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Data Innovation (DI) Instrument Manager Hematology Workspace Middleware for Sysmex XN and XN-L Series Analyzer

Purpose

This procedure provides instructions for results review and release process for the SYSMEX XN and XN-L series hematology analyzers, which are connected to the Data Innovation Instrument Manager and its middleware rules.

Principle

Instrument Manager, the flagship product from Data Innovations (DI), provides seamless connectivity and enables seamless integration across lab environments, supporting various instruments, including the SYSMEX XN and XN-L analyzers. The system is a tailored productivity solution that helps streamline lab processes, allowing staff to focus on critical tasks and enhance operational simplicity, standardization, and overall efficiency in laboratory environments.

Data Innovations Instrument Manager Hematology Workspace allows the middleware to automatically release results to the LIS that meet the customer-defined rule criteria. The results can be auto validated without further operator intervention to improve laboratory productivity and reduce the amount of time spent reviewing normal data.

Data Innovation Instrument Manager Hematology Workspace provides a sophisticated rule engine that allows real-time data checking based on test results, analyzer flags, and/or user-selected rule definitions.

Scope

The autoverification criteria apply to the SYSMEX XN & XN-L series analyzers in utilizing Data Innovation (DI) Instrument Manager (IM).

This procedure should be performed by a trained Clinical Laboratory Scientist (CLS) or Medical Laboratory Technician (MLT).

Policy

The list below states the policies followed by the organization:

- A licensed person must be physically present on-site in the clinical laboratory whenever auto verification is performed. They are responsible for the accuracy and reliability of the results being reported. The operator is responsible for suspending auto-verification in case of a problem with the test method, analytical instrument, or auto-verification criteria.
- The operator must ensure that all quality controls are performed within the appropriate time intervals with acceptable results before performing patient testing.

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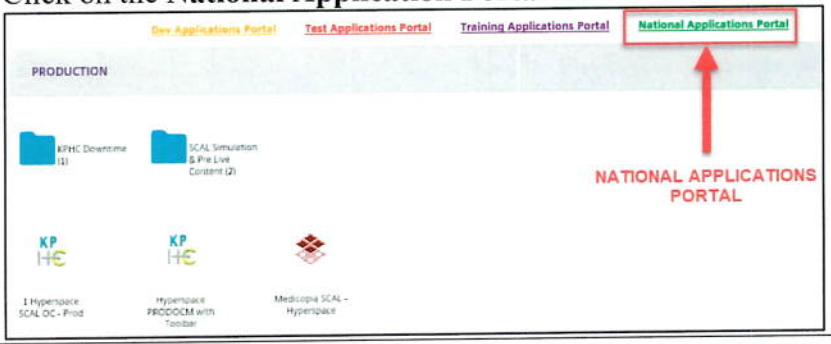
- If a problem is encountered with an instrument, the operator can turn off auto verification with menu options. When issues are resolved, auto verification may be turned back on.
- The Specimen Management Workspace in Instrument Manager is for results that meet the pre-established laboratory criteria of the middleware rules. The licensed laboratorian must investigate and make possible interventions before review/release.
- An audit trail will be used to identify all individuals who have entered or modified patient data or control files. If auto verification is used, the audit trail in the laboratory system should reflect that the result was verified automatically at a given date and time.
- Instruments that have autoverification enabled must be validated initially and at least annually or when there is a change to the system that could affect the autoverification logic and to confirm that algorithm decision rules are functioning correctly.

Safety

Refer to the safety manual for general safety requirements.

Logging In to Instrument Manager Procedure

Follow the steps below to log in to Instrument Manager.

Step	Action
1	Double-click on the **Regional Application Portal** icon on the desktop
2	Click on the **National Application Portal link.** 
3	Double-click on the **Instrument Manager SCAL (2)** icon.  **Note:** Use the folder listed above. Do not use Instrument Manager (1) or Instrument Manager DR (1)

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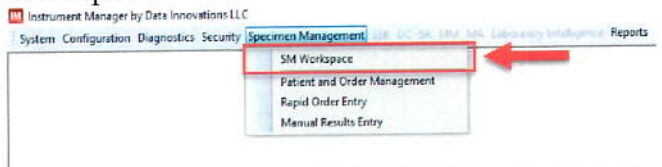
4	Double-click on the Instrument Manager icon 
5	When the Logon window displays, **enter your User ID (NUID)** and Password in the text field. The **password is your Windows** Active Directory password. Click Accept and Logon. 

Logging In to Instrument Manager Procedure, Continued

Instrument Manager Workspace	
Step	**Action**
1	The application will open after logging into the Instrument Manager. 
2	From the Specimen Management menu, click the SM Workspace. 
3	Click on the drop-down menu once the workspace window opens.

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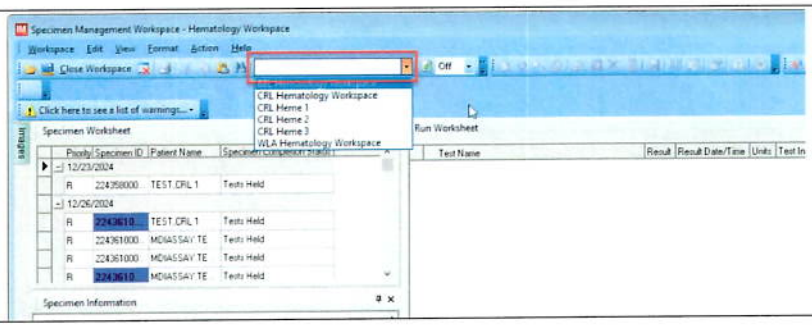
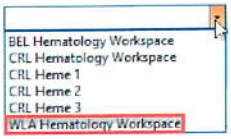
Data Innovation (DI) Instrument Manager Hematology Workspace Middleware for Sysmex XN and XN-L Series Analyzer, Continued

	
4	Select the instrument workspace for your site from the drop-down menu.  The window will populate, and the Specimen Worksheet pane will be populated with all the tests currently being held.

Logging In to Instrument Manager Procedure, Continued

Closing the DI IM Workspace	
Step	**Action**
1	Click on the "Close Workspace" button in the workspace window to close out of the IM Workspace using the Close. **Do not use the red "X" in the top right-hand corner of the window to close a workspace.** Doing so allows active workspace sessions to remain running in the background and will

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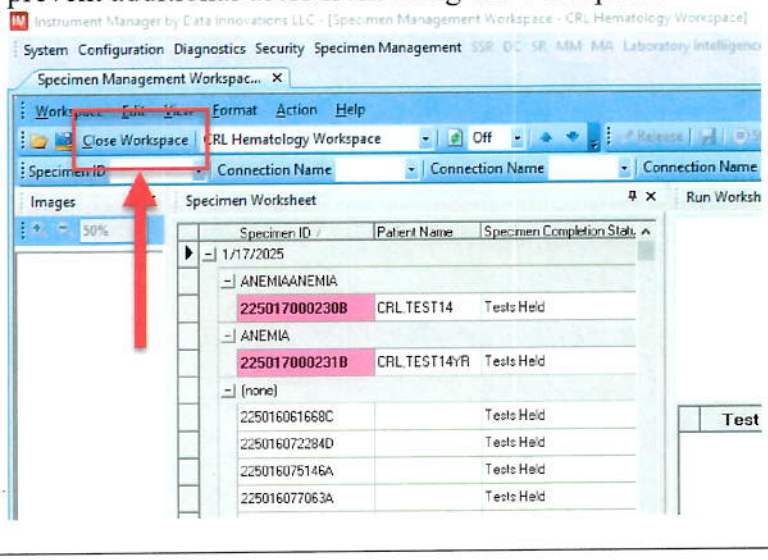
prevent additional users from using the workspace.

