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Hematology Caresphere Operation

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document is to provide guidance for hematology staff regarding the operation and functionality of Caresphere Workflow Solutions (WS).

II. PRINCIPLE:

Caresphere™ Workflow Solution (WS) is a data management and processing system for Sysmex hematology medical devices. Caresphere WS is a clinical support enterprise-wide solution designed to provide laboratory professionals with assistance in automating decision making tasks and to be compliant with Health Insurance Portability and Accountability Act (HIPAA) security standards. Caresphere Workflow Solution manages communication with laboratory instruments, while minimizing laboratory information system connectivity to a single order and results interface using ASTM or HL7 protocol. Caresphere WS processes samples across integrated health networks to standardize the handling of sample results. Results are evaluated against a rule set that can be configured to meet each customer's needs and auto-validation goals. Additional capabilities include the ability to track key performance indicators such as turnaround time and rule statistics.

III. ACRONYMS:

- A. Caresphere Workflow Solution (WS)
- B. Complete Blood Count (CBC)
- C. Complete Blood Count (CBND)
- D. Complete Blood Count with Differential (CBCWD)
- E. Differential (Diff)
- F. Hematocrit (HCT)
- G. Hematology Sysmex Transport (HST)
- H. Instrument Flags (INSTFL)
- I. Laboratory Information System (LIS)
- J. Mean Cell Volume (MCV)
- K. Mean Corpuscular Hemoglobin Concentration (MCHC)

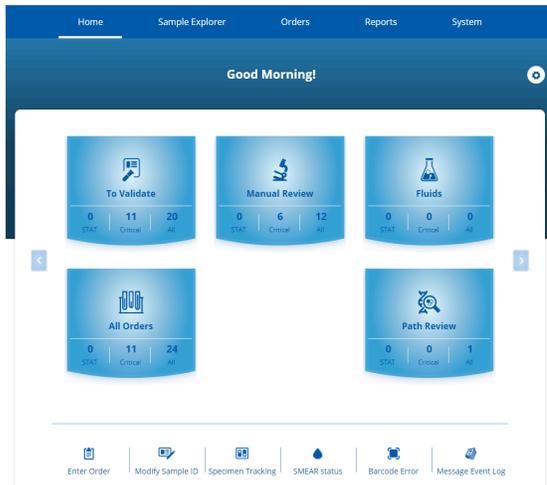
- L. Nucleated Red Blood Cell (NRBC)
- M. Platelet (PLT)
- N. Platelet Estimate (PLTE)
- O. Red Blood Cell (RBC)
- P. Red Blood Cell Morphology (RBCM)
- Q. White Blood Count (Reportable test code to the LIS) (WBC)
- R. White Blood Count (Original from Analyzer) (WBCOR)
- S. White Blood Count (Uncorrected from Analyzer) (WBCUN)
- T. White Blood Count Estimate (WBCEST)

IV. EQUIPMENT:

- A. Caresphere WS access via approved web browser
- B. Workstation
 - 1. Monitor - 1440 X 900 minimum resolution
 - 2. Web Browser minimum requirements
 - a. Google Chrome v.80.0.3987.149 preferred
 - b. Firefox v.74.0 or Safari v.13.0 are acceptable
 - 3. Network Printer
 - 4. LIS Interface to Caresphere WS
 - 5. Analyzer interface(s) to Caresphere WS

V. PROCEDURE:

- A. **Start-up:** To access the Caresphere WS software application, proceed as follows:
 - 1. Open web browser and proceed to site designated Caresphere WS
URL: <https://beaumonthealth.caresphere.sysmex.com>
 - 2. The Caresphere WS application will launch for immediate use.
 - a. Refer to downtime guidelines and/or contact IT for resolution if application fails to launch.
- B. **Log In:** The Log In box appears prompting entry of Username. (See your Caresphere WS Administrator for additional information.)
 - 1. Enter Username. Click Log In.
 - 2. Enter your Password and click Log In. You will be directed to the Home Page.



3. When logging in for the first time, a notification is sent to the customer's Caresphere WS Administrator defined within the Caresphere WS application to approve the user and allow access. Once assigned access rights, the user will be able to log in to Caresphere WS.
4. If unable to log in with assigned directory service credentials, contact IT department for assistance for access.

