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Cellavision DI-60 & DC-1 Operation

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. This procedure provides guidance for the operation of the Cellavision DI-60 and DC-1 analyzers.

II. PRINCIPLE

A. The Sysmex DI-60 and DC-1 are automated digital cell locating devices intended to aid Medical Technologists in the location and classification of white blood cells and non-WBC's such as nucleated red blood cells (NRBC), the characterization of red cell morphology and estimation of platelets in peripheral blood. Monolayer smears are made and stained and the dried smears are placed into a magazine for transport to the DI-60 via the Sysmex CF-70 (or other site specific method). The DI-60 and DC-1 scan one slide at a time using the 10x objective, XY coordinates of potential nucleated cells are located in the optimal monolayer area and the positions are recorded. Oil is applied to the slide and images are obtained through 50x magnification for red cell morphology. Each recorded 10x position is then examined using the 100x oil immersion objective to capture WBC images. The cells are analyzed by the Artificial Neural Network (ANN) and assigned a pre-classification. The system will also perform characterization of red blood cell morphology and platelet estimation. The operator reviews and verifies or modifies the suggested classification of each cell according to type.

III. SPECIMEN COLLECTION AND HANDLING:

A. Peripheral Blood

1. Whole blood should be collected in EDTA-2K or EDTA-3K anticoagulant.
2. Whole blood collected in a 4 mL vacutainer is preferred.
3. Capillary blood collected in an EDTA microtainer is also acceptable.

a. NOTE: 16 X 100 mL tubes (7mL tall tubes) must NOT be placed on the XN line.

b. NOTE: Smear preparation on specimens older than 4 hours may exhibit a loss of cellular integrity. Please follow laboratory protocol for smear preparation and review.

B. Slide Preparation

1. Peripheral smears

a. Smears for the DI-60 can be prepared from the SP-50 (preferable method), manual wedge technique, or mechanical spreader.

b. Smears for the DC-1 can be prepared from the manual wedge technique or mechanical spreader.

c. Requirements for good Peripheral smear quality:

i. There should be no pooling of specimen at the point of application.

ii. Both sides of the film should be less than 5mm from the edges of the slide.

iii. The feathered edge should be relatively straight and not pointed.

iv. There must not be any streaks, troughs, ridges, holes, or bubbles.

v. The blood film must be at least 30 mm in length and terminate 5-15 mm from the end.

vi. The smear must not be too thick. A thick smear will interfere with the Cellavision's ability to find a monolayer and with the Artificial Neural Network which may result in a large number of misclassified white blood cells (WBC's).

IV. SUPPLIES AND REAGENTS:

A. DI-60:

1. CF-70 Slide Storage Magazines (blue – for storing slides that have been processed on the DI-60 only).

2. CellaVision Immersion Oil pack – 150 mL oil bag (sufficient for approximately 3000 analyses).

3. Frosted glass slides, with clipped or rounded corners and ground edges. Acceptable slide dimensions in mm are: 75.0-76.0 x 25.0-26.0 x 0.9-1.2, such as Sysmex MS-101.

B. DC-1:

1. CellaVision Immersion oil bottle

2. Frosted glass slides, with clipped or rounded corners and ground edges. Acceptable slide dimensions in mm are: 75.0-76.0 x 25.0-26.0 x 0.9-1.2, such as Sysmex MS-101.

V. MAINTENANCE:

A. **DI-60 Weekly Maintenance**

1. Shutdown/Startup (DI-60 only)

a. Restart/shutdown the DI-60 IPU

i. Select [Exit] in the File menu.
ii. Pop-up box: "Do you want to quit?"
iii. Select [Yes].
iv. Log off of Windows program by clicking on the start icon in left corner of IPU and click on 'Shutdown'.
v. Switch off the slide scanning unit.

b. **IMPORTANT: DO NOT turn off the computer using the on/off switch**

c. Start up the DI-60
i. Switch on the Slide Scanning Unit (SSU) using the switch located on the front of the unit.
ii. Wait until the red status lamp stops flashing and is continuously lit.
iii. Switch on the system computer. (Located below the DI-60 unit)
iv. In the Log-on dialog box type assigned Username and Password.
v. Select the appropriate database from the drop-down menu.
vi. Click [OK].
vii. A message may appear regarding RBC grading units. Click [OK].
viii. Verify an empty blue magazine is in the magazine storage unit on the CF-70.
ix. System control View displays. Make certain the start-up test passes.
a. System self-checks are performed during the start-up that detect potential hardware or software problems. The DI-60 will not process slides if the start-up test fails.
b. Notification is given if Cell Location has not been performed within the last 24 hours.

