDYY format.

Example: 12-23-06



Enter in dashes between the MM-DD-YY format

- Touch **Print** icon to print control set up information for your records.



- Touch **Save and Exit** icon to save control set up information.



- Repeat step 1 until all lot numbers and expiration dates are entered for all levels.

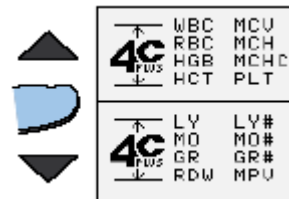
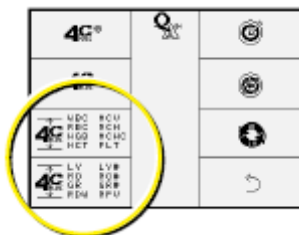
QUALITY CONTROL / SET UP

ENTERING ASSIGNED VALUES and EXPECTED RANGES.

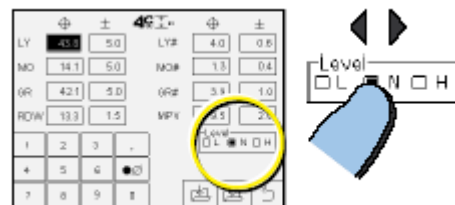
2. At Main screen, touch **QA** icon.



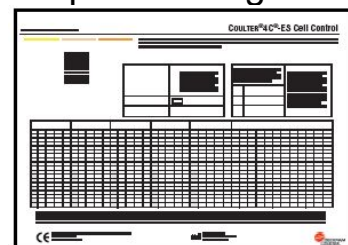
- At the QA screen touch one of the 4C Parameter icons



- Select the control level:

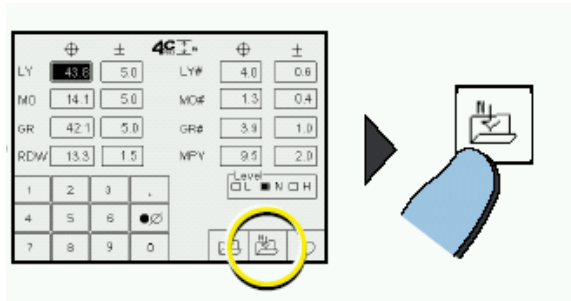


- Refer to **TABLE OF EXPECTED RESULTS** supplied with your control material for assigned values and expected ranges.



QUALITY CONTROL / SET UP

- On keypad enter the assigned values and expected ranges from **TABLE OF EXPECTED RESULTS**. Touch the **Save** icon to save the control file information.



- When you are finished entering all values for the control, touch **Save and Exit** icon.



- Repeat step 2 until all assigned values and expected ranges are entered for all levels.
- To print entered values

➤ Return to  screen. ➔ **4C Management** icon. 

➤ Select **A** for all levels.



➤ Touch **Print** icon.



DATA REVIEW

Refer to the A^C•T diff / A^C•T diff 2 *Installation and Training guide* or the *Operator's Guide* for information about patient sample collection and storage requirements, as well as instructions for handling irregular sample results. If sample is flagged, review the results per laboratory protocol.

CODES AND FLAGS

The A^C•T diff / diff 2 produces two types of flags:

- **CODES** that *replace* parameter results.
- **FLAGS** that appear *next to* parameter results. Up to two flags can be displayed for a parameter.

Replacement Flags (CODES)

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

- - - - - (Total Voteout)
- +++++ (Results exceed operating range)
- xxxxx (Aperture Alert)
- (Incomplete Computation)

Non-Replacement Flags

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

X (one or more Aperture Alert criteria not met)

+ (overrange result: greater than linear range but less than operating range)

WBC > 99.9 but < 150 X 10³ /μL

RBC > 7.0 but < 8.00 x 10⁶ /μL

Hgb > 25.0 but < 30.0 g/dL

Plt > 999 but < 3000 x 10³ /μL

***** (occurs on parameters influenced by +++++, +, or - - - -)

1, 2, 3, 4, M (where M means multiple region failure on WBC histogram)

Flagging on the Analyzer

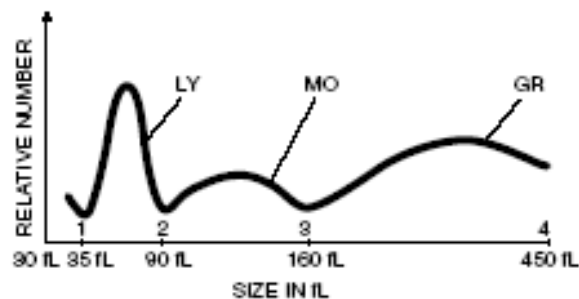
On the Analyzer you can set up three sets of **Patient Ranges** (1, 2 and 3) according to your laboratory's protocol.

You select the Range you want to use before running patient samples. The samples will be flagged with a **H** (High) when result is higher than the high patient sample limit or **L** (Low) when result is lower than the low patient sample limit.

Follow your laboratory's protocol for action to take.

Attention: Beckman Coulter does not claim to identify every abnormality in samples and suggests using all available flagging options to optimize the sensitivity of the instrument results. All flagging options include reference ranges (H/L), codes, and flags. Beckman Coulter recommends avoiding the use of single messages or outputs to summarize specimen results or patient conditions.

Histograms



WBC differential histogram areas

The percentage of leukocytes (WBC) that fall into each of the three population categories is derived from the WBC histogram.

WBC Differential Histogram Flagging

WBC differential results (% and #) may be flagged **1, 2, 3, 4, or M** depending on the regions that failed. **M** = multiple region failure.

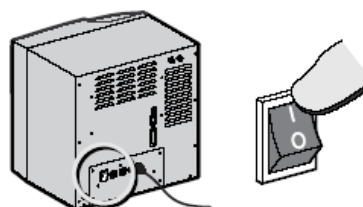
WBC differential results flagged *only* with * indicates interference with differential populations.

If both WBC **and** WBC differential results are flagged with *, this indicates the 35 fL check for interference failed.

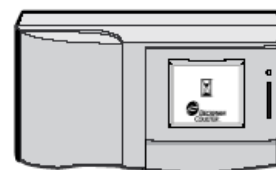
GENERAL PROCEDURES / POWER UP ANALYZER

Power Up Analyzer

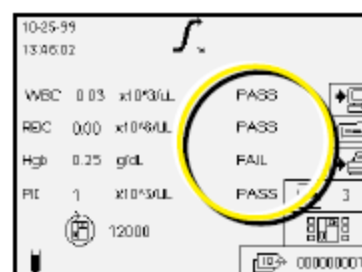
1. At the back of the instrument, press the on button to turn instrument ON.



2. For the next few minutes, the instrument performs its startup process. You will see various screen displays on the touch screen.



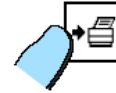
3. Next the instrument performs a background check and indicates a *PASS* or *FAIL* message for each parameter.



GENERAL PROCEDURES / POWER UP ANALYZER

4. If *PASS* appears for all parameters, print the results by touching the **Print** icon.
Note: If Autoprinting is ON, the report prints automatically.

PASS
PASS
PASS
PASS



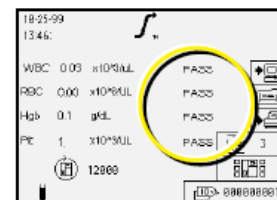
If *FAIL* appears for any parameter, do Startup again:

- Touch the **Main Screen** icon.
- Touch the **Startup** icon. The instrument goes through the startup process again.
- Allow the instrument to complete the startup routine.
- If *FAIL* appears for any parameter, repeat steps a through c.
 - 1) If, after repeating steps a through c two times, *FAIL* appears for any parameter refer to A^C•T diff Operator's Guide, Service and Maintenance chapter; Troubleshooting.
 - 2) If *PASS* appears for all parameters, print the results as described above.

FAIL



5. After the startup report prints, touch the Main Screen icon to continue.



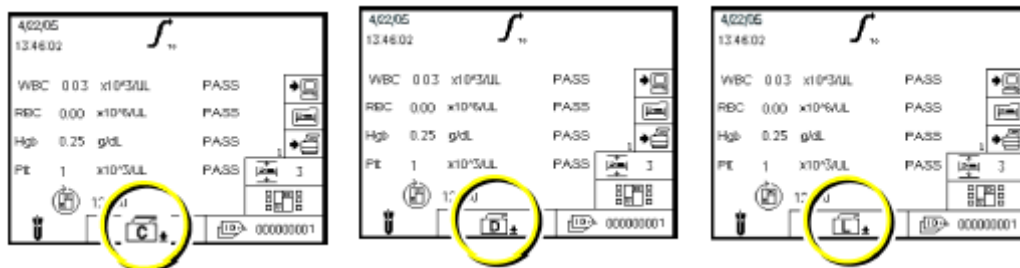
PASS
PASS
PASS
PASS



GENERAL PROCEDURES / REPLACING REAGENTS

REPLACING REAGENTS

A change of reagents may be necessary when you see one of these icons:

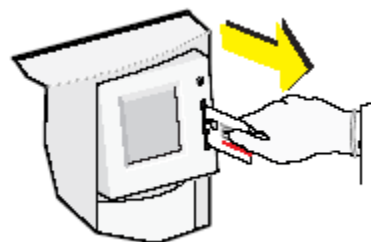


Replacing the COULTER® A^C•T diff Pak™ or Tainer Reagents™



1. Remove the A^C•T diff Pak or Tainer reagent management card from the instrument.

NOTE: Keep used reagent management card for downloading IQAP, if applicable.



