

OREGON HEALTH & SCIENCE UNIVERSITY
Hospitals and Clinics
Point of Care

**Cell-Dyn Maintenance for Open Mode Use
Detailed Quality Control Procedure**

Daily Maintenance:

1. All three levels of Quality Control (QC) shall be run at the beginning of each day of operation and at least one QC every 8 hours thereafter.
2. Allow the QC vials to sit at room temperature for at least fifteen minutes before testing.
3. The Cell-Dyn is programmed to start-up automatically.
4. Start the QC process by performing an Open Mode Background count. This will ensure the instrument is functioning within acceptable parameters prior to running the QC vials.
5. Press MAIN to return to the MAIN MENU screen if not already there. At the MAIN MENU screen enter in the Operator ID at the right side of the screen. Press RUN, press SPECIMEN TYPE, and then press NORMAL BACKGRND. Depress the Touch Plate to begin the Open Mode Background count.
6. Verify that the Open Mode Background count results are acceptable. The results shall be within the following specifications:

WBC	≤ 0.3 K/mm ³
RBC	$\leq .05$ 1000K/mm ³
HGB	≤ 0.1 g/dl
PLT	≤ 5 Kmm ³

7. If the Open Mode Background count results are acceptable, proceed to Step 10.
8. If the Open Mode Background count results fail, press CLEAR ORIFICE to clean the probe. The Status Box will read "Cleaning Orifice". When complete press SPECIMEN TYPE and then NORMAL BACKGRND. Lastly depress the Touch Plate to re run the Open Mode Background count.
9. If the Open Mode Background count results are acceptable after the orifice has been cleaned, proceed to Step 10. If the Open Mode Background count results still do not fall within acceptable parameters, contact Customer Support at 1-877-422-2688. Do not perform patient testing until the problem is resolved. Document all corrective actions taken on the Instrument Troubleshooting Logsheet.

10. Performing the QC:

- a. Press MAIN to return to the MAIN MENU screen if not already there. At the MAIN MENU screen, press RUN, press SPECIMEN TYPE, and then press QC TYPE.
- b. Select the appropriate QC level. Run the low control QC vial first, followed by the normal control QC vial and finish with the high control QC vial.

NOTE: The low control vial has the white lid, the normal control vial has the black lid and the high control vial has the red lid.

- c. To begin press LOW CONTROL. The screen will change to the LOW CONTROL screen. The file that is currently in use will be highlighted (to access one of the other four files, scroll up and down using the arrow keys). Press RETURN. The screen will change to the RUN Screen and the Status Box will display "Ready". The machine is now ready to run the control.
- d. Mix the QC vial by gently rolling it between the palms of the hands for 20 seconds. Invert the vial and roll it back and forth for another 20 seconds. Gently invert the vial 10 times.
- e. Repeat step d 3-4 more times.

NOTE: It is imperative that the contents of the QC vial are well mixed.

- f. Gently invert the QC vial 5 times immediately prior to testing. Do not place the QC vials on the specimen rocker.
- g. Unscrew to cap of the QC vial and hold the vial under the sample probe. For accurate sampling, ensure the probe is not resting on the bottom of the vial.
- h. Depress the Touch Plate for aspiration to begin.
- i. When "Dispensing Remove Specimen" is displayed on the screen, remove the QC vial. The probe will automatically retract into the instrument and the Status Box will display "Aspirating" on the screen.
- j. Verify that the QC results displayed are within acceptable limits. Unacceptable results will be highlighted in blue.
- k. Run the remaining control QC vials, following steps a-j.
- l. If all QC results are within acceptable limits, the machine is ready for patient testing. If the weekly run Levey-Jennings graphs are due, proceed to Step 2 of the Weekly Maintenance section.
- m. If one of the controls fails, repeat the QC process using the same QC vial again.
- n. If the repeat process displays acceptable limits, the machine is ready for patient testing. If the repeat process fails, repeat the QC process using a new QC vial.
- o. If the repeat QC process fails again using a new QC vial, do not perform patient testing until the problem is resolved. Contact Customer Support at 1-877-422-2688. Have the instrument model number, serial number, and a description of the problem available for the Customer Support Specialist.
- p. Document all corrective actions on the Instrument Troubleshoot Logsheet.
- q. Send patient samples to the Core Laboratory for testing until the problem is resolved.