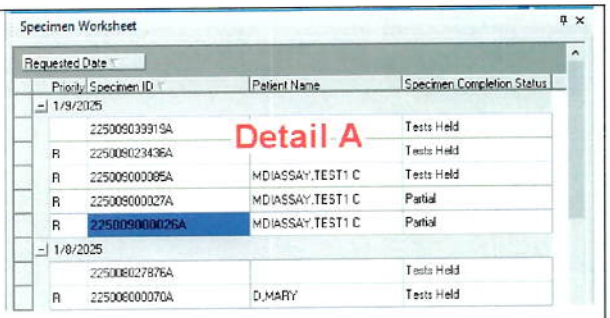


Result Review Overview Below is an overview of result review.

Specimen Worksheet

The Specimen Worksheet pane (Detail A) will display the following information:

- Order Priority
- Specimen ID (Accession Number)
- Patient Name
- Specimen Completion Status
  - Pending (The test has not been performed)
  - Test Held (The entire result is held)
  - Partial (Part of the order is held)
- Date



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Specimen Information

From the Specimen Worksheet pane, highlight the row with the accession number. The selected accession number will show the patient's demographics in the patient information pane (see Detail B).

The Specimen Information pane will display the following information:

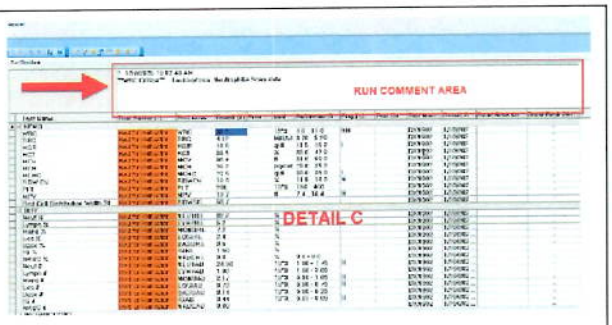
- Patient Name
- Patient ID (MRN)
- Specimen ID
- Operator ID
- Rack
- Location – Facility
- Patient Status
- Specimen Comment(s)
- Sex
- Date of Birth
- Patient Comment (s)
- Ordering Physician
- Position
- Location – Room
- Location – Bed
- Ordered Test

Result Review Overview, Continued

Run Worksheet

The Run Worksheet pane (Detail C) will display the test results, the appropriate flags, operator instructions, and the relevant directive or information on troubleshooting the specimen.

The Run Comment area of the Run Worksheet will display flags and rule comments for the displayed specimen. Run Comments alerts the user that criteria have been met to hold a specimen in the workspace and that further work may be needed by the user before release depending on the flag or rule that triggered for the specimen.



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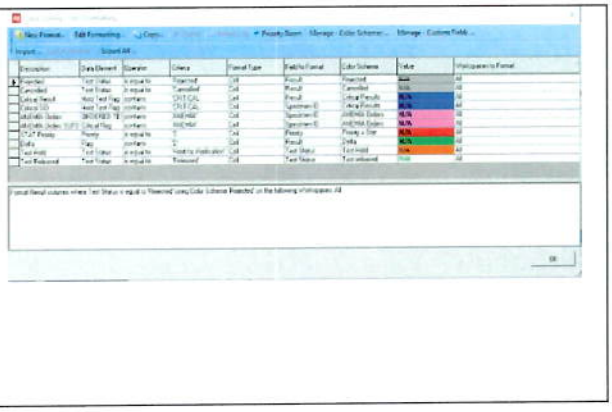
Color Coding

No Color		Routine
Gray		Cancelled Test
Purple		Critical Result
Pink		Anemia Panel
Red		STAT Order
Green		Delta Checks
Orange		Held For Verification



Result Validation Considerations

When validating results in the workspace, it is critical to decide what needs to be rejected versus released before results are released to Cerner. Once you have done so, it is preferred to reject results that you do not want prior to releasing any that you do. This is most important in the following scenarios.

1. Multiple runs from the instrument. Example: An individual CBC parameter reflexed a run based on individual rules. You would need first to reject the run that you do not want to be released before you release all other results.
2. Any peripheral smear sent to Cellavision will show as a separate run. If a manual differential was performed in Cellavision, you would want to reject the auto diff from the CBC run that you want to release so that the manual differential is released to Cerner.
3. Using the IM Cell Counter to perform a manual differential. If a manual differential were performed in the IM Cell Counter, you would want to reject the auto diff from the CBC run that you want to release so that the manual differential is released to Cerner.

Rejecting and Releasing Results

Different ways exist to reject or release results in the Specimen Workspace.

1. You can right-click on an individual result or test group and select reject or release from the menu.

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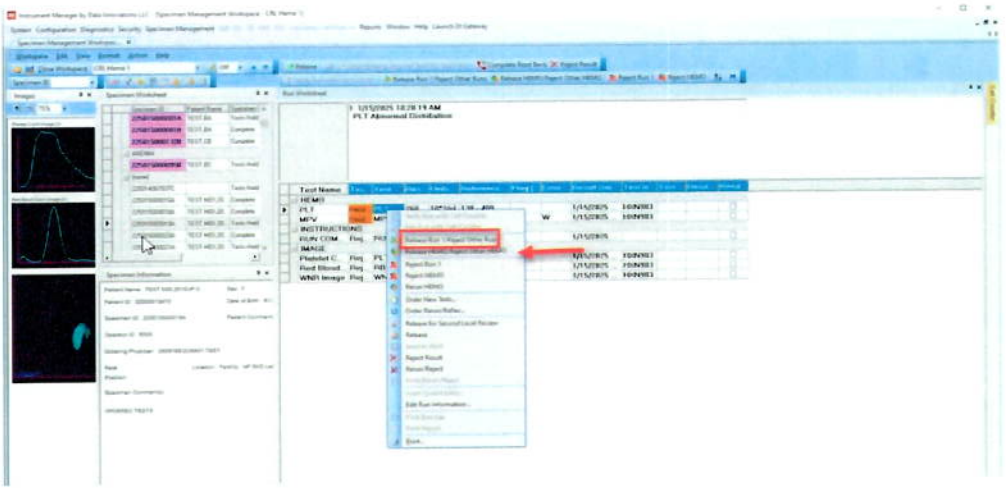
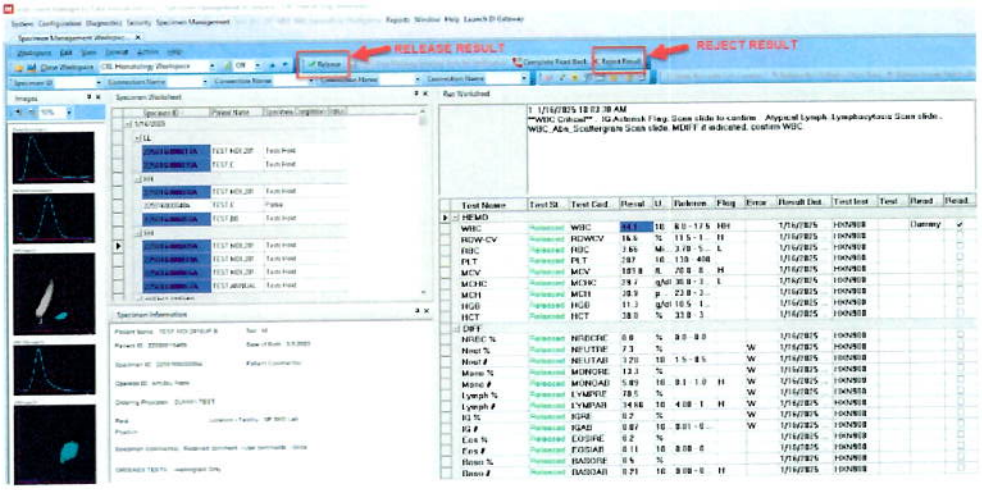