2. Entire XN line startup (If needed)
a. Press and release the green master switch located on the front of the line near the XN line start yard.
b. The status indicator LED will flash green.
c. The XN-IPU will automatically turn on.
d. The SP-50 will begin start-up.
e. The SP-50 Dialog box will appear.
i. Touch the name of the user to be logged on.
ii. Enter the Password and touch [OK].
iii. **NOTE**: If auto logon is enabled, the [SP-50 IPU Logon] dialog box does not appear. Display of the user name varies depending on the number of users.

f. The CF-70 will begin start-up.
g. A prompt appears on the SP-50:

i. Start SP/CF – select this to start both instruments.

ii. Start CF only – select this to start the instrument without starting the SP-50.

h. When the CF-70 turns on – it executes initial operation and self-check and the LED light turns green.

i. Each XN analyzer will begin start-up. The XN screen will display the login. Enter user name and password.

j. **NOTE**: All CF-70 errors will be communicated and resolved via the SP-50 IPU.

3. Clean hood

a. Wipe the hood with a moist cloth when necessary. Use only water for cleaning.

B. **As Needed Maintenance – DI-60**

1. Refill Immersion Oil

a. Change the oil pack following the instructions in the User Manual. Follow the correct instructions for your analyzer connector. Reference the DI-60 User Manual - Maintenance section for instructions.

b. Once replacement is complete, Click [Maintenance] – [Oil].

c. If oil pack ran completely dry, Choose [Prime Oil].

d. Click [Reset Oil Drop Counter] – [Yes] – [Close].

2. Cleaning of Objectives and LED Table

a. Open the hood.

b. Use a soft lint free cloth to gently wipe the LED table.

c. Use new dry lens paper and gently wipe the 10x objective lens.

d. Use new dry lens paper and gently wipe the 100x objective lens.

e. Process two slides to help eliminate bubbles and delete the slides from the database.

f. Run a cell location test.

3. Delete unsigned and failed orders in the “Data Base View” to minimize the size of the database.

4. Clear system control log: click "Clear Log" to delete samples from the System Control View.

5. Cleaning of slide storage magazines (blue and/or grey).

C. **DC-1 Weekly Maintenance:**

1. Shutdown/Startup

a. Restart/Shutdown the DC-1

i. Select [Exit] in the File menu.

ii. Pop-up box: "Do you want to quit?"

iii. Select [Yes].

iv. Log off of Windows program by clicking on the start icon in left corner of IPU and click on 'Shutdown'.

v. Switch off the slide scanning unit.

b. **IMPORTANT: DO NOT turn off the computer using the on/off switch.**

c. Start up the DC-1

i. Press the Stand-by button on the front of the unit.

ii. The status light is steady lit yellow while the analyzer is starting up. Wait for the analyzer to start. **DO NOT open the input hatch during start-up.**

iii. Double click the CellaVision DM Software icon on the desktop.

iv. In the Log-on dialog box type assigned Username and Password.

v. Select the appropriate database from the drop-down menu.

vi. Click [OK].

2. Clean the analyzer

a. Wipe the outer casing as needed with a moist cloth.

b. Wipe any excess oil from the loading tray.

c. Pull out the drip tray and wipe clean any immersion oil.

3. Delete unsigned and failed orders in the “Data Base View” to minimize the size of the database.

a. Click Database View.

b. Select the orders you want to delete in the Processed Orders list.

i. To select a consecutive group of orders, click the first order then hold down Shift and click the last order.

ii. To select non-consecutive orders, hold down the Ctrl key then click each order to select.

c. Click Delete, then click Yes.

D. **Analyzer self-checks:**

1. Start-up test to detect hardware and software problems is performed.
2. Message to perform Cell Location if not performed in the last 24 hours.
3. **NOTE**: If the start-up test fails, the DI-60 or DC-1 will not process slides.