2. A^C•T diff Pak

Obtain new A^C•T diff Pak
Verify Expiration Date



- A^C•T diff Tainer

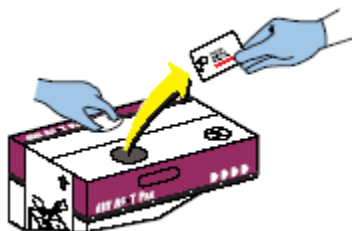
Obtain new A^C•T diff Tainer
Verify Expiration Date



GENERAL PROCEDURES / REPLACING REAGENTS

3. A^C•T diff Pak

Pull the perforated cardboard from the reagent container box, and remove the management card.

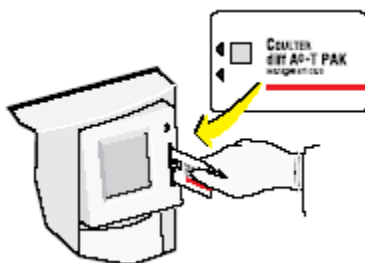


A^C•T diff Tainer

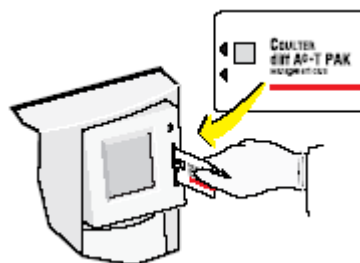
Remove the new reagent management card from the sleeve on the reagent container.



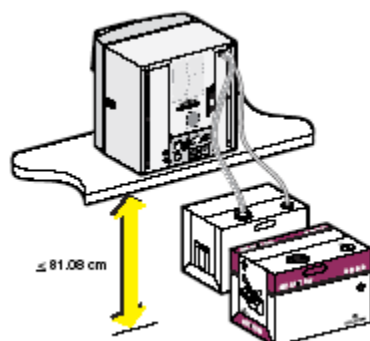
4. Insert A^C•T diff Pak reagent management card from new reagent container into slot at front of instrument.



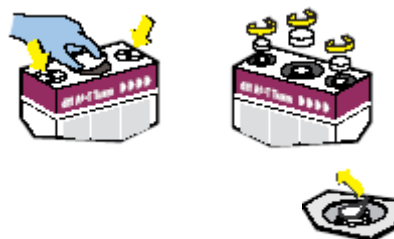
Insert A^C•T diff Tainer reagent management card from new reagent container into slot at front of instrument.



5. Place new A^C•T diff Pak reagent container next to empty container.



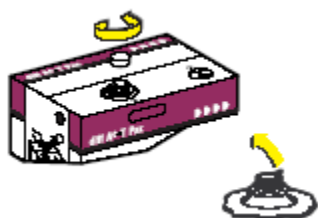
Unscrew the three white plastic caps from the A^C•T diff Tainer reagent container and remove seals to expose each opening.



GENERAL PROCEDURES / REPLACING REAGENTS

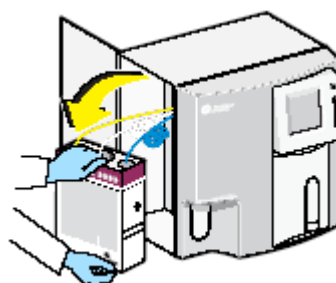
6. A^C•T diff Pak

Remove cap and seal for tube number 1 on A^C•T diff Pak container.



A^C•T diff Tainer

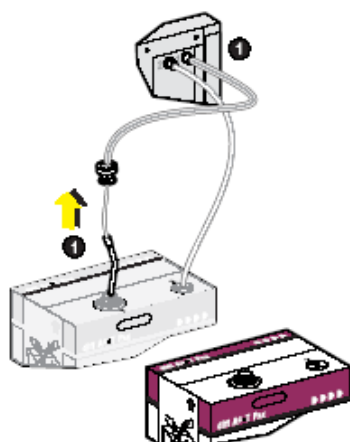
Open reagent compartment door and remove empty A^C•T diff Tainer reagent container.



IMPORTANT Risk of misleading results if the pickup tubes are contaminated. Ensure that the reagent pickup tubes remain clean and free of contamination. Avoid contact with lab surfaces or your gloved hands.

7. A^C•T diff Pak

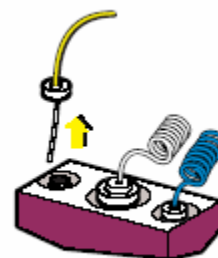
Remove reagent pickup tube 1 from empty reagent container.



A^C•T diff Tainer

Remove pickup tube 1 from reagent container:

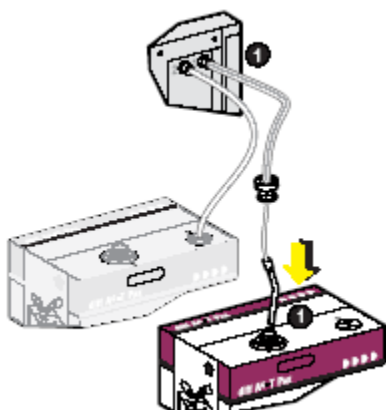
- Unscrew the cap
- Pull reagent tube 1 from container



GENERAL PROCEDURES / REPLACING REAGENTS

A^C•T diff Pak

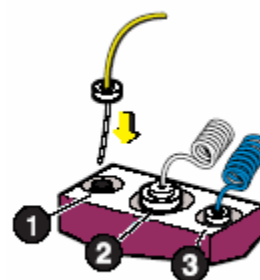
8. Insert reagent pickup tube 1 into New container and tighten cap.



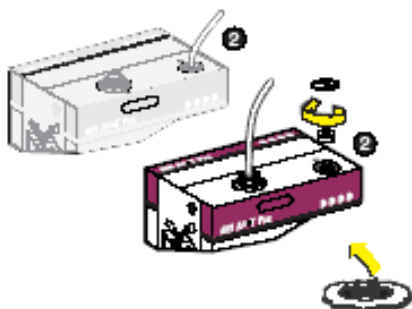
A^C•T diff Tainer

Connect pickup tube 1 to the new reagent container box:

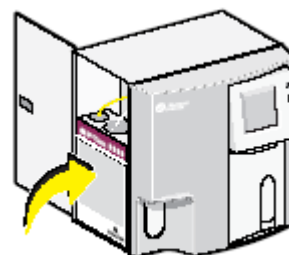
- Insert cap end of pickup tube 1 into opening 1 of reagent container
- Screw cap to container.



9. Repeat steps 7 and 8 for reagent with pickup tube 2.

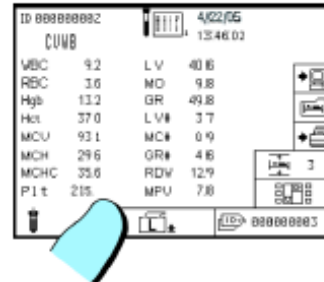


Repeat steps 7 and 8 for reagent pick up tubes 2 and 3 and place container with tubes attached in reagent compartment. Close compartment door.

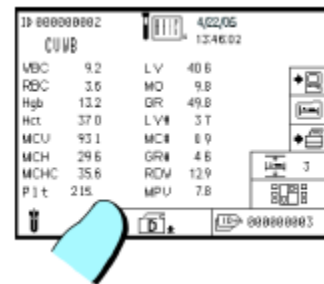


GENERAL PROCEDURES / REPLACING REAGENTS

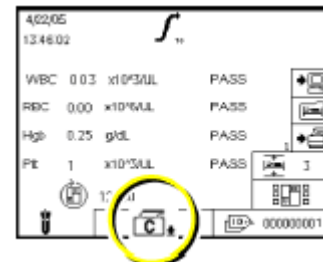
10. Touch **Lyse Prime** icon, if displayed.



11. Touch **Diluent Prime** icon, if displayed.



12. Touch **AcT Rinse Prime** icon if displayed



13. Follow your laboratory's protocol for recording reagent lot numbers and expiration dates of the new A^C•T diff Pak / A^C•T diff Tainer reagents.

