SUBJECT: CellaVision Maintenance and Basic Operation

I. Purpose:

This procedure explains basic operation and maintenance of the CellaVision Analyzer.

II. Principle:

The CellaVision automatically locates, presents images, organizes and preclassifies white blood cells, identifies and grades morphological characteristics of red blood cells and facilitates platelet estimation. This instrument serves to improve quality, efficiency, and standardization by automating the process of performing smear reviews and differentials.

III. Specimen Collection:

Sample Type	Container	Slide Preparation	Storage Temperature	Stability
Whole blood	Potassium EDTA	Optimal	18-26°C	<4 hours

A. Specimen Rejection Criteria
   1. Clotted samples, samples with microclots, and samples containing fibrin
   2. Improperly labeled specimens
   3. Specimens exceeding stability (Sample stability <48 hours @ 2-8 C or <24 hours @ 18-26 C)

B. Samples are mixed (20 complete inversions) before slide preparation

C. Specimen stability for smear preparation
   1. Optimal preparation is <4 hours from collection stored at 18-26 °C
   2. Loss of cellular integrity may occur at >4 hours

D. Allow refrigerated samples to come to room temperature before slide preparation

E. Peripheral smears are retained for a minimum of 7 days

IV. Materials:

Reagents / Media	**Supplies / Materials**	**Equipment**
● CellaVision Immersion Oil Pack (for DM9600) ● Trak 300 Automated Differential System Immersion Oil (for DM1200)	● Glass slides, clipped, round or beveled corner slides only ● Applicator sticks ● Lens paper ● Isopropyl Alcohol Pads ● Blood sampling device ● CellaVision Slide Magazine ● Zebra 2D barcode labels	● Automated Hematology Analyzer ● Automated slide stainer ● Mechanical slide maker ● CellaVision Analyzer ● Microscope ● Zebra 2D label printer

Date Effective:

V. Maintenance:

A. Weekly Maintenance

1. Shutting down the System

CAUTION! Always exit CellaVision Software before restarting or turning off the system computer. If the System computer is turned off abruptly, the database is at risk of crashing.

a. Wait for all slides to process. If needed, eject any magazines that may be in the system by selecting **TOOLS** and **EJECT MAGAZINE**. Click **OK** and the magazine is ejected into the output drawer.

b. To turn off the system computer, select **EXIT** in the File menu.

c. Choose the Windows start icon (bottom left) then select Power then choose SHUTDOWN

d. Turn off the Slide Scanning Unit (SSU) by pressing the power button or switch on the analyzer

2. Clean the Analyzer

a. Wipe the analyzer or hood with a moist cloth dampened with water only

b. DC-1 users wipe excess oil from the loading tray

c. Pull out the Bottom Plate Tray and wipe clean any immersion oil

3. DM1200 and DM9600 Clean the objectives and if applicable the LED table

a. Open the main hatch of the CellaVision instrument.

b. If required, move the Immersion Oil Dispensing Arm toward the rear of the instrument to gain access to the stage and objectives.

c. Pull-out the stop pin and open the magazine feeder

    a. Gently wipe the LED table with a soft lint free clothe

d. Clean the 10x objective by wiping gently with lens paper only. Make sure there is no oil on the low power (10x) objective.

e. On the high power wet objectives, remove most of the oil by wiping the high objectives with lens paper.

f. Once most of the oil has been removed, moisten a fresh lens paper with an alcohol pad (do NOT use lens cleaner). Use a cotton swab to gently hold the moistened lens paper against the objective while dragging the lens paper away from the objective. Do NOT use a circular motion to clean lenses as this increases the risk of scratching the surface.

g. Use a new piece of moistened lens paper or a clean section of lens paper any time the paper dries out or becomes oily.

h. Repeat this process on each lens until both are free of oil.

i. If necessary, move the Immersion Oil Dispensing Arm back into position by pulling it toward the front of the instrument. The arm will “click” into place once in the proper position.

j. CLose hatch door

4. DM9600 users Clean Magazine Feeder
    a. Open the input hatch
    b. Wipe the infeed conveyor and the outfeed shelf with moist cloth
5. Starting the System
    a. Restart or start the computer
    b. Power on the Slide Scanning Unit (SSU) by pressing the Power Switch or Button on the analyzer. The status light will flash yellow while the analyzer is starting.
    c. When the status light on the slide scanning unit is continuously yellow, log on with your User Name and Password and select the desired database. Select **OK** .
6. DM9600 and DM1200 users, run two “dummy” slides through the analyzer in order to clear any air bubbles on the objectives that may have been caused by cleaning with alcohol. Delete these slides from the **WORKLIST**.
7. Delete unsigned and failed orders in the database view to reduce size of database

B. As Needed Maintenance for DM1200

1. Immersion oil refill
    a. Log out, and then switch off the power to the Cellavision
    b. Open the main hatch of the CellaVision analyzer
    c. Unscrew the oil refill cap from the oil container
    d. Place a funnel into the hole at the top of the oil container and slowly pour in the Trak 300 Immersion Oil. Fill the oil container up to the black indicator line.
    e. Clean any immersion oil spillage with a Kim wipe and screw the oil refill cap back on
    f. Close the main hatch
2. Changing the bulb
    a. Log out, and then switch off the power to the Cellavision
    b. Wait for lamp housing and bulb to cool before touching
    c. Locate the lamp hatch on the right side of the analyzer. Loosen the 2 non-detachable screws by turning about half a turn counter clockwise using a 3 mm Allen key.
    d. Remove the hatch by pulling outwards and then upwards
    e. Loosen the non-detachable screws on top and rear of the black lamp house cover using the Allen key
    f. Lift and remove the cover of the lamp house.
    g. Press the bulb clamping levers and gently withdraw the old bulb from lamp housing.
    h. Obtain a new bulb. DO NOT TOUCH THE NEW BULB WITH BARE HANDS. Using a Kim wipe to hold the bulb, press the bulb clamping

levers and fully insert the new bulb pins into the pin holes. Release the bulb clamping levers to secure the bulb.

i. Refit the lamp house cover and tighten the screw of the lamp house cover.

j. Refit the lamp hatch and tighten the screws of the lamp hatch.

k. Switch on the CellaVision analyzer.

