ABBOTT

CELL-DYN® 1800 SYSTEM

Quick Reference Guide

List No. 07H92-01

FOREWORD

The CELL-DYN 1800 System is manufactured by Abbott Diagnostics, Abbott Laboratories, 2000 Abbott Park Road, Abbott Park, IL 60064, USA. Please direct all inquiries concerning information in this manual to the foregoing address.

Revision	Content Revised, Added, or Deleted
07H92-01	First release– April 2004

Any product information in this document should be used in conjunction with the latest version of the Operations Manual. If any discrepancies in information exist within this document or any others, the latest version of the Operations Manual takes precedence.

All samples (printouts, graphics, displays screens, etc.) are for information and illustration purposes only and shall not be used for clinical or maintenance evaluations.

Data shown in sample printouts and screens do not reflect actual patient names or test results.

Trademark	Trademark Statement
CELL-DYN®	CELL-DYN is a registered trademark of Abbott Laboratories

INTRODUCTION

Using this Quick Reference Guide

The CELL-DYN 1800 System Quick Reference Guide contains procedures used for CELL-DYN 1800 systems.

The Reference Guide is designed to be folded so that the procedures will be visible while operating the CELL-DYN 1800. The Reference Guide can be placed so that you can view two pages at a time.

All procedures in this Reference Guide were designed as step-by-step procedures. You should follow these procedures in the order they are presented.

Text Conventions Used in this Operator's Reference Guide

In this Reference Guide, procedural instructions are explained in logical groups, using numbered steps. Illustrations and drawings appear where they are useful to the explanation. Text conventions are as follows:

Menu Name

The menu name is shown in bold, uppercase, sans serif letters; for example, **SETUP**. The word "menu" is not capitalized, although it is referenced in this manual, and it does not appear on the display screen.

Softkeys (Screen Label Keys)

Directly below the screen is a row of eight unlabeled, pressure-sensitive softkeys that correspond to screen labels or menu options found on the lower segment of the display screen. Pressing one of these softkeys initiates the action specified by a corresponding screen label. Screen labels are shown in bold, uppercase, sans serif letters enclosed in brackets; for example **[QUALITY CONTROL]**.

PC Keyboard (Keys)

In some cases, the Operator must utilize the keys on the PC keyboard. Pressing the F1 through F8 function keys will initiate the action specified by a corresponding screen label. The alphanumeric keys (including punctuation symbols) may be used to enter specimen identification in a data entry field. Additional function keys such as the [↵] Enter key and the [ESC] key may be utilized as well. Special function keys, such as the arrow keys, may appear as a symbol substituted for the word. Instructions for special function keys will read; for example "Press the [↑] arrow key."

The Print Screen key on the PC keyboard can be used to print the screen as it is displayed on the LCD. This allows the Operator an option to print the screen when the **[PRINT]** key is not available.

NOTE: Press the Print Screen key only when the screen is at a static state. Pressing the key during an instrument action (e.g., Run cycle) may not print the screen properly.

Instrument Status

Instrument status is displayed in uppercase, regular letters; for example READY.

Screen Messages

Screen messages or other screen displays will appear in bold, Courier letters, for example, `Waste Full`.

CUSTOMER SUPPORT

If you need information or help in diagnosing a problem, technical assistance is available by telephone. In the U.S., this service is available 24 hours a day, seven days a week by calling Abbott Diagnostics Customer Service at: 1-877-4ABBOTT (1-877-422-2688).

For customer support in Canada, call: 1-800-387-8378

For customer support outside the U.S. and Canada, call your local Hematology Customer Support representative.

For correspondence, the address in the U.S. is:

Abbott Diagnostics Division
Customer Service
200 Abbott Park Road
Abbott Park, IL 60064, U.S.A.

Before You Call Us for Customer Support

Please have the following information ready:

1. Customer Account number
2. Instrument Model (CELL-DYN 1800)
3. CELL-DYN Serial Number
4. Software version in use
5. Lot Numbers being used for:
   a. Reagents
   b. Calibrators
   c. Controls
6. Test results printouts
7. Quality Control Log:
   a. Most recent calibration information
   b. Daily control Values
8. Maintenance Log information
9. Printed fault Log for Error Messages and Flags relating to the problem

SAFETY PRECAUTIONS

Operation, maintenance, and servicing of hematology systems may expose individuals to potential safety and health hazards. All work must be performed in accordance with procedures described in the CELL-DYN 1800 System Operator's Manual or as directed by an Abbott Representative.

Warnings are inserted in this Reference Guide to alert personnel to potential hazards.The standard warning conventions including signal words (*e.g.*, **CAUTION**) and icons are described below.

Signal Words

WARNING: Denotes a hazard which, if not avoided, could result in moderate to serious injury.

CAUTION: *Denotes a potential hazard that could result in minor injury. Also used for conditions or activities that could threaten equipment or performance.*

NOTE: *Denotes special operator information or standard practices.*

Warning Icons

The general hazard icon identifies an activity or area that may present a hazard to personnel or equipment.

The electrical hazard icon alerts personnel to the possibility of electrical shock if procedural or engineering controls are not observed.

The biohazard icon identifies an activity or area where personnel may be exposed to infectious substances if procedural or engineering controls are not observed.

Warning - Potential Biohazard: Consider all clinical specimens, controls, surfaces, or components that contain or have contacted blood, serum, or bodily fluids as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR, Part 1910.1030) or other equivalent biosafety procedures.

For detailed safety information, refer to the CELL-DYN 1800 System Operator's Manual.

NOTES

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NOTES

1 - Daily Procedures

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1.1 Daily Startup

Perform these tasks daily and document in the Maintenance Log.

If Standby or Initialized is displayed in the **MAIN** menu status box, press **[PRIME/RUN]** to bring the instrument to the Ready State.

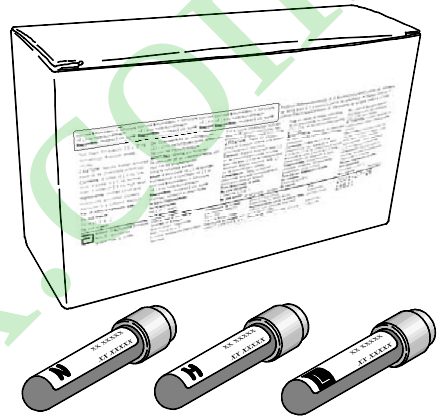
Necessary equipment:

- Protective equipment (gloves, lab coat and eye protection)
- Printer paper
- CELL-DYN 16 or CELL-DYN 22 Controls
- Reagents
- Maintenance log

1 Remove controls from refrigerator and allow to warm to room temperature for 15 minutes. Follow mixing and handling steps outlined on control assay sheet or CELL-DYN Calibrator and Control Mixing and Handling Instructions.

CELL-DYN 16 Control or CELL-DYN 22 Control

2



3

CELL-DYN Reagents:

Diluent (20L)

Diluent (4x3.8L)

Detergent (20L)

Detergent (4x3.8L)

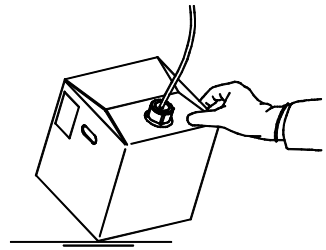
CN-Free Diff Lyse (3.8L)

CN-Free Diff Lyse (960mL)

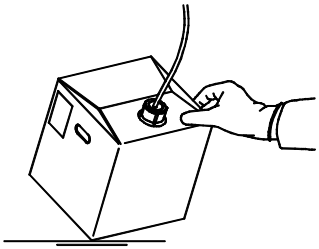
4 Check printer paper is installed and feeding correctly.

NOTE: *The CELL-DYN 1800 is compatible with printers that support ESC-P or Printer Control Language Release 3 (PCL-3). Any printer offering ESC-P or PCL-3 compatibility may be used to print reports generated by this instrument. For information on ordering printers, refer to* **Appendix A: *Parts and Accessories*** *in the CELL-DYN 1800 System Operator's Manual.*

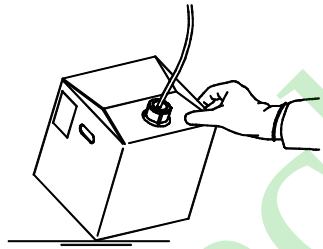
5 Check that the Diluent tubing is properly placed into reagent container and volume level is sufficient.



6 Check that the Lyse tubing is properly placed into reagent container and volume level is sufficient.



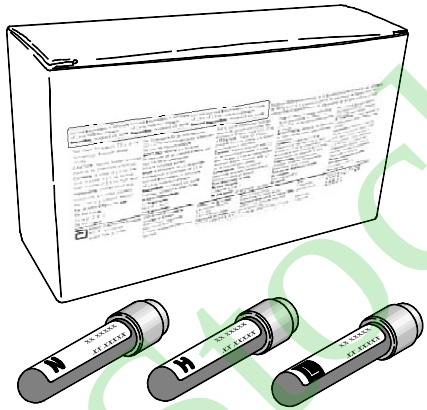
7 Check that the Detergent tubing is properly placed into reagent container and volume level is sufficient.



8 Run Background counts until acceptable results are obtained for all parameters (WBC RBC, HGB and PLT). For detailed instructions, see “1.2.1 Background Counts” on page 1-5.

Parameter	Specifications
WBC	≤ 0.5 K/µL
RBC	≤ 0.05 M/µL
HGB	≤ 0.1 g/dL
PLT	≤ 10.0 K/µL

9 Run a minimum of two levels of CELL-DYN controls. For detailed instructions, see “1.3.1 Performing Quality Control Runs”.



10 Rerun controls, if any QC results are outside allowable limits

11 Verify results are within acceptable limits before running any patient specimens.

You are now ready to run patient specimens. **12**

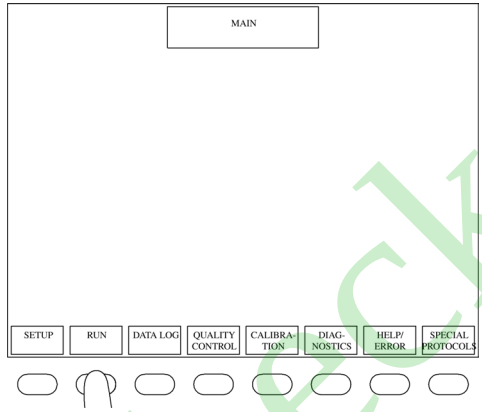
1.2 Background Counts

Background counts are routinely run to ensure sample analysis accuracy and proper system performance. The background count check may help in ruling out issues with fluidics or valve operation.

1.2.1 Background Counts

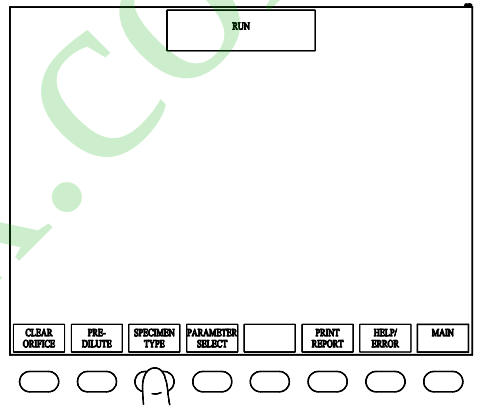
1

From **MAIN** menu, press **[RUN]**.



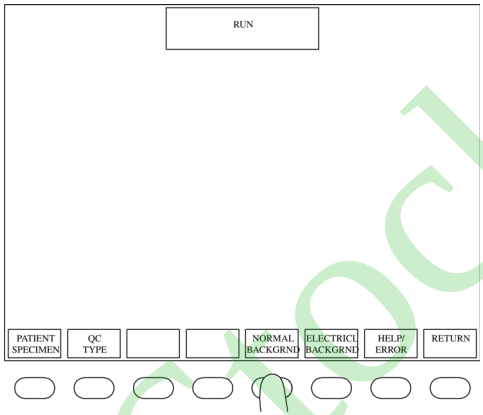
2

From **RUN** menu press **[SPECIMEN TYPE]**.



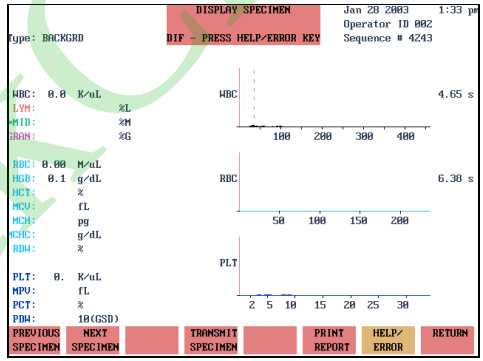
3

From **SPECIMEN TYPE** menu, press **[NORMAL BACKGRND]**.



4

When the following screen appears, press the touch plate to initiate background run.



5

Background count results are displayed when the run cycle is complete.

Compare the background results to the following acceptable ranges for these parameters:

Parameter	Specifications
WBC	≤ 0.5 K/µL
RBC	≤ 0.05 M/µL
HGB	≤ 0.1 g/dL
PLT	≤ 10.0 K/µL

If background counts do not fall within the acceptable limits, repeat the background count procedure. **6**	If results are still unacceptable, refer to **Section 6: *Troubleshooting Guide***. **7**

1.3 Quality Control

Controls are used to determine whether an instrument is operating with accuracy. Controls consist of stabilized blood cells with assayed ranges for each measured parameter.

CELL-DYN controls provide three levels (low, normal and high) for each measured parameter.

1.3.1 Performing Quality Control Runs

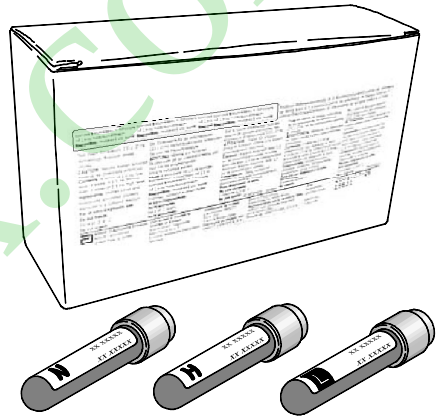
1

If the System has been idle for fifteen minutes or more, run a background prior to running any CELL-DYN controls. Remove the CELL-DYN Controls from the refrigerator and allow controls to warm at ambient room temperature for fifteen minutes. For operating instructions, refer to *CELL-DYN 1800 System Operator's Manual,* **Section 11: *Quality Control,* Subsection: *Quality Control Menu, Performing a QC Run***.

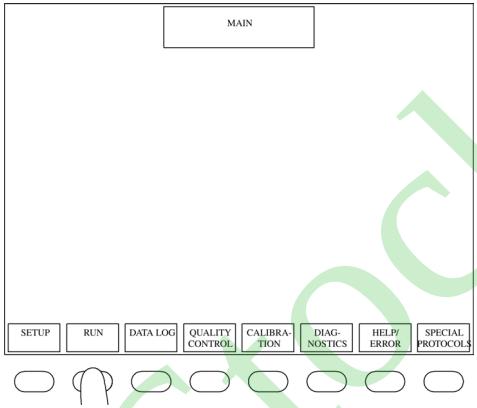
Necessary Equipment:

- Protective equipment (gloves, lab coat and eye protection)
- CELL-DYN 16 Controls or CELL-DYN 22 Controls

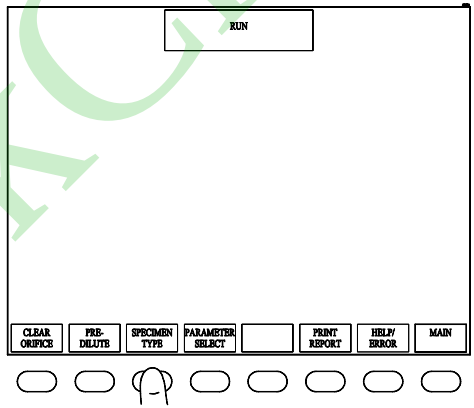
CELL-DYN Controls **2**



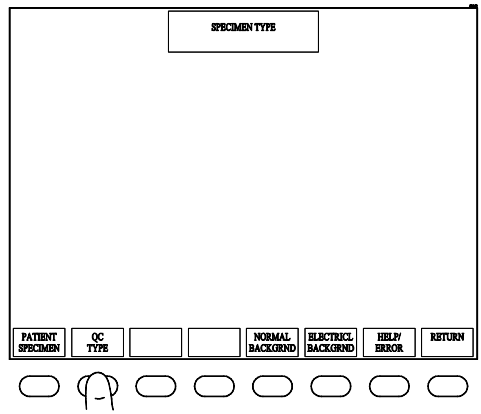
From **MAIN** menu, press **[RUN]**. **3**



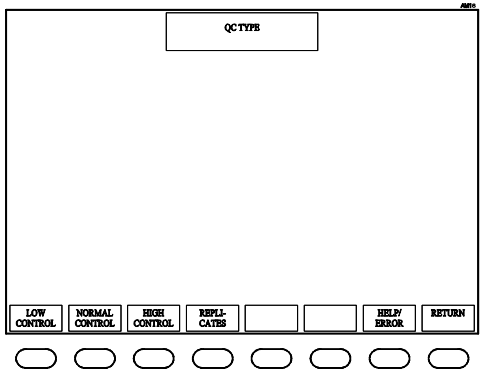
From **RUN** menu, press **[SPECIMEN TYPE]**. **4**



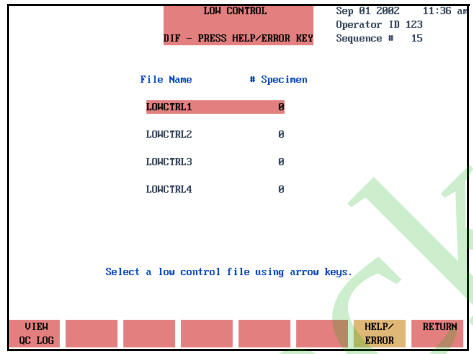
From **SPECIMEN TYPE** menu, press **[QC TYPE]**. **5**



6 From **QC TYPE** menu, press the level of control to be run.

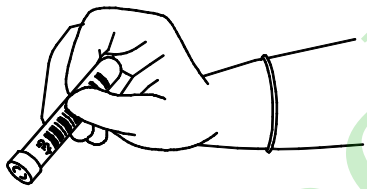


7 Use the [↑] and [↓] arrow keys on the PC keyboard to highlight the file into which you want to run your control.

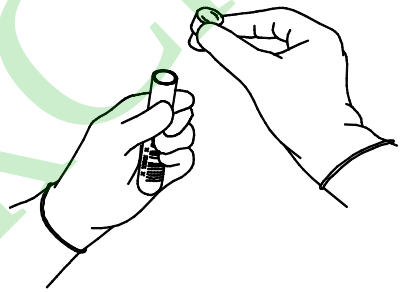


8 After the required file is highlighted, press **[RETURN]**. The file name will appear in the upper left corner of the **RUN** screen.

