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CD Sysmex CELLAVISION DC-1 Operation, QC and Maintenance

SCOPE:

This procedure provides instructions for use and maintenance of the CellaVision DC-1 analyzer with software version 7.1.

Performing locations effective 3/19/2025:

- Drexel Town Square Health Center
- Moorland Reserve Health Center
- Town Hall Health Center
- West Bend Health Center
- Holy Family Memorial Hospital
- Menomonee Falls Hospital
- · West Bend Hospital

PURPOSE:

CellaVision DC-1 is an automatic cell-locating device intended for in-vitro diagnostic use for the analysis of blood cell identification and morphology of peripheral blood smears.

The CellaVision DC-1 is not a total replacement for manual microscopy. The CellaVision DC-1 produces flat images and does not allow the tech to focus through the cell.

- If there are suspect flags for blasts or lymphoma cells a manual microscopy review (using the microscope) must be performed.
- if abnormal RBC morphology that might include RBC inclusions is present or suspected, a manual microscopy review must be performed.
- DC-1 software version 7.1 provides images for feathered edge examination so the smear can be

reviewed for platelet clumps or large cells within the feathered edge in addition to the WBC differential and RBC Morphology. If the only reason for smear review is platelet suspect messages, it will be faster to manually review the smear on a microscope.

PRINCIPLE:

CellaVision DC-1 is an automated digital cell locating device intended to aid morphologists in the location and classification of white blood cells and non-WBCs, the characterization of red cell morphology, platelet estimation and feathered edge review (v7.1 and above) in peripheral blood cell morphology. Monolayer smears are prepared, stained and placed into the loading tray. Oil is applied to the slide by the user. The slides are loaded for analysis one at a time. The DC-1 automatically locates blood cells and presents images of the blood cells for review.

A skilled operator trained in recognition of blood cells, identifies and verifies the suggested classification of each cell or reclassifies the cell according to type.

ANALYZER COMPONENTS

Major Parts

- XY Stage moves slide to and under microscope
- Microscope Module consists of objective, relay lens, and focus mechanism
- · Imaging Module captures images of slide and controls the motors
- LED Assembly provides light to the microscope
- System Computer embedded PC running Microsoft Windows and CellaVision DC-1 Software

Analyzer





- 1 Hood
- 2 Input hatch
- 3 Drip tray
- 4 USB
- 5 Status light
- 6 Stand-by button

SUPPLIES:

- 1. Microscope Slide Specifications
 - a. Standard ISO 8037/1-1986
 - b. Material Glass
 - c. Length 75.0 to 76.0 mm
 - d. Width 25.0 to 26.0 mm
 - e. Thickness 0.9 to 1.2 mm
 - f. Corners Clipped or round corners
 - g. Edges Ground edges
- 2. Slide Stain reagents
 - a. Drexel and Moorland Refer to <u>Aerospray Slide Stainer Operation/Maintenance Basofix</u> Stain
 - b. Town Hall Refer to Ames Hema-Tek Slide Stainer
 - c. West Bend Refer to Hema-Fast 3 Step Differential Stain
 - d. Holy Family Memorial Hospital Refer to Wescor 7120 Slide Stainer
 - e. Menomonee Falls Hospital Refer to Aerospray Slide Stainer Operation/Maintenance -

- 7 Imaging module 8 Microscope module 9 Loading tray
- 10 System computer

Basofix Stain

- f. West Bend Hospital Refer to Slide Stainer Operation/Maintenance
- 3. Slide Label
 - a. Use the "butt label" of Beaker accession label set to label slide. Use the CellaVision DC-1 barcode reader to enter sample ID into the DC-1.
 - b. During an LIS downtime, downtime barcode labels should be used. Manually type in the down time specimen ID and add "ER" prefix. The ER prefix allows the downtime specimen ID to be modified to the final specimen ID when downtime is resolved. If ER prefix is not used, the specimen ID cannot be modified.
 - c. If barcode labels are not available, labeling must be done on the white, smooth, frosted area of the slide. Printing must be clear and legible. Labeling must include two unique patient identifiers typically the patient name and specimen ID. If medical record is used in place of specimen ID, date must also be included.

4. Immersion Oil

- a. CellaVision Immersion Oil XU-10319, 50 mL
- b. To prevent slide processing faults and damage to the system, Immersion Oil used on CellaVision DC-1 must have a viscosity rating of 300. Do NOT substitute immersion oils with a different viscosity rating.

SPECIMEN:

Anti-coagulated human peripheral whole blood in K2/K3 EDTA

Optimal time for smear preparation is within 4 hours of collection. If a smear cannot be prepared within 4 hours, some loss of cellular integrity may occur.

Stability:

Froedtert stability times are based on stability studies performed on the XN analyzers.

Temperature	Time
Ambient	8 hrs
Refrigerated	24 hrs

Peripheral Blood Smear

- 1. CellaVision DC-1 has specific requirements when it comes to slides that it deems acceptable and suggest the usage of an automatic slide maker. The attached template may be used as a guide when making smears.
- 2. Requirements for a good smear:
 - There is no pooling of specimen at the point of application.
 - Both sides of the film are less than 5mm from the edges of the slide.
 - The feathered edge is relatively straight and not pointed.
 - There must not be any streaks, troughs, ridges, holes or bubbles.

- The blood film must be at least 30 mm in length and terminate 5-15 mm from the end.
- The smear must not be too thick. A thick smear will interfere with the DC-1's ability to find a monolayer and with the Artificial Neural Network that may result in a large number of misclassified WBCs.



- Thin smears are better than thick smears.
- Smears that are two short result in CellaVision DC-1 identifying broken cells in the feathered edge of the smear and artefact RBC morphology.
- Smears that are too long or two thick result in CellaVision reading in areas that are too thick for good cell identification and inappropriate for RBC morphology. Mononuclear cell discrimination is difficult in these circumstances.

Quality Control (Cell Location Test) Purpose

- 1. Validates the slide preparation and staining process.
- 2. Ensures analyzers ability to locate cells.

Frequency

- a. Run at beginning of each workday.
- b. Whenever a staining reagent is changed
- c. After stainer maintenance
- d. If modifications are made to the staining process

QC Process

- a. Prepare a freshly stained slide from a specimen with a normal to slightly elevated WBC count (7 to 13×10^3 /uL is recommended)
 - a. Label slide as QCmmddyy (mmddyy = date of analysis) or use CellaVision QC Slide labels.
 - b. Slides may be made in advance, but must be stained just prior to analysis. If manually labeling slides, the initial slide labeling should just be "QC". The date portion of the label

must be added immediately before staining the smear.

- b. Open the input hatch and place stained slide in loading tray
- c. Under System Control View, click within the Slide ID text box
 - a. Enter the slide ID from slide label beginning with "QC"
 - b. Select "Ok"
- d. Dispense two drops of immersion oil on slide
 - a. Hold tip of bottle close to slide without touching slide
 - b. Dispense drops over red marker
- e. Close input hatch
- f. Under System Control View select "Start"
 - a. The status light will be yellow while the analyzer is processing the slide
 - b. Once slide is processed the status light with flash green
 - i. Any problems while processing a warning will be issued with information on what went wrong
 - c. Open input hatch and remove slide, status light with turn solid green
- g. Examine cell location slide
 - a. Under Tools select "Cell Location"
 - b. In Cell Location Slides select the slide you want to examine
 - i. CellaVision DC-1 Software will open up first image from slide
 - c. Once in the Overview Image count any nucleated cells that have not been located
 - i. Enter number in "WBCs + NRBCs missed" text box
 - ii. Cells that have been located will be marked with a green, blue, or black box
 - Markings
 - Green: pre-classified as a nucleated cell Blue: pre-classified as a non-nucleated cell Black: cell located not pre-classified, but excluded since enough WBCs have been located
 - Boxes will not always be centered on cells, but as long as there is a box the cell has been located
 - There is no need to correct an incorrect pre-classification during QC test. The purpose is to ensure CellaVision is locating all nucleated cells present. Missed cells must be documented.



- d. Select "Next" to show the next image and repeat the previous step
 - i. Analyzer needs 20-80 Overview Images to locate required number of objects
 - ii. Fewer or greater than 20-80 images can be an indication of a poor slide
 - iii. Symbols
 - Green $\sqrt{\rm All}$ images from this slide have been examined and all nucleated cells located
 - Blue $\sqrt{\rm All}$ images from this slide have been examined but not all nucleated cells located
 - X Slide error, click slide in list cause of error will be displayed in Total Result text box
- e. Once all images have been viewed the analyzer will calculate the results of the test
 - i. Results will be displayed under "**Total Results**" as "Ratio of WBCs + NRBCs found"

Evaluation of Cell Location Results

- A. Under "Total Results" check that the ratio of WBCs + NRBCs found is \geq 97%.
- B. Select "Show History"
 - i. Cell Location History chart will appear on the screen
 - · Chart will show last 30 results
 - · Examine chart for any shifts or trends that may indicate a problem
 - If shifts or trends are observed, call Sysmex Technical Assistance Center (TAC): 1-888-879-7639.
- C. Document QC in Beaker or sign the maintenance log for Cell Location performance as appropriate for your lab.
 - i. If QC is deemed acceptable, no additional documentation is needed.
 - ii. If QC is unacceptable, document corrective action according to site specific process.

Procedure

A. The CellaVision DC-1 will normally be powered on and logged in. If this is not the case when you approach the analyzer, use the appropriate actions from this list to get it to an operating state. A generic log-in is used in the analyzer. Tech specific log-in credentials are used for CellaVision Remote Reviewer and Caresphere.

1. Power the analyzer on

- a. Hood and input hatch should be closed before starting analyzer
- b. Press the Stand-by button (power button)
 - i. Status light will be yellow
 - ii. Status light will flash red if start-up test fails followed with an error message
 - iii. Status light will be green when analyzer is operational
- 2. Log-in to CellaVision computer: User Name = Administrator, Password = cv2864400.

3. CellaVision DC-1 Software Start-up

- a. Double click the CellaVision DC-1 Software icon on analyzer computer desktop
- b. Log On dialog will pop up
 - i. Enter generic User Name and Password (example: admin/admin)
 - ii. In the Database list select the database "CellvDB"

c. Self-Test will automatically be performed after log-in

- i. Analyzer will perform a self-test during start-up and periodically during operation
 - Hardware and software components are being checked for anomalies and requirements for operation
 - · If LIS is enabled it will check connection status
- ii. Database size is compared to rule sets for archiving and automatic deletion of old entries. This ensures database is kept at a reasonable and manageable size
- iii. Error message will pop up to inform user if anything happens during processing or other operations
- d. Filter the database to display only your performing location
 - i. Open the database
 - ii. In the search box at top of screen, the default is to show all. Use the drop-down to select your location.
 - iii. Click the Search button
- B. CellaVision Remote Reviewer Log-in
 - 1. Locate the CellaVision Remote Reviewer icon on any network computer.



2. Ensure that the box for "Use Windows Authentication" is checked and the Database selected is CellvDB. Enter your network ID and Password (same as used for Epic).

	Log On		
	CELLA	VISION	
	Remote Review	Software	
3.	User name: Password: Database:	hncw5200	Click OK after all information is entered.
	Use Windows	Authentication	
	0	K Cancel	

C. QC (Cell Location Test)

- 1. Cell location test must be successfully completed each day before using CellaVision DC-1 for patient testing.
- 2. See Quality Control section of this procedure.

D. Prepare Slides

1. Prepare peripheral blood smears as indicated in Specimen section of this procedure.

E. Process Slides

- 1. Open input hatch and place peripheral blood smear in loading tray
 - Blood smear must be facing up on loading tray
 - Frosted end of slide must be to the right.
 - If slide is not properly positioned, analyzer may use the wrong part of the slide and give unreliable results
- 2. In System Control View click in Slide ID text box and scan slide barcode
 - If barcode is unavailable you must manually enter ID and double check for clerical errors.
 - If downtime barcode is used, manually type in the specimen ID and add "ER" prefix.
 - After ID is entered select "Ok"
- 3. LIS should auto generate patient information and testing that needs to be performed
 - If LIS or interface is down, manually enter patient name.
- 4. Add immersion oil by holding tip of bottle close to slide without touching the slide
 - Place two drops over red marker
 - When adding immersion oil, no bubbles should be present. Bubbles may cause interference in smear processing. Use a wooden stick to gently touch the bubble to break it if necessary.
- 5. Close the input hatch
- 6. In System Control View select the "Start" button (►)
 - Status light will be yellow

- 7. Once analyzer is done processing slide status light will flash green. Don't remove slide until CellaVision DC-1 gives message that it is OK to remove the slide.
 - If there is an issue a warning message will pop up with information on the problem
- 8. Open input hatch and remove slide. Status light will turn yellow
 - · After every processed slide analyzer will check motor positions

F. Unusual events

1. Need to abort the count due to clerical error in specimen ID.

a. Stop Slide Processing

- i. In System Control View select "Stop"
- ii. "Do you want to stop the slide processing?" will pop up select "Yes"
 - Analyzer will move slide to input hatch and status light will flash green
- iii. Open input hatch and remove slide status light will turn solid green
- iv. If slide processing is stopped images and results will be discarded
 - icon will appear in Processed Orders list of Database View screen. Delete the order and start slide processing again with correct specimen ID.
 - To delete the order, click on the order that was stopped so it highlights in blue. Then click on the trashcan icon at bottom of Database View screen.

2. Mechanical Error

- a. Status light will flash red if an mechanical error occurs during slide processing
- b. Restart the CellaVision DC-1 Software
- c. If start-up test fails status light will flash red
- d. Call Sysmex Technical Assistance Center (TAC): 1-888-879-7639

Results

After a slide has been processed the CellaVision will send pictures of the slide to the Database where it can then be viewed by a Lab Tech using the CellaVision Remote Reviewer.

The analyzer may provide tabs for WBC, RBC, Platelets and/or Feathered edge as appropriate to the smear review requirements of the sample. Caresphere will send the appropriate order to CellaVision.

Caresphere WS Test Code	Tabs opened on CellaVision Software	User Action on CellaVision Software
Smear1 or Smear2	WBC, RBC, PLT	The user has the ability to do a scan and send the automated differential to the LIS or can reclassify the images to perform a manual differential.
Smear5 or	WBC, RBC	The user has the ability to do a scan and send the automated

Smear6		differential to the LIS or can reclassify the images to perform a manual differential.
NEUT	WBC, RBC, PLT	Mandatory manual differential. User cannot verify automated differential.
FEDGE	FEDGE	Provides images of feathered edge for review. Must be used in conjuction with Smear# or NEUT. No results are provided from FEDGE tab. If only FEDGE is present, review smear at microscope.

Techs will review pictures in Database and either agree with the analyzer or modify cell classifications based on their morphology expertise. When the slide is signed out in CellaVision, the differential and morphology will cross interface to Caresphere. Caresphere calculates the absolute counts for the CellaVision differential. Final result review and validation is performed within Caresphere.

WBCs

- A. CellaVision DC-1 will pre-classify cells into these classes:
 - 1. Band Neutrophils
 - 2. Segmented Neutrophils
 - 3. Eosinophils
 - 4. Basophils
 - 5. Lymphocytes
 - 6. Monocytes
 - 7. Promyelocytes
 - 8. Myelocytes
 - 9. Metamyelocytes
 - 10. Blasts
 - a. Note: If blasts are identified by CellaVision or flagged by the Hematology Analyzer, scan the smear manually at the microscope to ensure the blast count appears accurate. Blasts often go to the side edges and feathered edges of the smear and can be missed by the CellaVision.
 - b. If blast count appears higher at the microscope, perform a manual differential in Caresphere.
 - 11. Lymphoma Cell Lymphoma cells must be confirmed by manual microscopy and can only be called if previously confirmed by pathologist.
 - 12. Plasma Cells
 - 13. Non-WBC objects are pre-classified into these classes:
 - a. Nucleated RBC transmits to Beaker as # per 100 WBCs.
 - b. Giant Thrombocytes transmits to Beaker as Giant platelets present. If only one giant platelet is present, reclassify it as artefact. Giant platelets are only reported as present if ≥2 are present.
 - c. Thrombocyte aggregations,

- d. Smudge Cells does not transmit to Beaker
- e. artefacts does not transmit to Beaker
- 14. Cells and objects pre-classified with a low confidence level will be labeled "Unidentified". These cells must be reclassified in order for the smear to be signed.
- B. If a "Smear Review with Manual Diff If Needed" is required,
 - 1. Review the DC-1 differential in full screen view.
 - 2. If any abnormal or immature WBCs are seen, reclassify cells as needed and report the manual diff from DC-1.
 - 3. If CellaVision count does not confirm auto diff, reclassify cells as needed and report the manual diff from DC-1.

Cells do not need to be reclassified when using

4. If CellaVision count agrees with auto diff, click Confirm Cell Counter to accept the

1

automated differential results

Confirm Cell Counter option.

- C. Techs can re-classify any cell or object.
 - Note: WBCs are only reclassified if a manual differential is being resulted. If the CBC instrument differential is being reported (Confirm Cell Counter), do not reclassify WBC.
 - 2. Only classify cells into categories that can be reported in manual differential. If cell is deteriorated and cannot be identified, classify it as artefact.
 - a. Reactive Lymphs are included in the total Lymphocyte count. Tech must determine if quantity is sufficient to report "Reactive Lymphs Present" in morphology or send for pathology smear review.
 - b. Other Cell is identified as a WBC but doesn't fit into a classification. Results of "Other" will map to Unclassified in Beaker manual differential. WBCs classified as "Other" will be included in the differential count. Free-text a description of the "Other" cell as an internal order comment in Caresphere and send for a path review.

Sysmex Caresphere	e™ WS					
			Add	New Commo	ent	×
		Home			INTERNAL REPORT	
Sample ID Name C 36512730			Туре	to search		Q
Sample Location		(any	Item	Items Selected: 0		Select All
		- manual review		Code	Text	
🏴 🍽 🔍 🕤	· ·	Test		COR	Corrected Results	
Order Comments		WDC		HEMO	Hemolyzed	
No record found		HGB		HYAL	Hyaluronidase Used	
		нст		ICT	Icteric	
	• •	MCV	-			
	•	MCH		ID	Sample ID Verified	
		мснс		LIPID	Lipemic	
	•	RDWCV		MSRP	Manual Smear Review Performed	
	· ·	RDWSD		ONS	Quantity Not Sufficient	
		PLI		415	Quality Hot Sufficient	
		MPV		RNV	Repeated & Verified	
		NRSCAS	Enter Te	er Text		
		NEUTOC				
	0.	IVADOR				
	0.	LACALORE			Cane	
		MONURE			Contra	

- c. Not Classed Cell is unidentifiable and excluded from differential. This is no different from classifying the cell as artefact or smudge cell. "Not Classed" does not transmit to Beaker.
- d. Lymphoma cell classification may only be used if Lymphoma cells have previously been confirmed by pathologist for this patient. Refer to Pathologist Smear Review Procedure for details.
- 3. WBC Morphology All morphology comments, including WBC morphology are entered on the RBC tab.

Handling Albumin Smears

- A. If CellaVision locates more than 15 smudge cells, an albumin smear is needed, same as if doing a manual differential.
- B. Do NOT sign the original diff results until the albumin smear is read.
- C. Use the same specimen ID for the albumin smear and put the slide on CellaVision to count.
- D. After albumin smear is counted, go through the images from first slide and sign-out slide one.
- E. The albumin smear will now appear. Go through the images, reclassify as needed, and sign-out the albumin slide. A message will appear answer yes.
- F. Uncheck slide one so only the Albumin smear results are reported.
 - 1. NOTE: If you have two acceptable slides on a low count and want to combine the results of two slides, leave both sets of results checked and the average will be reported.
- G. Click the check-mark in lower right of the screen to sign-out the specimen ID and transmit results to Beaker.

Combining Counts from 2 smears or 2 counts on same

smear

- A. If a WBC count is low, a tech may use 2 smears to reach 100 cells. If a WBC count is high, a tech may recount the same slide to include additional cells.
- B. Do NOT sign the first smear if you are going to count a second slide or recount a smear.
- C. After all counts are complete, go through the images from the first slide and sign-out slide one.
- D. The next smear/count will appear. Go through all of the images, reclassify as needed, and sign-out the next slide. A message will appear answer yes.
- E. Leave both slides checked. CellaVision will calculate the percent from all cells counted on smear/ count 1 and 2. Morphology will be the higher of two values from slides 1 and 2. Any comments entered in slide 1 and slide 2 will transmit to Beaker when specimen ID is signed.
- F. Click the check-mark in lower right of the screen to sign-out the specimen ID and transmit results to Beaker.

RBCs

- A. The RBC panel is composed of 8 100X fields. Note: The DI-60 should not be used to review for schistocytes/fragments. Cases flagging for or when schistocytes/fragments are suspected of being present must be reviewed manually under a microscope.
- B. If there is no significant morphology, select "Report all as O-Normal".
- C. Red cell morphology can be graded 1+ to 3+ by selecting "Use Characterization" and selecting the appropriate radio buttons for morphology. In addition, go to bottom of list and result RBC Morph as "Present" (1). The morphology must be resulted as Normal or Present to complete the smear review in Caresphere.
 - 1. The Zoom feature can be used to enlarge the image by one of the following methods:
 - a. Click on the magnifying glass icon (**Zoom Mode**) with +/- signs. Hold down the left mouse and move up or down on the image. Moving up zooms in; moving down zooms out.
 - b. "Zoom In" by clicking on the magnifying glass icon with a "+" sign. By clicking on the icon 5 times, an image equal to a 100X field displays. "Zoom Out" is identified by a magnifying glass with a "-" sign.
 - c. Return to full view by clicking on "Entire RBC Image" icon.
 - 2. Navigation within an image can be performed by using the **Scroll** (Hand) icon or by using the scroll bars on the bottom and right side of the screen.
 - a. To use the Scroll mode, click on the Hand icon. Place the hand on the image and hold down the left side of the mouse to move the image from side to side and up/down.
- D. Refer to Manual Differential procedure for morphology criteria.
- E. Morphology is pre-characterized by shape, color and size with suggested preliminary grading for the following:
 - 1. Polychromatic

- 2. Poikilocytosis
- 3. The tech should adjust grading as needed. Column 1 = 0 (normal), Columns 2-4 = 1+, 2+, 3+ respectively.
- 4. Morphology components that are not reported by Froedtert labs appear in the morphology list as ** and will show grading. Those components do not transmit to Caresphere/Beaker and can be ignored.
- F. Most morphology components are reported in Beaker as "Present". Mark as present by clicking in the "1" column for the appropriate morphology. Do not mark any column other than "1". (NOTE: the first column in CellaVision is "0", the second column is "1".
 - 1. Morphology list on RBC tab includes WBC morphology comonents
 - 2. RBC Morphology "1" reports RBC Morphology Component as Present. If any morphology is being reported, RBC Morphology must be marked as "1" (present).
- G. Schistocytes and Spherocytes should be graded at the microscope. In CellaVision Morphology for Schistocytes and Spherocytes,
 - 1. 1 = 0-2
 - 2. 2 = 3-5
 - 3. 3 = 6-10
 - 4. For greater quantities, use Morphology Comments.
- H. RBC Comment
 - Additional morphology comments for RBCs and Platelets are available in CellaVision RBC tab under RBC comment section. Click on the RBC comment "add comment" icon to open list of available comments.
 - 2. Double-click on the comment that you want to report. The comment will appear in the RBC Comment box above the comment list.
 - 3. When all appropriate comments have been selected, click on OK.

Platelet Review

- A. Platelets that are classified as Giant Platelets must be reclassified as artefact unless they are the size of a normal RBC or larger and there are more than one present in the differential.
- B. The platelet analysis, when present, will need to be completed or excluded in CellaVision before signing the smear.
- C. Do not rely on platelet tab to determine if platelet clumps/fibrin are present. If PLT Clumps? suspect message was generated by Sysmex analyzer, see Feathered Edge Review below.
- D. Platelet Estimation: CellvDB is not set up to calculate platelet estimates.
- E. PLT Tab options
 - 1. Use Confirm Analyzer Count icon in top tool bar if count is confirmed
 - If PLT CLUMPS are present: use estimate (Marked Decreased, Decreased, Normal, Increased). These estimate can only be used when platelet clumps are present. The send a comment to Beaker that includes the phrase "Unable to report platelet count due to platelet clumps"

- 3. If none of the above, Use the "Do not Report" icon at bottom.
 - a. This may be used for scenarios such as PLT Satellitosis (be sure to mark this in morphology) or PLT/NRBC size overlap. PLT-F should resolve this issue, but option is available just in case there is still a mismatch between count and smear.
- F. Platelet comments are located on RBC tab. Report any additional platelet morphology or platelet related comments in Caresphere before validating results.

Feathered Edge Review

- A. The Feathered Edge overview image can be used to find cells and other objects of interest, and to get an overall impression of the feathered edge in a peripheral blood sample.
 - 1. The overview image is a magnification of the area inside the rectangle shown in the mini map in the Navigation panel.
 - 2. The highlighted areas in the mini map indicate viewed areas of the overview image.
 - 3. Feathered Edge is only added when PLT Clumps? or Blasts? suspect messages are generated by the Sysmex analyzer. No results are generated from the Feathered Edge tab.
- B. In an open order, click the Feathered Edge tab.
 - 1. The Mini Map shown in the Overview displays the entire sample area.
 - a. Click in the Mini Map to enlarge a specific area. The magnified area displays in the large image.
 - b. Move within the Mini Map by using the keyboard arrow keys or the navigation arrows on the DM screen. Scroll mode is used by holding left mouse button down and pan in any direction with the mouse.
 - c. Zoom by using the slider in the Zoom panel.
- C. If any abnormal cells are noted in the FEDGE, the smear must be taken to the microscope for further evaluation.
- D. Platelet clumps and fibrin strands can be identified using FEDGE.

Sign-out Slide

- A. When all WBCs have been classified, and appropriate RBC, PLT, and FEDGE tabs have been reviewed, the smear must be signed.
- B. User log-in and password automatically fill in
- C. Click OK
- D. Results will transmit to Caresphere

Preliminary Verification

A. When CBC results need to be released to Cancer Care before the CellaVision manual differential is completed, choose VALIDATE CBC in Caresphere. The CBC results will transmit to Beaker and prelim verify. Prelim results will appear on patient chart and are designated with superscript P to

alert provider of preliminary result status.

- B. The differential results will be blank on the patient chart until the manual differential is completed.
- C. After the CellaVision differential is complete and signed, ensure CellaVision differential results and comments have accurately crossed to Beaker. Manually add additional morphology comments as needed. Then final verify both the CBC and CellaVision differential together.

Result Verification

Signed CellaVision results transmit to Caresphere. Tech must review all results within Caresphere and ensure all tests have a result. Scan through entire list under Manual section. If Result is "...", the test needs to be completed before results are validated. When all results are complete, choose "Validate All" in Caresphere and results will transmit to Beaker and Autoverify.

Result Correction

After a slide is signed, results cannot be corrected in CellaVision. If result correction is needed, it must be done in Caresphere or Beaker depending upon where in the validation/verification process the error was identified. If a change is made in Caresphere, add an Internal Order Comment explaining the reason for correction. Follow Result Correction process in Beaker if result was already validated in Caresphere and verified in Beaker.

Remote Review Notes

Remote Review is a Citrix based application that allows the database to be viewed from any network computer by an authorized user.

Hematology Technical Specialists have remote review access and can be consulted if there are questions about cell identification.

Remote review does not replace sending a blood smear to a pathologist for pathology smear review. Pathologist may use remote review "view only" access to view the same images that the tech saw when doing the differential. Unclassified cells sent for path review need to be marked on the smear in addition to identifying the cell as "other" in CellaVision.

Maintenance

Daily Maintenance

The CellaVision DC-1 has no daily maintenance.

Weekly Maintenance

The following should be done once a week to insure optimal performance

A. Restart analyzer

- 1. Make sure no slides are being processed or are in the analyzer
- 2. Exit CellaVision DC-1 Software

- a. Under FILE select "Exit"
- b. NOTE: If analyzer is shut off prior to exiting out of CellaVision DC-1 Software the database may become corrupted. Always Exit software and shutdown through software.
- B. Click on Windows icon in lower left corner of the CellaVision computer screen and select "Power > Shut Down" from the Windows icon in lower left corner of the screen.
 - a. Perform the other weekly cleaning items while the analyzer is powered off.

C. Clean the Analyzer

- a. All cleaning should be done with a soft cloth moistened with water
- b. Wipe outer casing
- c. Wipe away any excess oil from loading tray
- d. Pull out drip tray and wipe clean
 - i. The drip tray is spring loaded. Push in to release the tray, then pull out.
- D. When cleaning is complete, press the power button on the CellaVision DC-1 to restart the analyzer.

Remedial Maintenance - perform as needed

- 1. Clean microscope objective lens if images are not clear
- 2. CellvDB is a network server database. No user maintenance is needed.

Troubleshooting

Troubleshooting guide can be found in attached CellaVision DC-1 Instructions for Use 7.0

Limitations

- Do not make any changes to the settings unless authorized to do so. Changing settings may result in erroneous results reported to LIS.
- CellaVision can only produce a flat image of a cell. It is not possible to focus through a cell as you can with manual microscopy. If inclusions are suspected, take the slide to the microscope and scan the smear.
- CellaVision does not examine the feathered edge for blasts and platelet clumps. If these are suspected, take the slide to the microscope and scan the smear.

References

Cell Image Analysis System for CellaVision® Software Version 7.1 DC-1; Sysmex America, Inc; CF-08077, Rev. 1, 12/2023

Attachments

- Scaresphere internal comment.png
- 𝗞 CellaVision DC1 Instructions for Use v70.pdf
- **©** Cellavision icon.png
- © CELLAVISION maintenance log 11-18-22.xls
- Sconfirm Cell Counter Results.png
- S CV remote Review login.png
- Slide Template for Cellavision.pdf

Approval Signatures

Step Description	Approver	Date				
	Carolyn Webb: Heme Technical Specialist	02/2024				
Applicability						
Community Physician, Froedtert Menomonee Falls Hospital, Froedtert West Bend Hospital						
Standards						

Stanuarus

No standards are associated with this document