C. As Needed Maintenance for DM9600

1. Change immersion oil pack

a. Open the hood

b. Put a clip on the hose

c. Push down on the oil hose connection and pull out the hose

d. Remove and discard the old oil pack according to local regulations

e. On the new oil pack, put the clip on the hose

f. Cut the hose above the line where the arrow points.

Note: Cut must be straight with no remnants of arrow stick left on hose

g. Put the new oil pack in place.

h. Push the hose into the oil hose connection. Confirm it is pushed all the way down

i. Remove the clip from the hose

j. Start the CellaVision software. On the **Maintenance** menu, select **Oil**

k. If oil pack ran dry and hoses are empty, select **Prime Oil**

l. Select **Reset Oil Drop Counter**

2. Remove stuck slide from the gripper

a. On the Maintenance menu, select Gripper Service

b. In the Go to gripper service position dialog, select OK

c. The message will display ‘The gripper is in service position’

d. Log off and power off the analyzer

e. Open the hood

f. Pull out the sop pin and open the magazine feeder

g. Remove the slide

h. Close the hood and magazine feeder

i. Restart the Slide Scanning Unit and the CellaVision DM Software

D. Record all instrument maintenance and function checks on the maintenance log

E. Refer to CellaVision User’s Manual for additional maintenance and troubleshooting

VI. Quality Control:

A. **Start-up Test:** The system performs self-tests during startup of the software and at certain points during the operation of the system. These self-tests ensure that the hardware, software, and LIS communications are working properly.

1. DM9600 users, confirm Magazine Feeder Unit Input Hatch and Outfeed Shelf are empty and all covers and hatches are closed.
2. Switch on the Slide Scanning Unit (SSU) using the button located on the front of the unit.
3. Observe status light at the front of the CellaVision analyzer. Once the status lamp turns a steady yellow, log onto the CellaVision software by typing in a username and password and select the appropriate database from the drop down menu.
4. Click **OK**
5. The system will perform a self-test. Results of the self-test can be viewed by selecting **VIEW** and **STARTUP TEST**
6. If the self-test fails, an error message is displayed. Refer to the CellaVision User's Manual for troubleshooting steps related to startup errors. The CellaVision analyzer will not process slides if the startup test fails. Record all troubleshooting steps on the CellaVision Maintenance Log.
7. Record results of the self-test on the CellaVision Maintenance Log

B. **Cell Location:** Perform the cell location procedure at least DAILY, after maintenance on the CellaVision and/or after maintenance of stainer or any change in stain procedure.

1. Select a CBC specimen with a WBC count above $7x10^3$/uL. Prepare a peripheral smear according to procedure. Label the smear with a QC barcode label (starting with 'QC') and allow the slide to air dry. Stain the slide according to the individual lab's stain procedure. Or use a slide prepared on SMS and labelled with 'QC' followed by the month and day.
2. Put the slide in a magazine and/or place it in the CellaVision to process the slide.
3. When the analysis has finished, select **TOOLS** and **CELL LOCATION**. The most recent QC slide will be at the top of the slide list (with the current date).
4. Select the QC slide at the top of the slide list.
5. Review each image for any MISSED NUCLEATED CELLS. Missed nucleated cells are those cells not marked with a GREEN box.
    - Green boxes mark nucleated cells. The cell does not need to be inside or touching the green box. It may be completely separate as long as there is a box associated with a cell.
    - Blue boxes mark artefacts, smudge cells, or other found objects that are not nucleated cells. The number of these objects must not exceed 50%.
    - Black boxes mark the number of cells that were located but not needed for the test.
6. For each image, enter the number of missed cells, if any, in the input field.
7. A checkmark will appear next to each image field once examined.

8. Once all images of the QC slide have been examined, a result is automatically calculated. The percentage indicates how many nucleated cells the system found compared to the actual number observed.
9. A result of 97% or greater indicates a passing result. If a passing result is not obtained, follow troubleshooting procedures outlined in the CellaVision User's Manual. Patient slides cannot be processed without a passing Cell Location.
10. Record results of Cell Location in Cerner and on the CellaVision Maintenance Log and record troubleshooting measure(s) if applicable.

C. Stained peripheral smears are checked for proper staining and good cell distribution under the microscope before being read. Record stain quality on log.