9 Verify that the Control level being run corresponds to the file selected in Step 8. Follow the mixing and handling steps outlined on the control assay sheet, or the CELL-DYN Calibrator and Control Mixing and Handling Instructions.



10 Remove the cap from the pre-mixed control tube.



11

NOTE: *Procedure continued on next page.*

11 Place the open tube under the Sample Aspiration Probe and raise the tube so that the end of the probe is deeply immersed in the control material.

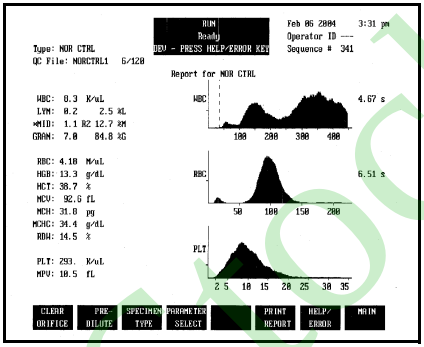
12 Press the touch plate to activate the run.

13 After the control specimen has been aspirated from the tube, the probe moves up through the wash block. There will be an audible beep and the message line displays: **<REMOVE SPECIMEN...>**

Remove the tube and replace the cap.

14 After the cycle is complete, the results displayed on the **RUN** screen will automatically print if that option was selected.

Optionally, press **[PRINT REPORT]** for a printout of the results before running the next specimen.



15 Press **[SPECIMEN TYPE],** followed by **[QC TYPE],** to select the next control to be run. Repeat this procedure to run other levels of control in their respective files.

When all controls are complete, verify controls are within limits.

Values out of limits will be highlighted on screen or underlined when printed.

If any values are out of limits, repeat control. If controls continue to be out of range, call Abbott Diagnostics Customer Service for assistance.

If controls are within limits, you can run patient specimens.

2 - Specimen Processing

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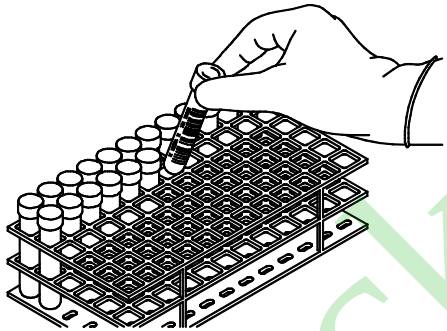
2.1 Specimen Processing

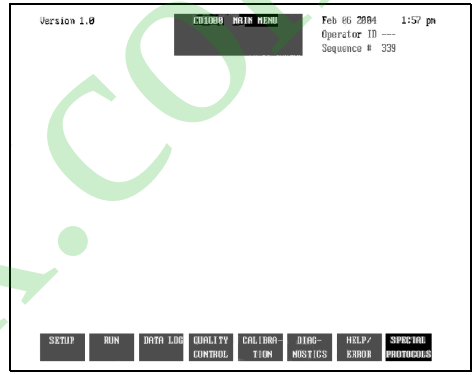
Necessary equipment:

- Protective equipment (gloves, lab coat and eye protection)
- Anticoagulated (EDTA) whole blood specimen

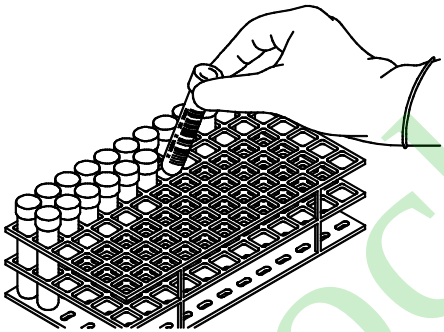
After specimen is collected, place it in a rack near the CELL-DYN 1800 System. **1**



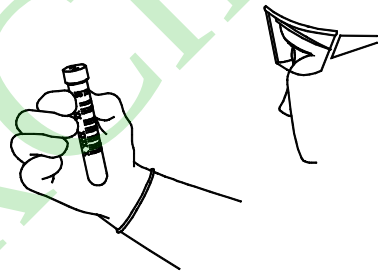
After daily startup is completed, go to **MAIN** menu. **2**



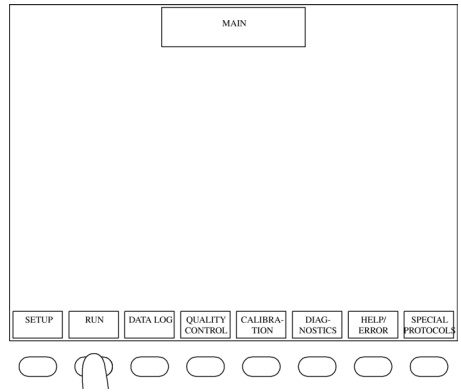
Select the desired specimen tube from the rack. **3**



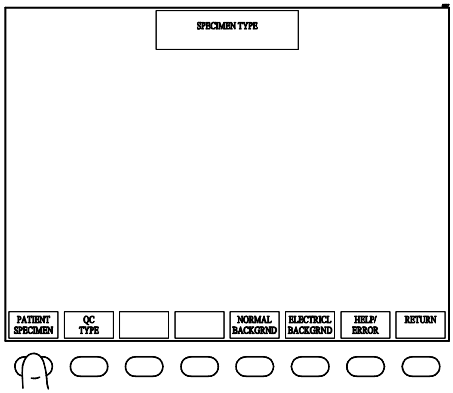
Confirm specimen ID on the tube. **4**



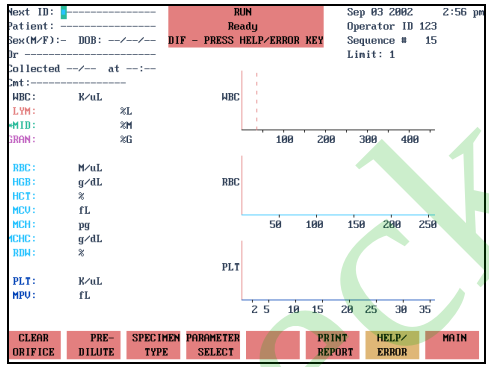
From the **MAIN** menu, press **RUN**. **5**



From the **RUN** menu, press **[SPECIMEN TYPE]**, then press **[PATIENT SPECIMEN]**. **6**

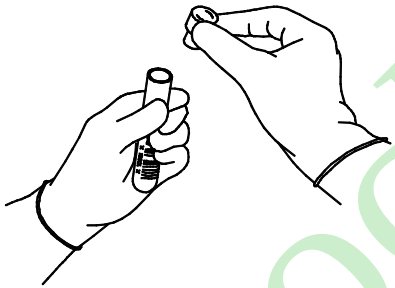


Using the PC keyboard, enter specimen ID information and demographics. **7**



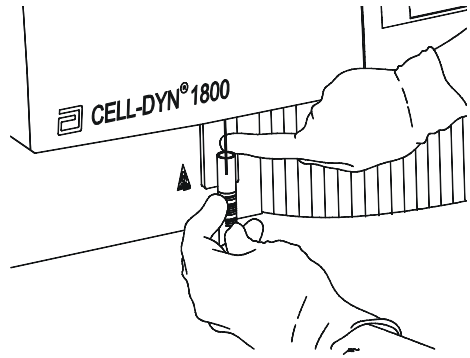
With the cap tightly secured, gently invert the tube 10 to 15 times. **8**

Remove the cap from the pre-mixed specimen tube. **9**



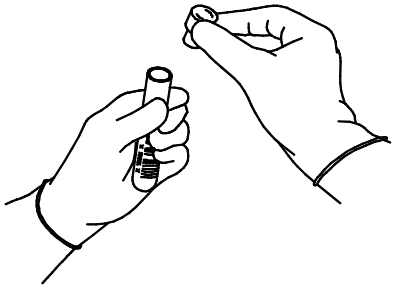
Place tube under sample aspiration probe and raise the tube so that the end of the probe is deeply immersed in the specimen. **10**

Press touch plate to activate run. **11**



12

After the instrument aspirates the specimen, the probe moves up. There will be an audible beep and the message line displays **REMOVE SPECIMEN**. Remove the specimen and replace the cap.

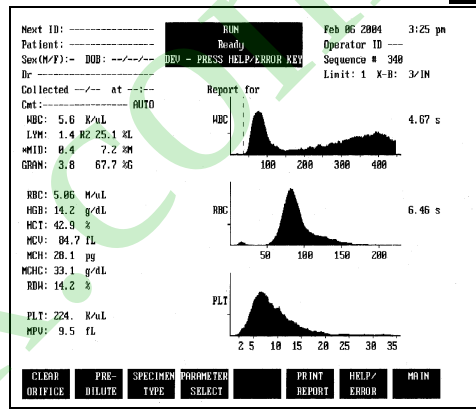


13

After the cycle is completed, the results will display on the **RUN** screen and will automatically print if that option was selected.

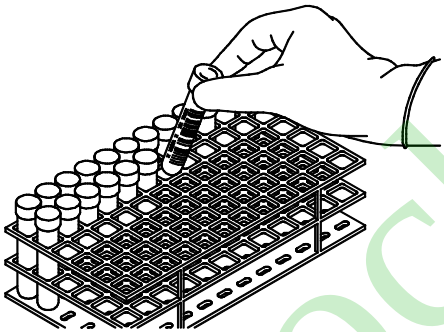
Optionally, press **[PRINT REPORT]** for a printout of the results before running the next specimen.

14



15

When the **READY** message appears, continue specimen processing with another tube if necessary.



3 - Maintenance

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3.1 Maintenance Log

Documentation of all maintenance performed is an important part of good laboratory practices. Maintenance procedures performed in a timely manner will assist in keeping instrument performing as expected.

CELL-DYN 1800 MAINTENANCE LOG

MONTH_____ **YEAR** _____

	DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
DAILY	Daily Startup																															
	Daily Shutdown																															
WEEKLY	Auto Clean																															
	Clean Aspiration Probe Exterior																															
MONTHLY	Rinse Lyse Inlet Lines																															
	Rinse Reagent Inlet Lines																															
SEMI-ANNUAL	Clean Printer																															
AS-REQUIRED	Clean HGB Flow Cell																															
	Clean Pre-Mixing Cup																															
	Empty Instrument Waste																															
	Clean/Replace Aperture Plate																															
	Clean/Replace Aspiration Probe																															
	Clean/Replace Aspiration Probe Wash Block																															
	Clean/Replace Syringes																															
	Clean/Drain Vacuum Accumulator																															
	Clean Bar Code Scanner Lens																															
	Clean "Y" Fitting																															
	Supplemental Aperture Cleaning																															
	Prepare Instrument for Extended Period of Non-Use or Shipping																															

3.2 Error Message Logsheet

The Error Message Log is used for documentation of problems seen during daily operations, such as fault messages, error messages and unexpected data obtained. Keeping a record of how the problem was resolved is a helpful aid for future troubleshooting. A copy of the Error Message Logsheet has been provided for your reference. Refer to **Appendix C – Sample Logs and Worksheets** found in the *CELL-DYN 1800 System Operator's Manual* for additional templates.

ERROR MESSAGE LOGSHEET

Instrument Serial Number: _____

DATE	TECH	TIME	SEQUENCE #	OBSERVATION	RESOLUTION

3.3 Auto Clean

The Auto Clean procedure uses an enzymatic cleaning solution to clean and drain the fluidics system and reduce protein buildup in lines and apertures.

3.3.1 Auto Clean Procedure

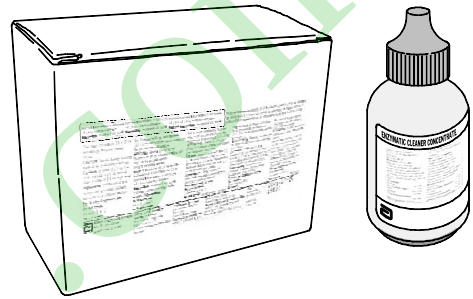
1

Materials needed:

- Protective equipment (gloves, lab coat and eye protection)
- CELL-DYN Enzymatic Cleaner
- Maintenance log
- Standard specimen tube (no anticoagulant)

CELL-DYN Enzymatic Cleaner

2



Dispense a portion (3/4 full) of the enzymatic cleaner into a clean standard specimen tube. Label with name and date.

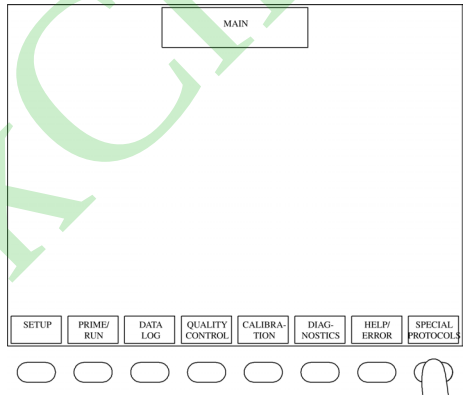
3

Return bottle to refrigerator but allow the dispensed enzymatic cleaner to warm at room temperature.

CAUTION: *Enzymatic Cleaner is extremely slippery. Wipe excess cleaner off top of tube before inserting stopper.*

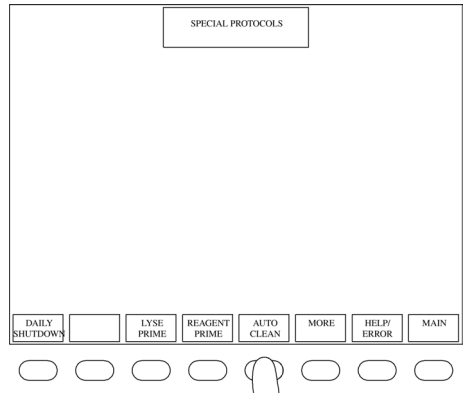
From **MAIN** menu, press **[SPECIAL PROTOCOLS]**.

4

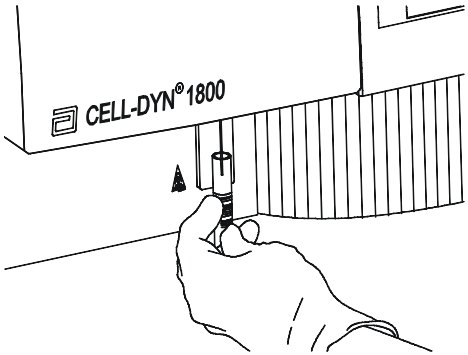


Press **[AUTOCLEAN]** to begin the Auto Clean cycle.

5

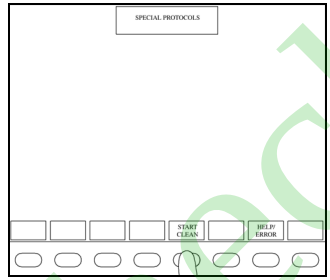


6 Place the tube with enzymatic cleaner under the aspiration probe. Raise the tube so that the end of the probe is deeply immersed in the enzymatic cleaner.