GENERAL PROCEDURES / REPLACING REAGENTS

REPLACING A^C•T Rinse™ Shutdown Diluent (with PAK only)

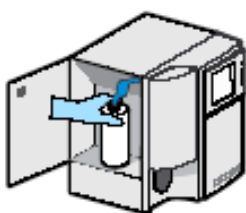


Replace Rinse container when you see this screen:

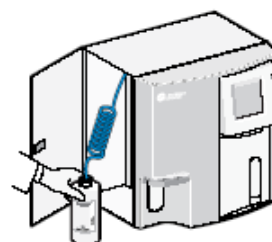


1. Open reagent compartment door and remove Rinse container with tubing still attached.

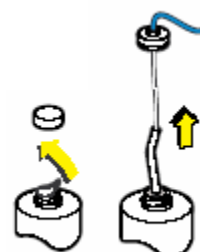
A^C•T diff



A^C•T diff 2



2. Remove pickup tube from Rinse container:
 - a. Unscrew cap
 - b. Pull tube from container



GENERAL PROCEDURES / REPLACING REAGENTS

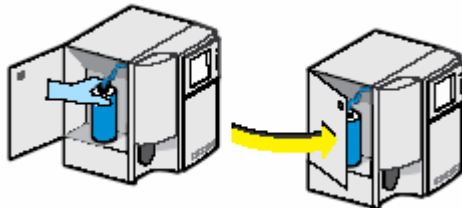
IMPORTANT Risk of misleading results if the pickup tubes are contaminated. Ensure that the reagent pickup tubes remain clean and free of contamination. Avoid contact with lab surfaces or your gloved hands.

3. Connect pickup tubes to new Rinse container:
 - a. Insert pickup tube into Rinse container
 - b. Screw cap to bottle

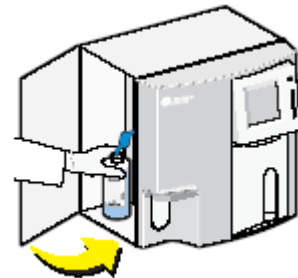


-
4. Place new Rinse container into reagent compartment and close door.

A^c•T diff



A^c•T diff 2



-
5. Touch **Continue** icon to prime Rinse.

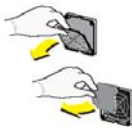


GENERAL PROCEDURES / SCHEDULE

GENERAL PROCEDURES SCHEDULE

Procedure	Frequency	Situation
Clean the baths 	When necessary	• Before any type of calibration • Increased voteouts, MCV values, X flags • Decreased cell counts • Failure to recover control values • Erratic MCV, RBC, and WBC counts • Aperture alerts not remedied by zapping the apertures
Replace Hydrophilic Diluent Filters 	At least every 6 months or 5,000 cycles	• When you get platelet background failures • When you get chronic "Diluent Empty" messages
Replace peristaltic pump tubing (A^C•T diff) 	Every 12 months or every 10,000 cycles	• <u>When you replace diluent filters</u> • When you get excessive diluent empty messages • When tubing is worn to the extent that it looks almost worn through
Replace diluent filters (A^C•T diff) 	When necessary	• <u>When you replace peristaltic pump tubing</u> • When you get excessive diluent empty messages • When a filter is clogged
Replace syringe pistons and seals (A^C•T diff) 	Every 12 months or every 10,000 cycles	• Excessive fluid leaks • You see build-up around a syringe

GENERAL PROCEDURES / SCHEDULE

Procedure	Frequency	Situation
Clean Dust Filter (A ^C •T diff 2) 	Approximately every 6 months	Dust is visible on filter
Replace waste filter (A ^C •T diff 2 only) 	Every 12 months or every 10,000 cycles	- Waste does not drain from the baths and VIC - Baths overflow
Replace Vacuum Fluid Barrier 	As required based on vacuum readings	Repeated vacuum errors
Replace RBC Diluent Filters (A ^C •T diff 2 only) 	Every 6 months or every 5,000 cycles	Chronic Platelet Background Failures

GENERAL PROCEDURES / ZAPPING THE APERTURES

GENERAL PROCEDURES

This section documents the most common A^C•T diff Series general procedures, including cleaning and replacement procedures.

Performing these procedures ensures product performance.
Document all procedures performed in the maintenance log included with the *Reference Manual*.

For additional information consult the chapters in A^C•T diff *Operator's Guide* (PN 4237416), or A^C•T diff 2 *Operator's Guide* (PN 4237495): Troubleshooting; Cleaning Procedures; and Replacement Procedures.

CLEANING PROCEDURES

ZAPPING THE APERTURE

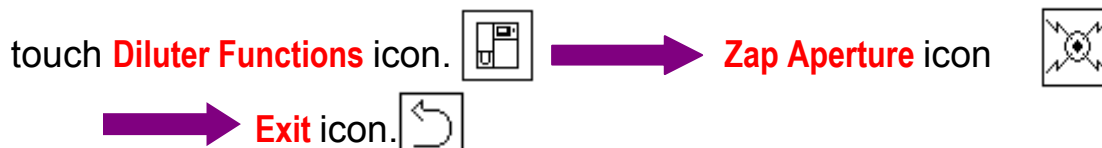
Perform this procedure when instrument produces

- increased Aperture Alerts, Voteouts, or MCV values
- decreased cell counts
- erratic MCV, RBC and WBC counts

OR

- fails to recover control values

1. At Main screen



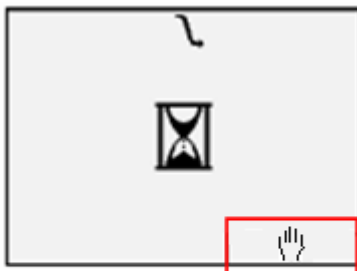
GENERAL PROCEDURES / CLEANING BATHS

CLEANING (BLEACHING) THE BATHS

NOTE: This procedure must be performed before Calibration. Otherwise, perform the procedure as needed by referring to A^C•T diff / A^C•T diff 2 *Operator's Guide*.

1. Fill a tube with more than 1 mL of high-quality, fragrance-free, gel-free bleach (5 to 6% solution of sodium hypochlorite - available chlorine).
2. At Main screen
 - touch **Diluter Functions** icon.   **Clean Baths** icon 
3. Place tube of bleach at probe so that tip is well into bleach, and press aspirate switch. The instrument cleans the baths.
4. The cleaning procedure takes approximately **15 minutes** to complete 

NOTE: To cancel cleaning procedure before 15 minute cleaning period ends, touch **Stop** icon. 



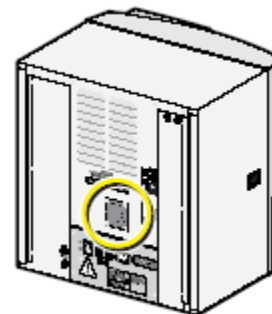
5. On Diluter Functions screen, touch **Exit** icon. 

GENERAL PROCEDURES / DUST FILTER

CLEANING THE FAN'S DUST FILTER (A^C•T diff 2)

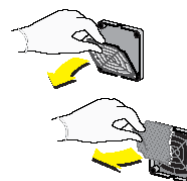
The fan is located on the back panel, and the filter is inside the fan's housing.

Clean the filter every 6 months unless the laboratory is in a dusty environment. Then more frequent cleaning is recommended, depending on conditions.



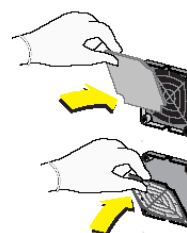
1. Turn instrument OFF and unplug from power source.

2. Remove grill and filter.



3. Clean filter in water and dry thoroughly.

4. Replace filter and grill.



6. Plug instrument into power source.

7. Turn instrument ON and resume normal operation.

GENERAL PROCEDURES / VACUUM FLUID BARRIER

REPLACEMENT PROCEDURES

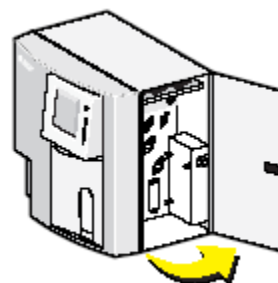
REPLACING VACUUM FLUID BARRIER

Vacuum Fluid Barrier PN 6232803

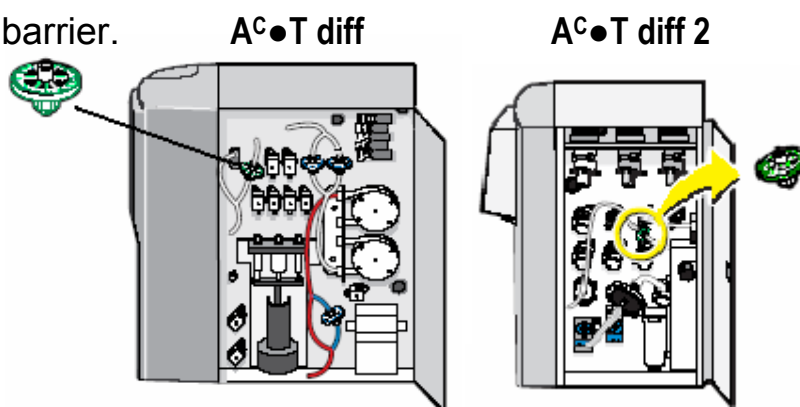


1. Turn instrument OFF and unplug from power source.

2. Open right compartment door.

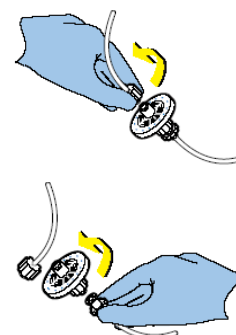


3. Locate vacuum fluid barrier.



4. Remove vacuum fluid barrier from the tubing:

- Twist off top connector.
- Twist fluid barrier off bottom connector.