C. Log Out:

1. Click the user profile in the upper right-hand corner of the application.
2. Click Log Out.
3. Close the web browser.

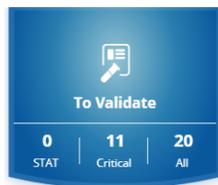
D. Site Selection:

If the user is assigned to more than one site, the system will default to the first site listed upon initial login. Subsequent logins will default to the last site accessed by that user.

1. To access a different site, the user can select the site from the drop-down menu at the top right of the screen. 

E. Result Validation:

1. From the Caresphere WS Homepage screen, select the To Validate panel.



- a. NOTE: The default setting for the To Validate panel is to allow only those Sample IDs with results that are pending, rerun, or to be validated.
2. The Result Validation screen will display for qualifying Sample IDs and results for selection and review.
 - a. **Sample list**
 - i. Sample IDs are displayed at the far right of the screen, in priority order.
 - ii. Sample IDs appear in alphanumeric order within each category.

Sample ID List	
	36 items
Time Limit	C S12345678901
Yellow box	C S12345678902
STAT	S12345678903
Red background with white letters	S12345678904
Critical	C S12345678537
Bold red C	S12345678321
Record Lock	S12345678321
Lock icon	S12345678537
	S12345678537
	S12345678537
Registered	S12345678537
White background, no highlighting	S12345678537
	S12345678537
Unregistered	S12345678537
White letters, blue background	S12345678537
	S12345678541

- iii. Click a Sample ID to display all applicable information.
- iv. A sample that is in use by another user will display in the Sample List with a lock icon to the right of the Sample ID. 
- v. The software performs a default scan of the database every 30 seconds to refresh the Sample List by adding new samples and removing fully validated samples.
- vi. Unregistered samples do not have an order from the LIS but have results. All Unregistered Sample IDs with pending orders will remain on the list until the order is validated or canceled by the user.

b. Result Color Coding: Results are color-coded to indicate their status:

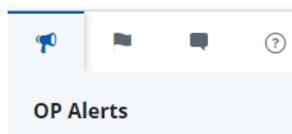
- i. Critical Results:
 - a. Critical low = Blue background/ Yellow letters
 - b. Critical high = Red background/Yellow letters
- ii. Delta Value:
 - a. Delta = Lime green background/Blue letters

F. Select Sample for Processing:

1. Select a sample ID from the sample list by clicking on the specific sample ID. To select a different sample ID, use the up/down arrows and select enter or click on a different sample ID.
2. Use scroll bar to view additional sample IDs.

G. Review the Operator Alerts:

1. Left side of screen contains Operator Alerts containing site specific instructions to process the specimen.



H. Select a Rerun (if applicable):

1. NOTE: Run 2 will automatically be selected. Follow the steps below to select another run if needed.
2. Click the Rerun button. 
3. In the Rerun screen, select the rerun to validate.
4. Click the top checkbox in the run to select.
 - a. Results from multiple runs may be selected by first selecting the top checkbox for the run containing the main results to be reported, then by selecting individual test checkboxes from a different run (i.e. Top checkbox for Run 1 selected, PLT checkbox selected for Run 2).
5. Click OK to accept the run selection and return to the Result Validation screen.

I. Add Test Level Code or Freetext Comment (if applicable):

1. In the Result Validation screen, click on the comment bubble for a specific test code. 
2. The Comment screen will display as a pop-up window.
3. Click on the Add Coded Comments hyperlink. An additional pop-up window will be opened displaying the coded comment(s). Select the code you would like to add and/or enter freetext in the Enter Text

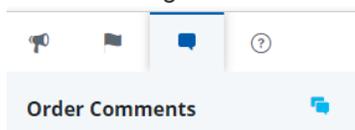
box. Click the OK icon.



4. Select Save to accept the Comment(s) and return to the Result Validation screen.
5. The comment code will be displayed on the Result Validation screen with a number next to the comment bubble, indicating the number of comments that have been added. Hovering over the bubble will display the comment. 