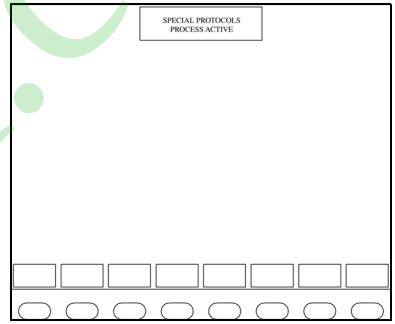
7 Press the **[START CLEAN]** soft key to aspirate the enzymatic cleaner. When the enzymatic cleaner has been drawn from the tube, the probe will move up through the wash block, and the **REMOVE SPECIMEN** message appears on the display screen.

NOTE: *Do not press the touch plate*



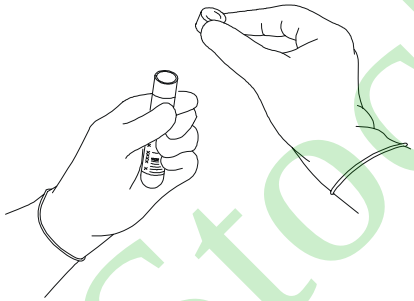
8 During the cleaning process a message **<PROCESS ACTIVE…>** appears on the screen.

NOTE: *The complete cycle takes approximately seven minutes.*

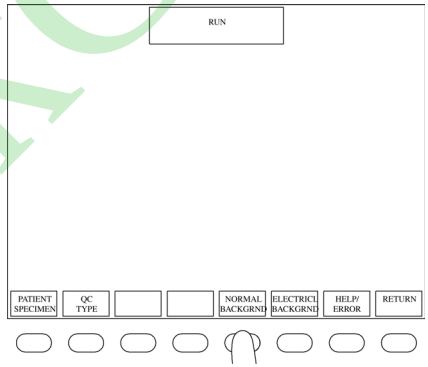


9 When process is complete, press **[MAIN]** to return to **MAIN** menu.

Save the remaining enzymatic cleaner in the refrigerator for up to one week. Discard enzymatic cleaner if it becomes cloudy or if original bottle reaches expiration date.

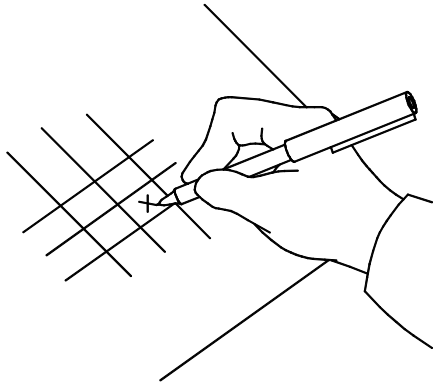


10 From the **MAIN** menu, press **[Run]** followed by **[SPECIMEN TYPE]** and **[NORMAL BACKGRND].** Run background counts until acceptable results are obtained for all background parameters.



11 Press **[MAIN]** to return to the **MAIN** menu.

Record this maintenance in the Maintenance Log **12**



3.4 Special Procedures

These procedures are performed as needed, when additional cleaning is required. See *CELL-DYN 1800 System Operator's Manual*, **Chapter 9**, for a complete list of cleaning procedures.

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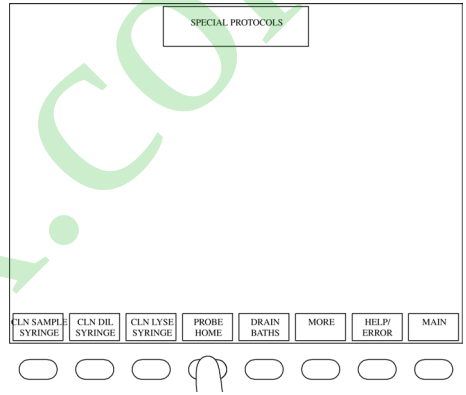
3.4.1 CELL-DYN 1800 Aperture Plates Cleaning Procedure

On rare occasions debris buildup could clog the opening in the aperture plates. If aperture clogs are suspected, first perform an Auto Clean procedure. See **Section 3.3: Auto Clean**. If the fault persists, clean the aperture plate using the procedures in this section.

Materials needed:

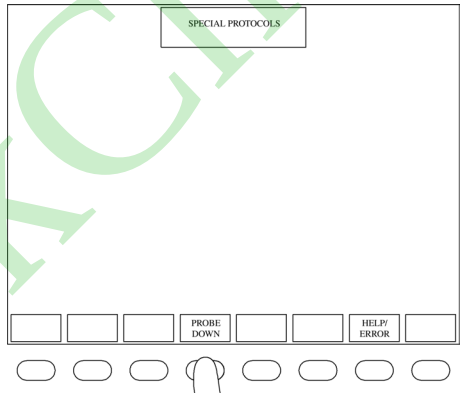
- Protective equipment (gloves, lab coat and eye protection).
- Deionized water for rinsing.
- Cleaning solution (20 drops of CELL-DYN Enzymatic Cleaner to 20 mL of warm deionized water **OR** 5 mL of 5% sodium hypochlorite (bleach) to 15 mL of warm deionized water).
- Small beaker or cup (50 mL)
- Aperture brush
- Microscope (optional)

1 From the **MAIN** menu, press **[SPECIAL PROTOCOLS]**, followed by **[MORE]** then **[PROBE HOME]**.

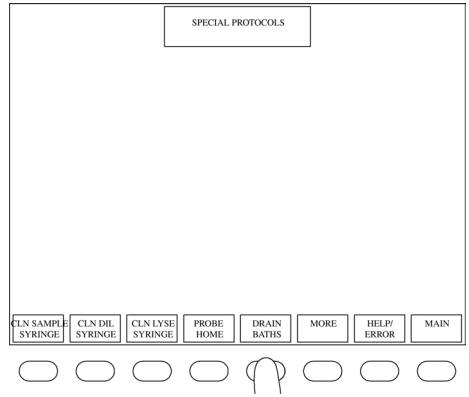


2 Open Front Covers (Remove Lower Cover, if applicable). Refer to the CELL-DYN 1800 System Operator's Manual, Section 2: Installation Procedures and Special Requirements, Installation, Inspection and Tubing Installation, Opening/Removing Front Covers.

3 Press **[PROBE DOWN]**.



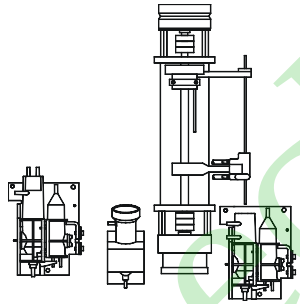
4 Press **[DRAIN BATHS].** Liquid in both chambers of the von Behrens RBC/PLT and WBC transducers drains to the waste system.



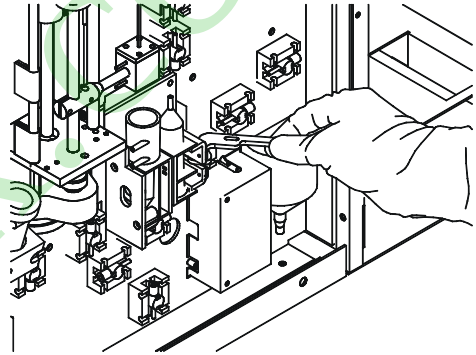
5 Prepare a fresh cleaning solution into a small beaker or cup.

NOTE: *Cleaning solution containing 20 drops of Enzymatic Cleaner to 20 mL of warm deionized water **OR** 5 mL of 5% sodium hypochlorite (bleach) to 15 mL of warm deionized water.*

6 Locate the two tagged red levers attached to the von Behrens RBC/PLT and WBC transducers. The von Behrens WBC transducer bath is located on the left side of the front panel and the von Behrens RBC/PLT transducer bath is located on the right side.



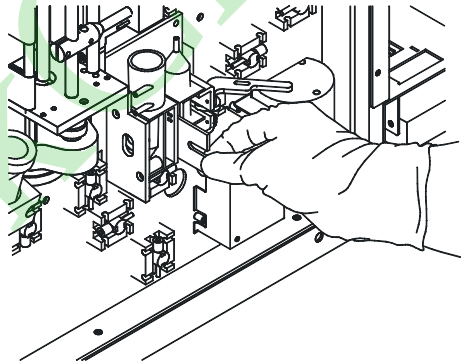
7 Grasp each lever and swing it all the way to your right.



8 On the right side of the instrument, grasp the RBC/PLT aperture plate, located in the slot separating the two chambers of the von Behrens RBC/PLT transducer. Pull the aperature plate straight out. Note that the aperture plate is etched with the letters **R/P.**

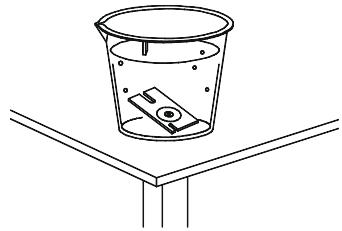
On the left side of the instrument, grasp the WBC aperture plate, located in the slot separating the two chambers of the von Behrens WBC transducer. Pull the aperture plate straight out. Note that the aperture plate is etched with the letters **WBC**.

9 .



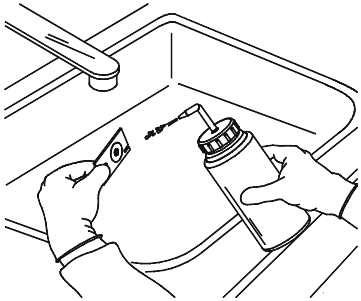
10 Immerse the aperture plates in the cleaning solution for about 5 minutes Remove the aperture plates from the solution. Using the aperture brush only, gently clean both sides of the aperture plate using a rotating motion to clean the plate. Dab the bristles into the center hole to dislodge any large particles.

NOTE: *Using other brushes or paper will damage the aperture plates.*



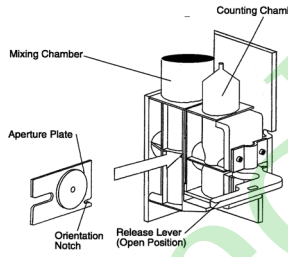
11

Rinse each plate thoroughly with a fine stream of deionized water. Gently shake excess water from the plate before reinstalling it. DO NOT wipe or blot the aperture plate. If possible, use a microscope to inspect the plate for debris. If debris remains, repeat the cleaning procedure.



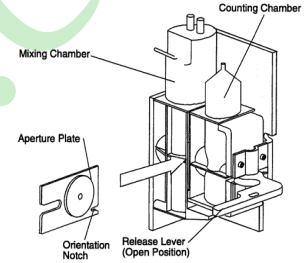
12

Identify the aperture plate etched with **R/P**. Position the RBC/PLT aperture plate with the orientation notch towards the lower edge. Insert the aperture plate into the slot between the two chambers of the von Behrens RBC/PLT transducer, located to the right of the aperture probe. Slide the aperture plate until it is completely seated in the slot. Swing the red lever all the way to your left to secure the plate in place.



13

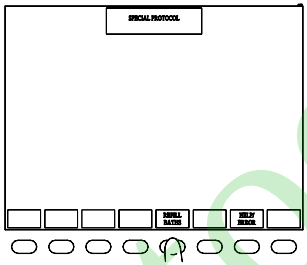
Identify the aperture plate etched with **WBC**. Position the WBC aperture plate with the orientation notch towards the lower edge. Insert the aperture plate into the slot between the two chambers of the von Behrens WBC transducer, located to the left of the aspiration probe. Slide the aperture plate until it is completely seated in the slot. Swing the red lever all the way to your left to secure the plate in place.



14

Press **[REFILL BATHS]**. Both transducers are refilled. Check the right-hand chambers of both transducers to ensure they are completely filled with liquid.

NOTE: *If air bubbles are observed at the top of the right-hand chamber of either transducer, repeat the process of draining, and refilling the bath.*

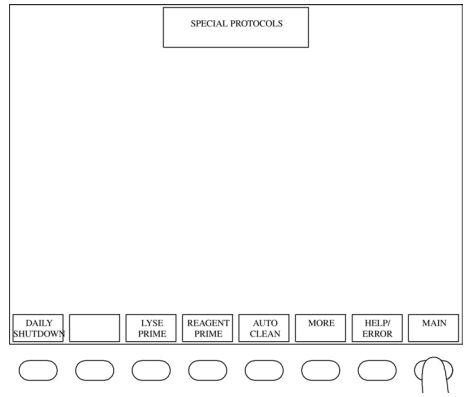


15

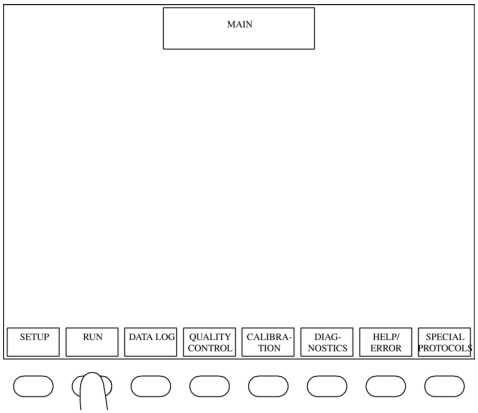
Press **[PROBE HOME]**. Reattach and/or close the front covers.

16

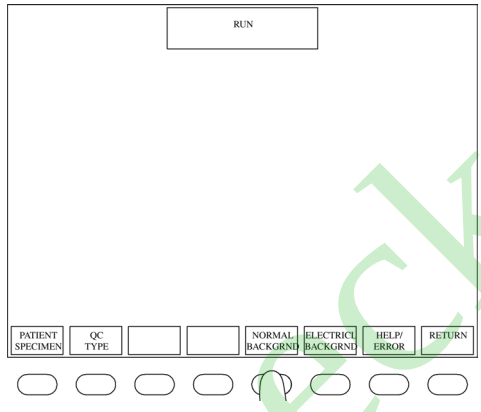
Press **[PROBE DOWN]**. Press **[MAIN]** to return to **MAIN** menu.



From **MAIN** menu, press **[RUN]**. **17**



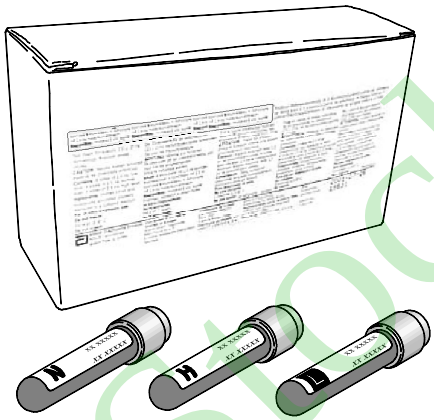
From **RUN** menu press **[SPECIMEN TYPE]**, then press **[NORMAL BACKGRND]**. **18**



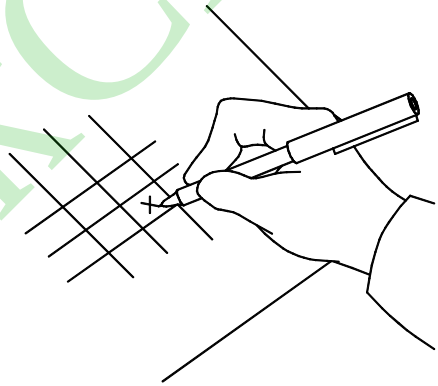
Run background counts. Press the touch plate to activate a run cycle. Run background counts until acceptable results are obtained for all parameters (WBC, RBC, HGB and PLT). **19**

Parameter	Specifications
WBC	≤ 0.5 K/µL
RBC	≤ 0.05 M/µL
HGB	≤ 0.1 g/dL
PLT	≤ 10.0 K/µL

Run a minimum of two levels of controls and verify results are within range before running any patient specimens. **20**



Record this maintenance in the Maintenance Log. **21**



3.4.2 CELL-DYN 1800 Supplemental Aperture Cleaning Procedure

The supplemental aperture cleaning procedure is used to remove stubborn restrictions in the RBC and WBC apertures when there is a marked increase in the RBC and/or WBC count times that cannot be resolved through normal auto cleaning. If this procedure does not solve the problem, remove and clean the aperture plates.

Materials needed:

- Protective equipment (gloves, lab coat and eye protection).
- Undiluted, unscented household bleach.
- Cleaning solution:
  Add 9.5 parts deionized water to 1 part bleach to obtain a 0.5% sodium hypochlorite solution, or for example, 9.5 mL of deionized water to 1.0 mL of bleach (5.25% sodium hypochlorite), to obtain a 0.5% solution of sodium hypochlorite.
- Small beaker or container

1

From the **MAIN** menu, press **[RUN]**. Ensure that the instrument has been initialized, and READY is displayed in the status box.

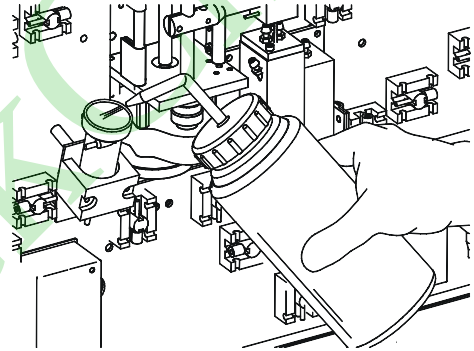
- Press **[MAIN]** to return to the **MAIN** menu
- Press **[SPECIAL PROTOCOLS]**
- Press **[MORE]**
- Press **[PROBE HOME]**

2

Open Front Covers (Remove Lower Cover, if applicable). Refer to the CELL-DYN 1800 System Operator's Manual, Section 2: installation Procedures and Special Requirements, Installation, Inspection and Tubing Installation, Opening/Removing Front Covers.