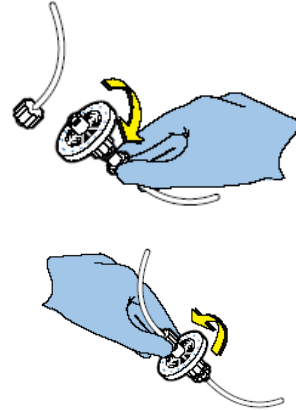


GENERAL PROCEDURES / VACUUM FLUID BARRIER

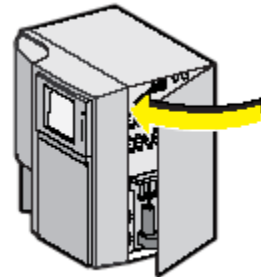
5. Properly dispose of used fluid barrier.

6. Connect a new fluid barrier to tubing by inserting tubing end into filter and turning connector until secure.

- Repeat above procedure to connect other end of fluid barrier.



7. Close right door.



8. Plug instrument into power source and turn Instrument ON to resume normal operation.

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

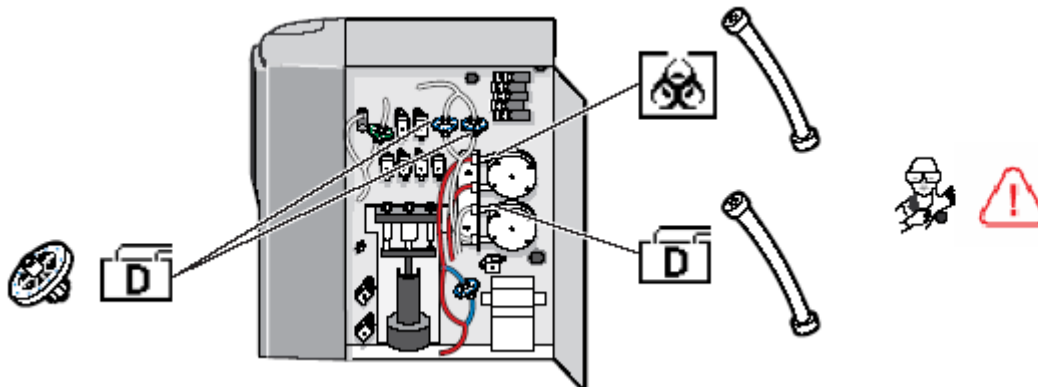
GENERAL PROCEDURES / PERISTALTIC PUMP TUBING

REPLACING PERISTALTIC PUMP TUBING (A^C•T diff only)

Peristaltic Pump Tubing PN 3213214

IMPORTANT! Risk of misleading results. Worn or damaged peristaltic pump tubing can cause misleading results. To avoid misleading results, replace the peristaltic pump tubing every 12 months or 10,000 cycles. **Replace Diluent Filters when replacing tubing.**

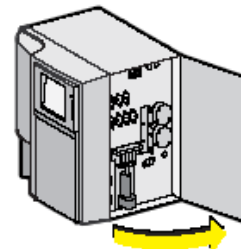
To optimize instrument performance, replace the peristaltic pump tubing when you get excessive diluent empty messages. In addition, check periodically for defects or twists in the tubing or for pump rollers that are not rotating properly, as these things may cause the tubing to wear more quickly.



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 instrument is cycling.

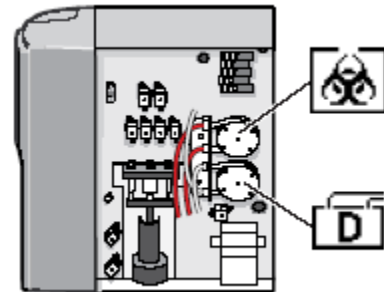
1. Turn instrument OFF and unplug from power source.

2. Open right compartment door.



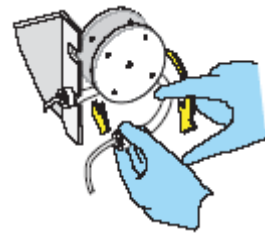
GENERAL PROCEDURES / PERISTALTIC PUMP TUBING

3. Locate biohazard waste pump and diluent/rinse pump.



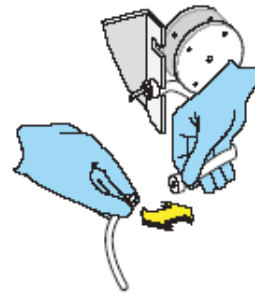
WARNING Risk of biohazard. The waste filter can contain biohazardous material that could cause contamination. Handle and dispose of filter according to acceptable laboratory protocol.

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

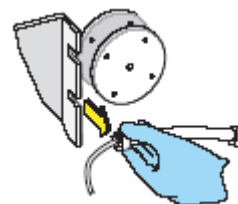


5. Disconnect pump tubing by pulling it apart from the fitting.

Note: When disconnecting the permanent tubing mark them as lower and upper, this will aid when installing the new peristaltic tubing in step 12.

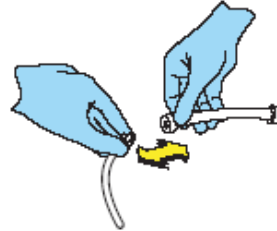


6. Pull tubing from bottom groove.



GENERAL PROCEDURES / PERISTALTIC PUMP TUBING

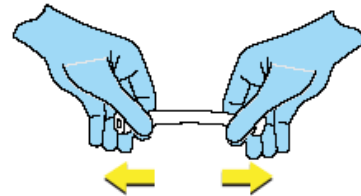
7. Disconnect pump tubing by pulling
8. it apart from the other fitting.



-
9. Properly dispose of used pump tubing.



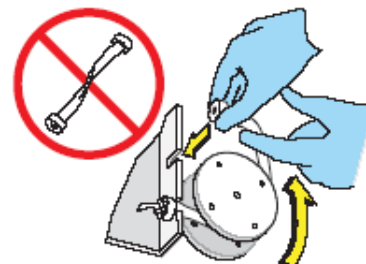
-
10. Stretch new pump tubing before connecting to the bottom fitting.



-
11. Place newly connected pump tubing in bottom groove.



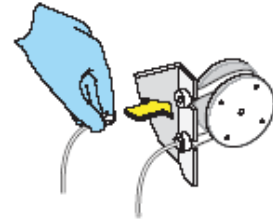
-
12. Stretch tubing around pump, using care not to twist or crimp tubing. Insert tubing into top groove.



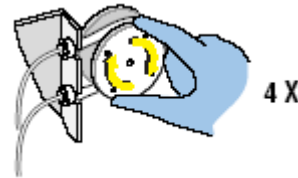
GENERAL PROCEDURES / PERISTALTIC PUMP TUBING

13. Connect tubing to top connector of pump tubing.

Note: Make sure to connect permanent upper and lower tubing correctly.



-
14. Rotate pump clockwise 4 times.



-
15. Repeat steps 3 through 13 for remaining pump.

-
16. Continue with **Replacing Diluent Filters** procedure.

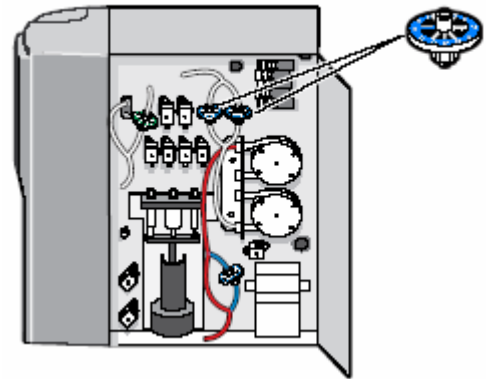
GENERAL PROCEDURES / DILUENT FILTERS

REPLACING DILUENT FILTERS (A^C•T diff only)

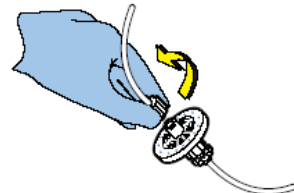
Diluent Filters PN 6233052



1. Locate diluent filters.



2. Remove diluent filter from the tubing:
 - Unscrew locking connector until completely loosened from fitting.
 - Pull tubing from diluent filter.