J. Add Internal or Report Order Comment (if applicable):

1. In the Result Validation screen, click the Comment bubble icon next to the OP Alert display to display the order Comment screen.
2. Click on the light blue comment button.



3. Select Add New Comment.



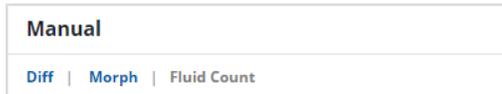
4. Select a button for Internal or Report comment type. 
5. Select the code you would like to add and/or enter freetext in Enter Text box. Click the OK button.
6. Click Close to return to the Result Validation screen.
7. The comment will appear under the order comments on the left side of the screen.

K. Move Sample to Manual Review Workflow (if applicable):

1. In the Result Validation screen, click the Manual Review checkbox above the Instrument Results.
 Manual review
2. Click the Save.
3. Current sample moves from the current panel to the Manual Review panel.

L. Perform a Manual Differential (if applicable):

1. From the Result Validation screen, select Diff in the Manual Section.



2. Confirm the Counter type from the menu at the bottom left of the screen. MDIFF counter will display by default.
 - a. Start counting cell types as you view them under the microscope.
 - b. Select the key that represents the cell type.
 - i. To remove cells, switch toggle button from Add to Subtract and count cell types to remove.



- ii. Switch toggle back to Add to continue counting manual diff. 

- c. When the number of cell types reaches the count limit (default 100), a sound will play (if device capable) and the keyboard will lock from adding more cells.
 - i. To perform a second differential review, the toggle button can be selected to switch from Count 1 to Count 2. Follow same procedure as above to perform Count 2.



- d. Click Save
 - i. When two differentials have been performed, you will be prompted to select Count 1, Count 2 or an Average.
 - ii. If cell limit has not been reached, the message “You have counted less than the limit of

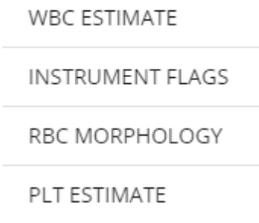
(default 100) cells. Do you really want to store the uncompleted result?" Click Yes to accept the results, click No to go back to counting.

M. Perform Morphology (if applicable):

1. From the Result Validation screen, select Morph hyperlink under Manual Column to open up the Morphology Module.



2. Option One:
 - a. Click the ellipsis in the result field of the appropriate row for the morphology test.
 - b. The Coded Result screen will display.
 - c. Click the appropriate row that represents the result type (e.g., 1+, 2+ 3, + or few, moderate, many).
 - d. Click the OK button to return to the Morphology screen.
3. Option Two:
 - a. User may enter the result directly on the result field.
4. Continue to add morphology results as appropriate.
5. **NOTE:** Four morphology checks must be completed for each order: WBC Estimate, Instrument Flags, RBC Morphology, and PLT Estimate.



6. Comments may be appended to a test by clicking on the comment icon.
7. Click SAVE to return to the Result Validation screen.

N. Validate Results

1. In the Result Validation screen, the Manual Differential and Morphology results will display as To Be Validated. Select one of the following to validate:

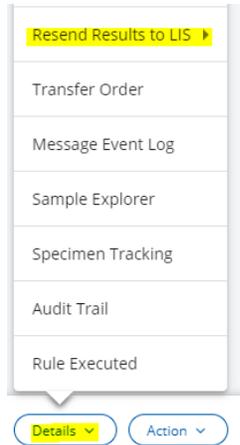


- a. Validate All – Click the Validate All icon. This will validate all available results on the Result Validation screen.
- b. Validate CBC – Click the Validate CBC icon. This will validate CBC results on the Result Validation screen.
- c. Validate Selection – Select individual test results for result approval and then click on the Validation Selection icon.

O. Resend Results to the Laboratory Information System (LIS)

1. In the Result Validation Screen for a Sample ID:

a. Select Details > Resend Results to LIS

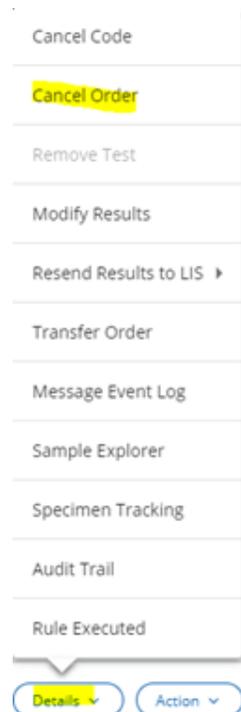


- i. Resend: System will resend all test results with “Sent to LIS” status to LIS.
- ii. Force Results: System will send all test results with “Pending”, “To be Validated”, “Validated” and “Sent to LIS” status to LIS.

VI. NOTES

A. Cancel Orders in Caresphere:

1. Select the sample ID from the results validation screen. Click Details and Cancel Order.



2. Click Yes.
3. Select cancellation reason and click OK.

B. **Message Event Log:** To view additional information on the sample.

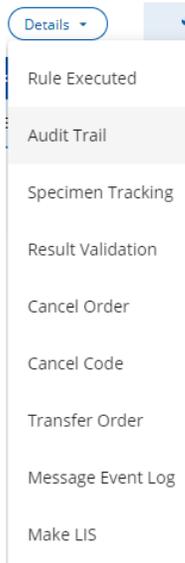
1. Select the sample ID from the results validation screen. Click Details and Message Event Log.



2. NOTE: A new tab will open.
3. Review the information and close the tab to return to the result validation screen.

C. **Sample Explorer:** Allows users to perform specific searches based on all available criteria.

1. Select the Sample Explorers icon from the homepage. 
2. Enter the search criteria and click Apply to perform the search.
3. The order will appear in the search result field.
4. Check the box next to the order and click Details to branch to another panel or to perform needed tasks. 



- D. **Specimen Tracking:** Recording of all barcode reads of a sample ID on the automation system. It can be useful to physically track down a specimen. The Specimen Tracking screen can be used to search, filter, or print all previous locations of a specimen.

1. Select Specimen Tracking icon from the homepage.

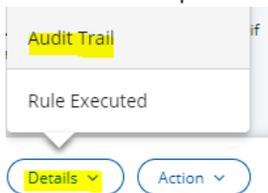


Specimen Tracking

2. Enter sample ID. Note: Once three characters are entered, a dynamic search is performed. Matching results will get more specific as more of the sample ID is entered.
3. Click Apply.
4. Review the sample ID tracking history.
5. NOTE: Specimen tracking is also accessible through the result validation screen via the Details dropdown menu.

E. **Audit Trail:** Displays all actions and results.

1. Select the sample ID from the results validation screen. Click Details and Audit Trail.



2. NOTE: A new tab will open.
3. Review the information and close the tab to return to the result validation screen.

F. **Smear Status:** Check whether slides are ready for manual differential/RBC morphology.

1. Select Smear Status icon from homepage.



SMEAR status

2. Select Result Type Show Latest or Show All.
3. Select one or more filters if needed: Sample ID, Smear Status.
4. Click Apply.
5. Review the status of the smear:
 - a. In Process: Yellow
 - b. Pending: White
 - c. Completed: Green
 - d. M-Completed (manually completed): Blue
 - e. Error: Red

G. **Barcode Error Management:** The Barcode Error screen can help to identify the analyzer, rack, and tube location of the sample with the error.

1. Select the Barcode Error icon from the homepage.



Barcode Error

2. Note: The past 24 hours is the default search criteria.
3. Change search criteria if needed and click Apply.

H. Smear Orders

1. Smear 1: makes 1 slide. Routine is white slide, stat is pink slide.
2. Smear 2: makes 2 slides. Routine are white slides, stat are pink slides.
3. Smear 4: makes 2 pink slides for path consult, bone marrow CBC, and schistocyte review.

VII. DAILY MAINTENANCE:

- A. Click the Barcode Error icon on the Homepage to view all barcode errors.



Barcode Error

- B. Fully pending orders will automatically delete and any pending results will be auto completed after defined time specified in General Parameter settings.