D. Do not report patient results if quality control is not within the acceptable range.

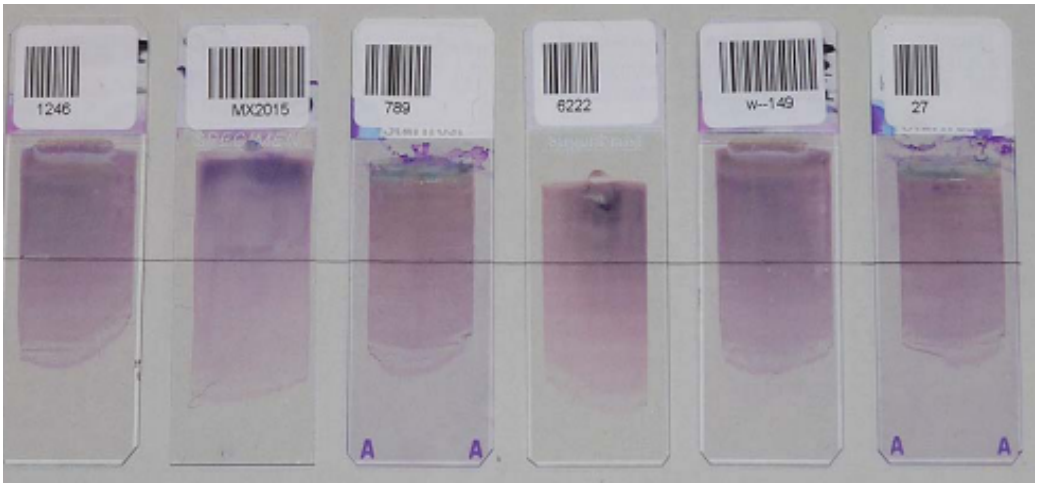
VII. PROCEDURE:

A. Slide Preparation

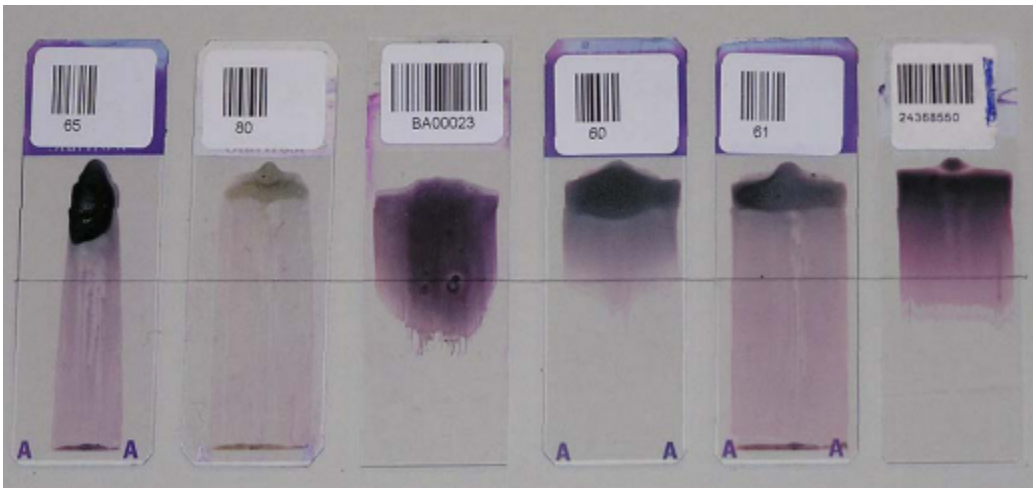
NOTE: Use only clipped/round/beveled corner slides.

1. Samples are completely inverted 20 times immediately prior to slide preparation
2. Place a small drop (5uL to 10 uL) near the labeled end of the slide
3. Optimally use mechanical spreader to make a thin wedge smear
4. Blood smears that do not meet acceptable specifications as follows will need to remade:
   a. There is no pooling of specimen at application point
   b. Smear must be at least 30 mm long and must terminate 5 to 15 mm from the edge
   c. Smear must start near the frosted end and there must be a gradual transition in thickness, without any grainy streaks, troughs, ridges, holes or bubbles. The smear must cover approximately ⅔ to ¾ of the slide.
   d. A thick smear interferes with CellaVision's ability to find a monolayer and may result in misclassification of WBCs and RBC morphology grading.

Acceptable Smears



Unacceptable Smears



1. Each slide must be labelled with accession number and patient last name.
2. Allow each slide to air dry for approximately 15 minutes and stain slides according to the individual lab's slide stainer procedure or on SMS.
3. Stain slides within 1 hour of slide preparation

B. Slide Processing

1. DM1200 and DM9600 users, insert the stained slides into the orange CellaVision magazine with barcode facing up. Slide position 1 is located at the bottom of the magazine; a total of 12 positions are available.

   Note: If necessary, carefully blot excess oil from the slide before loading. Make sure slides are fully inserted to the back of the magazine to avoid jamming.
2. Load the magazines into the CellaVision. DC-1 users, insert the stained slide directly into the slot with barcode facing up.
3. The CellaVision is configured to automatically start slide analysis when a magazine is loaded. If the system has been stopped, restarted, or if an error has occurred, slide processing must be manually started by clicking on the START button 
4. The tree in the SYSTEM CONTROL panel displays a status log of processed magazines and slides
   - Analyzing/Processing
   - ✓ Finished/OK
   - Warning: Slide processed with a warning.
   - Stopped: Slide processing stopped by the user. No results exist.
   - Error: All ordered analysis failed. No results exist.
   - Cancelled: The slide was cancelled in the LIS. Slide not processed.
   - Empty: Empty slide position in the magazine or no barcode on slide.

5. Double-click on a slide to open the Slide Information dialog. Additional information on the processed slide (e.g. the cause of an error) is displayed here.
6. When all slides in the magazine have been processed, remove the magazine from the outfeed shelf.