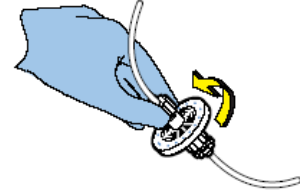
3. Repeat step 2 at other end, twisting filter *counterclockwise* to remove.

4. Properly dispose of diluent filter.



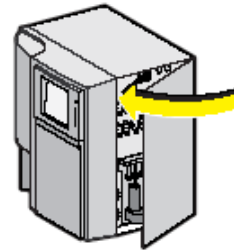
GENERAL PROCEDURES / DILUENT FILTERS

5. Connect a new diluent filter to tubing by turning connectors until secure.



6. Repeat step 5 to connect other end of diluent filter.

7. Close right compartment door.



8. Plug instrument in to power source and turn instrument ON.

9. Prime diluent lines:

- At Main screen, touch **Diluter Functions** icon.   **Wet Prime** icon. 

- When instrument is finished Priming, touch **Exit** icon 

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

GENERAL PROCEDURES / SYRINGE PISTONS

REPLACING SYRINGE PISTONS AND SYRINGE ASSEMBLIES

(A^C•T diff only)

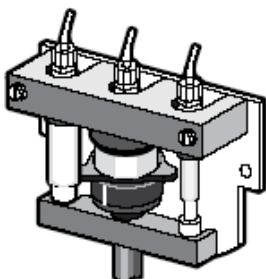
Syringe Pistons PN 2527677 (1 mL)
 PN 2527678 (250 µL)
 PN 2527679 (5 mL)



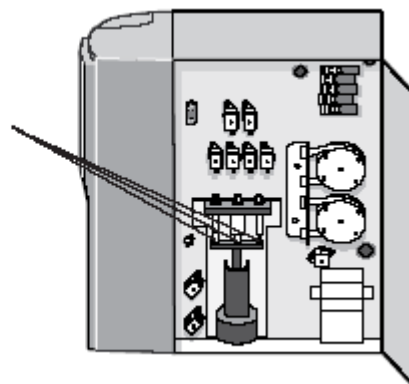
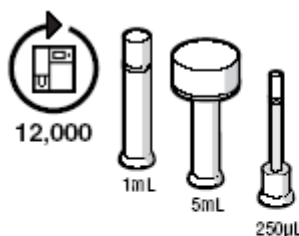
IMPORTANT! To optimize instrument performance, replace syringe pistons or syringe assemblies every 12 months or 12,000 cycles. When replacing more than one syringe piston, be sure to replace them one at-a-time to ensure that you do not misplace the plungers.

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.

OVERVIEW

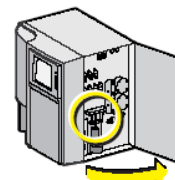


Syringe Assemblies



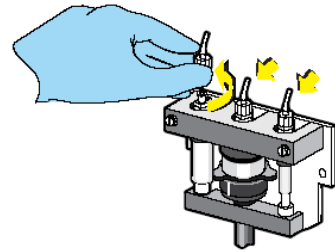
You need a regular, flathead screwdriver for this procedure.

1. Turn instrument off and unplug from power source.
2. Open right compartment door and locate syringes.

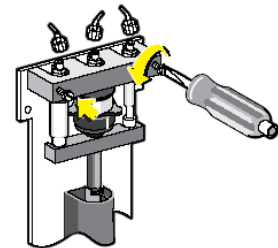


GENERAL PROCEDURES / SYRINGE PISTONS

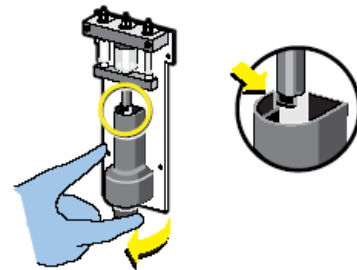
3. Remove connectors from syringes:
- Turn connectors clockwise until loosened.
 - Pull connector from syringe fitting.



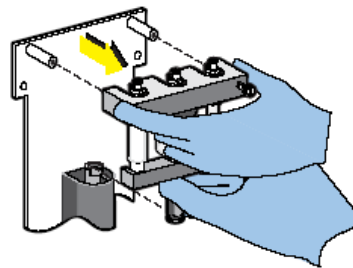
4. Unfasten screws securing top bracket.



5. Raise pistons until motor shaft coupling is visible.
- Locate knob on bottom of motor.
 - Turn knob clockwise until motor shaft coupling is visible.

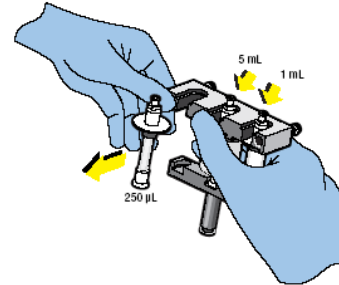


6. Remove syringe assembly.



GENERAL PROCEDURES / SYRINGE PISTONS

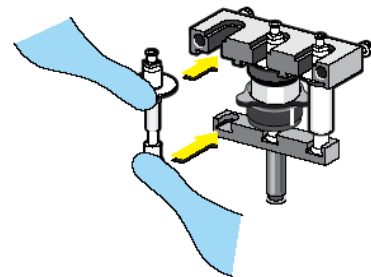
7. Remove syringe from bracket.



8. Properly dispose of the old syringe.



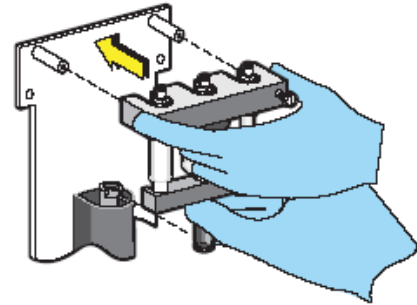
9. Insert replacement syringe assembly into bracket.
- Insert flange into groove.
 - Slide syringe all the way into bracket.



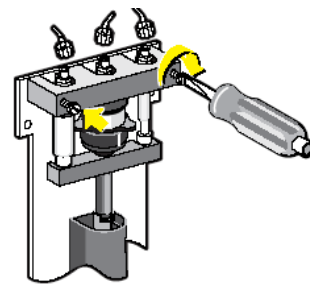
10. Repeat steps 7 through 9 as needed for the other syringes.

GENERAL PROCEDURES / SYRINGE PISTONS

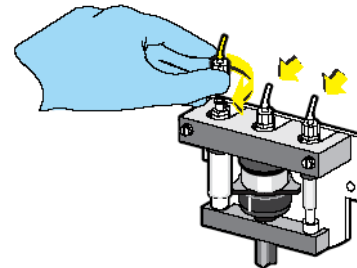
11. Slide syringe assembly onto screw posts and motor shaft.



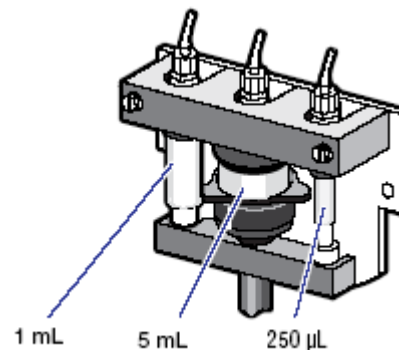
12. Secure bracket onto posts using screws you unfastened in step 4.



13. Reattach connectors to fittings and firmly tighten connectors.

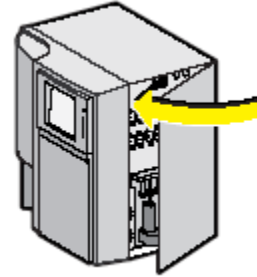


14. Be sure syringes are in bracket as shown.



GENERAL PROCEDURES / SYRINGE PISTONS

15. Close right compartment door.



-
16. Plug instrument into power source and turn instrument ON.

-
17. At Main screen, touch **Diluter Functions** icon.   **Wet Prime** 

-
18. After instrument finishes wet prime, touch **Exit** icon. 

-
19. Cycle a sample with known results to verify instrument performance.

GENERAL PROCEDURES / WASTE FILTER

REPLACING WASTE FILTER (A^C•T diff 2 only)

Waste Filter PN 6233045

TOOLS / SUPPLIES NEEDED

- Waste filter
- Pliers



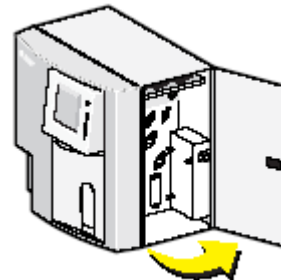
Be sure to wear full face protection when performing this procedure.