E. Document all maintenance performed on the site specific maintenance log.

VI. QUALITY CONTROL (QC):

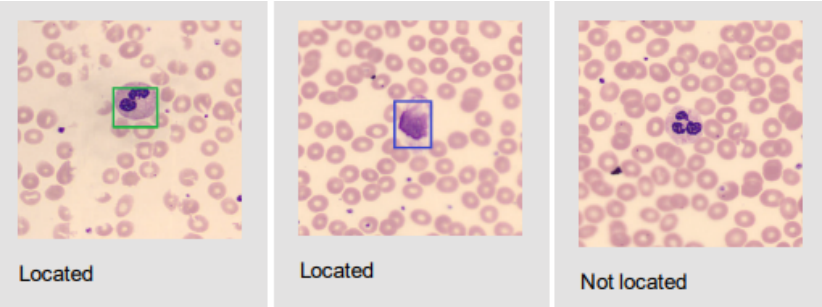
A. **Perform QC Cell location daily – Peripheral Blood**

1. Select a blood sample with a WBC count between $7.0x10^3$/µl to $14.0x10^3$/µL to reduce the processing time.
2. Prepare a slide using one of the following methods for the DI-60 or DC-1:

a. DI-60: Use the manual mode of the SP-50.
    i. Enter the specimen ID as [QCXXXXXX] where X's represent the date of preparation DDMMYY. Once the slide is stained it will automatically be transported to the DI-60 via the CF-70.
    ii. The slide will be scanned using the same method used to collect images for patients' samples.

b. DC-1:
    i. Prepare a smear from the manual wedge technique or mechanical spreader.
    ii. Open the input hatch and place the slide, with the blood smear facing up, in the loading tray.
    iii. In System Control View, click in the Slide ID test box. A dialog box opens.
    iv. Enter the slide ID as [QCXXXXXX] where X's represent the date of preparation DDMMYY.
    v. Click [OK].
    vi. Hold the tip of the oil immersion bottle close to the slide without touching the slide, aim for the red colored marker, and place two drops of the oil on the slide.
    vii. Close the input hatch.
    viii. In System Control View, click the Start button to start processing.

3. Once processing is complete, click [Tools] on the top tool bar, select [Cell Location]. Select the new slide at the top of the list. (Cell location images automatically delete after 5 days).
    a. Review each image for any missed nucleated cells. Double-click an area for magnification if necessary.
        i. Green boxes mark nucleated cells.
        ii. Blue boxes mark artifacts or other objects. The blue boxes will be counted as others next to the total number of cells. The number of these objects must not exceed 50%.
        iii. Missed cells are those not marked with any box.
        iv. Black boxes mark cells not needed in the 200 cell process for cell location.
        v. NOTE: The box isn't always centered over the cell. As long as there is a box associated with a cell, that cell has been located.



b. Review all images by clicking the right arrow. For each image, enter the number of missed cells in the input field. When all images have been examined, the result will appear as a "%".

c. Record results on the appropriate log. Results may also be printed by clicking [Print Result] if analyzer is connected to a printer.

d. Results must be >97%.

   i. NOTE: Do not process patient slides until the cell location result is within the acceptable range.

   ii. NOTE: Cell location results that do not meet 100% criteria will flag with a red check mark. Assess percentage for acceptability.

e. Using "Show History" will create a chart of the last 30 cell location results.

f. If Cell Location fails, dry clean the objective with lens paper and repeat the test. If the repeated Cell Location fails, prepare a new slide from a different sample and repeat.

4. Document on the site specific maintenance log.

VII. PROCEDURE:

A. **Slide Processing – Peripheral blood**

1. DI-60 Automatic Mode

a. Slides prepared on the SP-50 are placed in grey magazines and shuttled to the DI-60 via the CF-70 rear magazine storage unit.

b. The slide is removed from the grey magazine by the DI-60 gripper and the system checks for a readable barcode.

   i. If the barcode cannot be read, it is displayed as "ERR + date and time" (ERRYYYYMMDDhhmmss), in the System Control Log and Order List of the Database view.

c. An image is taken of the barcode and displayed in Order Data.

d. The slide is analyzed on the DI-60.

   i. System Control view displays ongoing slide processing.

   ii. The System Control Log, located in the upper left of the System Control view, shows the processing status for each batch and slide.

   iii. In Database view, "Analyzing" displays at the top of the screen.

e. Following analysis, the slide is inserted into a blue magazine. Once the blue magazine is filled (or ejected manually), the magazine is shuttled to the front magazine storage unit.