C. Viewing a processed slide

1. Select  to access the **Database View** screen
2. On the Database View screen, select one of the following:
   a. If a Worklist is used, double click on the Accession Number or highlight the Accession Number and select Open
   b. If a Worklist is not used, double-click on the Accession number on the Order List or highlight the Accession Number on the Order List and select Open
   c. Opening an unsigned slide in **Verification View**  allows WBC, RBC, and PLT fields to be reviewed

D. CellaVision Smear Review

1. Select the WBC tab.
2. Cells can be viewed in either the FULL SCREEN  or any of 3 GALLERY views.  It is recommended to use the WBC Full Screen view to review staining characteristics and perform the initial smear review.
3. Review the corresponding specimen results from the automated hematology analyzer printout. Take note of the flags/messages from the printout. Correlate cell images with the printout from the automated hematology analyzer.
4. Use the GALLERY view to carefully review each preclassified image.
   a. To view any cell of interest, select the cell type using the drop-down menu at the top of the gallery field or select by clicking on the name of each cell class in the display to the left of the gallery
   b. To enlarge a cell image, double-click on the image and use the scroll wheel to zoom in or out
5. Review all images in the WBC gallery. Observe cells for abnormalities or inclusions. Use the parameters listed in Differential Criteria and Pathology Review - Attachment 2 to determine if the specimen meets any of the criteria listed for performing a manual differential. If not, continue to step D.7.
6. Continue onto CellaVision Differential step E for any of the following:
   a. Specimen meets any criteria listed in Differential Criteria and Pathology Review - Attachment 2 for manual differential or Attachment 3 for pathology review.
   b. The specimen has an existing manual differential or RDIFF order.
   c. CellaVision images do not correlate with printed results and discrepancies cannot be validated or explained after reviewing clinical history or speaking with a nurse/physician.

d. Results do not meet criteria for manual differential or pathology review but are deemed significant in the professional opinion of the operator.

7. When the WBC review is complete and it is determined that the specimen does not require a manual differential, select **Confirm Cell Counter Results**  to accept the automated differential results. Continue to RBC review step F if it is determined that a differential is NOT required.

E. CellaVision Differential

1. Review each cell class and reclassify the cells if indicated

a. If a cell requires reclassification, left-click on the cell and drag to the correct cell category

b. If needed, right-click on any cell to view 1st, 2nd, and 3rd ranked suggestions for potential classifications of the cell

c. To reclassify an entire group of cells, select the first cell image in the group. Hold down the *Shift* key and select the last cell image in the group. A yellow box outlines the selected cells. Right-click on the selected group and drag the images into the correct gallery classification.

d. To reclassify scattered cells in different cell classes, hold down the *Ctrl* key and select each cell. When all cells have been highlighted, cells can be reclassified

e. A green box next to a cell classification indicates that all images in that cell category were classified by the CellaVision. A blue box indicates that at least one image within that particular cell class was reclassified into that category by the user.

f. To Split Cells

i. If more than one cell appears in an image, select the image  . The green box indicates what cells were classified within the image. If more than one cell is boxed, right-click and select **Split Cell** from the drop-down list.

ii. Two pictures of the same image will then be displayed with a red X on each cell.

iii. Reclassify the cells, if indicated.

g. Smudge cells are to be reported for patients that are suspicious of or have a history of chronic lymphocytic leukemia. If not, reclassify to **Artefacts**

h. Any cells that are labeled as Unidentified must be moved into a classification.

i. **Artefacts** must be reviewed but do not need to be reclassified.

j. Unidentified, suspicious, and/or questionable cell(s) may be placed in the **OTHER** category with a result comment stating: “Sent for further review and/or identification”. Any cells placed in the ‘**OTHER**’ category must be moved to the appropriate category following differential review.

2. Verify that all WBC cell classes have been viewed, a checkmark appears next to the classification name in the CellaVision differential display.
3. The System keeps track of all WBCs viewed by the operator. It is not possible to sign the slide unless all cell classes have been viewed.

F. RBC Review

1. Select the RBC tab. The RBC tab is used for characterization of the RBC morphology
    a. Scan the CellaVision RBC panel for clinically significant RBC abnormalities. The red cell morphology evaluation should correlate with instrument parameters for consistency and quality purposes.
    b. The RBC panel is composed of 8 – 100X (high power) fields. Use this panel along with the reported RBC indices to evaluate the RBC morphology. Use the various Zoom features to evaluate the morphology.

-  Zoom In  Zoom Out
-  Entire RBC Image – Shows the entire RBC image
-  Zoom Mode – Hold left mouse button down and zoom in/out
-  Scroll Mode – Hold down the left mouse button and pan the mouse in any direction.
- Double click anywhere in the RBC image to enlarge a limited area, and use the scroll wheel to zoom in/out.
- In the bottom right-hand corner of the RBC image there is a cross-shaped ruler that represents scale in micrometers. The ruler can be moved around the RBC image by moving the mouse pointer over the ruler, depressing the left mouse button and then by dragging it to its desired placement.