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

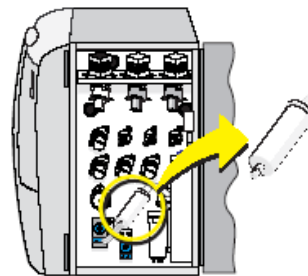


2. Turn instrument OFF *when Shutdown is completed* and unplug from power source.

3. Open right compartment door.



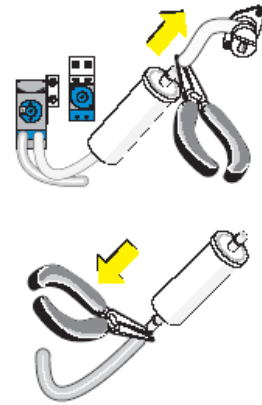
Locate waste filter



WARNING Risk of biohazard. The waste filter can contain biohazardous material that could cause contamination. Handle and dispose of the filter according to acceptable laboratory protocol.

GENERAL PROCEDURES / WASTE FILTER

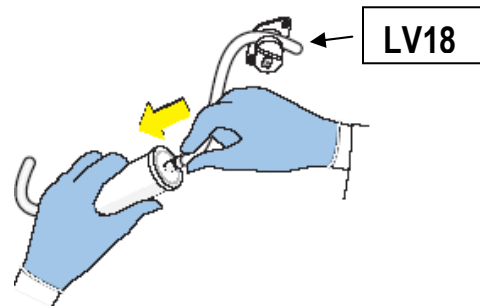
4. Using pliers, remove tubing from waste filter.



5. Properly dispose of used waste filter.

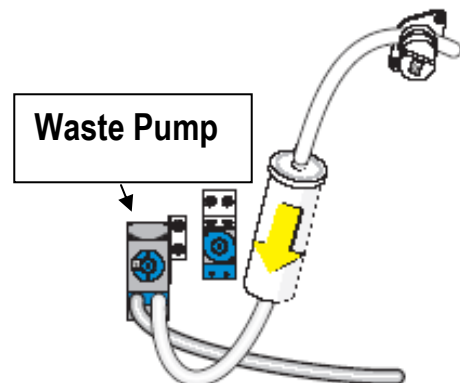


6. Connect tubing coming from LV 18 to port 1 of new waste filter. Port 1 is the end with flared outer ring.



7. Make sure arrow on the side of the filter points toward waste pump.

Note: The arrow on the filter is difficult to see. The picture is for illustration purpose only, your filter may be shaped differently.



GENERAL PROCEDURES / WASTE FILTER

8. Plug instrument into power source and turn instrument ON.

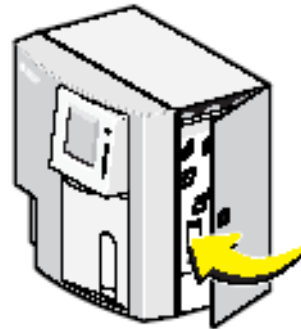
-
9. At instrument Main screen, touch **Startup** icon.



-
10. While Startup is running, verify that there are no fluid leaks around the waste filter area.

Verify that Startup passed.

-
11. Close right compartment door and resume normal operation.



GENERAL PROCEDURES / RBC DILUENT FILTER

Replacing the RBC Bath Diluent Filters (A^C•T diff 2 only)

The diluent filters should be replaced under the following conditions:

- Chronic platelet background failures
- At least every 6 months or 5,000 cycles

RBC Diluent Filters

PN# A51656

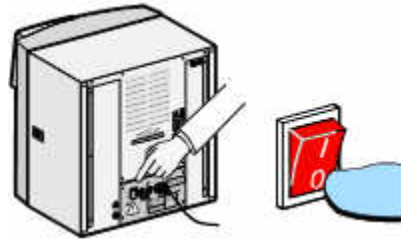
TOOLS / SUPPLIES NEEDED

- Diluent Filters (Qty. 2)
- Hemostat or similar tool



Be sure to wear full-face protection when performing this procedure!

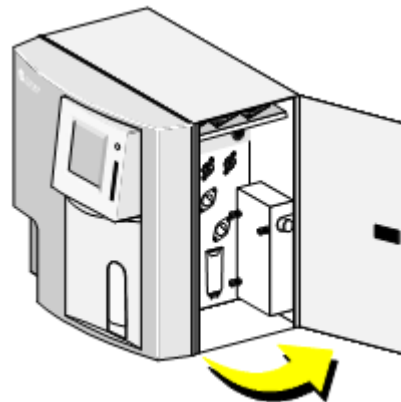
1. Turn the instrument off.



2. Unplug the instrument from the power source.

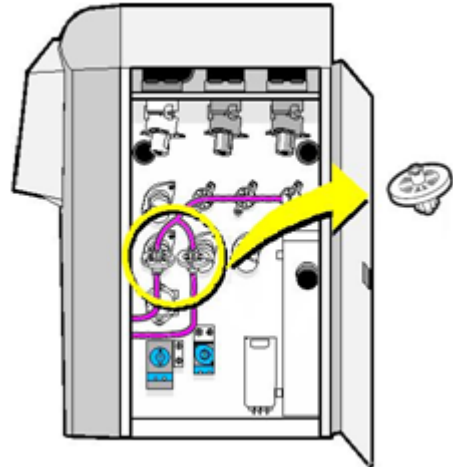


3. Open the right hand side compartment door.

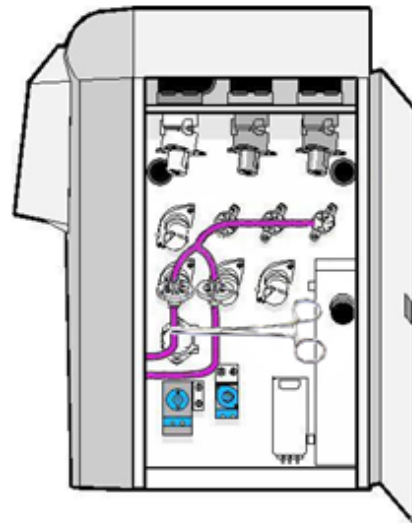


GENERAL PROCEDURES / RBC DILUENT FILTER

4. Locate the two RBC Bath diluent fluid filters.



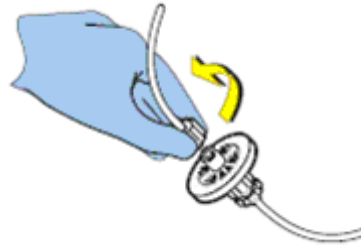
5. Clamp or pinch each tube connected to the bottom of the filter assembly with a hemostat or similar tool prevent draining of the RBC Bath.



GENERAL PROCEDURES / RBC DILUENT FILTER

6. Remove each fluid filter from the tubing

a Twist off the top connector



b Twist the fluid filter off the bottom connector

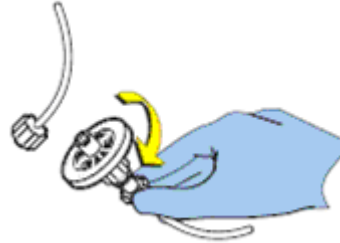


7. Properly dispose of the used fluid filters

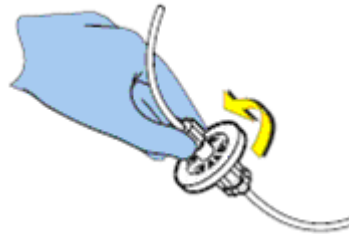


GENERAL PROCEDURES / RBC DILUENT FILTER

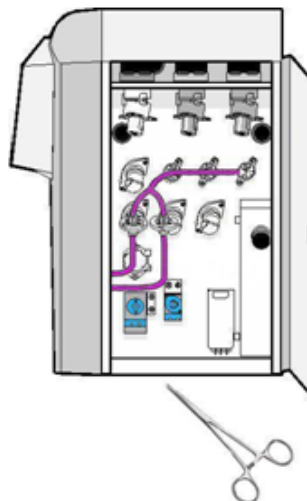
8. Connect each new fluid filter to the tubing by inserting tubing end into filter and turning the filter until secure.



-
9. Repeat step 8 to connect the other end of the fluid filter.

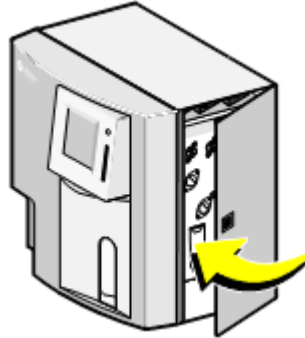


-
10. Remove hemostats from tubing.

