

OREGON HEALTH & SCIENCE UNIVERSITY  
Hospitals and Clinics  
Point of Care

**CBC and Platelet Count with Automated Three Part Differential  
by Abbot Cell-Dyn 1800 Hematology Analyzer**

Principle

The Cell-Dyn 1800 Hematology Analyzer performs a Complete Blood Count (CBC), Platelet Count, and a Three-Part Differential. Whole blood is aspirated, diluted, and then divided into two samples. One sample is used to analyze the red blood cells and platelets while the second sample is used to analyze the white blood cells and hemoglobin. Electrical impedance is used to count the white blood cells, red blood cells, and platelets as they pass through an aperture. As each cell is drawn through the aperture, a change in electrical resistance occurs generating a voltage pulse. The number of pulses during a cycle corresponds to the number of cells counted. The amplitude of each pulse is directly proportional to the cell volume.

Lyse reagent is added to the diluted sample and used to count the white blood cells. After the white blood cells have been counted and sized, the remainder of the lysed dilution is transferred to the Hgb Flow Cell to measure Hemoglobin concentration.

The Cell-Dyn uses electronic sizing to determine a three part automated differential. The percentage and absolute counts are determined for lymphocytes, neutrophil, and mid-size population of monocytes, basophils, eosinophils, blasts, and other immature cells.

Results will be used to monitor patient's cell counts and absolute neutrophil count and to determine if further chemotherapy should be administered.

Specimen Requirements

1. Whole blood collected in an EDTA tube.
2. Minimum sample volume is 0.5 mL using the Open Sample Mode. The instrument aspirates 30  $\mu$ L of patient sample.
3. Samples are stable at room temperature for eight hours.

## Reference Ranges

See Addendum 1 to this procedure for age-specific reference ranges.

## Critical Values

Critical/Alert Values are those results demonstrating such variance from normal as to represent a pathophysiological state with potential of being life threatening unless action is taken quickly. These results must be immediately reported to the care provider and be documented in the test record as to who was contacted, the time of contact, the person making contact, and if relevant, that the results were read back.

Parameter	Critical Value
<b>WBC (K/mm<sup>3</sup>)</b>	≤1.0 or ≥30.0
<b>HGB (g/dL)</b>	≤6.5 or ≥19.0
<b>HCT (%)</b>	≤20.0 or ≥60.0
<b>PLT (K/mm<sup>3</sup>)</b>	≤30.0 or ≥1000

## Interferences

1. Do not analyze clotted samples. If sample is clotted, recollect patient sample and repeat test.
2. Low sample volume of <1 mL may dilute patient samples with EDTA in the collection tube giving falsely low results. If a low sample volume is expected, use a pediatric EDTA tube; fill to the second line and mix well.
3. White blood cell counts ≥100,000 /mm<sup>3</sup> and platelet counts ≥1,000,000 /mm<sup>3</sup> are outside the linearity specifications of the instrument. Order a CBC with Differential in EPIC for the Core Laboratory to perform. Send the labeled specimen to the Core Laboratory for analysis.

## Analytical Measurement Range (Linearity)

Analyte	AMR
WBC (K/mm <sup>3</sup> )	0.5 – 99.9
RBC (M/mm <sup>3</sup> )	1.0 – 7.00
HGB (g/dL)	2.5 – 24.0
MCV (fL)	50 – 200
PLT (K/mm <sup>3</sup> )	10 – 999
MPV (fL)	5.0 – 20.0

## Quality Control

1. Commercial Quality Control (QC) vials must be run each eight hours of patient testing.
  - a. Run three levels of QC at the beginning of each day of patient testing. Do not perform patient testing until QC tests are performed and within acceptable limits.
  - b. Rerun at least one of the three levels of QC again after eight hours of patient testing to assure the instrument is still functioning properly.
  - c. See Cell-Dyn Maintenance and Daily Quality Control procedure for detailed instructions.
2. In addition to the daily QC runs, run the QC after any one of the following:
  - a. Change in reagent lot number.
  - b. Calibration.
  - c. Service call.
  - d. Component replacement.
  - e. Change in software version.
  - f. Maintenance procedures.
  - g. Unusual trend or shift in patient results.
3. If the QC results are within acceptable limits, perform patient testing.
4. If the QC fails follow the instructions detailed in the Cell-Dyn Maintenance for Open Mode Use Detailed Quality Control Procedure.

## Patient Sampling Procedure

1. Press MAIN to return to the MAIN MENU. At the MAIN MENU, enter in the operator ID and press RUN, next press SPECIMEN TYPE.
2. If the instrument has been idle for fifteen minutes or more, press NORMAL BACKGRND. Press the Touch Plate to run an Open Mode Background test. Verify that the Open Mode Background count results are acceptable. The results shall be within the following specifications.