VIII. CALCULATIONS:

- A. The WBC correction for Manual NRBC is hardcoded and is not configurable.
- B. Standard Calculations include: absolute calculations - differential, ALC (absolute lymphocyte count) calculation, and ANC (absolute neutrophil count) calculation.

IX. REPORTING RESULTS:

- A. See Attachment A - Caresphere Workflow.

X. TROUBLESHOOTING:

- A. The following are common Caresphere WS issues and recommended actions to resolution.

NOTE: Contact Sysmex if you are unable to resolve issue.

- B. **Patient Lock Record Issue:** Patient File Lock (Lock icon present on Sample ID)

1. Probable Cause

- a. More than one user trying to perform activities on the same Sample ID at the same time.
- b. User has walked away from Caresphere WS application while still in Sample ID and another user is trying to access.
- c. There was a power outage or shut down of the Caresphere WS workstation while in a patient record.

2. Corrective Action

- a. One user must navigate away from the Sample ID.
- b. Wait for Sample ID to unlock after 30 minutes (default).
- c. Notify Caresphere WS Administrator to unlock Sample ID via the Record Locking Management screen.
 - i. Note: The record locking steps can only be performed by an administrator.
 - ii. Click System, Monitoring, Record Locking Management from the top tool bar.
 - iii. Click unlock next to the sample ID.  A blue button with a white padlock icon and the text "Unlock".
 - iv. The sample ID will now be unlocked by the current user.

C. **No Sample ID Orders Issue:** Orders are not being transmitted from LIS to Caresphere WS.

1. Probable Cause

- a. Order is not received in LIS.
- b. LIS encountered error in transmitting from LIS.
- c. Problem with the LIS interface communication.
- d. No connectivity to Caresphere WS.

2. Corrective Action

- a. Receive order in LIS.
- b. Check LIS for transmission confirmation of order to Caresphere WS. Check for any interface errors.
- c. Check test code in LIS and Caresphere WS to ensure this is a code that Caresphere WS is configured to receive.
- d. Check the Interface Status to ensure that the interface is connected.

D. **No Results on Result Validation Screen or Rerun screen/module Issue:** Order is not available on Result Validation Screen when using the To Validate panel.

1. Probable Cause

- a. No results from analyzer – Pending.
- b. No communication to Caresphere WS.

2. Corrective Action

- a. Sample ID not run on analyzer yet.
- b. Check analyzer or devices for operational errors.

E. **Unable to Locate Orders in Sample Explorer Issue:** Unable to find orders in Sample Explorer Screen (No Records Found).

1. Probable Cause

- a. LIS not sending orders to Caresphere WS.
- b. User is logged into the wrong site in Caresphere WS.
- c. Incorrect Filter criteria selected.

2. Corrective Action
 - a. Check with LIS for issues with transmitting orders. Verify LIS communication in the Interface Status screen.
 - b. Check to see if user is logged into correct site. Change Site by selecting the site drop-down from the top right of the screen.

F. LIS Connection Issue: No new orders being processed by Caresphere WS.

1. Probable Cause
 - a. LIS not sending orders to Caresphere WS.
 - b. Issue with LIS connection to Caresphere WS.
2. Corrective Action
 - a. Check with LIS for issues with transmitting orders.

G. Scattergrams/Histograms Not Displaying Issue: No graphical images on Result Validation Screen.

1. Probable Cause
 - a. Emulator results – do not support images.
 - b. Analyzer IPU administrator username/password has been changed from default and what was programmed on initial connectivity.
 - c. Incomplete or no communication with Caresphere WS.
 - d. Customer firewall blocking image retrieval from analyzer IPU.
2. Corrective Action
 - a. Customer IT/Network work jointly with Sysmex to resolve.

XI. REFERENCES

- A. Caresphere™ Workflow Solution User Manual
- B. Caresphere™ Workflow Solution Quick Guide
- C. Caresphere™ Workflow Solution Communication Downtime Guidelines

Attachments

- [Attachment A - Caresphere Workflow v.4.pdf](#)
- [Attachment B - Caresphere Flagging Guide v2.pdf](#)
- [Attachment C - Caresphere Flagging Guide \(Royal Oak Stat Lab\).pdf](#)

Approval Signatures

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Applicability

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