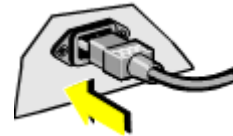


GENERAL PROCEDURES / RBC DILUENT FILTER

11. Close the right hand side door.



12. Plug the instrument into the power source.



13. Turn the instrument ON.



14. Perform a Startup on the instrument from the Main Menu.



GENERAL PROCEDURES / RBC DILUENT FILTER

15. Verify the Startup results “PASSED: for all parameters. If any parameter results have “FAILED” perform another Startup cycle.
-
16. Verify Calibration and run controls to verify instrument performance and resume normal operation

GENERAL PROCEDURES / HYDROPHILIC DILUENT FILTERS

REPLACING HYDROPHILIC DILUENT FILTERS

Hydrophilic Diluent Filters Kit PN 6915526



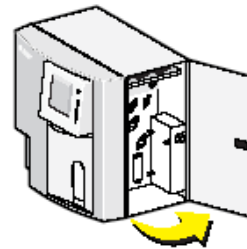
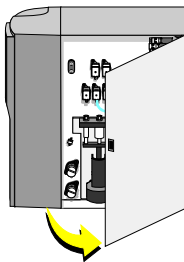
Perform this procedure at least every 6 months or 5,000 cycles

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



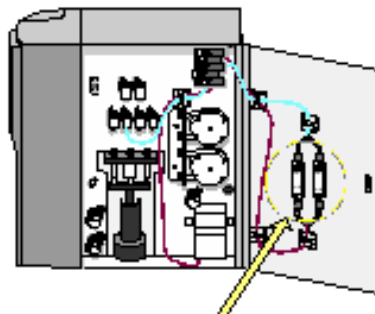
2. Turn instrument OFF *when Shutdown is completed* and unplug from power source.

3. Open right compartment door.

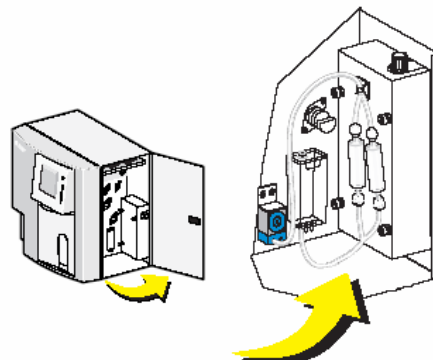


4. Locate the two hydrophilic filters.

A^c•T diff



A^c•T diff 2

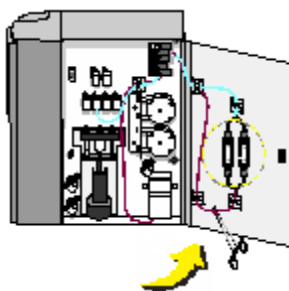


GENERAL PROCEDURES / HYDROPHILIC DILUENT FILTERS

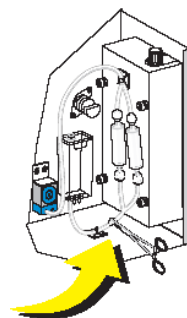
WARNING Risk of personal injury due to biohazard. Waste pump tubing can contain biohazardous material that could cause contamination. Handle and dispose of these components according to acceptable laboratory protocol.

4. Using a hemostat or similar tool, clamp or pinch the single tube connected to bottom of filter assembly to prevent Diluent reservoir from draining.

A^c•T diff

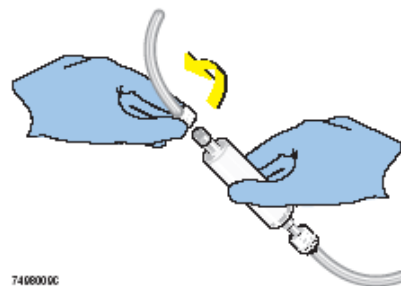


A^c•T diff 2



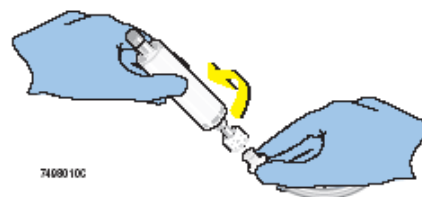
5. Remove each hydrophilic filter from the tubing:

- Twist off top connector



7408000C

- Twist off hydrophilic filter from bottom connector.



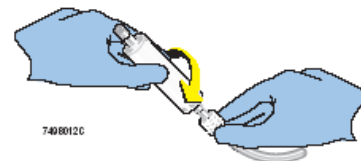
7408010C

GENERAL PROCEDURES / HYDROPHILIC DILUENT FILTERS

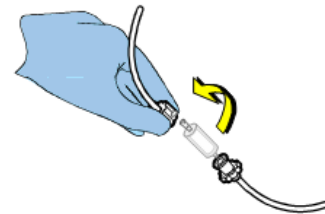
6. Properly dispose of used hydrophilic filters.



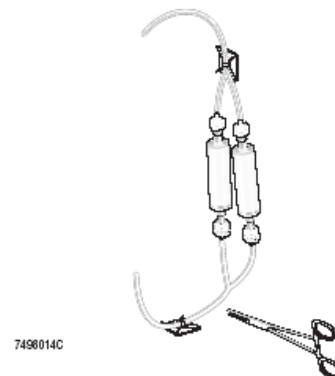
8. Connect each new hydrophilic filter to the tubing by inserting tubing end into filter and turning the connector until secure.



9. Repeat step 8 to connect the other end of the hydrophilic filter.



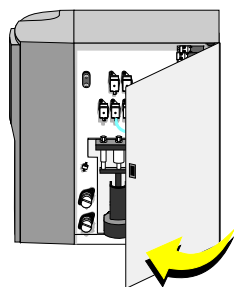
10. Remove hemostat from the tubing.



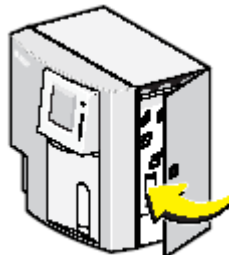
GENERAL PROCEDURES / HYDROPHILIC DILUENT FILTERS

11. Close right compartment door.

A^C•T diff



A^C•T diff 2



-
12. Plug instrument into power source and turn instrument ON.
-

13. If a “Diluent Empty” icon appears,
touch icon to perform reagent prime.



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

PREPARATION FOR CALIBRATION

Refer to A^C•T diff or A^C•T diff 2 *Operator's Guide* for information about frequency of calibration and other reasons to calibrate the A^C•T diff / diff 2 instrument.

To prepare the instrument, before calibrating, perform

- **Precalibration Checks**
- **Reproducibility**
- **Carryover**

Precalibration Checks

- ✓ Required maintenance has been performed on the instrument.
- ✓ Perform **Cleaning (Bleaching) the Baths** procedure.
- ✓ Average room temperature is within the system's operating temperature range.
- ✓ Sufficient reagent supply to complete these procedures.
- ✓ Perform **Startup**.

CALIBRATION / REPRODUCIBILITY

REPRODUCIBILITY

NOTE: Refer to the *Operator's Guide* for patient sample criteria for performing **Reproducibility**.

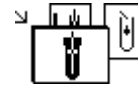


1. At Main screen
A^C•T diff



Select **Whole Blood mode**

A^C•T diff 2

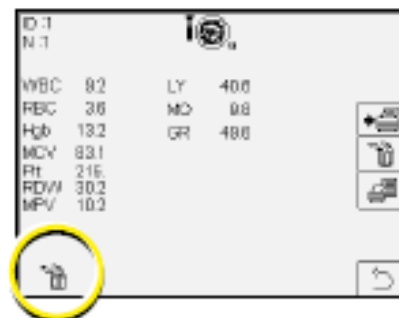


Select **Closed Vial Whole Blood mode**

2. Touch **QA** icon.  → **Reproducibility** icon  .

3. Thoroughly mix sample. Remember to mix sample gently between each cycle.
4. Analyze sample in **whole blood** mode for your instrument.

Trash icon appears at lower left corner of screen. You can manually delete *non-numeric results* or reject the sample, as required by touching the trash icon.



CALIBRATION / REPRODUCIBILITY

- When Reproducibility sample result displays, touch **Trash** icon to delete the **first** (prime) sample manually.

- Repeat step 4 until an **N of 11** is reached. (Look at upper left corner of screen for N#)

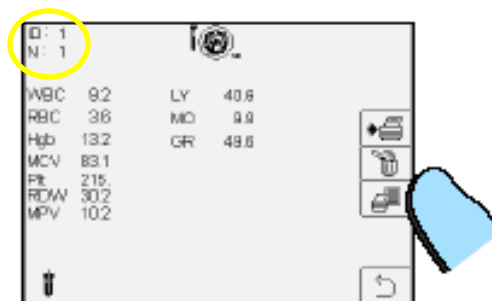
Verify **PASSED** for all parameters.