Parameter	Background Limit
WBC (K/mm <sup>3</sup> )	≤ 0.3
RBC (M/mm <sup>3</sup> )	≤ 0.05
HGB (g/dL)	≤ 0.1
PLT (K/mm <sup>3</sup> )	≤ 5

3. If the Open Mode Background count results are acceptable, proceed to Step 6.

4. If the Open Mode Background count results fail, press CLEAR ORIFICE to clear the orifice. When cleaning is complete, press NORMAL BACKGRND and depress the Touch Plate.
5. If the Open Mode Background count results are acceptable after the orifice has been cleaned, proceed to Step 7. 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.

6. To perform patient testing:

- a. Press MAIN to return to the MAIN MENU screen. Enter in the Operator ID and press RUN. Press SPECIMEN TYPE then press PATIENT SPECIMEN. Verify that RUN Ready is displayed in the Status Box.
- b. Scan patient specimen number and patient name

NOTE: If scanning is not successful, manually enter in the MRN and Patient Name using the keyboard.

- c. Expected ranges for blood counts differ based on gender and age. The Cell Dyn is programmed to display the correct reference range. The operator, however, must first manually type in the correct gender prior to running the patient sample. Once RUN Ready is displayed in the Status Box, use the ↓ key to scroll to the Limit prompt. Enter either “1” for Male or “2” for Female.
- d. Mix the patient sample well and remove the cap.
- e. 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.
- f. Press the Touch Plate to start the run. The Status Box on the RUN menu indicates the stage of the run.
- g. When Remove Specimen is displayed in the Status Box and the probe has moved up through the wash block remove the sample tube and replace the tube cap. A beep will indicate that the probe cleaning cycle has begun.
- h. After the probe cleaning cycle is complete, the probe will move down into position for the next sample and the results will be displayed on the screen.
- i. If needed, press PRINT REPORT for a hardcopy of the report.
- j. After sampling is complete, press MAIN to return to the MAIN MENU. Change the Operator ID to “000” for the next user.

## Results Reporting

**A review criterion was developed specifically for the hematology/oncology patients prior to chemotherapy.**

<b>Problem or Flag</b>	<b>Possible Cause</b>	<b>Action</b>
>>>> Chevrons displayed instead of numeric result.	Sample result is greater than the upper end of the Manufacturer's linear range and requires a dilution.	Send sample to the Core Lab for CBC/Diff.
MCHC > 37.0	Cold Agglutinins, lipemic, icteric, or hemolyzed sample.	Send sample to the Core Lab for CBC/Diff.
LRI (Lower Region Interference) displayed after PLT result.	LRI flag is generally non-biological interference caused by: Dirty aperture, contaminated reagent, electronic noise, micro bubbles.	Perform a background count. If it exceeds limits, troubleshoot using the Cell-Dyn manual. If it is within limits, rerun the sample. If flag persists, send sample to the Core Lab for a slide review to verify PLT count.
URI (Upper Region Interference) displayed after the PLT result.	URI flag is generally biological interference caused by: Microcytic RBC's, Schistocytes, giant platelets, sickle cells, platelet clumps. NOTE: a "bumpy" platelet histogram may indicate platelet clumps.	If the MCV is low and/or the histogram indicates poor separation in the RBC and PLT populations, send the sample to the Core Lab for CBC/Diff and platelet count verification.
No display for measured parameters other than MPV.	A "probable cause" message is displayed to the right of the affected measurement. If the time for fluid to reach either detector is too long, CLOG is displayed. If the time to reach either detector is too short, FLOW ERR is displayed.	Press CLEAR ORIFICE. Rerun sample. If CLOG appears again, notify the superuser. He/She shall refer to the Cell-Dyn Procedure manual for CLEAN APERTURES. If FLOW ERR appears again, go to SPECIAL PROTOCOLS, REAGENT PRIME.
No display for the MPV.	Potential platelet clumping, large platelets, RBC fragments.	Review histogram and patient history. Consult physician and send sample to the Core Lab for CBC/Diff if indicated.
<b>Differential Flags:</b>		
<b>R1, R2, R3, R4, or RM</b> Flag on the differential. This is displayed between the absolute and percent results.	There is difficulty in obtaining an accurate differential. Immature WBC's could be present.	Send sample to the Core Lab for CBC/Diff. Do not treat patient based on CellDyn's differential results.
MID % on differential is greater than 10% and the ANC is less than 750/ $\mu$ L.	There may be a population of immature cells.	Send sample to the Core Lab for CBC/Diff. Do not treat patient based on CellDyn's differential results

No results present for differential.	There is difficulty in obtaining an accurate differential. Immature WBC's could be present.	Send sample to the Core Lab for CBC/Diff. Do not treat patient based on CellDyn's differential results.

If the platelet concentration is low (thrombocytopenia) in combination with microcytic RBCs (MCV <70 fL), the analyzer may not generate the suspect URI Flag even in the presence of a falsely elevated platelet count. An important indicator in these situations is the platelet histogram. The platelet histogram must be examined for an abnormal shape, which may suggest the presence of microcytic RBCs interfering with the platelet count. If the platelet histogram is abnormal, a specimen should be sent to the Core Lab for confirmation.