2. When the RBC scan is complete and it is determined that the specimen does not require a full RBC Morphology Review, select **CONFIRM CELL COUNTER RESULTS**  and continue on to PLT Review step H
3. Continue onto full CellaVision RBC Morphology Review (step G) for any of the following:
    a. Specimen meets any criteria listed in Differential Criteria and Pathology Review - Attachment 1 for full RBC morphology review or Attachment 3 for pathology review.
    b. The specimen has an existing manual differential or RDIFF order.
    c. Scan of CellaVision RBC panel shows significant RBC abnormalities

G. Full CellaVision RBC Morphology Review

1. Use the CellaVision precharacterizations in conjunction with the automated hematology analyzer's flags/messages, the RBC indices, and other findings to evaluate/correlate the RBCs.
2. Click **REPORT ALL AS 0-NORMAL** if the slide contains no significant abnormal RBC morphologies.
3. The first six parameters (Polychromasia, Hypochromasia, Anisocytosis, Microcytosis, Macrocytosis, and Poikilocytosis) are precharacterized by the system. Select **USE CHARACTERIZATION** on the top left side of the screen to evaluate and grade RBC morphology
4. Red cell abnormal morphologies are graded on a scale of 0 to 3+. Refer to Morphology Grading Guide - Attachment 1 Morphology Grading Guide on how to grade individual RBC morphologies for significance.
    - 0 (normal) – Green dot in column 0. Deselect the green dot to remove the morphology from the report.
    - 1+ (slight) – Red dot in column 1 indicates that the morphology is present at low levels.
    - 2+ (moderate) – Red dots in column 1 and 2 indicate that the morphology is present at moderate levels.
    - 3+ (marked) – Red dots in columns 1-3 indicate that the morphology is present at a high level.
5. Click on the appropriate column grade (0-3) to report significant morphologies. If normal, remove the morphology from the report by deselecting the green dot.

   NOTE: Assessment of RBC morphologic abnormalities must include distinguishing between artefactual and pathological abnormalities. Common artifacts include stomatocytes, echinocytes (crenated cells) and rouleaux which should be viewed in the thin portion of the smear under the microscope or a new slide prepared.

H. PLT Review and Estimation

1. Select the PLT tab. The PLT tab is used to review platelet count and/or calculate an estimated PLT count

   NOTE: For specimens with a platelet flag in conjunction with an automated low platelet count or normal counts with a delta check flag, select the feathered edge tab and evaluate feathered edge for platelet clumps. If none are seen, add the comment 'No platelet clumps seen'.
2. Perform an approximate platelet count for specimens requiring a platelet review without a platelet flag. Select the **APPROXIMATE PLTs PER GRID SQUARE** button. Click on the grid fields to estimate an average platelet count per grid square and type the average estimate in the entry field.
3. Click **CALCULATE PLT RESULT**. Compare the concentration of the calculated estimate (i.e. decreased, normal, increased) to the automated platelet count. If a discrepancy is found, continue on to Step E CellaVision Platelet Estimate.
4. After PLT review, if the automated count is normal (with no delta check) and already reported or the PLT estimate is consistent with the automated platelet count select **CONFIRM CELL COUNTER RESULTS** 

5. Select the **SIGN SLIDE** tab. Click **SIGN**. The SIGN SLIDE dialog box appears. Enter USER NAME and PASSWORD and select **OK**.

I. CellaVision Platelet Estimate

1. Scan the feathered edge for platelet clumps, platelets adhering to neutrophils, and/or fibrin using the Feathered Edge feature or under the microscope. If platelet clumps and/or fibrin are observed, causing the automated count to be unreliable and an estimated count is not possible then the specimen must be rejected, reordered, and recollected in both EDTA and Sodium Citrate refer to Spurious Results Protocol.
2. If the specimen cannot be recollected and occasional platelet clumps observed, continue on with a Platelet Estimate.

   Note: Giant platelets, clumped platelets, and platelet satellitism will falsely decrease automated platelet count.

   Note: RBC fragments, schistocytes, organisms and/or very microcytic red cells may falsely increase platelet count.
3. Select the PLT tab. Count the platelets in each of the 9 grid squares. Select the **COUNT PLTs PER GRID SQUARE** button. One by one, click on each of the 9 grid fields, count the platelets in the corresponding image window, and type the number counted in the entry field.
4. Click **CALCULATE PLT RESULT.** Compare the Calculated Estimate to the automated platelet count. The estimate will convert to a concentration of Decreased, Normal, or Increased in Cerner. Alternatively, if the estimate was performed on the microscope select exclude PLT Analysis and add PLT comment.
5. If the automated count is determined to be inaccurate due to occasional platelet clumps, satellitism, giant platelets, organisms, or RBC interferences, the calculated numerical estimate will be performed if possible.
6. Select the **SIGN SLIDE** tab. Click **SIGN**. The SIGN SLIDE dialog box appears. Enter USER NAME and PASSWORD and select **OK**.

VIII. Interpretation of Results:

A. Specimens flagged for WBC smear review that do not meet criteria defined in Differential Criteria and Pathology Review - Attachment 2 and/or 3 require only a smear review (including WBC, RBC and PLT review) and confirmation of the automated results.

B. Specimens with a Manual Differential/RDIFF order or specimens that meet criteria in Differential Criteria and Pathology Review - Attachment 2 and/or 3 must have a Differential, RBC Morphology, and Platelet Estimate performed.

C. Specimens flagged for RBC Smear Review must have RBC Morphology and Platelet Estimate performed. Scan WBC tab for abnormalities and confirm WBC tab if manual differential criteria are not met.

D. Follow CellaVision Platelet Estimate procedure for any specimen with an automated platelet flag, low platelet counts with no previous results, and/or any platelet count discrepancies. Scan WBC and RBC tabs for abnormalities. Perform WBC differential and/or RBC Morphology if any criteria listed in Differential Criteria and Pathology Review - Attachment 2 and/or 3 are met.