REPRODUCIBILITY										
C7WS		Time: 11:35								
Date: 04-22-05										
REPRODUCIBILITY RESULTS										
N	WBC	LY	MO	GR	RBC	HGB	MCV	PLT	RDW	MPV
1	4.89	41.50	5.00	51.50	4.786	13.48	86.29	209.9	13.28	8.45
2	5.02	41.20	5.50	51.30	4.836	13.50	86.55	198.8	13.53	8.45
3	5.11	41.80	5.20	51.00	4.919	13.79	86.73	213.8	13.22	8.65
4	5.04	41.10	6.30	51.60	4.961	13.74	85.85	201.2	13.87	8.84
5	5.04	40.40	7.30	51.30	4.940	13.88	85.49	199.8	13.15	8.65
6	5.09	41.30	6.50	51.20	4.898	13.87	85.77	206.6	13.10	8.65
7	5.11	40.10	6.30	51.60	4.879	13.66	85.97	198.1	13.75	8.45
8	5.08	40.00	7.60	51.40	4.909	13.82	86.09	194.7	13.21	8.55
9	5.12	41.20	6.90	51.90	4.916	13.91	85.94	212.3	13.60	8.45
10	5.11	40.80	6.30	51.90	4.894	13.75	86.16	201.3	13.84	8.45
11	5.16	39.00	8.20	51.80	4.865	13.92	86.09	217.1	13.05	8.65
SUMMARY STATISTICS ROWS										
Mean	5.09	40.69	6.61	51.79	4.902	13.79	86.06	205.8	13.93	8.59
sd	0.04	0.82	0.92	0.52	0.036	0.13	0.36	1.1	0.25	0.13
MCV	86.87	1.03	13.88	6.80	0.74	0.86	0.63	1.07	1.06	1.61
Station	PASSED	PASSED	PASSED	PASSED	PASSED	PASSED	PASSED	PASSED	PASSED	PASSED

Reproducibility Limits for CBC

N = 10

Parameter	%CV
WBC	<= 3.0%
RBC	<= 3.0%
Hgb	<= 2.0%
MCV	<= 3.0%
Plt	<= 7.0%
MPV	<= 3.0%



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



CALIBRATION / CARRYOVER

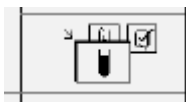
CARRYOVER

NOTE: Refer to the *Operator's Guide* for patient sample criteria for Performing **Carryover**. You may use 4C cell control as an alternative to normal whole-blood sample



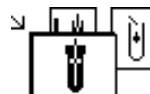
1. At Main screen, select

A^C•T diff



Whole Blood mode

A^C•T diff 2



Closed Vial Whole Blood mode

2. At  screen,  **Carryover** icon.



3. **Thoroughly mix sample and cycle in whole blood mode two times.**

4. **Repeat steps 3 for the *second* sample.**

5. **A^C•T diff**

Run a blank sample by pressing aspirate switch.

- A^C•T diff 2**

Run a blank sample by closing tube holder.

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

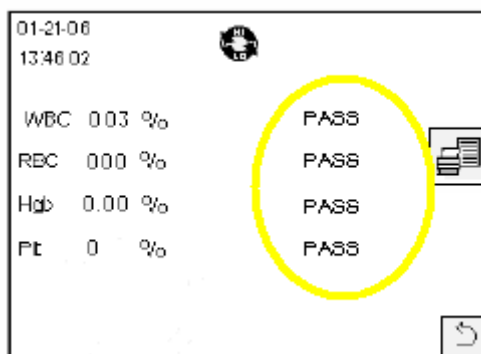
CALIBRATION / CARRYOVER

7. Touch **Summary** icon to view carryover summary screen.

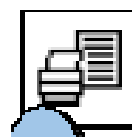


High-to-Low Carryover on the A^c•T diff System should meet these limits:

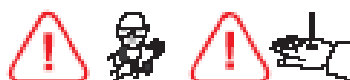
ALL parameters should show that Carryover is $\leq 2.0\%$



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



AUTOCALIBRATION with COULTER S-CAL[®] CALIBRATOR



Make sure that you have performed all **Precalibration Checks** listed in this document.

Beckman Coulter recommends using S-CAL calibrator.

1. Prepare S-CAL calibrator according to instructions in S-CAL package insert.

Confirm that lot number and expiration date on vial match information in the Table of Assigned Values.

Do use Calibrator if it has expired.



2. Print calibration setup report.

- At Main screen, touch **Setup** icon  → touch **Setup Report** icon. 

- After calibration setup report prints, touch **Exit** icon. 
(These are the “current” calibration factors in the instrument.)

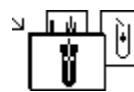
3. At Main screen, select

A^C•T diff



Whole Blood mode

A^C•T diff 2



Closed Vial Whole Blood mode

CALIBRATION

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



Calibration icon



Calibration assay screen appears.

WBC 9.0 RBC 4.27 Hgb 13.0
MCV 87.5 Plt 206 MPV 10.5

1	2	3	+
4	5	6	•
7	8	9	=

⏪ ⏴ ⏵ ⏩

- Refer to **Table of Assigned Values** supplied with your calibration material.
5. On screen, use the keypad to enter values from **Table of Assigned Values**.

- When you have entered all values, touch

Continue icon.



- The **Run Screen** appears.

WBC 9.0 RBC 4.27 Hgb 13.0
MCV 87.5 Plt 206 MPV 10.5

1	2	3	+
4	5	6	•
7	8	9	=

⏪ ⏴ ⏵ ⏩

ID: 00000001 4/22/05
N: 1 13:00:03

WBC	9.2	x10 ³ /μL
RBC	3.81	x10 ⁶ /μL
Hgb	13.2	g/dL
MCV	83.1	fL
Plt	215	x10 ³ /μL
MPV	25.4	fL

6. Mix the S-CAL calibrator according to the package insert instructions.



7. Run S-CAL **11 times** in **whole blood** mode.

Mix S-CAL vial gently between each cycle.

The instrument does not use the result from the first run. It performs statistics on runs 2 through 11 for a total of 10 runs. The instrument automatically saves the results.

The instrument displays but automatically rejects non-numeric result.

If you choose to reject a result, you can only reject the last sample analyzed.

8. After 11 acceptable results, the **Summary** icon will appear. 

Touch the  to view the Calibration 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 touching **Print Summary** icon.



9. Review results status on the Report Summary.

- *PASSED* for all parameters means calibration adjustment is not required. Touch **Return** icon. 
- *NEEDED* for any of the parameters means calibration adjustment is required.

If calibration is *NEEDED*, be sure to perform the next four steps!

- Touch **Save and Exit** icon  to automatically replace *NEEDED* (current) calibration factor with new calibration factor.
 - Print *new* calibration factor for your records (log book).
 - At Main screen, touch **Setup**   **Print Setup Report** icon. 
 - Verify calibration by analyzing **three** levels of 4C-ES cell control.
- If *FAILED* appears, the % diff value and/or %CV exceeds high acceptable limit. DO NOT calibrate.
 - You will not be able to save the changes for the parameters that show *NEEDED*
 - Call your Beckman Coulter Representative for assistance.

IMPORTANT! After you have finished Calibration, be sure that you have the following printouts for your records:

- Reproducibility Summary results
- Carryover Summary results
- Current CAL factors (prior to Calibration)
- Calibration Summary results
- New CAL factors (after Calibration)

APPENDIX / PRODUCTS

RECOGNIZE THE PRODUCTS

Take a moment to familiarize yourself with the frequently mentioned products below.

Human whole
blood specimen

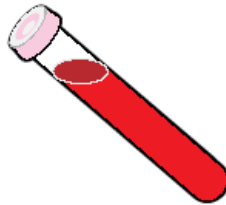


Table of Expected
Results

COULTER 4C-ES Cell Control			
[Color Calibration Bar]		[Small Data Table]	
[Large Grid for Results]			
CE		[Logo]	

4C® Plus cell
control



4C®-ES cell control



A^C•T™ Series
PAK



S-CAL® calibrator



A^C•T™ Series Tainer
(Not available in all
markets.)



LIN-C® linearity
Control



A^C•T™ Series
Rinse



APPENDIX / PARTS LIST

PARTS LIST

Component	Part Number (PN)
Diluent Filter (A ^C ●T diff)	PN 6233052
Peristaltic Pump Tubing (A ^C ●T diff)	PN 3213214
Syringe Pistons (A ^C ●T diff)	PN 2527677 (1 mL) PN 2527678 (250 µL) PN 2527699 (5 mL)
Fluid Barrier	PN 6232803
Waste Filter (A ^C ●T diff 2)	PN 6233045
Hydrophilic Diluent Filter Kit (A ^C ●T diff 2)	PN 6915526
RBC Diluent Filters (A ^C ●T diff 2)	PN A55482
Hydrophilic Diluent Filter Kit(A ^C ●T diff)	PN 6915577

To order replacement parts, please contact your Beckman Coulter Representative (800) 526-7694.

APPENDIX / REVISION STATUS

Issue AB, December 2009

Initial Issue

APPENDIX / TRADEMARKS

A^C•T, A^C•T diff, A^C•T diff 2, diff A^C•T Pak, diff A^C•T Tainer, A^C•T Rinse, S-CAL, 4C, 4C-ES, Lin-C, COULTER, BECKMAN COULTER logo, BECKMAN COULTER, are trademarks of Beckman Coulter, Inc.

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