**If a sample meets the above criteria, it is recommended that the sample be sent to the Core Laboratory for CBC confirmation or a slide review:**

1. Order a CBC, with Differential in EPIC. Send the sample, the new test label, and a copy of the Cell-Dyn instrument printout to the Core Laboratory for testing.
2. Cell-Dyn patient results are to be used for screening purposes only and the clinic will not bill for the test.
3. Samples sent to the Core Laboratory will be billed by the Core Laboratory. The CBC/Diff results for testing performed in the Core Laboratory will be entered in the computer.
4. All other patient results will be reported to the provider.
5. Record date and initials on the Cell-Dyn instrument printout.

Calibration (Performed by POCT Staff)

1. Calibration is performed with a whole blood calibrator.
2. Calibration is performed:
  - a. When indicated by Quality Control Data.
  - b. After major maintenance or service.
  - c. When recommended by the manufacturer.
  - d. Every 6 months.

Calibration Procedure (Performed by POCT Staff)

1. Remove calibrator from refrigerator and allow to warm at room temp for 15 minutes. Do not mix during this time
2. Verify that the lot number on the container matches the number on the assay sheet.
3. After successfully running the three levels of liquid controls. From the replicate file, run a normal blood sample 10-20 times to obtain the 'pre-calibration' CV's for WBC, RBC,

HGB, MCV, and PLT. If the CV's pass precision test (see parameters below), move to step 5. Otherwise troubleshoot the instrument.

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

4. To perform testing, from **Main** menu, enter your operator ID, press **Calibration**, press **Whole Blood**.
  - a. Print the old calibration factors.
  - b. From the assay sheet to enter the values for WBC, RBC, HGB, MCV, PLT.
5. Hold the calibrator tube vertically between palms of your hands and roll it back and forth for 20 seconds. Flip tube over and roll tube between your hands and roll it back and forth for 20 seconds. Invert the container 10 times. Repeat 3 times.
6. Remove the cap from the tube, insert under sample aspiration probe and press the Touch plate to activate the run. Run the calibrator three times, capping and remixing the specimen prior to each aspiration. Refer to Calibration Procedures, section 6 in the Cell-Dyn 1800 Operator's Manual.
7. Print new calibration factors.
8. Run all three levels of QC. Monitor QC values for any shifts or out of range results.
9. Run normal blood sample 10-20 times under precision mode.
10. Review precision parameter limits (see step 4 above).
11. If precision fails, recalibration may be necessary.
12. Document results in the maintenance log.

## Reagents

1. Cell-Dyn Diluent:
  - a. Stable at room temperature until the expiration date on the container.
  - b. Protect from direct sunlight, extreme heat, and freezing during storage.
  - c. Do not use if reagent has been frozen.

2. Cell-Dyn Lytic Agent:
  - a. Stable at room temperature until the expiration date on the container.
  - b. Protect from direct sunlight, extreme heat, and freezing during storage.
  - c. Do not use if reagent has been frozen.
3. Cell-Dyn Detergent:
  - a. Stable at room temperature until the expiration date on the container.
  - b. Protect from direct sunlight, extreme heat, and freezing during storage.
  - c. Do not use if reagent has been frozen.
4. Enzymatic Cleaner:
  - a. Stable at 2-8°C until the expiration date on the container.
  - b. Do not use if reagent has been frozen.
5. Cell-Dyn Whole Blood QC:
  - a. Unopened QC vials are stable at 2-8°C until the expiration date on the vial. Opened QC vials are stable at 2-8°C for 7 days after opening. Do not use expired QC.
  - b. Allow QC to sit at room temperature for fifteen minutes before testing.
  - c. Mix QC vial by rolling the vial between palms for 20 seconds.
  - d. Invert the vial and roll it back and forth for another 20 seconds.
  - e. Gently invert the vial 10 times.
  - f. Do not shake.
  - g. Continue to mix in this manner until cells are completely suspended (3-5 times).
  - h. Gently invert the pre-mixed vial 5 times immediately before testing.
  - i. Return vial to refrigerator when testing is complete.
6. Whole Blood Calibrator:
  - a. Unopened calibrator vials are stable at 2-8°C until the expiration date on the vial. Opened calibrator vials are stable at 2-8°C for 7 days after opening. Do not use expired calibrators.
  - b. Allow the calibrator to sit at room temperature for fifteen minutes before testing.
  - c. Mix the calibrator vial by rolling the vial between the palms for 20 seconds.
  - d. Invert the vial and roll it back and forth for another 20 seconds.
  - e. Gently invert the vial 10 times.
  - f. Do not shake.
  - g. Continue to mix in this manner until cells are completely suspended (3-5 times).
  - h. Gently invert the pre-mixed vial 5 times immediately before testing.
  - i. Return vial to refrigerator when calibration is complete.

## References

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