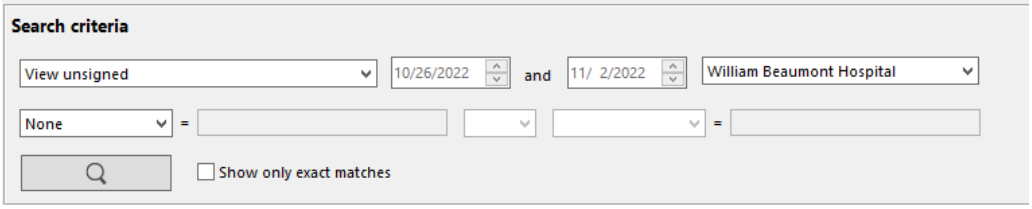
2. DI-60 Manual Mode – (loading of stained smears with no oil on smear)
    a. Load the grey magazine with frosted end of slides facing forward.
    b. Place the magazine on the rear magazine storage unit to be conveyed to the DI-60.
    c. For "STAT" smears – the CF-70 can be paused by pushing the start/stop button on the front of the conveyor.
    d. NOTE: The loaded magazine will not be conveyed until the magazine in the slide removal position is conveyed to the magazine storage unit. When the interrupted conveyed magazine finishes, automatic magazine conveyance resumes.
3. Reanalyzing a slide on the DI-60
    a. Prior to reanalyzing a slide on the DI-60, gently wipe the oil off the slide.
    b. Place the slide into a blue magazine designated for "oil slides".
    c. Follow instructions for "Manual Mode".
4. DC-1 Manual Mode
    a. Open the input hatch and place the slide, with the blood smear facing up and frosted end is facing right, in the loading tray.
    b. In System Control View, click in the Slide ID text box.
    c. Enter the slide ID exactly as it is written on the slide or use the barcode reader to read the barcode on the slide.
    d. Click [OK].
    e. Hold the tip of the oil immersion bottle close to the slide without touching the slide, aim for the red colored marker, and place two drops of the oil on the slide.
    f. Close the input hatch.
    g. In the System Control View, click the Start button triangle to start processing. The status light is steady lit yellow while the analyzer is processing the slide.
    h. The status light will flash green when completed.
    i. Open the input hatch and remove the slide. The green status light is now steady lit.
5. Reanalyzing a slide on the DC-1
    a. Prior to reanalyzing a slide on the DC-1, gently wipe the oil off the slide.
    b. Reprocess the slide following steps a through i above in section 4.
    c. In the database view, the order ID will have the 2- slide icon for the user to review.

VIII. SLIDE REVIEW - PERIPHERAL BLOOD:

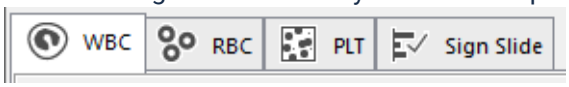
A. Slides that are ready for review display in the Database view.

B. An unopened order is in black text. Open orders display in blue text. Slides being reviewed by another user at a Remote Review Station display in orange.

C. To view all unsigned orders at a specific test location, select View Unsigned from the drop down box in the search criteria area. Select applicable laboratory. Click the magnifying glass.



D. Double-click on a slide/order to open the Verification view screen to review the images. WBC, RBC, and PLT images are divided by tabs at the top of the screen.



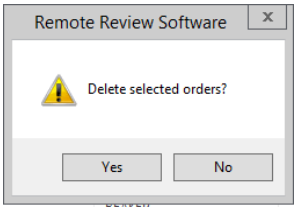
E. **Criteria for review of slide under the microscope:**

1. Low WBC <2.0
2. Platelet clump(s) flag or platelet clumps seen
3. Fragments? flag
4. First time blasts seen
5. Suspect APL
6. Albumin slide
7. Schistocytes/bite cells/blister cells present
8. All slides sent for pathologist review
9. Second level reviews
10. Cold agglutinin patients (warmed slide)
11. "Other" cells seen
12. Nucleated red blood cells (NRBC) in disagreement with analyzer result
    a. **NOTE**: Will need to correct WBC manually in the middleware. Refer to the XN CBC Corrections procedure.
13. Intracellular organisms seen
14. Hemoglobin crystals seen
15. Megakaryocytes seen
16. Platelet satellitosis seen
17. * All other flags, review at technologist discretion for viewing under the microscope.
18. **NOTE**: Orders being resulted in the middleware for any of the above criteria, the order should be deleted from the Cellavision.

a. From the database view, select the order number.

b. Click the delete icon on the bottom of the screen. 

c. Click Yes to delete the order.