NOTE: If testing is not performed within 4 hours, the Cell-Dyn machine goes into

an automatic shutdown mode.

Twice Weekly Maintenance:

1. Perform the Auto Clean:
 - a. Press MAIN to return to the MAIN MENU if not already there. At the MAIN MENU, enter in the Operator ID. Press SPECIAL PROTOCOLS. Press AUTO CLEAN.
 - b. Remove the vial (test tube) labeled as Enzymatic Cleaner. Remove the top and place the sample probe in the tube so that the end is immersed in the sample but not resting on the bottom of the tube. Press START CLEAN. The machine will automatically begin to clean tubing and other parts that come in contact with patient samples.
2. Perform Aspiration Probe Exterior cleaning:
 - a. Mix one part enzymatic cleaner with one part distilled water in a 15mL conical tube. Label the tube "1:1 Enzymatic Cleaner for Probe Exterior Cleaning".
 - b. Using a lint-free tissue, wipe the outside of the probe with the diluted enzymatic cleaner.
 - c. Using a lint-free tissue wipe the probe with plain distilled water.
 - d. Perform an Open Mode Background count following Step #4 of the Daily Procedure. Continue to perform background counts until acceptable results are obtained for all background parameters.
 - e. Document on the Cell-Dyn 1800 Maintenance Log.

The results must be within the following specifications:

WBC	≤ 0.3 K/mm ³
RBC	$\leq .05$ 1000K/mm ³
HGB	≤ 0.1 g/dl
PLT	≤ 5 Kmm ³

- f. If background count results fail, press CLEAR ORIFICE, then press NORMAL BACKGRND.
- g. If background count results fail again, do not perform patient testing until problem is resolved. Contact Customer Support at 1-877-422-2688.

Document all maintenance on the Cell-Dyn 1800 Maintenance Log. Document all corrective actions on the Instrument Troubleshooting Logsheets.

Weekly Maintenance:

1. Review Levey-Jennings graphs for all commercial Quality Controls:
 - a. Press MAIN to return to the MAIN MENU if not already there. Enter in the Operator ID.
 - b. Press QUALITY CONTROL and then press LOW CONTROL.

- c. Select the appropriate control file using the arrow keys to scroll through the four files.
- d. With the appropriate file highlighted press VIEW QC LOG. Review the values. To scroll through pages use the Pg Up and Pg Dn keys on the keyboard. To scroll through individual values on a page, use the arrow keys. If it is clear there was a mistake running the QC control by the Operator on one of the days, delete the erroneous value by highlighting the value and pressing DELETE SPECIMEN. Press CONFIRM DELETE to confirm the deletion. If a value is skewing the Levey-Jennings graph without reason choose to reject the value by pressing REJECT SPECIMENS. This will help prevent distortion in the Levey-Jennings graph. The value itself, however, will still be saved in case there is need for further QC review.
- e. Press LEVEY JENNINGS.
- f. Press PRINT to print a copy of the graph. The graphs display the last 10 days of QC results.
- g. Place the graph on the Levey-Jennings clipboard.
- h. Press RETURN three times to return to the QUALITY CONTROL screen.
- i. Press NORMAL CONTROL and follow steps c-g.
- j. Press HIGH CONTROL and follow steps c-g.
- k. Each graph shall be reviewed for shifts or trends.

A **shift** would be an abrupt change in the results. Two or three results are distinctly higher or lower than previous results.

A **trend** indicates a situation where the results move in the same direction for several consecutive runs.