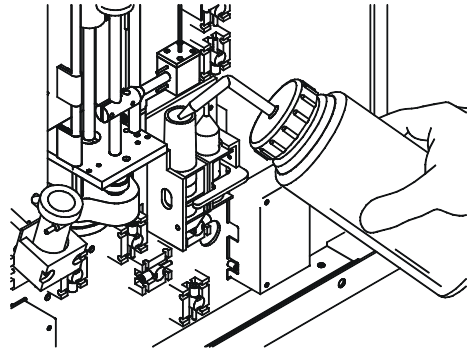
3

Carefully pour 5 mL of the cleaning solution into the Pre-Mixing Cup. It is the glass cup located near the center of the instrument, to the left of the aspiration probe.



4

Carefully pour 5 mL of undiluted unscented bleach into the mixing chamber of the RBC bath (notice that the bath is open at the top), located to the right of the aspiration probe.



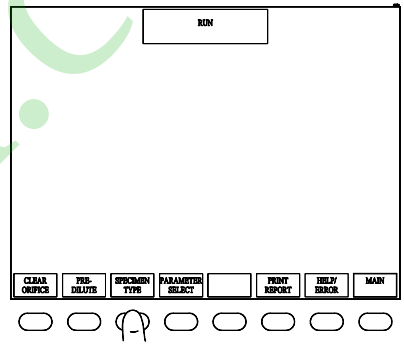
5 Reattach and/or close the Front Covers.

6
- Press **[PROBE DOWN]**.
- Press **[MAIN]** to return to the **Main** menu.
- Press **[RUN]**.

Wait two minutes to allow the Pre-Mixing Cup to soak.

7 After the soak period, press **[SPECIMEN TYPE]**.

NOTE: *Do not use [CLEAR ORIFICE] because it will drain the cleaning solution from the cups.*



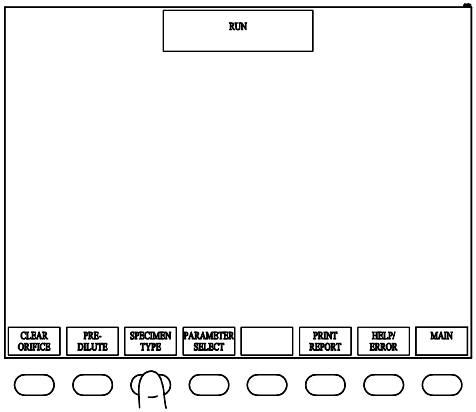
8 Press **[SHIFT]** and the **[#]** key on the PC keyboard at the same time. The **GAIN ADJUST** screen is displayed.

9 The cleaning solution in the Pre-Mixing Cup is transferred to the WBC bath. Both baths are bubble mixed. Wait for another two minutes for the baths to soak.

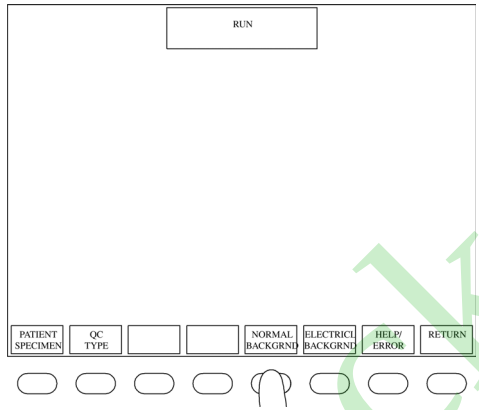
After the soak period, press the touch plate to run three consecutive count cycles to aspirate the cleaning solution through the WBC and RBC apertures.

10 If a FLOW or CLOG message displays, ignore them and continue to run the three counts.

11 Press **[SPECIMEN TYPE]**.



12 Press **[NORMAL BACKGRND]**.

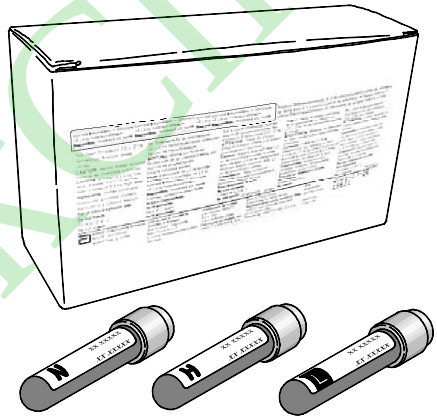


13 Press **[CLEAR ORIFICE]** to reset the running average program and drain the baths.

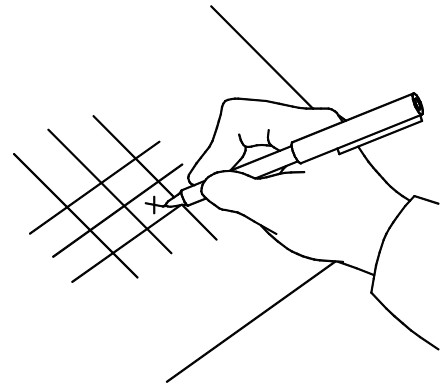
14 Run background counts and verify the background results are within appropriate specifications.

Parameter	Specifications
WBC	≤ 0.5 K/µL
RBC	≤ 0.05 M/µL
HGB	≤ 0.1 g/dL
PLT	≤ 10.0 K/µL

15 Run a minimum of two levels of controls and verify results are acceptable before running any patient specimens.



16 Record this maintenance in the Maintenance Log.



3.4.3 “Y” Fitting Cleaning Procedure

This procedure is used to remove stubborn restrictions in the “Y” fitting under the Pre-Mixing Cup that cause overflow or improper draining of that cup.

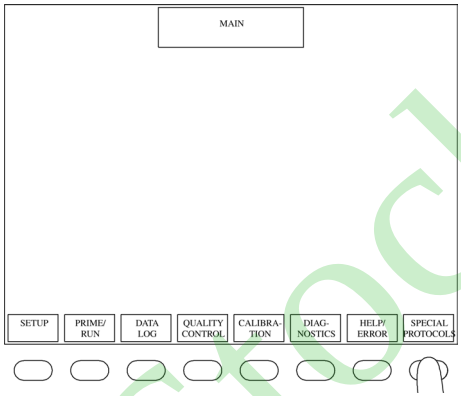
Materials needed:

- Protective equipment (gloves, lab coat and eye protection).
- 25% cleaning solution
- Small beaker or container
- 10 mL syringes
- Plastic disposable pipettes

1 From the **MAIN** menu, press **[RUN]**. Ensure that the instrument has been initialized, and READY is displayed in the status box.

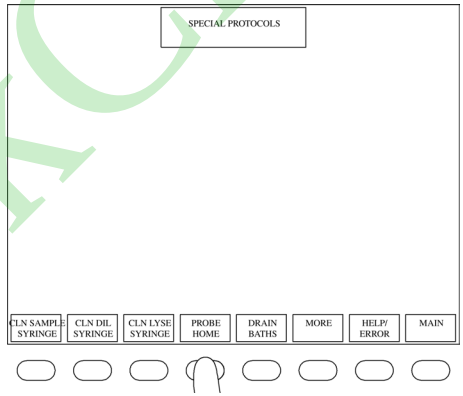
Press **[MAIN]** to return to the **MAIN** menu.

2 From the **MAIN** menu, press **[SPECIAL PROTOCOLS]**.



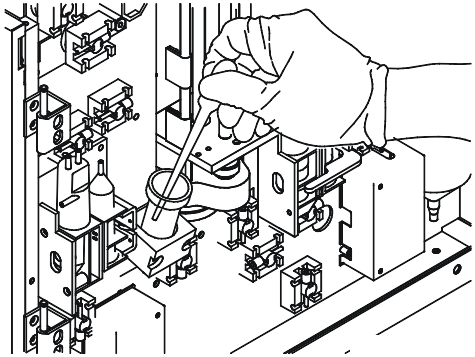
3 Press **[MORE]**

Press **[PROBE HOME]**

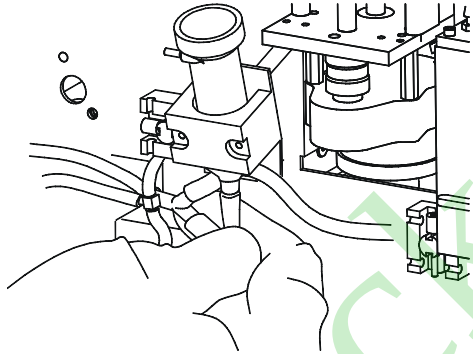


4 Open Front Covers (Remove Lower Cover, if applicable). Refer to the CELL-DYN 1800 System Operator’s Manual, Section 2: Installation Procedures and Special Requirements, Installation, Inspection and Tubing Installation, Opening/Removing Front Covers.

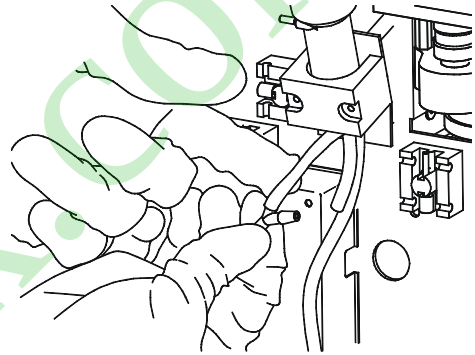
5 Carefully remove any liquid inside the Pre-Mixing Cup with a disposable pipette and discard according to local, state, and federal regulations.



6 Locate the “Y” fitting below the Pre-Mixing Cup.



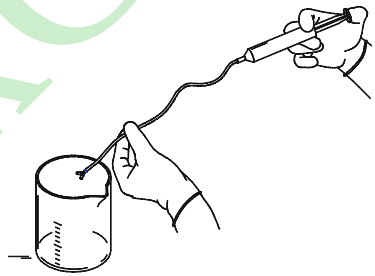
7 Carefully remove the tubing on all three sides of the “Y” fitting.



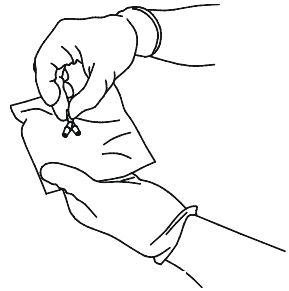
8 Place the “Y” fitting inside the beaker. Pour the cleaning solution into the beaker. Soak for five minutes.

9 Attach tubing to a syringe and fill with water. Using the syringe, flush water through all three sides of the fitting, verifying that water flows freely from all three outlets.

CAUTION: *DO NOT use hypodermic needles, as they may puncture the fitting and tubing.*

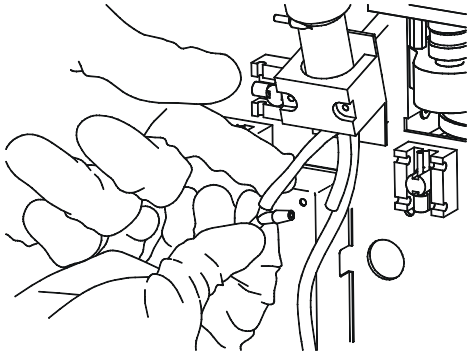


10 Rinse off fitting with water and blot dry.



11 Reconnect the tubing to all three sides of the "Y" fitting.

- Press **[PROBE DOWN]**.



12 Press **[MAIN]** to return to the **MAIN** menu. Press **[RUN]**, then **[SPECIMEN TYPE]** and **[NORMAL BACKGRND]**.

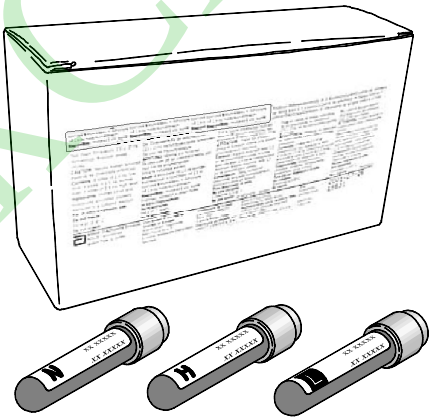
Run background counts to verify Pre-Mixing Cup is draining completely and there are no leaks originating from the fitting.

13 Reattach and/or close the Front Covers.

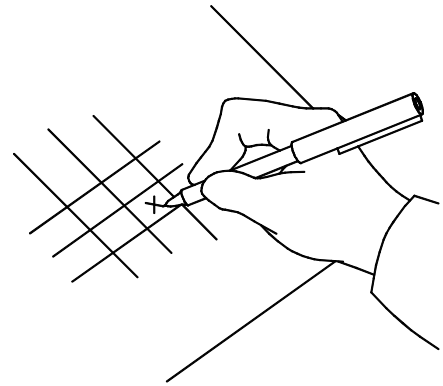
14 Run background counts. Verify that acceptable background counts are obtained for all background parameters (WBC, RBC, HGB and PLT).

Parameter	Specifications
WBC	≤ 0.5 K/µL
RBC	≤ 0.05 M/µL
HGB	≤ 0.1 g/dL
PLT	≤ 10.0 K/µL

15 Run a minimum of two levels of controls and verify results are within range before running any patient specimens.



16 Record this maintenance in the Maintenance Log.



3.4.4 CELL-DYN 1800 Hemoglobin Flow Cell Cleaning Procedure

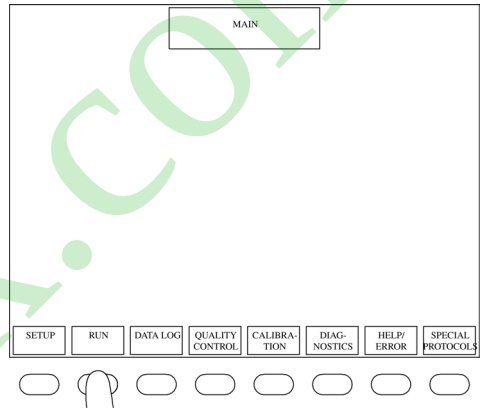
The CELL-DYN 1800 uses a sodium hypochlorite cleaning solution to ensure thorough cleaning of the HGB flow cell.

Materials needed:

- Protective equipment (gloves, lab coat and eye protection).
- Cleaning solution of 10 mL 5% sodium hypochlorite (bleach) to 10 mL of warm deionized water.
- Small beaker or container
- Hemostats

1

From the **MAIN** menu, press **[RUN]**. Ensure that the instrument has been initialized and READY is displayed in the status box.

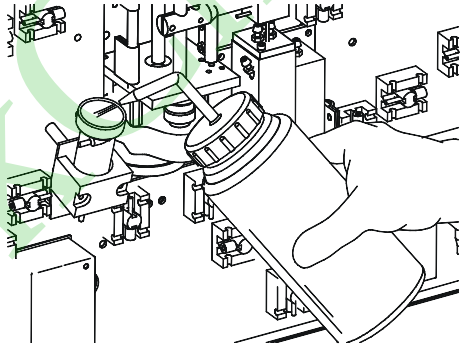


2

Open Front Covers (Remove Lower Cover, if applicable). Refer to the CELL-DYN 1800 System Operator's Manual, Section 2: Installation Procedures and Special Requirements, Installation, Inspection and Tubing Installation, Opening/Removing Front Covers.

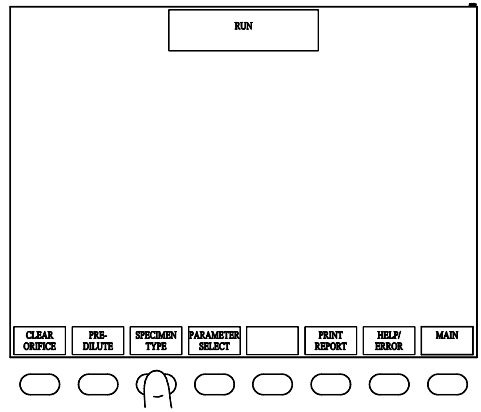
3

Carefully pour the cleaning solution into the Pre-Mixing Cup. It is the glass cup located near the center of the instrument, to the left of the aspiration probe.



4

- Press **[SPECIMEN TYPE]**.

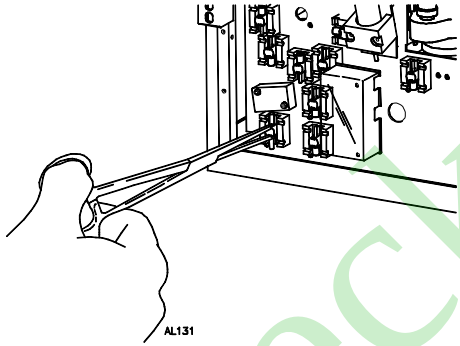


5

Press **[SHIFT]** and the **[#]** key on the PC keyboard at the same time. The **GAIN ADJUST** screen is displayed, and the cleaning solution is transferred from the Pre-Mixing Cup to the WBC bath.