F. **WBC Review**

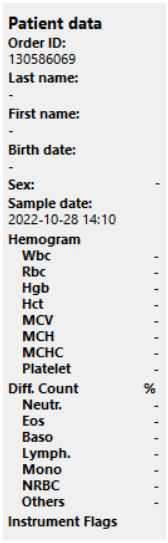
1. Cells can be viewed in different formats:

   a. The [Full Screen] view displays all cells grouped by pre-classification. 

   b. The galleries display 1, 2, or 3 classes of cells in side-by-side format. In the gallery fields, select the cell type to view using a drop-down at the top of the fields. When viewing in the gallery format, the WBC and Non-WBC parameters are displayed to the left. Check marks beside a parameter indicate that required review was performed. 

2. A library of reference cells is available for different cell classes. To view in gallery 2 or 3, select the box [Reference cells]. Use the drop-down to select the reference cell type.

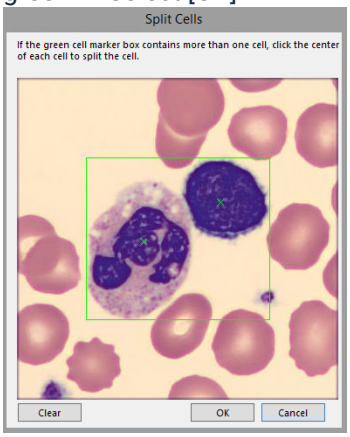
3. Double clicking on a cell enlarges it. Use the mouse wheel to zoom in and out.
4. All cell classes must be viewed prior to signing a slide.
5. All “unidentified” cells must be classified.
6. Demographic information, hemogram, auto differential and analyzer flags are displayed on the far lower left of the screen.



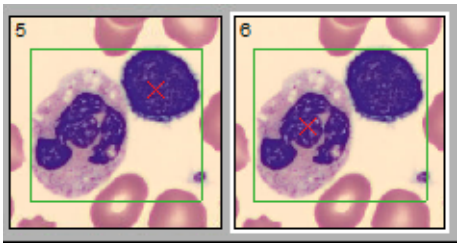
7. NOTE: To add a WBC comment, add the comment in the diff comment field in the middleware or the LIS before signing the slide in the Cellavision.

G. **Reclassification of WBC's**

1. Left click on the cell and drag it to the correct classification in a gallery or to the cell name in the WBC or Non-WBC panel to the left of the gallery.
2. Right click on a cell and select the appropriate classification from a drop-down menu.
3. To reclassify a grouping of cells, click on the first cell in the group, hold down the Shift key and click on the last cell of the group; this marks the entire group. Click on the group and drag it to a classification or right click to reclassify with the drop-down menu.
4. To reclassify non-consecutive multiple cells, hold down the Ctrl key while clicking on each cell. Once all cells are marked, click on a cell to drag all cells to the appropriate classification or right click to display the drop-down menu, and select the appropriate classification.
5. To split cells: If more than one cell appears in an image, click on the [Cell Marker] button to display a green box around the cells in each image.  Right click on the image and select [Split Cell] from the drop-down menu. Click on the cells in the box to mark with a green X. Select [OK].



Two pictures of the same image display. For each image, classify the cell that is marked by a red X.

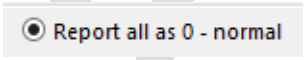


H. **Confirm Cell Counter**

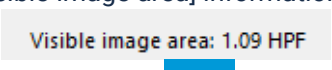
1. Review cell classifications in full screen view for abnormal cells.
2. If no abnormal cells are found, review cell counter (automated) differential displayed in the Patient Data field on the left side of the screen.
3. Click [Confirm Cell Counter] to accept the XN automated differential results. 

I. **RBC Review** The RBC panel is composed of 8 - 100x fields

1. If there is no significant morphology, select [Report all as 0-Normal].

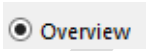
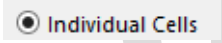
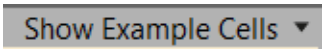
   

2. Red Cell morphology can be graded 1+ to 3+ by selecting [Use Characterization] and selecting the appropriate radio buttons. 