Rejecting and Releasing Results, Continued

2. You can select an individual result or test group and select the icons in the toolbar to reject or release.



3. You can release or reject an entire run using the icons in the toolbar or by right-clicking on the run and selecting Release Run #/Reject Other Runs or Reject Run #

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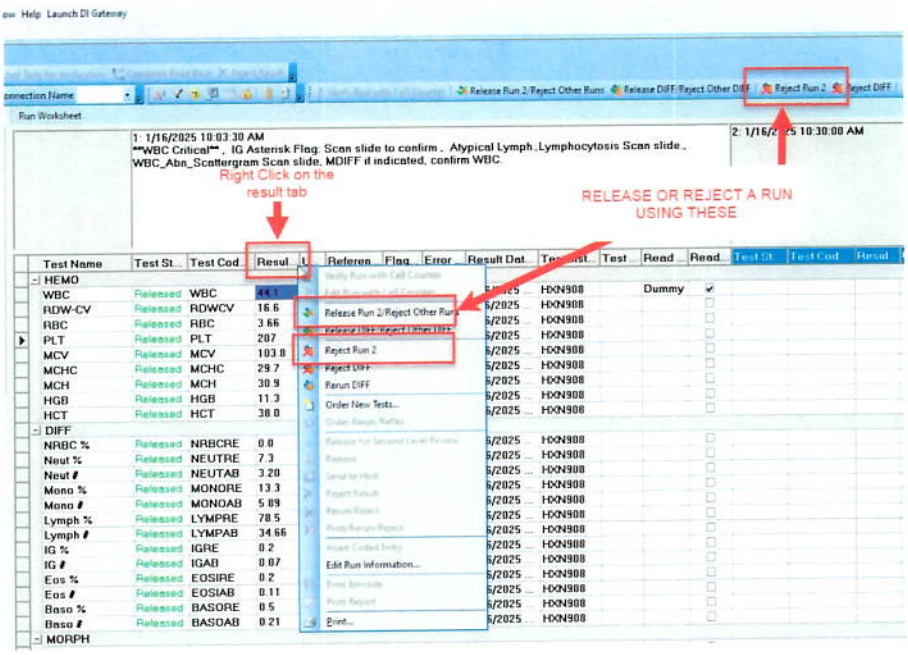

Repeating and Rerunning Tests

Follow the steps below to repeat and rerun results.

Step	Action
1	To identify the rack and location of the specimen to be repeated, in IM workspace right click on the acc# and click on specimen tracking.

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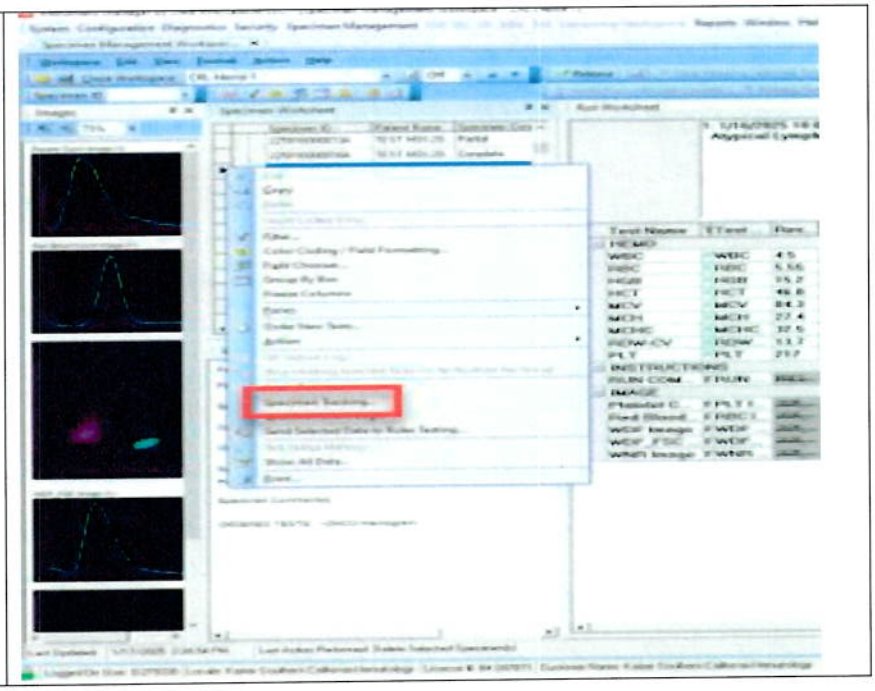
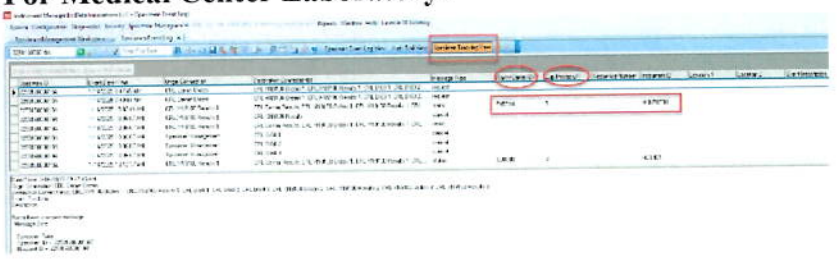
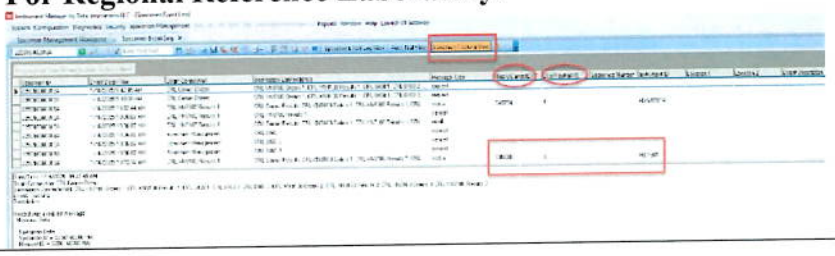


Repeating and Rerunning Tests, Continued

Step	Action
2	It will take you to the Specimen Event log window and specimen Tracking View will be highlighted. **For Medical Center Laboratory:**  **For Regional Reference Laboratory:** 

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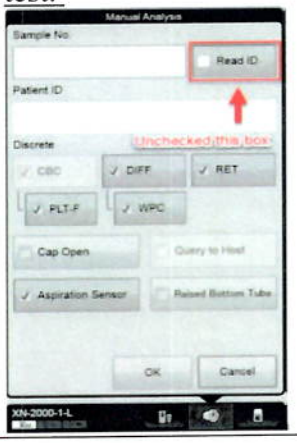
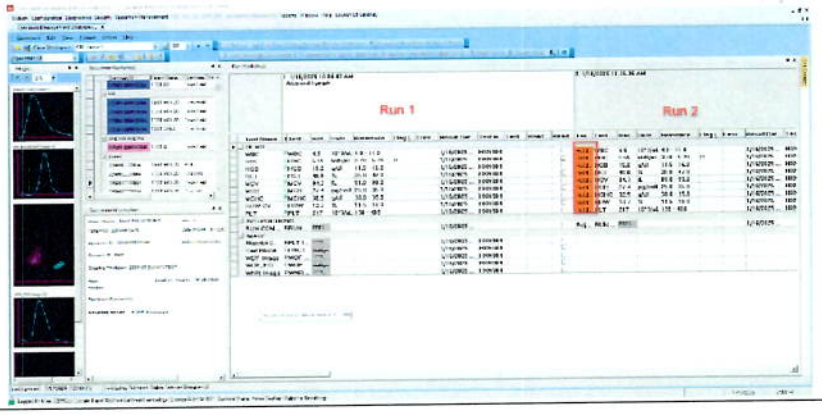
Repeating and Rerunning Tests, Continued