6

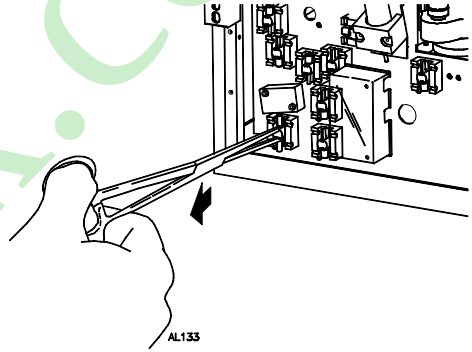
When **READY** is displayed in the status box, locate Valve 2-7 directly underneath the HGB flow cell. Grip the center of Valve 2-7 (top and



bottom slots on valve plunger) with a pair of hemostats.

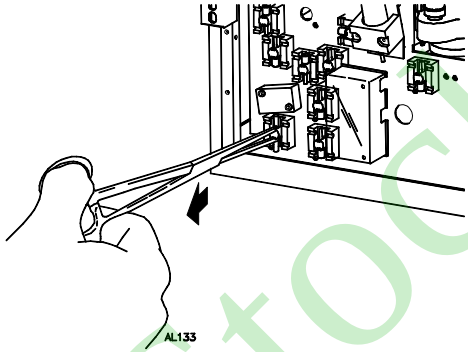
7

While observing the solution level in the left side of the WBC bath, pull open Valve 2-7 until 3/4 of the solution has drained out. Close Valve 2-7 and allow the solution to soak for three to five minutes.



8

When the time has elapsed, open Valve 2-7 and drain the remainder of the solution from the left side of the WBC bath. Close Valve 2-7 when left side of WBC bath is empty.



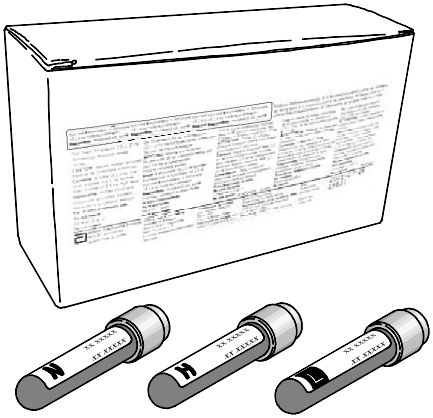
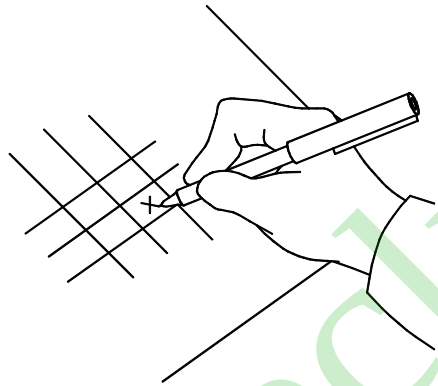
9

Reattach and/or close the Front Covers.

10

Press **[SPECIMEN TYPE]** followed by **[NORMAL BACKGRND]**. Run a background count. Run background counts until acceptable results are obtained for all background parameters (WBC, RBC, HGB and PLT).

Parameter	Specifications
WBC	≤ 0.5 K/µL
RBC	≤ 0.05 M/µL
HGB	≤ 0.1 g/dL
PLT	≤ 10.0 K/µL

Run a minimum of two levels of controls and verify results are within range before running any patient specimens. **11** 	Record this maintenance in the Maintenance Log. **12** 

4 - Quality Control Setup

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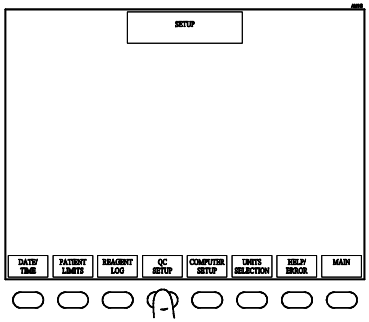
4.1 Entering Means & Limits (Manual Method)

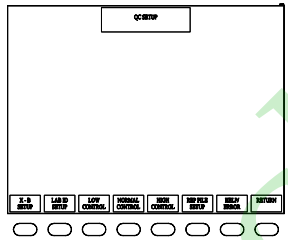
1

- From the **MAIN** menu screen, press **[SETUP]**.
- Press [**QC SETUP**].



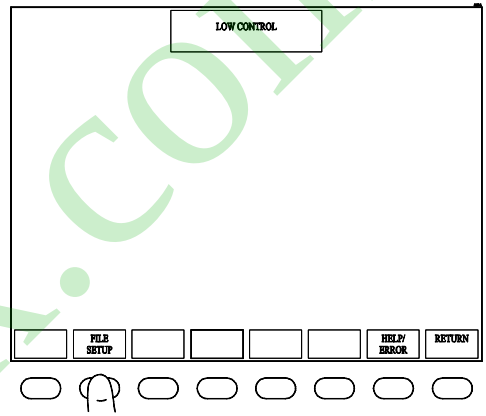
2

- In the **QC SETUP** menu, press the corresponding key for the desired type of control to be updated: **[LOW CONTROL]**, **[NORMAL CONTROL]**, or **[HIGH CONTROL]**.
- Use the [↑] and [↓] arrow keys on the PC keyboard to select one of four control files displayed.



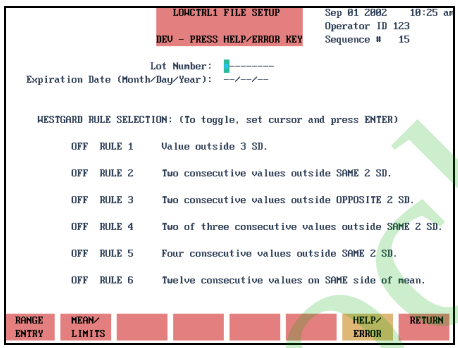
3

- Press **[FILE SETUP]** to display the File Setup screen.



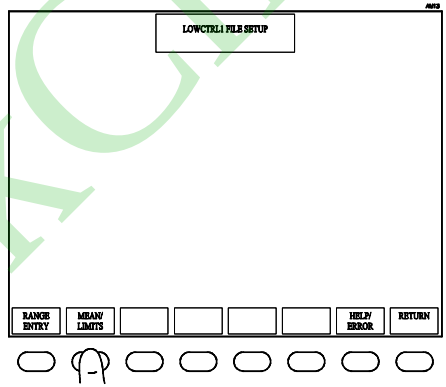
4

From the Control Assay Sheet, enter lot number and press **[ENTER]** to go to the next line. Enter the expiration date then press **[ENTER]**.



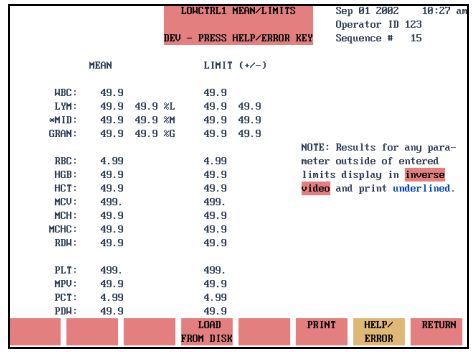
5

Press **[MEAN/LIMITS]**.



6

When the **MEAN/LIMITS** menu appears, the cursor will be at the WBC MEAN line.



7 Enter the value from the Control Assay Sheet corresponding to CELL-DYN 1800. Use the arrow keys on the PC keyboard to move and enter the limits for WBC. Press **[ENTER]** to go to the next line.

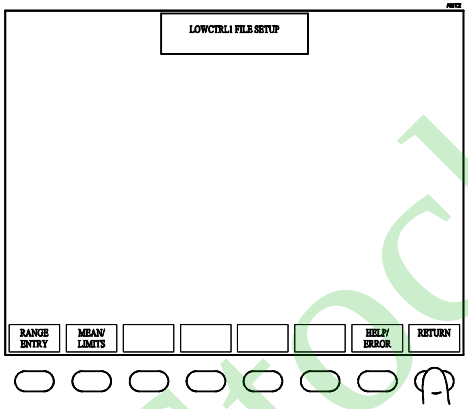
NOTE: *Type over to change the value present in the field.*

Continue entering all values using the numeric keyboard and the **[ENTER]** key.

8 When assay values are updated, press **[PRINT]** to print entered values. Use the Control Assay Sheet to confirm all entered values are correct for that level.

9 Press **[RETURN]** and verify lot number and expiration date are correct.

10 Press **[RETURN]** twice to display the **QC SETUP** menu screen.



11 Repeat the process for the NORMAL and HIGH control levels.

12 When all assay values have been updated, press **[RETURN]** until **SETUP** menu is displayed and press **[MAIN]** to return to the **MAIN** menu.

Save the Control Assay Sheet for documentation purposes. **13**	You are now ready to run controls in your newly updated files. **14**

4.2 Entering Means & Limits (by Upload from Disk)

On the CELL-DYN 1800 there is an option to automate means & limits entry of Quality Control assay values.

This procedure will automatically enter QC means & limits, lot number and expiration date into a selected file. The information is transferred to each file level, one at a time.

NOTE: *If an instrument is using any of the following unit selections: 2=SI UNITS, 3=SI Units (HGB/MCHC in mmol/L, MCH in fmol), 4=SI UNITS (HCT/PCT in %), the unit selection must be changed to 1=Factory (United States) prior to loading Assay Values from the disk. For instructions on changing units of measure, refer to the CELL-DYN 1800 System Operator's Manual,* **Section 5: *Operating Instructions***.

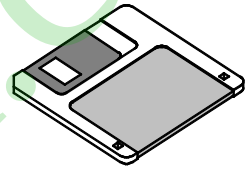
Necessary equipment:

- CELL-DYN 16 Control Assay Sheet
- CELL-DYN 16 Control Assay Disk
- CELL-DYN 22 Control Assay Sheet
- CELL-DYN 22 Control Assay Disk

1

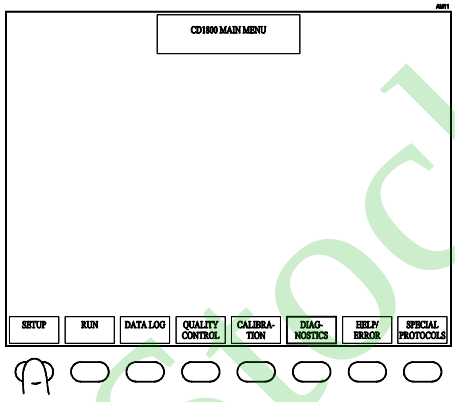
Confirm control name, lot number and expiration date on disk label are correct for the assay values to be loaded.

Insert the Control Assay disk into CELL-DYN 1800 System disk drive.



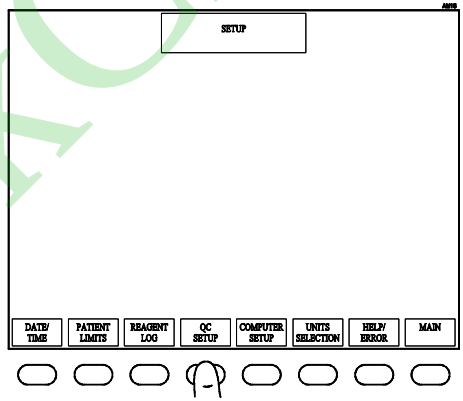
2

From **MAIN** menu, press **[SETUP]**.



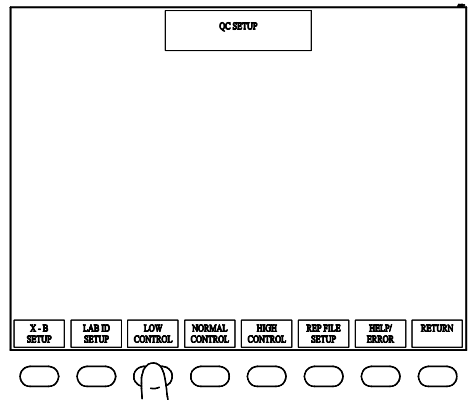
3

From **SETUP** menu, press **[QC SETUP]**.



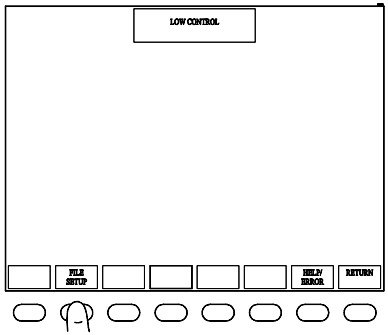
4

Press the key corresponding to the data to be loaded (LOW, NORMAL or HIGH Control). For this example, LOW Control has been selected.

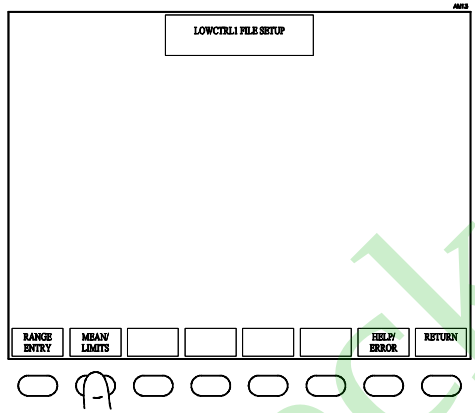


5 When the list of LOW Control files display, use the [↑] and [↓] arrow keys on the PC keyboard to move cursor to the desired file.

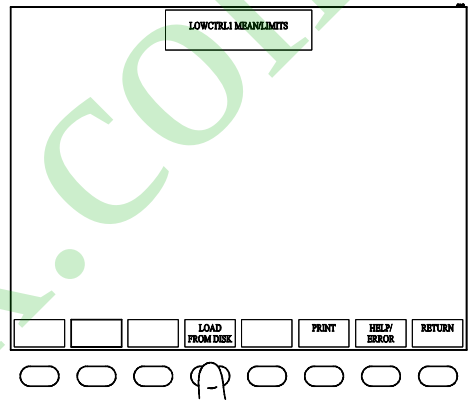
NOTE: *Selected file must be empty. Press **[FILE SETUP]**.*



6 From **FILE SETUP**, press **[MEAN/LIMITS]**.



7 When MEAN/LIMITS screen appears, press **[LOAD FROM DISK]**.



8 Follow the instructions that appear on screen. Press **[CONFIRM LOAD]**.

9 When assay values are displayed, press **[PRINT]** to print assay values. Use the Control Assay Sheet to confirm Assay Values are correct for the selected level. Press **[RETURN]** to verify lot number and expiration date are correctly displayed for the selected Control Level.

10 Press **[RETURN]** twice to display the **QC SETUP** screen.

Repeat Steps 4 through 10 to load assay values into another QC File. **11**	When all assay values have been updated, press **[RETURN]** until **SETUP** menu is displayed and **[MAIN]** to return to the **MAIN** menu. **12** **NOTE:** *If unit selection was changed at the beginning, reselect desired units at this time.*	Remove disk and store in a safe place in case it is needed to reload data for this lot. Save the Control Assay sheet for documentation purposes. **13** Discard disk when lot number is expired.
You are now ready to run controls in your newly updated files. **14** Three control assay levels for the CELL-DYN 1800 System are displayed.		

5 - Calibration

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5.1 Pre-Calibration Procedures

- Pre-Calibration Checklist
- Precision Test
- Calibration Verification

5.1.1 Pre-Calibration Checklist

To ensure accuracy of calibration performed, follow this checklist for procedures to be completed before starting calibration.

Date _____

Serial Number _____

Operator _____

Reason for calibration _____

1. Ensure that all maintenance is current before calibrating the instrument. Refer to the *CELL-DYN 1800 System Operator's Manual,* **Section 9: *Service and Maintenance*** for further information. Document maintenance performed in the Maintenance Log.
2. Confirm that reagent containers are at least one half full. Replace them as necessary and document in appropriate Reagent Logs.
3. Verify that the CELL-DYN reagents have not reached the expiration date. Record the reagent expiration dates and lot numbers in the spaces below:

Diluent Lot No. _____ Exp. date _____

Detergent Lot No. _____ Exp. date _____

CN-Free Diff Lyse Lot No. _____ Exp. date _____

4. Verify that the calibrator has not reached the expiration date:

Calibrator Lot No. _____ Exp. date _____

5. Confirm that the waste container is not more than half full–empty it if necessary.
6. Confirm that Normal Background is within limits. Record the background results and attach a printout to this document. If the system has been idle for 15 minutes or more, a Normal Background should be run immediately prior to running any calibration specimens.

	Background obtained	Specifications
WBC	_____	≤ 0.5 K/µL
RBC	_____	≤ 0.05 M/µL
HGB	_____	≤ 0.1 g/dL
PLT	_____	≤ 10.0 K/µL

7. Verify instrument precision by analyzing a fresh normal whole blood specimen twenty (20) times in succession. Run the specimen in an empty replicate file and record the CV% below and attach a file printout to this document. The CV% obtained should be less than or equal to the CV% limits listed below.