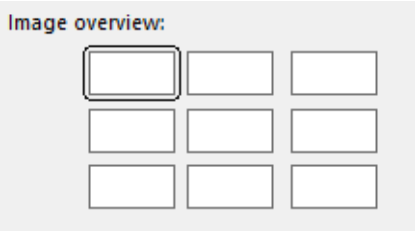
   a. NOTE: Hypochromasia should only be graded 2+ or 3+. 1+ will not cross to the Laboratory Information System (LIS).
   b. NOTE: All fields that cross as "present" into the LIS can be marked as 1+, 2+, or 3+.
   c. NOTE: If schistocytes, bite cells, or blister cells are suspected: review the slide under the microscope, result in the middleware, and delete from the Cellavision.
3. 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 5-7 times, an image equal to a 100x field displays. With Vs. 5 software and above, use the [Visible image area] information to determine the size of the field being viewed. 

   "Zoom Out" is identified by a magnifying glass with a "-" sign.  Return to full view by

clicking on [Full RBC Image] icon. 

4. Navigation within an image can be performed by using the RBC Grid. Using the RBC grid will automatically zoom in to a 1.0 HPF view. Using arrows will allow navigation up, down, right and left. The grid will indicate the section of the images by: 
    a. Green indicates viewed.
    b. Blue indicates current view.
    c. Red indicates not viewed.
    d. To exit the RBC grid, click on the RBC grid icon again.
5. NOTE: To add a RBC comment, add the comment in the diff comment field in the middleware or the LIS before signing the slide in the Cellavision.
6. Advanced RBC Application
    a. The Advanced RBC Application allows for the Pre-characterization of all standard RBC morphologies. To view the morphology classes more closely, you can:
        i. Click Overview to view the RBC overview image. 
        ii. Click Individual Cells to view the classified cells individually. 
        iii. Click on one of the headers in the list to the left to view cells or click on one of the morphologies under the header to view cells.
        iv. Double-click on a cell image to view an enlarged image, including the surrounding parts of the image.
        v. Use the scroll wheel to zoom in and out.
        vi. Example cells are available to view when the [Show Example Cells] arrow is clicked under the Individual Cells view. 
        vii. If the red blood cells have been reclassified a triangle will appear in the corner of the image.  Click on the cell in the Individual Cells view to show the original name.

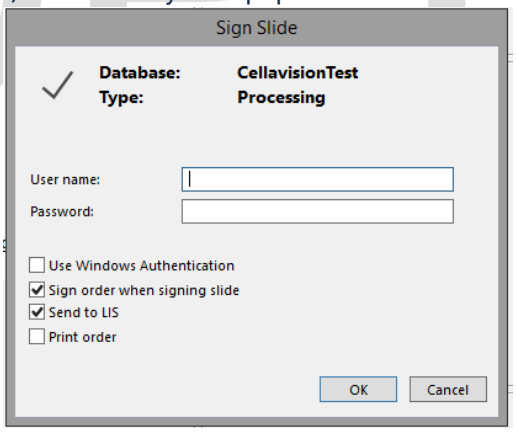
J. **Platelet Review**
    1. The PLT image corresponds to 9 – 100x fields.
    2. Gridlines can be added to aid in estimation by clicking [Help Lines] icon. 
    3. Click on each blank box to view all 9 fields.



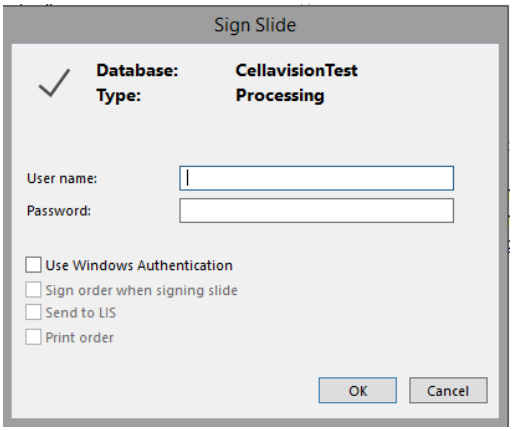
4. Estimating the platelet concentration level (Manual)
    a. Report “decreased”, “normal”, or “increased.”
    b. Select the concentration level from the drop-down menu.
        i. NOTE: DO NOT USE the "significantly decreased" option.
5. NOTE: To add a PLT comment, add the comment in the diff comment field in the middleware or the LIS before signing the slide in the Cellavision.