E. Normal Reference Range

Test	Age	Male	Female	Unknown
Abs Neut (K/uL)	0 - 3 days	3.0 - 11.0	3.0 - 11.0	
	4 - 7 days	2.0 - 4.7	2.0 - 6.7	
	8 - 14 days	1.9 - 5.6	1.7 - 5.9	
	15 - 30 days	1.3 - 4.3	1.4 - 4.9	
	1 - <2 months	1.2 - 4.6	1.3 - 5.6	
	2 - < 6 months	1.1 - 4.2	1.4 - 5.7	
	0.5 - <2 years	1.4 - 4.6	1.5 - 4.8	
	2 - <6 years	1.8 - 5.6	1.9 - 5.6	
	6 - <12 years	1.9 - 5.6	2.0 - 5.7	
	12 - <18 years	2.0 - 5.5	2.2 - 5.9	
	≥ 18 years	1.7 - 7.6	1.9 - 8.2	1.7 - 8.2
Abs Lymph (K/uL)	0 - 3 days	1.8 - 4.4	1.8 - 4.5	
	4 - 7 days	2.4 - 5.8	1.4 - 5.5	
	8 - 14 days	2.3 - 5.6	3.0 - 5.7	
	15 - 30 days	2.4 - 5.9	2.6 - 5.8	
	1 - <2 months	1.9 - 5.6	1.8 - 5.7	
	2 - < 6 months	2.7 - 5.7	3.3 - 5.7	
	0.5 - <2 years	2.8 - 5.7	3.3 - 5.8	
	2 - <6 years	2.2 - 5.0	2.3 - 5.2	
	6 - <12 years	1.7 - 3.8	1.8 - 3.7	
	12 - <18 years	1.5 - 3.1	1.6 - 3.1	
	≥ 18 years	1.0 - 3.2	1.1 - 3.1	1.0 - 3.2
Abs Mono (K/uL)	0 - 3 days	0.5 - 1.6	0.6 - 1.5	
	4 - 7 days	0.6 - 1.9	0.3 - 1.5	
	8 - 14 days	0.7 - 1.7	0.6 - 2.2	
	15 - 30 days	0.6 - 1.5	0.5 - 1.5	
	1 - <2 months	0.5 - 1.4	0.5 - 1.4	
	2 - < 6 months	0.5 - 1.2	0.5 - 1.3	
	0.5 - <2 years	0.5 - 1.2	0.4 - 1.1	
	2 - <6 years	0.4 - 1.0	0.4 - 0.9	
	6 - <12 years	0.4 - 0.9	0.4 - 0.8	
	12 - <18 years	0.4 - 0.8	0.4 - 0.8	
	≥ 18 years	0.3 - 1.1	0.2 - 0.9	0.2 - 1.1
Abs Eos (K/uL)	0 - 3 days	0.0 - 0.7	0.0 - 0.6	
	4 - 7 days	0.0 - 0.7	0.1 - 0.8	
	8 - 14 days	0.0 - 0.7	0.0 - 0.7	
	15 - 30 days	0.0 - 0.7	0.0 - 0.7	
	1 - <2 months	0.0 - 0.5	0.0 - 0.5	
	2 - < 6 months	0.1 - 0.6	0.0 - 0.4	
	0.5 - <2 years	0.1 - 0.4	0.1 - 0.4	
	2 - <6 years	0.1 - 0.5	0.1 - 0.4	
	6 - <12 years	0.1 - 0.5	0.1 - 0.4	
	12 - <18 years	0.1 - 0.4	0.0 - 0.3	
	≥ 18 years	0.0 - 0.5	0.0 - 0.5	0.0 - 0.50
Abs Basos (K/uL)	0 - 3 days	0.0 - 0.1	0.0 - 0.1	
	4 - 7 days	0.0 - 0.1	0.0 - 0.1	
	8 - 14 days	0.0 - 0.1	0.0 - 0.1	
	15 - 30 days	0.0 - 0.1	0.0 - 0.1	
	1 - <2 months	0.0 - 0.1	0.0 - 0.1	
	2 - < 6 months	0.0 - 0.1	0.0 - 0.1	
	0.5 - <2 years	0.0 - 0.1	0.0 - 0.1	
	2 - <6 years	0.0 - 0.1	0.0 - 0.1	
	6 - <12 years	0.0 - 0.1	0.0 - 0.1	
	12 - <18 years	0.0 - 0.1	0.0 - 0.1	
	≥ 18 years	0.0 - 0.1	0.0 - 0.1	0.0 - 0.1
IG (%)	≥ 18 years	0.0 - 0.5	0.0 - 0.5	0.0 - 0.5

Test	Age	Male	Female	Unknown
Neut (%)	0 - 3 days	34.2 - 76.3	33.2 - 75.8	
	4 - 7 days	20.4 - 59.7	23.2 - 66.2	
	8 - 14 days	21.7 - 62.2	20.1 - 57.2	
	15 - 30 days	16.6 - 55.7	18.6 - 61.8	
	1 - <2 months	16.0 - 63.0	17.8 - 62.0	
	2 - < 6 months	17.5 - 46.2	18.6 - 59.8	
	0.5 - <2 years	19.6 - 48.5	21.1 - 47.9	
	2 - <6 years	28.5 - 58.1	29.2 - 57.8	
	6 - <12 years	35.3 - 62.5	36.5 - 62.9	
	12 - <18 years	39.8 - 64.8	43.2 - 66.9	
	≥ 18 years	43.5 - 73.5	42.7 - 76.8	42.7 - 76.8
Lymph (%)	0 - 3 days	15.6 - 40.2	15.0 - 48.2	
	4 - 7 days	30.1 - 57.9	19.2 - 57.8	
	8 - 14 days	25.2 - 60.6	30.2 - 61.3	
	15 - 30 days	34.1 - 64.4	34.0 - 65.0	
	1 - <2 months	27.9 - 66.4	30.9 - 64.5	
	2 - < 6 months	39.0 - 70.5	28.4 - 67.2	
	0.5 - <2 years	37.9 - 68.8	39.6 - 68.7	
	2 - <6 years	30.1 - 59.0	31.3 - 60.2	
	6 - <12 years	25.1 - 51.1	26.3 - 51.0	
	12 - <18 years	22.9 - 46.3	23.0 - 44.4	
	≥ 18 years	15.2 - 43.3	16.0 - 45.9	15.2 - 45.9
Mono (%)	0 - 3 days	5.5 - 15.2	5.7 - 15.3	
	4 - 7 days	8.1 - 17.3	8.2 - 16.9	
	8 - 14 days	7.7 - 19.9	7.9 - 17.5	
	15 - 30 days	8.3 - 20.0	7.0 - 19.2	
	1 - <2 months	7.5 - 18.6	6.7 - 17.8	
	2 - < 6 months	7.5 - 17.2	6.7 - 13.1	
	0.5 - <2 years	6.3- 13.3	5.7 - 12.1	
	2 - <6 years	5.9 - 11.3	5.4 - 10.4	
	6 - <12 years	6.1 - 11.1	5.5 - 10.4	
	12 - <18 years	6.4 - 11.5	5.8 - 10.3	
	≥ 18 years	5.5 - 13.7	5.5 - 13.7	5.5 - 13.7
Eos (%)	0 - 3 days	0.3 - 5.5	0.2 - 5.0	
	4 - 7 days	1.4 - 7.4	1.1 - 7.1	
	8 - 14 days	1.1 - 6.3	0.8 - 6.1	
	15 - 30 days	0.8 - 6.9	0.9 - 7.5	
	1 - <2 months	0.4 - 5.2	0.2 - 5.3	
	2 - < 6 months	0.9 - 6.6	0.3 - 4.9	
	0.5 - <2 years	0.7 - 4.8	0.7 - 4.4	
	2 - <6 years	0.9 - 6.0	0.7 - 4.4	
	6 - <12 years	0.9 - 6.8	0.7 - 5.5	
	12 - <18 years	0.9 - 6.1	0.6 - 4.3	
	≥ 18 years	0.8 - 8.1	0.5 - 7.0	0.5 - 8.1
Baso (%)	0 - 3 days	0.2 - 1.0	0.3 - 1.0	
	4 - 7 days	0.2 - 1.0	0.2 - 1.1	
	8 - 14 days	0.2 - 0.9	0.2 - 0.9	
	15 - 30 days	0.1 - 0.7	0.1 - 0.7	
	1 - <2 months	0.1 - 0.5	0.1 - 0.7	
	2 - < 6 months	0.2 - 0.5	0.2 - 0.4	
	0.5 - <2 years	0.2 - 0.7	0.2 - 0.7	
	2 - <6 years	0.3 - 0.8	0.3 - 0.8	
	6 - <12 years	0.3 - 0.9	0.3 - 0.9	
	12 - <18 years	0.3 - 0.9	0.3 - 0.9	
	≥ 18 years	0.2 - 1.5	0.2 - 1.3	0.2 - 1.5
Blasts (%)	All	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0

CBC/Diff Reference ranges updated 4/1/2025. Ranges applicable for testing performed at French Hospital, Arroyo Grande, and Marian Medical Center Clinical Laboratories. The pediatric reference ranges align with those published by Am J Hemat Vol (2020). Adult ranges are adapted from Beckman Coulter and local patient population reference range study conducted in 2024.

Date Effective:

F. Critical Results:

Test	AGE	Critical Low	Critical High	Units
WBC	All	N/A	>100	K/uL
Hemoglobin	<90 days	<8	>22	gm/dL
	≥90 days	<6.5	>20	
Platelet	<30 days	<50	>500	K/uL
	≥30 days	<20	>999	
Abs Neut	All	<0.5	N/A	K/uL
Blasts	All	N/A	>5	%

IX. Result Reporting:

A. SCAN: WBC/RBC/PLT Scan with CellaVision Confirmation Only

1. Enter the specimen accession number in Accession Result Entry to access automated DxH results in Cerner.

   Note: In most instances, all hemogram results have already been verified before a smear review is performed. Any automated results in question remain in PERFORMED status until confirmed by smear review.

2. Ensure that a checkmark appears next to the SCAN result, Right click and select COMMENT, or click the COMMENT icon. Alternatively, select all differential results and add BATCH COMMENT (this allows the provider to view comments).

3. The Comment box appears. Select EDIT and enter the result comment ‘Confirmed by Smear Review’ or ‘Smear Reviewed’.

4. Once the comment has been entered, ensure that all valid results (including the SCAN result) have a checkmark and select VERIFY.

B. DIFM: CellaVision Manual Differential with RBC morphology and PLT estimate

1. Enter the specimen accession number in Accession Result Entry to access automated DxH results in Cerner.

2. Prior to performing manual differential, in the SCAN field, open the dropdown box, select DIFM, UNCHECK ALL AUTOMATED DIFFERENTIAL RESULTS (and all other questionable results) and select PERFORM. Once performed, the DIFM order will automatically cancel the automated differential in Cerner and place an order for a Manual Differential and RBC Morphology.

3. Place a checkmark next to each result to be released and select VERIFY. Perform CellaVision WBC differential, RBC morphology, and PLT estimate and Sign Slide to transmit results.

4. Once signed, the CellaVision differential, RBC morphology, and PLT estimate results automatically populate into the Manual Differential and zMorphology orders in Cerner.

   NOTE: Prolymphocytes, ‘Other’ category, giant platelets, thrombocyte aggregation, and vacuolization do not cross into Cerner and manual entry is required.

5. Re-enter the accession number if necessary; review CellaVision results for acceptability. Compare results to previous results, correlate with other clinical findings, and resolve any discrepancies. If necessary, add a Result Comment or Result Note to explain discrepancies, abnormalities, or to document communications.
6. Ensure a checkmark appears next to each result and select VERIFY.

C. SCAN/MORPH: RBC Morphology and PLT Estimate only

1. Enter the specimen accession number in Accession Result Entry to access automated DxH results in Cerner.
1. In the SCAN field, open the dropdown box and select SCAN/MORPH.
2. Ensure that a checkmark appears next to all valid results and select PERFORM.
3. Once in performed status, verify all results which do not require CellaVision confirmation. Place a checkmark next to each result to be released and select VERIFY. Do not release any result with a System (R, N, or P) Flag or any flag/message which may indicate an inaccurate result (i.e. platelet clumps).
4. Review WBC tab and CONFIRM AUTOMATED RESULTS. Perform RBC morphology, PLT estimate and SIGN SLIDE to release results.
5. Once signed, CellaVision RBC morphology and PLT estimate results automatically populate into the ZMorphology order in Cerner.
6. Enter the specimen accession number in Accession Result Entry to access the CellaVision results in Cerner.
7. Review CellaVision results for acceptability. Compare results to previous results, RBC indices, correlate clinically, and resolve any discrepancies. If necessary, add a RESULT COMMENT or RESULT NOTE to explain discrepancies or to document communications.
8. Ensure a checkmark appears next to each result and select VERIFY.

D. PLATELET FLAGS with or without DISCREPANCIES

1. Enter the specimen accession number in Accession Result Entry to access automated DxH results in Cerner.
2. In the SCAN field, open the dropdown box and select SCAN.
3. After following the CellaVision platelet estimate procedure, if the automated count is consistent with the platelet estimate, select the automated platelet result field and attach the result comment ‘Confirmed by manual platelet count estimate’ and note clumping or large platelets if necessary.
4. If automated platelet count is found to be inaccurate and a reliable estimate can be performed, click in the automated platelet result field. Replace the automated platelet count with the numerical platelet count estimate performed on CellaVision. Attach the result comment to the platelet result field ‘Hematology Analyzer unable to perform accurate platelet count due to [*add reason*]. The reported platelet count is an estimation determined by computer assisted image analysis.’
5. If the specimen is too clumped to estimate and recollection is not possible then right-click in the field, select CONVERT RESULT and then select FREETEXT. Type “TNP”. Attach a comment to the platelet result field indicating the reason for omitting the platelet result such as ‘Automated platelet count unreliable due to

platelet clumps. Too clumped to perform an estimated count. Suggest recollecting on Sodium Citrate and EDTA if clinically indicated.'

6. Ensure that a checkmark appears next to all valid results and select PERFORM followed by VERIFY.

X. Limitation of Procedure:

A. The CellaVision is intended to be used by skilled operators. Each trained operator must identify, reclassify, or verify the suggested classifications of each cell type.

B. Distinctions between band and segmented neutrophils, metamyelocytes, myelocytes and promyelocytes, lymphocytes and reactive lymphocytes are subject to variations among individual operators.

C. The RBC panel includes a list of all morphologies handled by the system, but only polychromasia, hypochromasia, anisocytosis, microcytosis, macrocytosis, and poikilocytosis are precharacterized by the system and confirmed/re-characterized by the operator. All other RBC morphologies are characterized by the operator according to procedure.

D. Smear review, manual differential, and pathology review criteria are meant to be used as guidelines to standardize practices. CLS personnel may perform smear reviews, manual differentials, or send slides for peripheral smear review at their discretion if results do not meet stated criteria but are deemed significant.

E. CLS personnel may use professional judgment in determining the significance of flagged results/messages based on clinical findings, prior results, or other circumstances. All information used in determining action contrary to this procedure will be documented as a comment in Cerner.

F. Results released on suboptimal specimens are accompanied by a comment noting the condition of the sample and if possible, the effects that the specimen's condition will have on the reported results.

XI. References:

A. College of American Pathologists, Hematology and Coagulation Checklist. Northfield, IL, Current Addition.

B. CellaVision User's Manual. CellaVision AB, Sweden, 2012.

C. Suggested Criteria for Action Following automated CBC and WBC Differential Analysis. International Consensus Group for Hematology Review, 2004.

D. Clinical Hematology and Fundamentals of Hemostasis, 5th Edition. Denise M Harmening, F.A. Davis Company. Philadelphia, PA, 2009.

E. Higgins V, Tahmasebi H, Bohn MK, Hall A, Adeli K. CALIPER Hematology Reference Standards (II). Am J Clin Pathol. 2020 Aug 5;154(3):342-352

F. Staffa, S.J., Joerger, J.D., Henry E., Christensen, R.D., Brugnara, C. and Zurakowski, D. Pediatric hematology normal reference ranges derived from pediatric primary care patients. Am J Hematol, 95. 2020.