Parameter	Result	CV%
WBC	_____	≤ 2.5%
RBC	_____	≤ 1.7%
HGB	_____	≤ 1.2%
MCV	_____	≤ 1.5%
PLT	_____	≤ 6.0%
MPV	_____	≤ 6.0%

8. If any problems are detected, document the problem observed in the Error Message Logsheet.

5.1.2 Precision Test

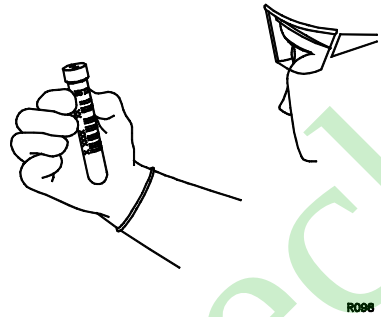
Precision is the degree that a parameter value varies when running a specimen multiple times. The variability between samplings is expressed as coefficient of variation (CV%). If the precision test fails, it indicates a potential problem with the CELL-DYN 1800.

5.1.2.1 Precision Test

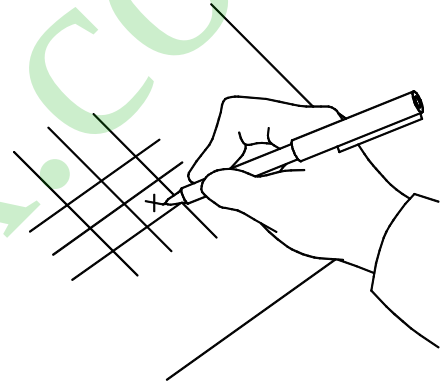
Necessary equipment:

- Protective equipment (gloves, lab coat and eye protection)
- A fresh whole blood specimen (EDTA) from a normal donor.

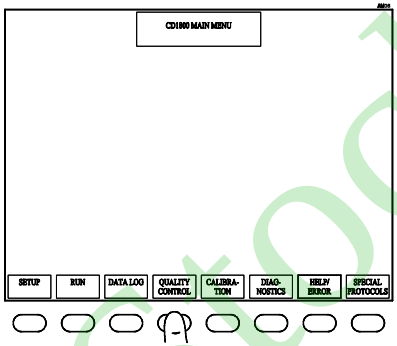
1 Obtain a fresh whole blood specimen (EDTA) from a normal donor. Specimen must be less that 4 hours old.



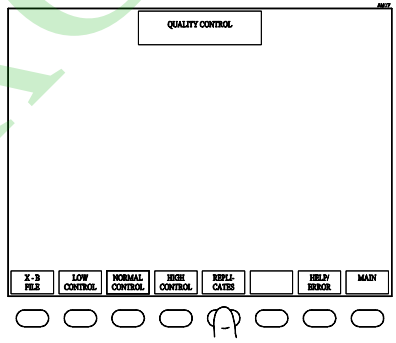
2 Ensure that maintenance is current and daily startup has been completed.



3 From **MAIN** menu, press **[QUALITY CONTROL]**.

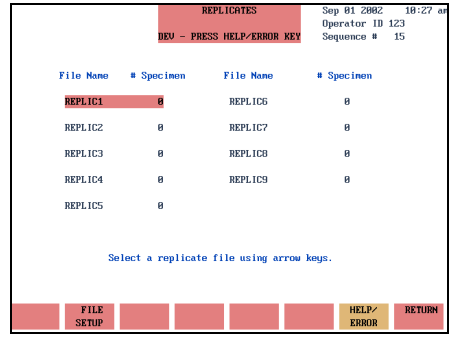


4 From the **QUALITY CONTROL** menu, press **[REPLICATES]**.



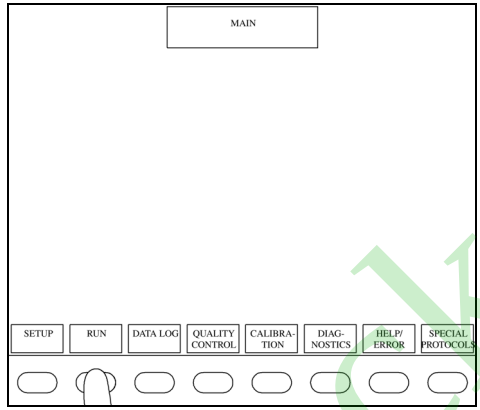
5 On the **REPLICATES** menu, find an empty file and make note of that file number. If no files are empty, purge a file.

NOTE: *If the file to be purged contains data that must be kept, print the file prior to purging.*

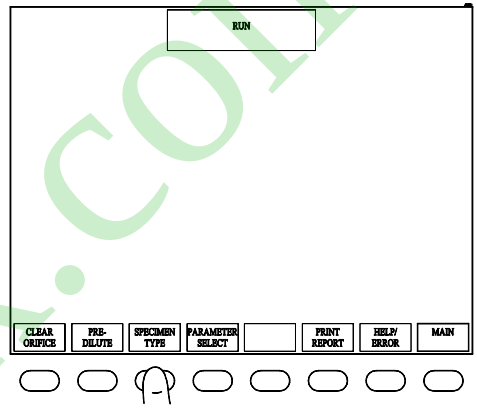


Press **[RETURN]** followed by **[MAIN]** to go to the **MAIN** menu. **6**

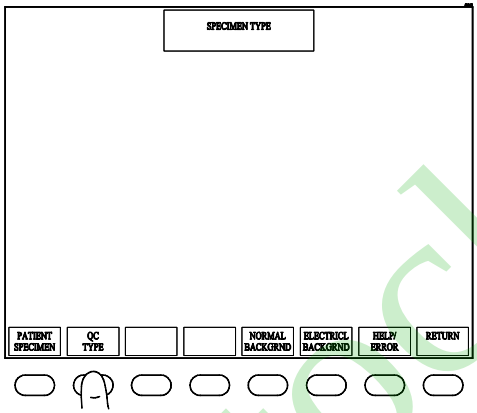
From **MAIN** menu, press **[RUN]**. **7**



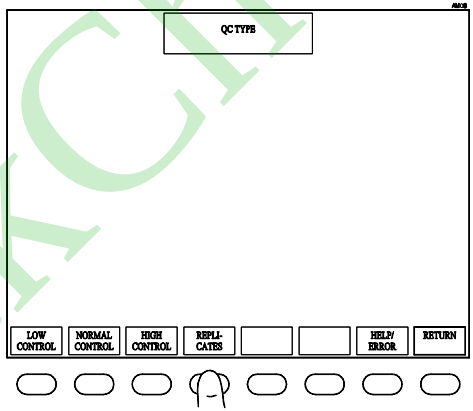
From **RUN** menu, press **[SPECIMEN TYPE]**. **8**



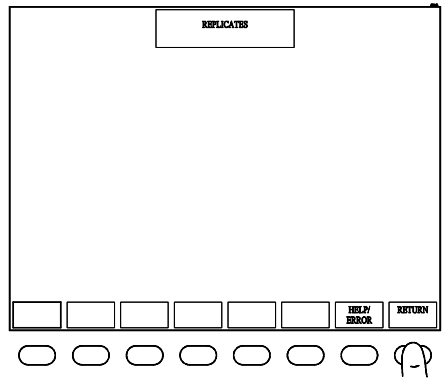
From the **SPECIMEN TYPE** menu, press **[QC TYPE]**. **9**



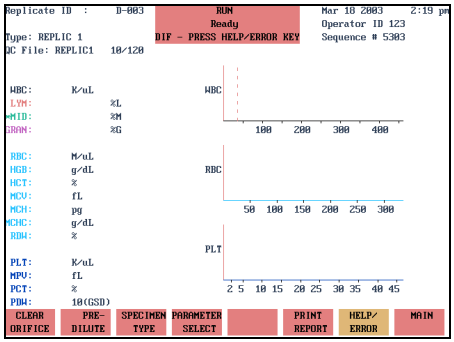
From **QC TYPE**, press **[REPLICATES]**. **10**



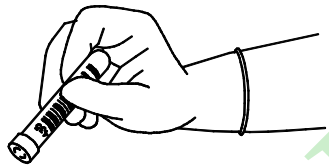
Using the arrow keys on the PC keyboard, move cursor to the empty replicate file selected in Step 5. Press **[RETURN]** to go to the RUN screen. **11**



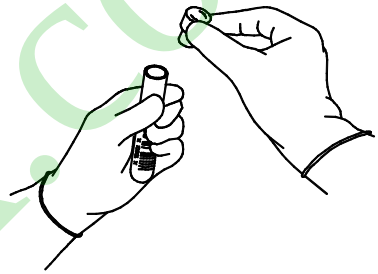
12 Verify the pre-selected empty replicate file is displayed in the upper left corner of the screen.



13 Gently invert the tube 10 to 15 times before the first run.



14 Remove the cap from the tube before each run.



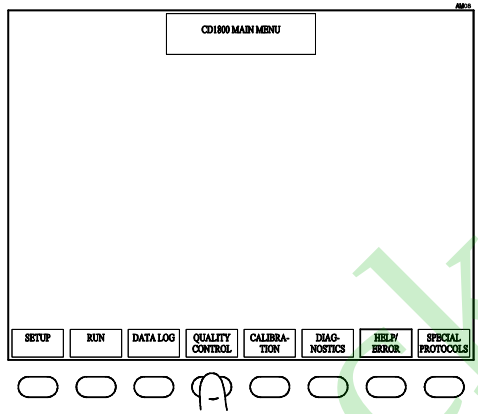
15 Run the specimen twenty (20) times, capping and remixing the specimen prior to each aspiration.

16 Ensure there are valid results for all parameters on all runs and there are no error messages.

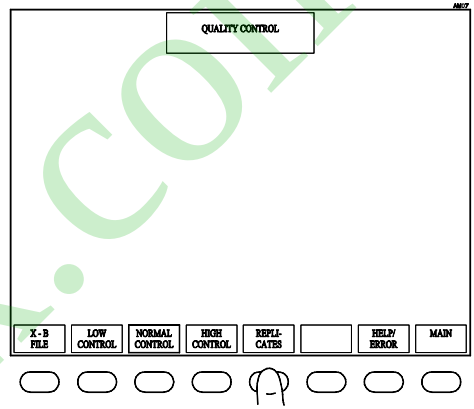
17 Reject any invalid results caused by improper flow or aspiration. Run additional samplings until twenty (20) valid results are completed.

18 When twenty (20) valid results are completed press **[MAIN]** to return to the **MAIN** menu.

19 From **MAIN** menu, press **[QUALITY CONTROL]**.



20 From **QUALITY CONTROL** menu, press **[REPLICATES]**.



21 Move cursor using the arrow keys, on the PC keyboard to the previously selected file under which the specimen was run. Press **[VIEW QC LOG]**.

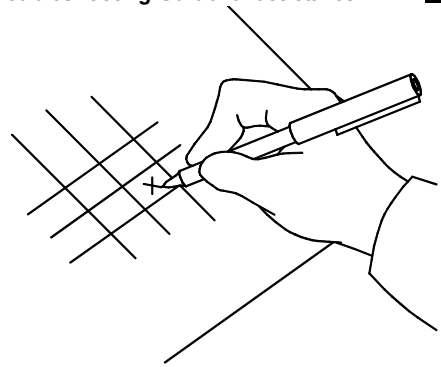
22 Press **[PRINT QC LOG]** to print that file.

On the printout, the CV(%) field displays the coefficient of variation for each parameter. Compare the values obtained from the runs performed to the acceptable CV(%) limits on the following table:

Precision Specifications

Parameter	CV%
WBC	≤ 2.5%
RBC	≤ 1.7%
HGB	≤ 1.2%
MCV	≤ 1.5%
PLT	≤ 6.0%
MPV	≤ 6.0%

23 If the precision test failed, refer to **Section 6: *Troubleshooting Guide*** for assistance.



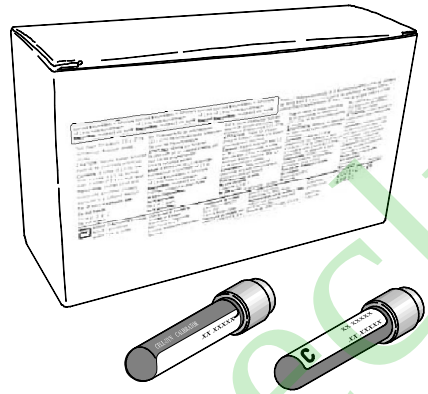
5.1.3 Calibration Verification

Calibration verification is a procedure performed to determine or confirm if current calibration is valid.

Materials needed:

- Protective equipment (gloves, lab coat and eye protection)
- CELL-DYN Calibrator or CELL-DYN 22 Calibrator
- Reagents
- Maintenance Log

1 CELL-DYN Calibrator or CELL-DYN 22 Calibrator.



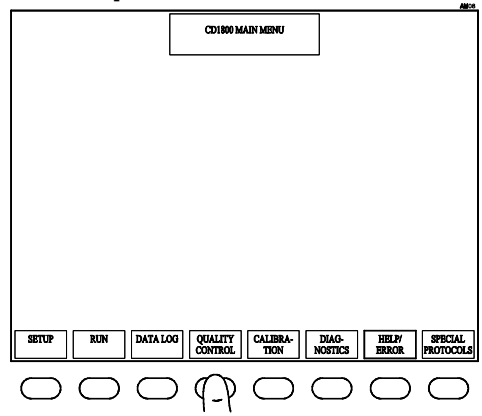
2 CELL-DYN Reagents

- Diluent 20 L
- Diluent 4 X 3.8 L
- Detergent 20 L
- Detergent 4 X 3.8 L
- CN-Free Diff Lyse (3.8 L)
- CN-Free Diff Lyse (960 mL)

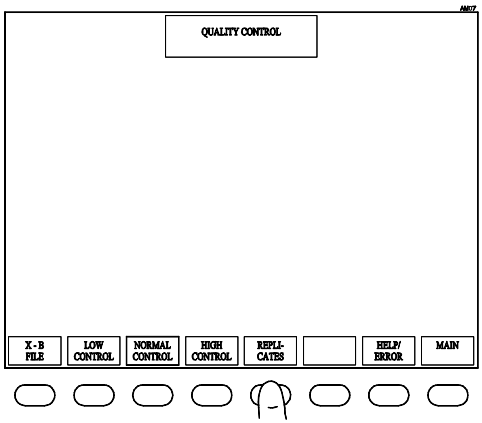
3 Perform daily startup and ensure scheduled maintenance is up to date.

4 Obtain a tube of CELL-DYN Calibrator from the refrigerator and allow it to warm at ambient room temperature for fifteen minutes. Follow the mixing and handling steps outlined in the Calibrator Assay Sheet or the CELL-DYN Calibrator and Control Mixing and Handling Instructions.

5 From **MAIN** menu, press **[QUALITY CONTROL]**.

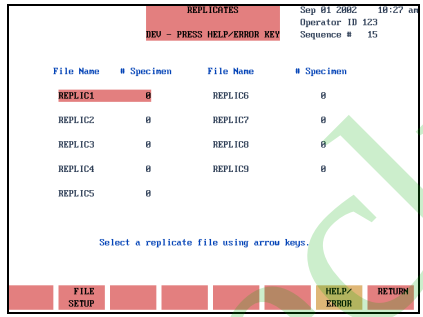


From **QUALITY CONTROL**, press **[REPLICATES]**. **6**



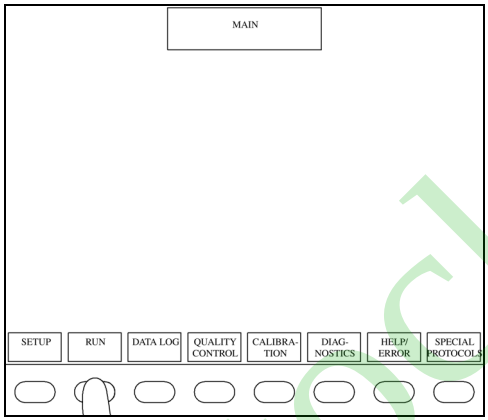
While in the **REPLICATES** menu screen, select an empty replicate file and make note of that file number. If no files are empty, purge a file. **7**

NOTE: *If the file to be purged contains data that must be kept, print the file prior to purging.*

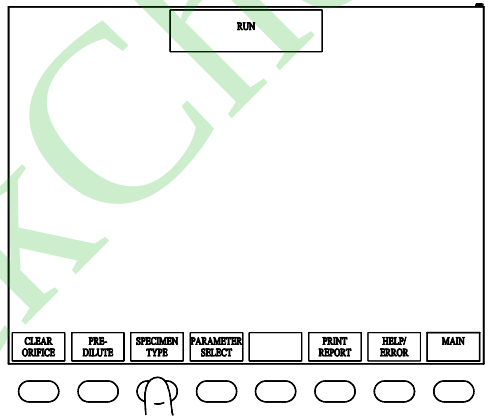


Press **[RETURN]** followed by **[MAIN]** to go to the **MAIN** menu. **8**

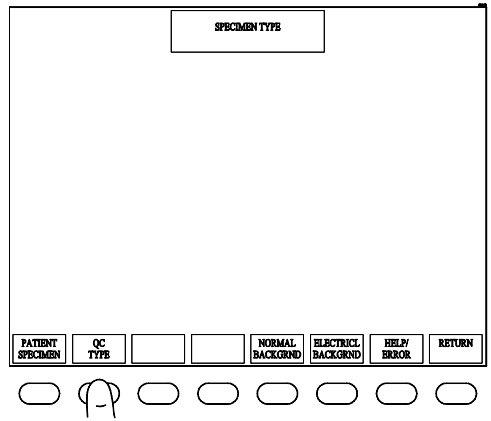
From **MAIN** menu, press **[RUN]**. **9**



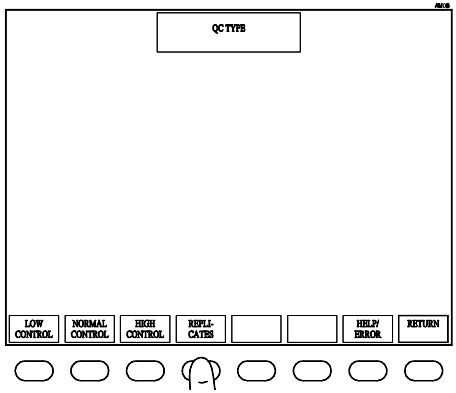
From **RUN menu**, press **[SPECIMEN TYPE]**. **10**



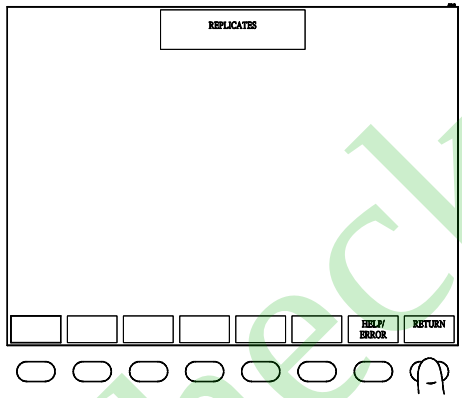
From **SPECIMEN TYPE** menu, press **[QC TYPE]**. **11**



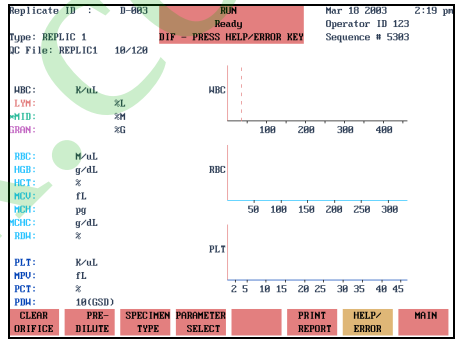
From **QC TYPE**, press **[REPLICATES]**. **12**



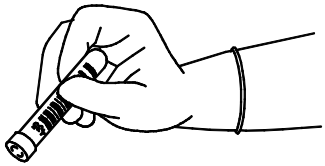
Using the arrow keys, on the PC keyboard move cursor to the empty replicate file previously selected. Press **[RETURN]** to go to the RUN screen. **13**



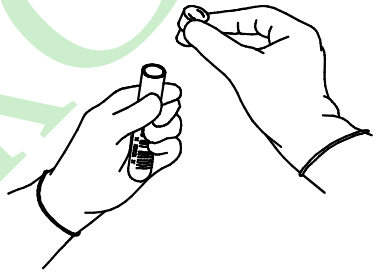
Verify the pre-selected empty replicate file is displayed in the upper left corner of the screen. **14**



Follow the mixing and handling steps outlined in the Calibrator Assay Sheet or the CELL-DYN Calibrator and Control Mixing and Handling Instructions. **15**



Remove the cap from the tube before each run. **16**



Run the calibrator three times, capping and remixing the specimen prior to each aspiration. **17**

18 Ensure there are valid results for all parameters on all runs and there are no error messages.

19 Reject any invalid results caused by improper flow or aspiration. Run additional samplings until three valid results are completed.

20 Using the worksheet provided in the CALIBRATOR assay sheet:

- Enter the values obtained for any or all given parameter(s) in its corresponding column.
- Enter the mean value or average obtained for the calibrator in the next row.

21

- Using the worksheet, determine if values obtained fall within the recovery limits specified.
- Calculate the variance or difference between the mean value obtained and the published assay value and enter it in the next row.
- Repeat the process for all other main parameters.

22 Any values obtained that fall outside the tolerance limits indicate that calibration is required for that parameter.

23 If all parameters fall within the recovery limits specified, calibration is NOT required.

Keep a printout of the Replicate file used and the CALIBRATOR assay sheet with the completed worksheet for documentation purposes.	**24**

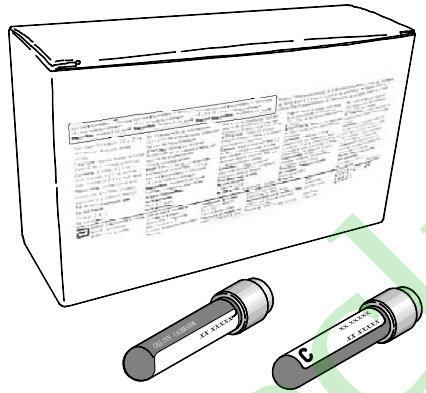
5.2 Auto Calibration

The Auto Cal method allows the Operator to automatically calibrate the CELL-DYN 1800 using calibrator or whole blood. Through the **AUTO CAL SELECT** menu, the Operator enters reference or target values, runs specimens, and the instrument compares the results with previously entered values. A mean factor for each selected parameter, based on the total number of runs from all specimens, is also calculated. With the Calibrator Method, one specimen is used for calibration. With the Fresh Whole Blood Method, multiple specimens are used. The Calibrator method is used for this procedure.

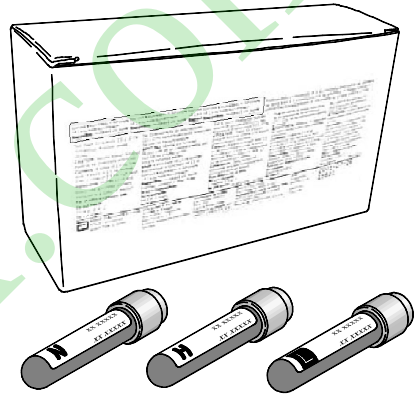
Necessary equipment:

- Protective equipment (gloves, lab coat and eye protection)
- CELL-DYN Calibrator or CELL-DYN 22 Calibrator
- CELL-DYN 16 or CELL-DYN 22 Controls
- Reagents

CELL-DYN Calibrator or CELL-DYN 22 Calibrator **1**



CELL-DYN 16 Control or CELL-DYN 22 Control **2**



CELL-DYN Reagents **3**

Diluent 20L 1

Diluent 4X3.8 L

Detergent 20L

Detergent 4X3.8 L

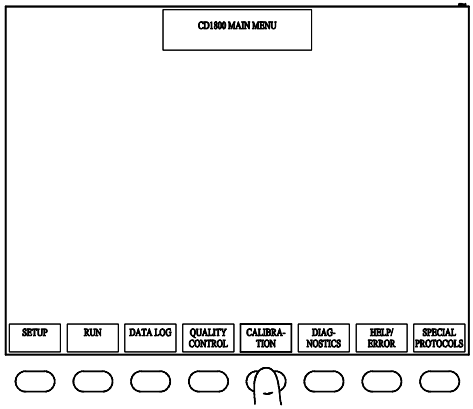
CN-Free Diff Lyse 3.8 L

CN-Free Diff Lyse 960 mL

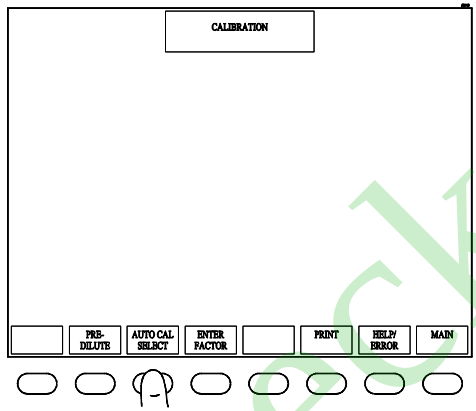
Perform daily startup and ensure scheduled maintenance is up to date. **4**

Obtain a tube of CELL-DYN Calibrator from the refrigerator and allow it to warm at ambient room temperature for fifteen minutes. Follow the mixing and handling steps outlined in the Calibrator Assay Sheet or the CELL-DYN Calibrator and Control Mixing and Handling Instructions. **5**

6 From **MAIN** menu, press **[CALIBRATION]**.



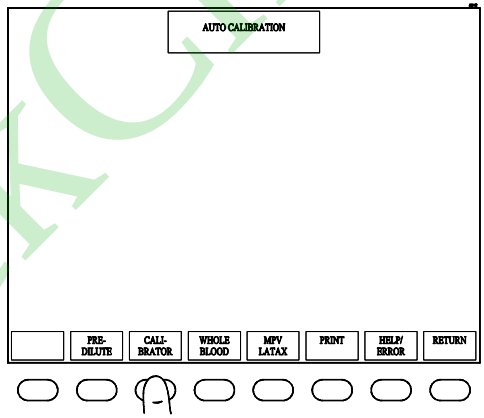
7 From **CALIBRATION** menu, press **[AUTO CAL SELECT]**.



8 The AUTO CALIBRATION screen displays current calibration factors for five main parameters (MPV is factory calibrated only), the method used to determine the factors, the date the factors were entered and the operator ID. Across the bottom of the screen, soft keys are displayed that allow you to select a calibration method.

9 Press **[PRINT]** to print the current calibration factors and save for your records.

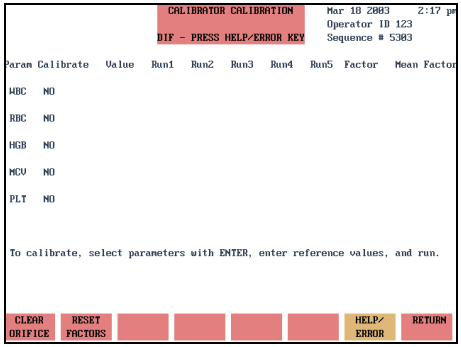
10 From **AUTO CALIBRATION** menu, press **[CALIBRATOR]**.



11 Remove the Calibrator Assay Sheet from the CELL-DYN Calibrator package. Use the sheet to enter reference values for each of the five main parameters.

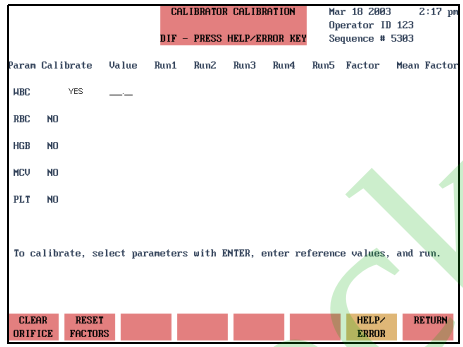
12

Notice that the cursor in the **AUTO CALIBRATION** menu is next to the **CALIBRATE NO** field. Press **[ENTER]** to change to **YES**.



13

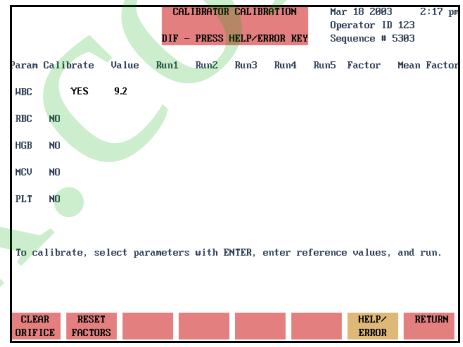
Use the PC keyboard to enter reference values for each parameter that you want to calibrate. You do not have to enter the decimal.



14

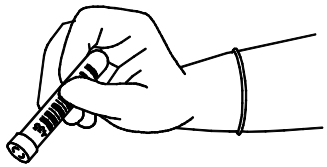
Any reference value remaining blank is not calibrated and not displayed later in the RUN CAL menu.

Calibrator runs can now be started.



15

Follow the mixing and handling steps outlined in the Calibrator Assay Sheet or the CELL-DYN Calibrator and Control Mixing and Handling Instructions.

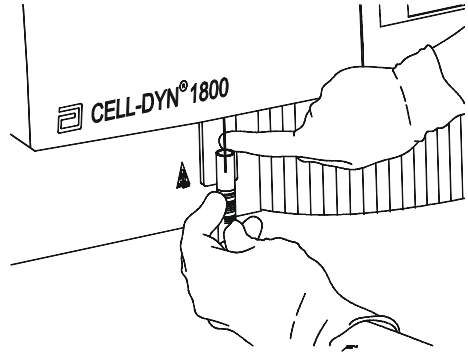


16

Remove the cap from the mixed calibrator and place tube under the Aspiration probe. Raise the tube so that the end of the probe is deeply immersed in the calibrator tube.

17

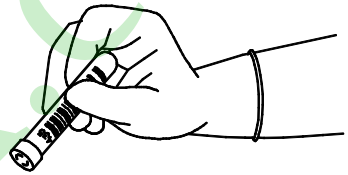
Press the touch plate to start the cycle.



18 When the instrument aspirates the specimen from the tube the probe moves up. A message line displays REMOVE SPECIMEN. Remove the calibrator tube and replace the cap.

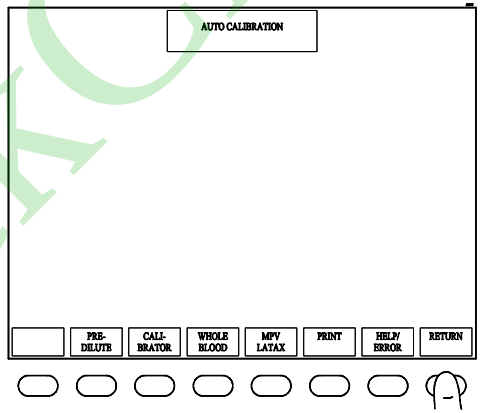
19 The calibrator values for the first run appear on screen. If any values are not acceptable they will be highlighted and will not be included in the final calculations.

20 For the second run, gently invert the tube five times. Remove the cap and place the calibrator tube under the Aspiration Probe. Press the touch plate.



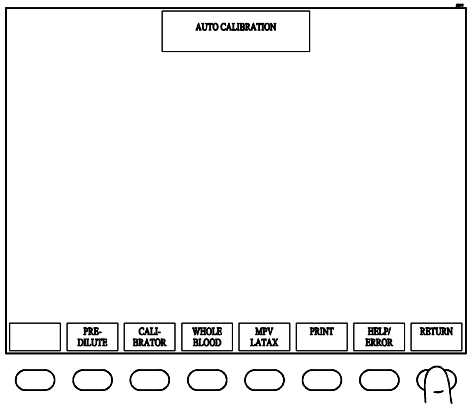
21 Repeat the process for the third run. After three acceptable runs, (the instrument will allow a maximum of five (5) runs) the new calibration factors are displayed.

22 Press **[RETURN]** to save the new calibration factors. A message CAL FACTORS SAVED is displayed.



23 Press **[PRINT]** to print the new calibration factors. Save this information for your records.

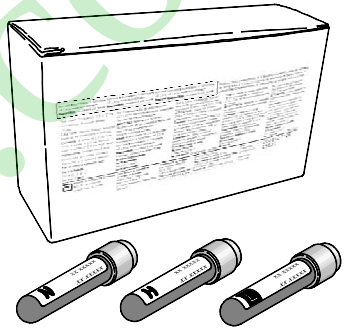
24 Press **[RETURN]** to return to the **CALIBRATION** menu.



25 Press **[MAIN]** to return to the **MAIN** menu.

26 Press **[RUN]** to display the **RUN** menu.

Run a minimum of two levels of controls and confirm that the results obtained for all parameters are within the control limits specified on the Assay Sheet or within your own established laboratory ranges for the controls lot number.



6 - Troubleshooting Guide

For additional procedures, refer to the CELL-DYN 1800 System Operator's Manual, **Section 10, *Troubleshooting and Diagnostics***.

DATA Problems	Probable Cause(s)	Corrective Action(s)
Background data is unacceptable	Contaminated Diluent or Detergent	Use a disinfectant solution containing 0.5% sodium hypochlorite for cleaning and disinfecting the flow system. Change reagent and flush system. (See CELL-DYN 1800 System Operator's Manual, **Section 9: *Service and Maintenance***, **Subsection: *As-Required Maintenance***.) Leave the power ON. Repeat system flush with distilled water. Change diluent or detergent and repeat system flush.
	Reagents are too cold	Allow reagents to warm to room temperature. See CELL-DYN 1800 System Operator's Manual, **Section 1: *Use or Function***, **Subsection: *Reagent Storage*** Rerun Background Count.
	Interference from other electrical devices	Use dedicated power source or line regulator. Relocate instrument to an area free from interfering devices. Press **[RUN]**, **[SPECIMEN TYPE],** and **[ELECTRICL BACKGRND]**. Rerun Background Count. Verify that electrical background is zero.
	Contaminated Transducer bath or Aperture plate	Perform AutoClean procedure. Clean Aperture Plate. Perform Supplemental Aperture cleaning.
	Contaminated Lyse (WBC background only)	Clean the Lyse Syringe. (See CELL-DYN 1800 System Operator's Manual, **Section 9: *Service and Maintenance***, **Subsection: *As-Required Maintenance***.) Install fresh Lyse Reagent.

DATA Problems	Probable Cause(s)	Corrective Action(s)
Background data is unacceptable (continued)	Diluent was frozen	Replace with new reagent.
	Vacuum Accumulator contaminated	Clean the Vacuum Accumulator. (See CELL-DYN 1800 System Operator's Manual, **Section 9: *Service and Maintenance***, **Subsection: *As-Required Maintenance***.)
`FLOW ERR` message is displayed in place of Count Time	Air bubbles are trapped in the dilution baths	Press **[CLEAR ORIFICE]** to backflush the aperture and reset the maximum count time. Rerun the specimen. If the situation occurs repeatedly, go to the **SPECIAL PROTOCOLS** menu and press **[MORE]**, followed by **[DRAIN BATHS]** to drain the liquid from each transducer. When the process is complete, press **[REFILL BATHS]**. This process removes any bubbles trapped inside the transducers. Clean the Aperture Plates. Check the Diluent Syringe and the tubing in the Diluent Normally Closed Valve on the Flow Panel.
	Normally Closed Valve tubing pinched or not properly seated	Remove the tubing in the Diluent Normally Closed Valve in the upper left corner of the Flow Panel. Massage the tubing to remove any crimps. Reseat the tubing in the valve. (See CELL-DYN 1800 System Operator's Manual, **Section 2: *Installation Procedures and Special Requirements***, **Subsection: *Inspection and Tubing Installation***.)

DATA Problems	Probable Cause(s)	Corrective Action(s)
Clog message is displayed in place of Count Time	Debris, fibrin clots, or protein buildup is restricting fluid flow through the aperture	Press **[CLEAR ORIFICE]** to backflush the aperture and reset the maximum count time. If situation continues, perform the Auto-Clean procedure. Clean the Aperture Plates. Perform the Supplemental Aperture Cleaning. Check the specimen for fibrin clots or red blood cell agglutination. Redraw and rerun the specimen as required.
	Flow system blockage resulting from pinched tubing or reagent particles may be in the Flow Panel.	Verify correct reagents are installed. Check Diluent Syringe installation. If the situation continues, perform the maintenance procedures to prepare the instrument for shipping. (See CELL-DYN 1800 System Operator's Manual, **Section 9: *Service and Maintenance***, **Subsection: As Required Maintenance, *Preparing the Instrument for Extended Periods of Non-Use or Shipping***.)
QC specimen results exceed acceptable limits	Improper mixing or handling of QC specimen	Refer to the CELL-DYN 1800 System Operator's Manual, **Section 11: *Quality Control*, Subsection: *Quality Control Procedures***.
	Incorrect QC setup Running a control in an incorrect QC file	Check that expected QC values are entered correctly. (See the CELL-DYN 1800 System Operator's Manual, **Section 11: *Quality Control***, ***Subsection: Quality Control Procedures***.) Verify that the control is being run into the correct control file.
	Dilution error	Re-run QC specimen. If problem persists, perform Auto Clean. (See the CELL-DYN 1800 System Operator's Manual, **Section 9: *Service and Maintenance***, **Subsection: *Weekly Maintenance Procedures***.)

DATA Problems	Probable Cause(s)	Corrective Action(s)
QC specimen results exceed acceptable limits (continued)	Insufficient or no dilution mixing.	Open the Upper Front Cover. Press the Touch Plate and observe the bubble mix in each bath and the Pre-Mixing Cup. If required, call Abbott Diagnostics Customer Service.
	Dirty Aperture Plate	
Erratic results	Improper bubble mix	Verify bubble mix to Pre-Mixing Cup, WBC and RBC transducer baths. Perform cleaning procedures: 1. Aperture plates cleaning. 2. Supplemental Aperture cleaning. 3. Hemoglobin flowcell cleaning. 4. "Y" fitting cleaning.
	Improper dilution	Verify Pre-Mixing Cup, WBC and RBC transducer baths are draining properly. Perform cleaning procedures: 1. Aperture plates cleaning. 2. Supplemental Aperture cleaning. 3. Hemoglobin flowcell cleaning.
	Patient specimen	Check specimen for clots.
	Control specimen	Re-mix controls and rerun. Open new vials and rerun.
Leaking instrument	Obstructions	Inspect Pre-Mixing Cup for overflow. Clean "Y" fitting under Pre-Mixing Cup.
	Disconnected tubing	Inspect front panel for disconnected tubing and reconnect.
	Reagents above instrument level	Place reagents below or beside instrument.
	Leaking syringe	Replace syringe

DATA Problems	Probable Cause(s)	Corrective Action(s)
`Detergent Empty` **message is displayed**	Detergent container is empty	Install a fresh container of detergent. Press **[CLEAR ALARM]**. Run a Background Count.
	Incorrect reagent was installed	Install proper reagent. Verify detergent tubing is correctly installed. Press **[CLEAR ALARM]**.
	Detergent is not being pulled into the flow system	Massage the tubing to remove any crimps, then reseat the tubing. (See the CELL-DYN 1800 System Operator's Manual, **Section 2: *Installation Procedures and Special Requirements*, Subsection: *Inspection and Tubing Installation***.) Check for crimps in the detergent line from inside the detergent container to the Reagent Inlet Panel. Verify that the reagent line is completely immersed in the reagent. Press **[CLEAR ALARM]**.
`Diluent Empty` **message is displayed**	Diluent container is empty	Install a fresh container of diluent. Press **[CLEAR ALARM]**. Run Background Count
	Incorrect reagent was installed	Install proper reagent. Check diluent tubing for correct installation. Press **[CLEAR ALARM]**. Run Background Count.

DATA Problems	Probable Cause(s)	Corrective Action(s)
`Diluent Empty` **message is displayed (continued)**	Diluent is not being pulled into flow system	Massage the tubing in the Normally Closed Valve to remove any crimps, then reseat the tubing. (See the CELL-DYN 1800 System Operator's Manual, **Section 2: *Installation Procedures and Special Requirements*, Subsection: *Inspection and Tubing Installation***.) Verify that the reagent line is completely immersed in the diluent. Check for crimps in the diluent line from inside the diluent container to the Reagent Inlet Panel. Verify that the Diluent Syringe Knurl Nut is tight. Press **[CLEAR ALARM]**.
	Diluent Syringe is loose	Verify Diluent Syringe is mounted properly. Press **[CLEAR ALARM]**.
`Lyse Empty` **message is displayed**	Lyse container is empty	Install a fresh container of Lyse.
	Incorrect reagent was installed	Install proper reagent. Verify lyse tubing is mounted properly. Press **[CLEAR ALARM]**.
	No liquid was detected by the internal Lyse Sensor	Confirm that the end of the lyse tubing is immersed in reagent. When the container is empty, replace it with a fresh container of lyse. Press **[CLEAR ALARM]**. Check the entire Lyse Inlet Tubing for crimps. Run a Background Count.
	Lyse syringe not moving properly	Verify Lyse Syringe is mounted properly. Clean Lyse Syringe. (See the CELL-DYN 1800 System Operator's Manual, **Section 9: *Service and Maintenance*, Subsection: *As-Required Maintenance***.) Press **[CLEAR ALARM]**.

DATA Problems	Probable Cause(s)	Corrective Action(s)
`Lyse Empty` **message is displayed (continued)**	Lyse not being pulled into the flow system	Remove the tubing from the Lyse Normally Closed Valve. Massage the tubing to remove any crimps, then reseat the tubing (See the CELL-DYN 1800 System Operator's Manual, **Section 2: *Installation Procedures and Special Requirements*, Subsection: *Inspection and Tubing Installation***.) Press **[CLEAR ALARM]**.
	Lyse Inlet Tubing is clogged	Rinse the Lyse Inlet Line. (See the CELL-DYN 1800 System Operator's Manual, **Section 9: *Service and Maintenance*, Subsection: *Monthly Maintenance Procedures***.) Press **[CLEAR ALARM]**.

7 - Parts and Accessories List

TABLE OF CONTENTS

7.1 CELL-DYN Equipment, Parts, and Accessories

Abbott List Number/Part Number	Description of Part	Configuration
03H54-01	Accessory Kit (NOTE: For a list of items in the Kit, see the Accessory Kit Table)	1
07H80-01	Operator's Manual	1
07H79-01	Interface Specifications	1
20821-01	Okidata Printer (120V)	1
20822-01	Okidata Printer (220V)	1
03H10-03	HP Inkjet Printer (110V)	1
03H10-07	HP Inkjet Printer (110V/220V)	1
03H56-01	Keyboard	1
92274-01	Aperture Plate WBC	100 Micrometer
92264-01	Aperture Plate RBC	60 Micrometer
28561-01	Lyse Syringe	2.5 mL
04H36-01	Diluent Syringe	10 mL
28514-01	Sample Syringe	100 µL
21704-01	Waste Dummy Plug	1
93164-01	Sample Probe	1
54305-01	Aperture Brush	1
20005-01	Printer Cable	1

Abbott List Number/Part Number	Description of Part	Configuration
07H81-01	Bar Code Scanner	1
03H96-01	Pull Ring, Solenoid	1
99650-01	Code 39 Bar Code Labels	1000 pkg.
07H67-01	Lyse Cap for 960 mL container	5
07H67-02	Lyse Cap for 3.8 L or 20 L container	5

7.2 CELL-DYN 1700/1800 Accessory Kit (List No. 03H54-01)

Abbott List Number/Part Number	Description of Part	Configuration
1403204	Keyboard Cover	1
5100161 *	Fuse, SB 2.5 amps 250 V	2
60160-01 *	Fuse, SB 5.0 amps 220/240 V	2
93501-01	Power Cord	1
5406753	Allen Wrench 3/32"	1
5406754	Allen Wrench 7/64"	1
54305-01	Aperture Brush	1
91072-01	Reagent Line Kit	1
20005-01	Printer Cable	1
9150143	Instructions for Mixing and Handling	1
93476-01	Silicon Tubing (S2)	1 (24")

*For CELL-DYN 1700 System use only.

7.3 CELL-DYN 1800 Reagent Line Kit (List No. 91072-01)

Abbott List Number/Part Number	Description of Part	Configuration
03H82-01	Reagent Line Assembly, Lyse (1L)	1
03H92-01	Detergent Line Inlet Assay	1
92161-02	Waste Line Assembly	1
92163-01	Diluent Line Inlet Assembly	1
92178-01	Lyse Line Inlet Tube	1

7.4 CELL-DYN Reagents

US-Only List Number	International List Number	Description of Part	Configuration
07H84-01	07H84-01	CN-Free Diff Lyse (3.8L)	3.8 liter cube
07H84-02	07H84-02	CN-Free Diff Lyse (960mL)	1 x 960 mL bottle
08H18-04	99320-01	Detergent	20 liter cube
08H18-01	99326-01	Detergent	4 x 3.8 liter bottles
08H18-02	98329-01	Detergent	1 x 3.8 liter bottle
08H17-04	99220-01	Diluent	20 liter cube
08H17-01	99226-01	Diluent	4 x 3.8 liter bottles
08H17-02	99229-01	Diluent	1 x 3.8 liter bottle

7.5 CELL-DYN Controls and Calibrators

Abbott List Number/Part Number	Description of Part	Configuration
99109-01	CELL-DYN 16 Tri-Level Control	12 x 2.5 mL; 4 of each level
99105-01	CELL-DYN 16 Tri-Level Control (Half Pack)	6 x 2.5 mL; 2 of each level
02H40-01	CELL-DYN 16 Normal Control	6 x 2.5 mL; 6 of normal control
01H92-01	CELL-DYN 16 Control Assay Disk	1
99110-01	CELL-DYN Calibrator	2 x 2.5 mL
93111-01	CELL-DYN 22 Tri-Level Control	12 x 2.5 mL; 4 of each level
99106-01	CELL-DYN 22 Tri-Level Control (Half Pack)	6 x 2.5 mL; 2 of each level
99103-01	CELL-DYN 22 Normal Control	6 x 2.5 mL; 6 of normal control
01H91-01	CELL-DYN 22 Control Assay Disk	1
99120-01	CELL-DYN 22 Calibrator	2 x 2.5 mL

7.6 CELL-DYN Consumables

Abbott List Number/Part Number	Description of Part	Configuration
99644-01	Enzymatic Cleaner Concentrate	2 x 50 mL
30005-01	OKIDATA® Graphics Paper	3000 sheets/pkg.
13401-01	Ribbon OKIDATA® 320	1
03H10-04	HP Printer Cartridge (Black)	1
30010-08	HP Printer Paper	
99605-01 (US Only)	CELL-DYN Counting Cups	500/pkg.
99606-01 (US Only)	CELL-DYN Counting Cups	3000/pkg.
99605-02 (International)	CELL-DYN Counting Cups	500/pkg.
99606-02 (International)	CELL-DYN Counting Cups	3000/pkg.

TO BRING THE SYSTEM OUT OF STANDBY

From the **MAIN** menu, press **[PRIME/RUN].**

The instrument will initialize and run an Auto Background.

<READY> message appears.

The instrument is ready to run specimens.

If the Auto Background is out of specifications, follow the "to Perform a Background Check" instructions.

RUNNING CONTROLS

From the **MAIN** menu, press **[RUN].**

From the **RUN** menu, press **[SPECIMEN TYPE].**

From the **SPECIMEN TYPE** menu, press **[QC TYPE].**

From the **QC TYPE** menu, press the appropriate control:

[LOW CONTROL], **[NORMAL CONTROL],** or **[HIGH CONTROL].**

Use arrow keys to highlight the appropriate file.

Press **[RETURN].**

Place the appropriate well-mixed control specimen under the Sample Aspiration Probe, then raise the tube so that the end of the probe is deeply immersed in the specimen.

Press the Touch Plate to start the cycle.

Remove the specimen tube after the probe has moved up.

Confirm that the results obtained for all parameters are within the control limits specified on the Assay Sheet or within your own established laboratory ranges for the current Lot Number.

RUNNING PATIENTS

From the **MAIN** menu, press **[RUN].**

From the **RUN** menu, press **[SPECIMEN TYPE].**

From the **SPECIMEN TYPE** menu,

Press **[PATIENT SPECIMEN].**

Enter the patient's ID and appropriate demographics.

Place the well-mixed patient specimen under the Sample Aspiration Probe, then raise the tube so that the end of the probe is deeply immersed in the specimen.

Press the Touch Plate to start the cycle.

Remove the specimen tube after the probe has moved up.

TO PERFORM A BACKGROUND CHECK

From the **MAIN** menu, press **[RUN].**

From the **RUN** menu, press **[SPECIMEN TYPE].**

From the **SPECIMEN TYPE** menu,

Press **[NORMAL BACKGRND].**

Press the Touch Plate to start the cycle.

Ensure results meet the following specifications:

WBC ≤ 0.5 K/µL

RBC ≤ 0.05 M/µL

HGB ≤ 0.1 g/dL

PLT ≤ 10.0 K/µL

PREVENTIVE MAINTENANCE

Daily

- Perform Daily Startup (initialize from a STANDBY state.
- Perform Daily Shutdown

Weekly

- Perform Auto Clean
- Clean the Aspiration Probe Exterior

Monthly

- Rinse the Lyse Inlet Line
- Rinse the Reagent Inlet Lines

Semiannual

- Clean the Printer

As Required

- Clean HGB Flow Cell
- Clean Pre-Mixing Cup
- Empty Instrument Waste
- Clean/Replace Aperture Plates
- Clean/Replace Aspiration Probe
- Clean/Replace Aspiration Probe Wash Block
- Clean/Replace Syringes
- Drain/Clean Vacuum Accumulator
- Clean Bar Code Scanner Lens
- Clean "Y" Fitting
- Supplemental Aperture Cleaning
- Prepare Instrument for an Extended Period of Non-Use or Shipping

CUSTOMER TECHNICAL SUPPORT

In the US: 1-877-422-2688 (1-877-4ABBOTT)

Outside the US: Call your local customer support representative.

NOTE: If the system has been idle for fifteen minutes or more, a Normal Background should be run immediately prior to running a patient or control specimen.
*For detailed instructions, refer to the CELL-DYN 1800 System Operator's Manual.

CELL-DYN® 1800 Quick Reference