Step	Action
3	Rerunning samples must be performed in manual mode ONLY. **Make sure the Read ID button is <u>unchecked</u>.** Barcode must be scanned or entered manually for it to be processed. <u>NOTE: Rerunning samples by means of loading them on the Sysmex racks (RACK MODE) will not run the desired discrete test.</u> 

Repeating and Rerunning Tests, Continued

Step	Action
4	Along with the default test set on the XN, check the desired discrete test that is needed to be rerun.
5	Reruns will show in IM Workspace as a separate run and will be held. 

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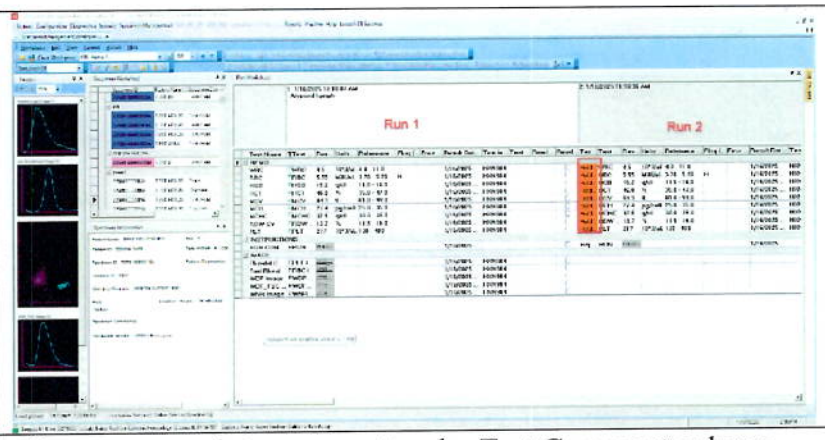
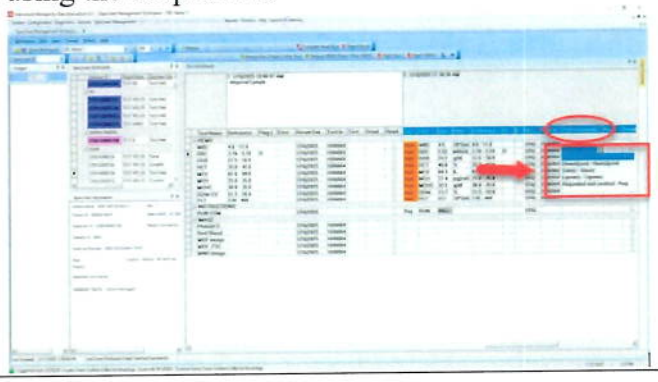
Data Innovation (DI) Instrument Manager Hematology Workspace Middleware for Sysmex XN and XN-L Series Analyzer, Continued

	
6	Choose appropriate comment under Test Comment column using the drop down. 

Specimen Dilution

Specimen dilutions are performed to verify and troubleshoot results that are above analytical reported ranges, linearity ranges or troubleshooting suspect flags. Refer to the Run Comment section for instructions for necessary dilutions.

Note: Perform Dilution using Manual Mode ONLY. Do not use the 1:7 Dilution on the XN analyzer.

Step	Action
1	On a separate tube, dilute the sample according to the Run Comment instruction with CellPack DCL
2	Reprint the accession label and place it on the diluted sample.
3	Run the sample manually on the XN analyzer. Mix the sample well by gentle inversion before running.
4	Using the accession number including the container letter, manually program the accession number on the sample no. Field

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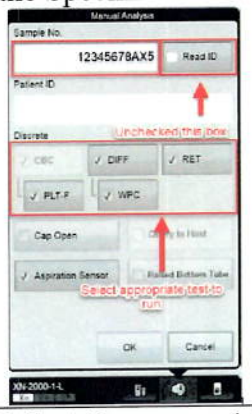
	and add "X#." The "#" represents the dilution factor applied on the dilution. **Example:** You have a flag for Retic Abnl Scattergram that requires times 5 dilution. Your accession number is 1-24-123-45678A. In the XN manual analysis screen remove the Read ID check mark and enter 1412345678AX5 or 1412345678x5 into the Specimen No. 
5	Select the appropriate test to run and whether "Aspiration Sensor" needed
6	Results are calculated in the Instrument Manager Worksheet screen
7	Enter the dilution in the dilution field of the Rerun tab
8	Complete the result release process if no other troubleshooting is necessary.

CellPack Replacement

Cell Pack replacement is performed to troubleshoot results affected by cold agglutinin, lipemia or icteric which can cause erroneous results. Refer to the Run Comment section for instructions for necessary troubleshooting guides.

Step	Action
1	Reprint the accession label and place it on the DCL Replacement sample
2	Mix well and rerun the specimen **immediately** after prewarming.
3	Using the accession number including the container letter, manually program the accession number on the sample no. Field and add "-SAL."

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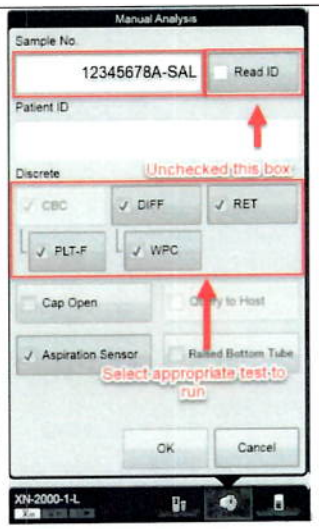
Data Innovation (DI) Instrument Manager Hematology Workspace Middleware for Sysmex XN and XN-L Series Analyzer, Continued

	
4	Select the appropriate test to run and whether "Aspiration Sensor" needed
5	When a sample is rerun with an"-SAL" following an accession, the WBC and PLT is automatically rejected
6	Complete the result release process if no other troubleshooting is necessary. Select the WBC and PLT from the original run.

Sample Incubation

Perform the CellPack replacement as described on the Analytical Interference on CBC Samples Procedure

1	Incubate the CBC sample in a 37°C dry bath for at least 15 minutes
2	Reprint the accession label and place it on the diluted sample.
3	Mix well and rerun the specimen **immediately** after prewarming.
4	Using the accession number including the container letter, manually program the accession number on the sample no. Fielc and add "-INC."

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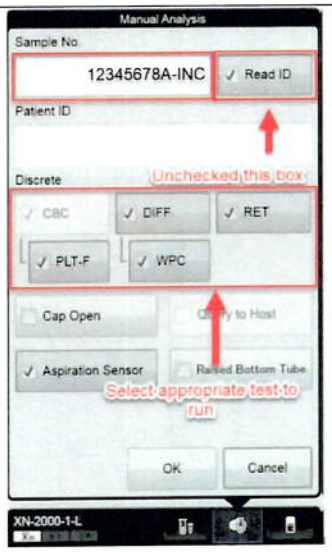
Data Innovation (DI) Instrument Manager Hematology Workspace Middleware for Sysmex XN and XN-L Series Analyzer, Continued

	
5	Select the appropriate test to run and whether "Aspiration Sensor" needed
6	Complete the result release process if no other troubleshooting is necessary.

Specimen Comments

Specimen comments can be added in the Test Comments of the Run Worksheet, the rest need to be entered in the Cell Counter. Comments that will replace a numeric result need to be completed in the Cell Counter (ex. platelet clumps or a dimorphic RBC population).

Comments that can be selected from the drop-down in the Test Comment field in the run worksheet include:

Comment	Test Comment
PWAR	Cold agglutinin present. CBC was done on a prewarmed sample. 
PLCLUMP	Platelet clumps present which may be due to the EDTA anticoagulant. Please redraw in both EDTA and Sodium Citrate to rule out clumping due to EDTA. 

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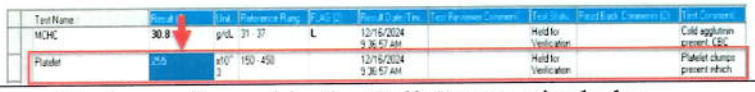
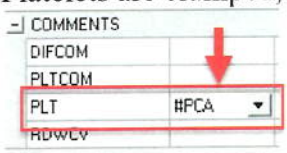
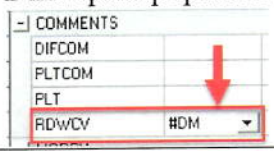
PLTCLUMP	Unable to perform platelet count due to clumping in EDTA. 
Comments that need to be performed in the Cell Counter include:	
PCA	Platelets are clumped, but appear adequate in number 
PCD	Platelets are clumped, but appear decreased in number
PCI	Platelets are clumped, but appear increased in number.
DM	Dimorphic population of cells 

Specimen Comments, Continued

Note: If you have replaced a numeric result with a comment you will need to also go to the Cerner and verify the results. When the Cerner is expecting a numeric result and receives a free text comment the results stay at a performed status

- **Example**: PLT comments in the PLT test field of the Cell Counter or a dimorphic red blood cell population comment in the RDWCV test field of the Cell Counter.

Comments generated by IM as prompts for techs are shown in the Test Reviewer comments field.

- **Example**: Pathology Review criteria met, dilution needed, and specimen exceeds stability.

Manual Differential Count Procedure

White Blood Cell (WBC), Red Blood Cell (RBC), and Platelet (PLT) Differential analysis can be conducted using the SYSMEX Cellavision DI-60 Digital Imaging Analyzer. For comprehensive instructions, please refer to Sysmex DI-60 Automated Digital Morphology Analyzer Policy and Procedure.

Step	Action
1	The Cell Counter window is where the manual differential is counted on the 10-key numeric keypad. To activate it from the

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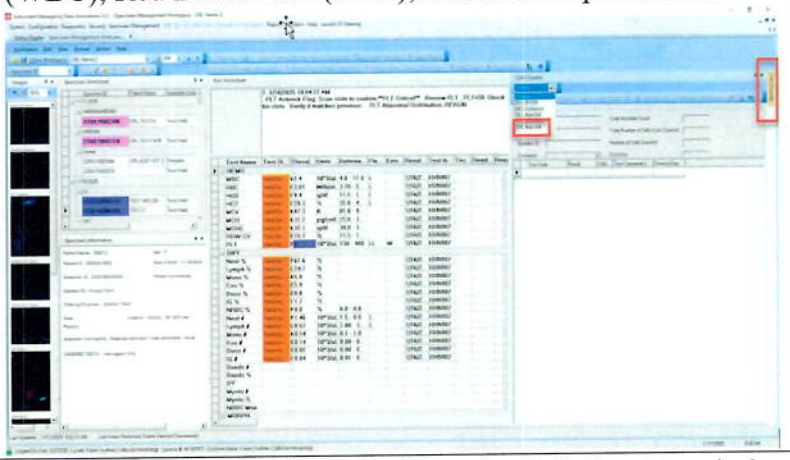
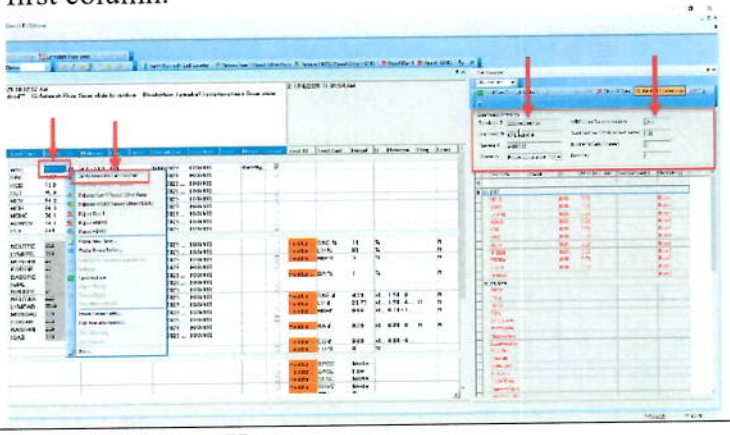
	Specimen Management Workspace, click on the Cell Counter tab on the right side of the window or go to the view menu, select panes, then select cell counter. Click on the drop-down arrow to select your site-specific manual differential interface. The Cell Counter window will populate with White Blood Cell (WBC), Red Blood Cell (RBC), and Platelet parameters. 
2	For your specimen to be pulled into the Cell Counter window and the absolute white cell values to be correct, you must first click on the WBC value in the Run Worksheet to highlight it. Then select the Verify Run with Cell Counter button on the tool bar. This brings the specimen into the cell counter. After doing so, you will now note that the LIS accession number is in the Specimen ID field and the total WBC value is in the Total Absolute count field. Cells and counting keys are denoted in the first column. 
3	1. Cell Counter Keys

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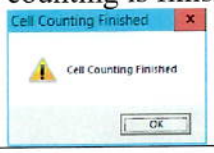
Data Innovation (DI) Instrument Manager Hematology Workspace Middleware for Sysmex XN and XN-L Series Analyzer, Continued

	If not enabled, click the Cell Counter Keys from the menu to utilize the Cell Counter keys. Using the number keys associated with each cell type, perform the manual differential until the number of cells counted equals the number of cells to be counted. 2. Manual Entry For the manual of the differential count, click on the cell type and manually type in the value for each cell type. **Note:** The Total Number of Cell to be Counted can be changed for differential with very low White Blood Cell Count (WBC).
4	Once the cell counter has reached the total number of cells to be counted, a window will pop up alerting the user that the cell counting is finished. 

Manual Differential Count Procedure, Continued

Step	Action
5	**Morphology:** This is where morphology and any appropriate comments are entered. Select the associated coded comment in the result field. • RBCM is a required test field: Select (Reviewed) if RBC morphology is reported. Select (Normal) if the RBC morphology is normal. • PLTE is a required test field. Select the appropriate result from the coded results dropdown (Adequate, Decreased, Increased, Significantly Increased). **Note:** Failure to result either RBCM and/or PLTE will cause the sample to remain pending in the LIS.

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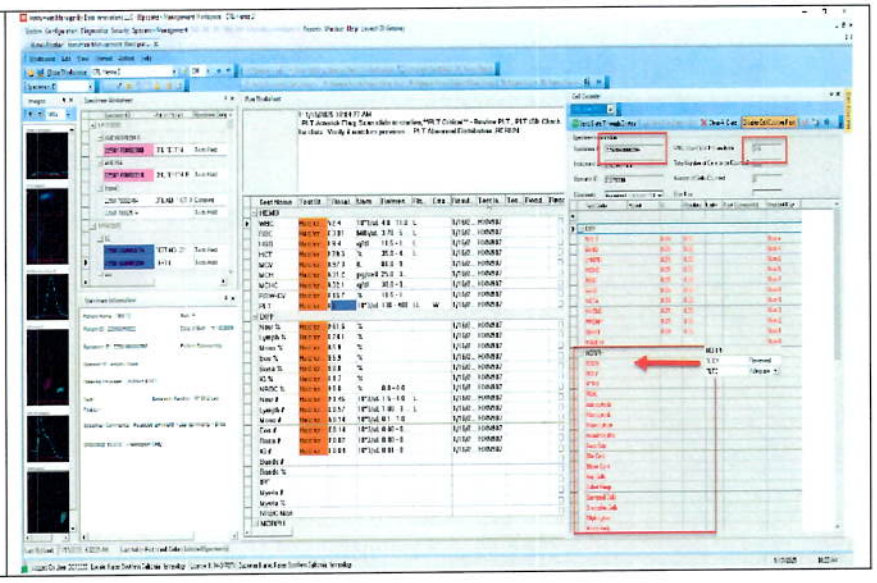
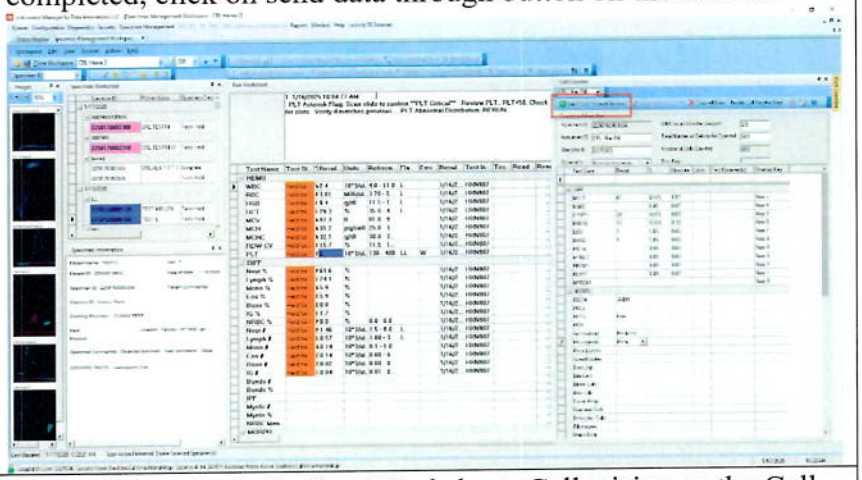
Data Innovation (DI) Instrument Manager Hematology Workspace Middleware for Sysmex XN and XN-L Series Analyzer, Continued



Manual Differential Count Procedure, Continued

Step	Action
6	Once counted, and morphology and platelet estimate has been completed, click on send data through button on the tool bar. 
7	Once all the tabs in the Run Worksheet, Cellavision or the Cell Counter have been reviewed, and manual results and comments entered the sample is ready for release to Cerner. **Note:** It is important to reject all other results/runs before releasing the results so that a single XN run, differential, either auto or manual, and morphology are released to Cerner simultaneously.

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Data Innovation (DI) Instrument Manager Hematology Workspace Middleware for Sysmex XN and XN-L Series Analyzer, Continued

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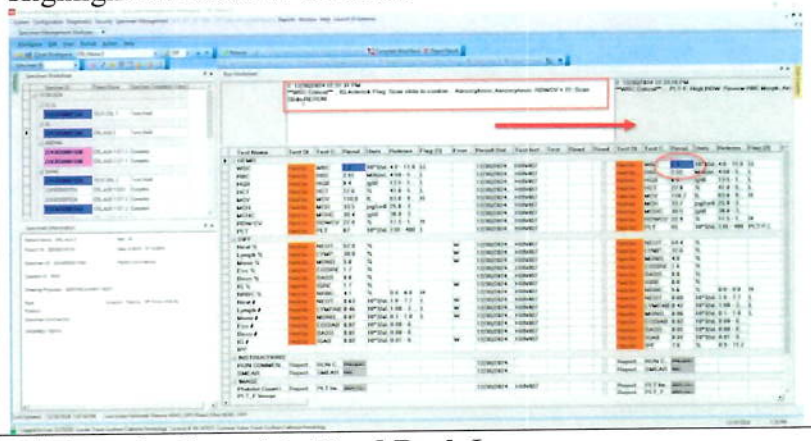
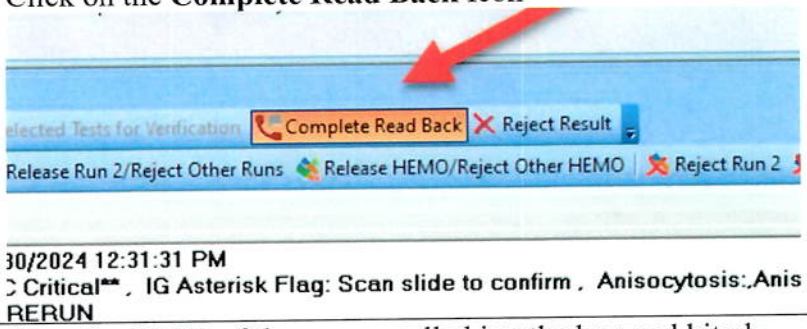
Critical Call Documentation

All critical results will be highlighted in Purple and will be grouped whether it is Critical Low (LL) or Critical High.

Step	Action
1	Highlight the result to be called 
2	Click on the **Complete Read Back** Icon 
3	Enter the NUID of the person called ion the box and hit ok.

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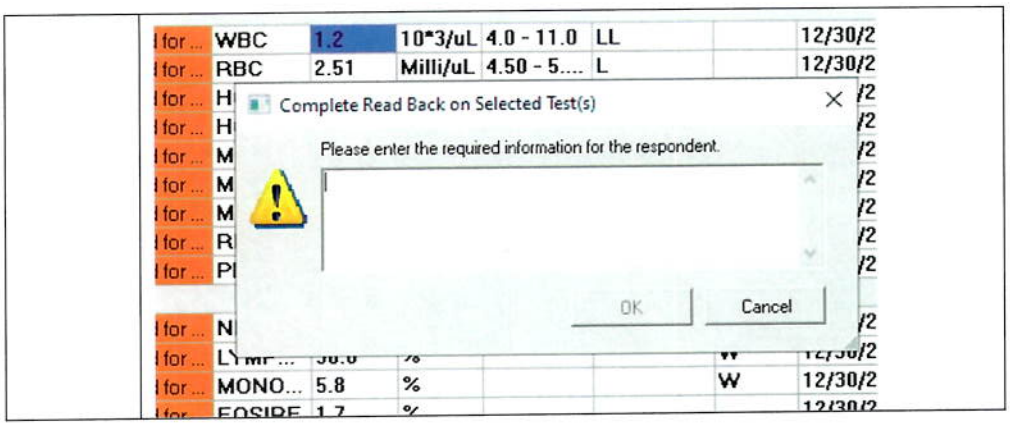
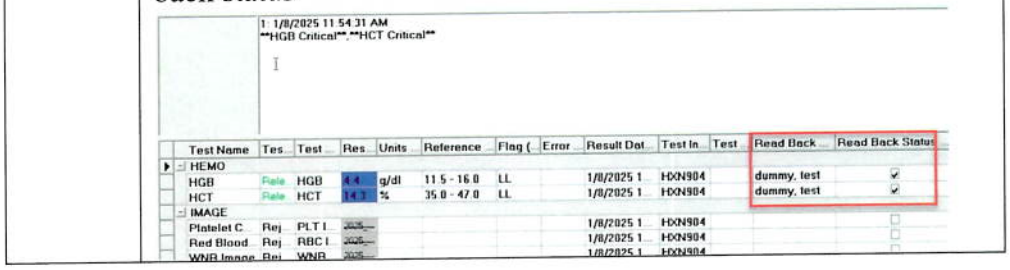
Data Innovation (DI) Instrument Manager Hematology Workspace Middleware for Sysmex XN and XN-L Series Analyzer, Continued



Critical Call Documentation, Continued

Step	Action
4	Once documentation is completed, the NUID of the person called should show on your Run worksheet and a √ on the read back status



Body Fluid Analysis

This procedure describes how to result a body fluid cell count performed on the SYSMEX XN series analyzer or manual hemacytometer and cell differential using the Data Innovation Instrument Manager middleware.

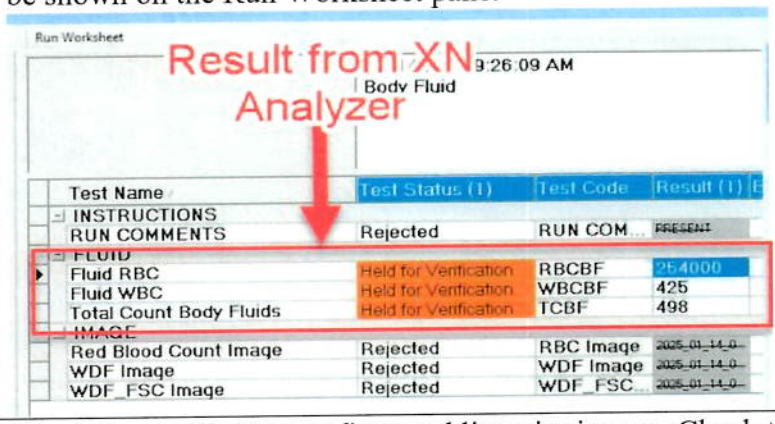
NOTE: For comprehensive instructions on performing Body Fluid Cell Count on the XN Series Analyzer or Manual Cell Count using a Hemocytometer, please refer to local Policy and Procedure.

Step	Action
1	Perform the automated body fluid cell count by running the approved body fluid source(s) on the Sysmex XN series analyzer.

Continued next page

Data Innovation (DI) Instrument Manager Hematology Workspace Middleware for Sysmex XN and XN-L Series Analyzer, Continued

Body Fluid Analysis, Continued

Step	Action
2	From the Specimen Worksheet pane of the Instrument Manager, select the Specimen ID of the body fluid sample. The result will be shown on the Run Worksheet pane. 
3	Check the results for any flags and linearity issues. Check the run Comment sections for any troubleshooting flags and comments.
4	Perform the gross examination and differential of the specimen if there are no issues found with the automated results. Gross examination and fluid differential can be done through the Cell Counter window.
5	Click on the TC value in the Run Worksheet to highlight it. Then select the Verify Run with Cell Counter button on the tool bar. This brings the specimen into the cell counter

Body Fluid Analysis, Continued

Step	Action
6	Ensure that the appropriate site and module from the dropdown menu is selected.

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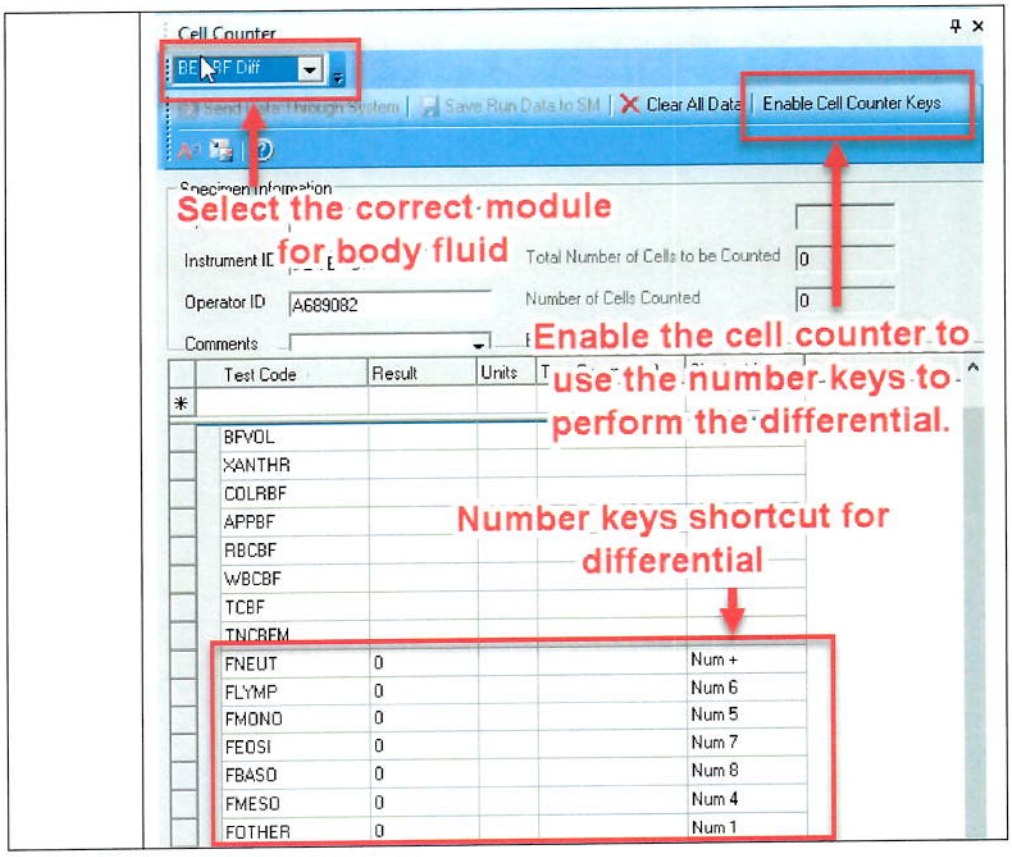
Data Innovation (DI) Instrument Manager Hematology Workspace Middleware for Sysmex XN and XN-L Series Analyzer, Continued



Body Fluid Analysis, Continued

Step	Action
6	Using the counter key, perform the Body Fluid Differential. Counting will automatically stop at 100 cell count.

TEST	COUNTER KEY
FNEUT	+
FLYMPH	6
FMONO	5
FMESO	4
FEOSI	7
FBASO	8
FOTHER	1

Continued next page

Data Innovation (DI) Instrument Manager Hematology Workspace Middleware for Sysmex XN and XN-L Series Analyzer, Continued

7	Click the "**Enable Cell Counter Keys**" to use the number keys to perform the Cell differential or input the value for each cell type directly on the result field that corresponds to each cell.

Body Fluid Analysis, Continued

Step	Action
8	Perform the gross examination by completing the following parameters, if applicable:

Test Code	Interpretation
BF Volume	**Body Fluid Volume (If Applicable)** Manually enter BF total volume (if applicable)
XANTHR	**Xanthochromia (If Applicable)** From the dropdown, enter Xanthochromia response • YES • NO
COLRBF	**Body Fluid Color** From the dropdown, enter body fluid color response • COLORLESS • YELLOW • PINK • RED
APPBF	**Body Fluid Appearance** From the dropdown, enter body fluid appearance response • BLOODY • CLEAR • CLOUDY • CLOTTED • HAZY • SLIGHTLY HAZY
RBCBF	**Red Blood Cell Body Fluid** Total RBC Count result from the automated BF analysis
WBCBF	**Total White Blood Cell Body Fluid** Total WBC Count result from the automated BF analysis
TCBF	**Total Nucleated Cell Body Fluid** Total TNC Count result from the automated BF analysis

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Data Innovation (DI) Instrument Manager Hematology Workspace Middleware for Sysmex XN and XN-L Series Analyzer, Continued

	TCBFM	**Total Nucleated Cell Body Fluid** Total TNC Count result from the manual BF analysis

Body Fluid Manual Cell Count (Hemacytometer)

If a Manual Cell Count using a hemacytometer is warranted, the user can place the raw data into the cell counter and instrument manager will perform the calculation.

Manually enter the hemocytometer results in the following field **HEMOCYTOMETER GROUP.**

Test Code	Interpretation
TCSQSZ/ RBCSQS	**TOTAL NUCLEATED / RED BLOOD HEMACYTOMETER CHAMBER SQUARE TYPES COUNTED** Select which square counted on the hemacytometer • Large • Small
TNCSD1/ RBCSD1	**RAW COUNT ON ONE CHAMBER OF THE HEMOCYTOMER** Manually enter the TNC or RBC raw count of one chamber of the hemacytometer
TNCSD2/ RBCSD2	**RAW COUNT ON THE OTHER CHAMBER OF THE HEMOCYTOMER** Manually enter the TNC or RBC raw count of the other chamber of the hemacytometer **NOTE:** The counts from each chamber must agree within an established bias or the count must be repeated.
TCDIL/ RBCDIL	**DILUTION FACTOR** Manually enter the dilution factor. If no dilution performed enter 1
TCSQ/ RBCSQ	**NUMBER OF SQUARES COUNTER IN EACH CHAMBER OF THE HEMACYTOMETER** Manually enter the number of squares counted

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Data Innovation (DI) Instrument Manager Hematology Workspace Middleware for Sysmex XN and XN-L Series Analyzer, Continued

Body Fluid Manual Cell Count (Hemacytometer), Continued

After completing the body fluid differential, gross examination, or the manual cell count, select the "**Send Data Through System**" to activate the calculation in and send the results in the "Run Worksheet."

Test Code	Interpretation
TCSQSZ/ RBCSQS	**TOTAL NUCLEATED / RED BLOOD HEMACYTOMETER CHAMBER SQUARE TYPES COUNTED** Select which square counted on the hemacytometer • Large • Small
TNCSD1/ RBCSD1	**RAW COUNT ON ONE CHAMBER OF THE HEMOCYTOMER** Manually enter the TNC or RBC raw count of one chamber of the hemacytometer
TNCSD2/ RBCSD2	**RAW COUNT ON THE OTHER CHAMBER OF THE HEMOCYTOMER** Manually enter the TNC or RBC raw count of the other chamber of the hemacytometer **NOTE:** The counts from each chamber must agree within an established bias or the count must be repeated.
TCDIL/ RBCDIL	**DILUTION FACTOR** Manually enter the dilution factor. If no dilution performed enter 1
TCSQ/ RBCSQ	**NUMBER OF SQUARES COUNTER IN EACH CHAMBER OF THE HEMACYTOMETER** Manually enter the number of squares counted

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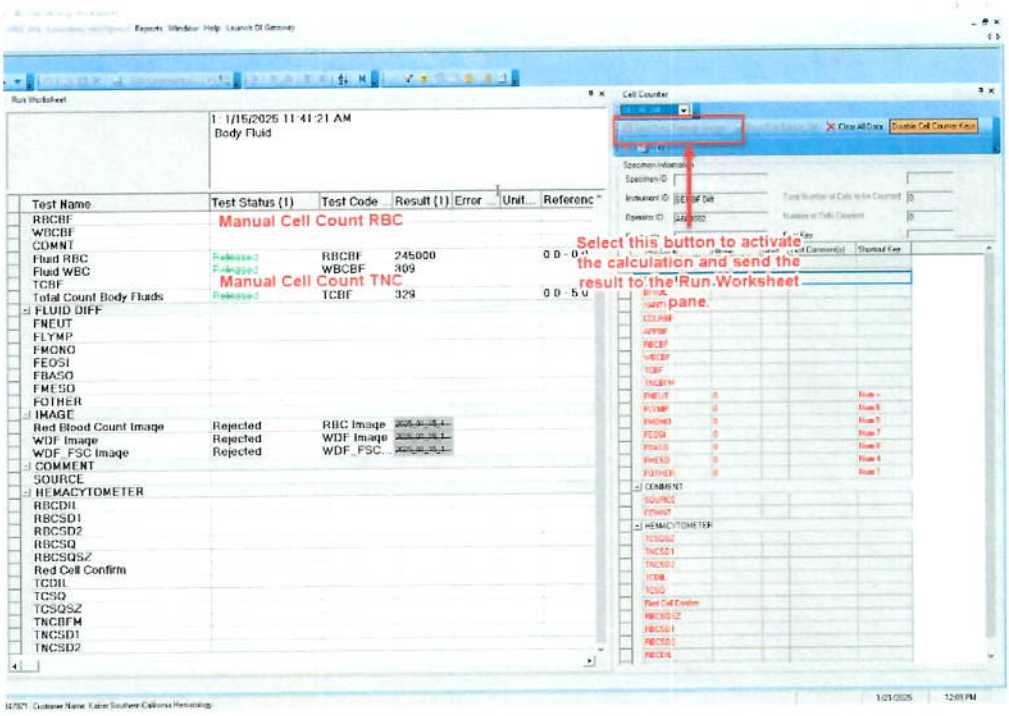
Data Innovation (DI) Instrument Manager Hematology Workspace Middleware for Sysmex XN and XN-L Series Analyzer, Continued

Body Fluid Manual Cell Count (Hemacytometer), Continued



Calculations

The following Calculations are performed by the Data Innovation Instrument Manager

Manual Differential Absolute Calculations

- WBC x (NEUT% + BAND%) /100 = ANC
- WBC x (LYMPH% + ATYLY%) /100 = ALC
- (MONO% x WBC)/100 = MONOAB
- (EOS% x WBC)/100 = EOSAB
- (BASO% x WBC)/100 = BASOAB

Body Fluid Calculation

- TNCBFM - (TNCBFM x (FMESO + FOTHER)/100)

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Data Innovation (DI) Instrument Manager Hematology Workspace Middleware for Sysmex XN and XN-L Series Analyzer, Continued

Interpretation / Results / Alert Values	N/A
Limitations	N/A
Controlled Documents	The following controlled documents support this policy. **None**
Non-Controlled Documents	The following non-controlled documents support this policy. Data Innovations Specimen Management Instrument Manager™ User guide Version v8.16 MR1 Date of Issue: 2018.06.29
Author(s)	• *Hematology Working Group*

Regional Parent Document Reference Number: SCPMG-PPP-0616 Rev: 01

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Signature Manifest

Document Number: RIV-PPP-1201 **Revision:** 01

Title: DI Middleware for Sysmex XN and XN-L Series Analyzer

Effective Date: 10 Mar 2025

All dates and times are in Pacific Standard Time.

Hematology Regional Documents

Operations Director Approval

Name/Signature	Title	Date	Meaning/Reason
Annaleah Raymond (Q741709)	Laboratory Operations Director	06 Feb 2025, 04:50:30 PM	Approved

Medical Director Approval

Name/Signature	Title	Date	Meaning/Reason
Mark Taira (P161328)	CLIA Director	09 Mar 2025, 07:05:24 PM	Approved