- l. If a shift or trend is noted, call the POCT coordinator at 4-5497 for advice or call Cell Dyn Customer Support at 1-877-422-2688.

Monthly Maintenance:

Perform the Lyse Lyne Cleaning:

- a. Fill the container labeled "Lyse Lyne Cleaning" with warm distilled water.
- b. Remove the Lyse Tubing from the Lyse Reagent Container and place the end of the tubing in the container of warm distilled water. Keep the Lyse Tubing attached to the Reagent Inlet Panel.
- c. Replace the Lyse Reagent Container with a new bottle is solution is low.
- d. At the MAIN MENU, enter in the Operator ID and press SPECIAL PROTOCOLS.
- e. Press LYSE PRIME to start the Lyse Priming cycle.
- f. When Lyse Empty appears in the Status Box, press CLEAR ALARM to perform the rinse cycle with warm distilled water.
- g. Repeat 3-5 times.
- h. Remove the Lyse Tubing from the container of distilled water and place the wet end on a paper towel. Dry the excess water from the tubing. Keep the tube of the tubing exposed to air and press CLEAR ALARM to cycle air through the tubing.

- i. Remove the cover located on the left side of the instrument.
- j. Re-insert the tubing into the Lyse Reagent Container and press LYSE PRIME. Observe the Lyse Syringe to verify that lyse is flowing into the syringe (the Lyse Syringe is the syringe closest to the back wall). Watch for bubbles. If bubbles appear, make sure the end of the tubing is completely submerged in the Lyse Reagent.
- k. Press LYSE PRIME 3-5 more times to perform multiple prime cycles.
- l. Press MAIN to return to MAIN MENU.
- m. Press RUN, then SPECIMEN TYPE, then NORMAL BACKGRND.
- n. Press the Touch Plate to perform an Open Mode Background count. Perform Open Mode Background counts until acceptable results are obtained for all background parameters. Refer to #4 of the Daily Maintenance section for instruction.
- o. Document maintenance on the Cell-Dyn 1800 Maintenance Log.

Semi-Annual Maintenance (Performed by POCT staff):

1. Enter new lot number of quality control using floppy disk sent with controls.
 - a. From MAIN MENU screen, press SETUP followed by QC SETUP.
 - b. Select LOW CONTROL to access Low Control file group.
 - c. Press selection of appropriate control file in which to load control assay values.
 - d. File must be empty to receive data.
 - e. Press FILE SETUP followed by MEANS/LIMITS. QC MEANS/LIMITS ENTRY screen will appear. (Do not manually enter anything at this screen.)
 - f. Press LOAD FROM DISK to display the LOAD FROM DISK screen.
 - g. Insert the disk for the appropriate lot number into the Data Station disk drive.
 - h. Press CONFIRM LOAD.
 - i. When upload is complete, limits are displayed for the selected file.
 - j. Print and compare values to those on assay sheet.
 - k. Press RETURN to return to FILE SETUP screen.
 - l. Press RETURN to return to QC SETUP screen.
 - m. Repeat steps b-l for the normal and high controls
2. Run both old and new lots for one week to verify new lot number. Adjust QC means in QC Setup after 10 samples if needed.
3. Verify that all daily, weekly, and monthly scheduled maintenance has been performed. Perform any missed maintenance now before calibrating.
4. Confirm that normal background is within normal limits.
5. Verify instrument precision. See the Performance Characteristics and Specifications section of the Cell-Dyn Operators Manual for precision limits.
6. Perform Calibration according to Cell-Dyn System Operation Manual section on calibration using Cell-Dyn commercial calibrator.

7. Run 10-patient correlation samples on Cell-Dyn and compare results with the Core Lab.
8. Run linearity check on Cell-Dyn.
9. Document in Maintenance Log.

References

Cell-Dyn System 1800 Operator's Manual. Abbott Diagnostics Division, January 2006.

Revised 6/11/11