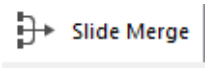
K. **REPORTING RESULTS ON THE DI-60 or DC-1**

1. Once all tabs have been reviewed, select the [Sign Slide] tab.
    a. All cell lines must be reviewed with no cells left as “unidentified” unless using the Confirm Cell Counter option.
    b. RBC characterization must be reviewed.
    c. PLT tab must be reviewed.
2. The [Sign Slide] dialog displays if all ordered analyses have been viewed.
3. Enter Username and Password, if not already auto-populated.

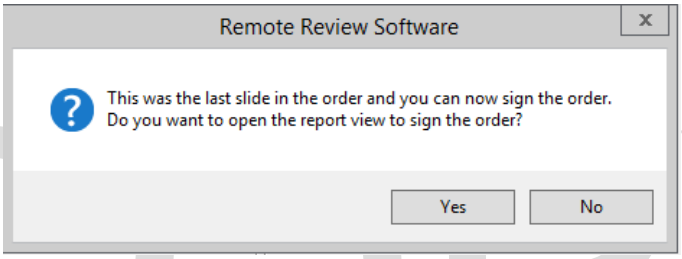


4. If not already selected (as default settings), select [Sign order when signing slide], [Send to LIS] and/or [Print order].
5. NOTE: The Option to “Sign order when signing slide” is not available if the slide is part of a multi-slide order; all slides must be signed before the order can be signed. The order cannot contain a slide that has “Confirm Cell Counter”.



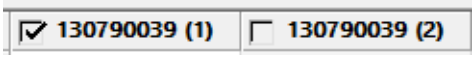
6. To merge multiple slides from an order, click the [Slide Merge] tab 

in [Report View]  OR Click Yes on the pop-up window after reviewing the last slide.

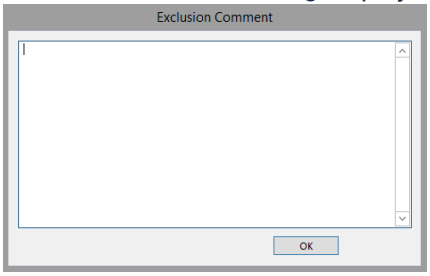


Results from all slides in the order display. (only signed slides can be included).

a. Click in the check box next to a slide ID to include it in the results of the order.



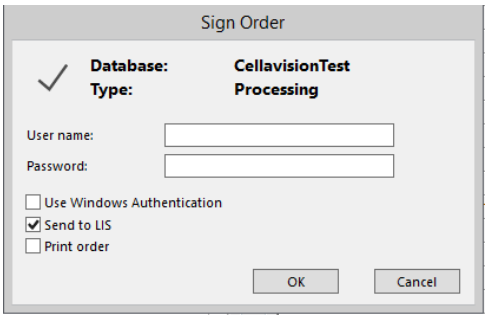
If a slide is excluded, a dialog displays to enter the explanation of exclusion.



b. Review the reported result column before signing the order. The reported result column results will cross into the LIS. 

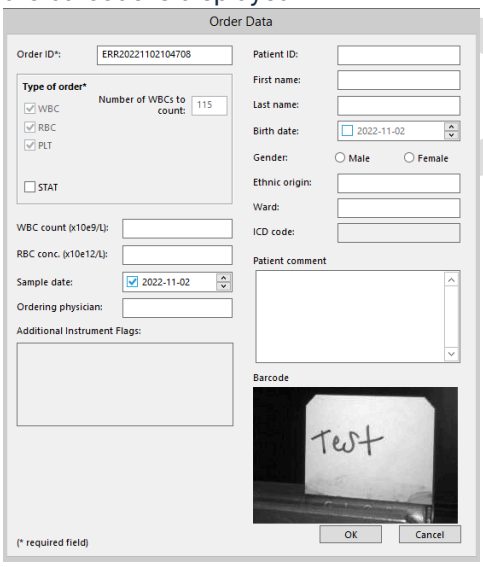
c. Click the sign order icon. 

d. Enter Username and Password.

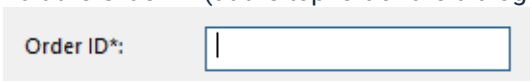


e. If not already selected (as default settings), select [Send to LIS] and/or [Print order].

7. NOTE: Rules will trigger the results to hold in the middleware after signing out the slide in Cellavision. Check the middleware to see if any comments or results should be added and then Validate All.
8. Barcode errors on slides can be edited in Order Data and reported to the LIS.
    a. Prior to reviewing the slide, double-click on the error slide/order to open the Verification view screen. Click on the [Order Data] icon.  An image of the barcode is displayed.



b. Edit the Order ID (at the top left of the dialog box) with the correct number.



c. When the slide/order is signed, the results will be sent to the LIS.

IX. TROUBLESHOOTING:

A. For comprehensive information on troubleshooting, refer to the Troubleshooting Section of the Sysmex DI-60 IFU or the CellaVision DC-1 Instructions for Use.

B. If the system fails the startup test, log off and power off the computer, and log back on before attempting other corrective action.

C. When troubleshooting the system, note the circumstances under which the error occurred and refer to the Troubleshooting Chart in the User's Manual to determine resolutions.

D. For jammed or broken slides, refer to the DI-60 User's Manual for complete instructions and images.

E. **GRIPPER SERVICE**: to Release a Stuck Slide

1. Go to Maintenance, click Gripper Service.
2. Click OK.
3. Wait until The gripper is in service position dialog appears.
4. Open the hood.
5. Remove the slide.
6. Close the hood.
7. Restart the slide scanning unit and the CellaVision software.
8. For jammed magazines, refer to the User's Manual for complete instructions and images.

F. Emergency Shutdown:

1. DI-60: Switch the slide scanning unit (SSU) on the front of the unit.
2. DC-1: Select Exit from the File menu.
    a. Click Start, select Power, and then select Shutdown.
    b. Press the Stand-by button on the analyzer.
        i. NOTE: make sure the input hatch is closed when the analyzer is not in use.

X. REFERENCES:

1. Sysmex XN-9100 Instructions for Use (North American Edition), Sysmex Corporation, Kobe, Japan.
2. Sysmex XN series Administrator's Guide (North American Edition), Sysmex Corporation, Kobe, Japan.
3. Clinical and Laboratory Standards Institute (CLSI). Laboratory Documents: Development and Control; Approved Guideline; Fifth Edition. (GP2-A5, 2006).
4. Sysmex DI 60 Instructions for Use, Sysmex Corporation, Kobe, Japan
5. Koepke, John. Practical Laboratory Hematology. Churchill Livingstone Inc. 1991. p. 24-25, 36-39.
6. Sysmex Reagents of America, Inc. MSDS sheets and reagent product inserts.
7. College of American Pathologists (CAP) Hematology-Coagulation Checklist,
8. Stewart, Charles and Koepke, John. Basic Quality Assurance Practices for Clinical Laboratories, Van Nostrand Reinhold, 1989, p 189.
9. Sysmex XN-Series Automated Hematology Systems Flagging Interpretation Guide, Document Number: 1166-LSS
   Reagent Unit RU-20 Instructions for Use. Sysmex Corporation, Kobe Japan
10. Release Information, CellaVision® Body Fluid and Advanced RBC Applications.
11. XN Series Influence of Interfering Material on Hematology Parameters, Document Number:

1028-MKT

12. Cellavision DC-1 Quick Guide, Sysmex America, Document Number 1529 - CFL Rev 3, 10/2020.
13. CellaVision DC-1 Instructions for Use, Use v7.0, Sysmex Corporation, Kobe, Japan, Document Number PM-10895-01, Rev 2021-10-31.

Attachments

b64_048fe36e-f8eb-4429-a48a-c785afe3a237

b64_cbebdd4c-c21f-47d6-8134-efaad3a5b68b

b64_e325bd97-6145-482b-8063-5198af9e0afb

b64_f8afdfc0-0a65-4f04-b970-a0492c181cdb

Approval Signatures

Step Description	Approver	Date
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	Hassan Kanaan: OUWB Clinical Faculty	7/31/2024
	Jeremy Powers: Chief, Pathology	7/29/2024
	John Pui: Chief, Pathology	7/29/2024
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Ashley Beesley: Mgr, Laboratory	5/14/2024
Kristen DiCicco: Mgr, Laboratory	5/7/2024
Megan Masakowski: Mgr, Division Laboratory	4/18/2024

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne