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Owner	McKenzie Stahl (Konitzer)
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Applicability	WDL CP FMLH FMFH FWBH Enterprise

Sysmex Caresphere Workflow Solution

PURPOSE

The Sysmex Caresphere Workflow Solution is a cloud-based software used for Sysmex hematology, urinalysis and chemistry medical devices for data processing and management. It is designed to provide laboratory professionals assistance in automated decision making. Caresphere can process samples across integrated health networks to standardize the handling of sample results by evaluting results against built system rules configured to each customers needs.

PRINCIPLE

Orders are placed in the LIS and bar-coded samples are loaded onto the Sysmex analyzers. The analyzer then queries Sysmex Caresphere for patient demographics and test orders. When analysis is completed, results are sent from the analyzers to Caresphere and evaluated using a database of custom rules. The rules engine allows for real-time data checking based upon test results, analyzer flags and/or user selected rule definitions that can automatically generate a test rerun, allow for reflex testing or slide making. Samples that are NEGATIVE and do not trigger any rules will auto verify (see Auto-verification). After completion of reflex test(s), reruns and/or slide reviews samples are evaluated by the technologist and results are validated in Caresphere. Upon verification in Caresphere, data is sent to the LIS.

SPECIMEN REQUIREMENTS

Refer to site specific Sysmex SOP

AUTO VERIFICATION

GENERAL DEFINITION

A. Auto-verification is the instrument's ability to automatically send "filtered" results (based on defined

laboratory settings) to the LIS and the LIS' ability to release or "hold" this information as indicated in instrument interface (data stream)

B. Criteria include IP flags and message (suspect and abnormal) settings (auto-verification criteria) within the instrument. Once set, the criteria allow the instrument to "filter/categorize" data as **abnormal (not ready for auto-verification)** and **normal (ready for auto-verification)**

C. After sample analysis is completed, an electronic and visual indication about the sample is displayed (on instrument / printout) and transmitted to the LIS

D. ***Visual indicators*** – All XN and X-series instruments provide the unique ability to indicate to the operator/LIS if data is abnormal (**POSITIVE)**, requires further technical intervention or normal (**NEGATIVE**), does not require further intervention

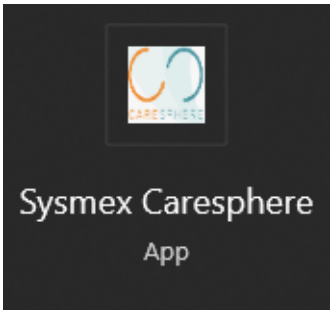
E. If the sample is (**POSITIVE**), a further indicator will be displayed to guide and direct the operator as to the possible area abnormality (see classification table for examples):

Classification	Explanation	Laboratory action (SOP)
Diff Abnormal	Possible abnormality in the WBC differential / parameters	Make and review smear
Morph Abnormal	Possible abnormality in cell morphology	Make and review smear
Count Abnormal	Possible abnormality in blood cell numerical count	Review count, perform appropriate intervention and notify clinician if critical value
Action	Possible presence of abnormality in within NRBC or RET channel	Select appropriate test code and repeat analysis
ERROR	Instrument encountered interruption during analysis	Check sample repeat analysis
Blast?	Possible presence of Blasts	Perform a slide review for blasts and perform a manual differential if indicated
Fragments?	Possible presence of schistocytes	Perform a manual microscopic smear review for schistocytes

SOFTWARE COMPONENTS

LOGGING ON & OFF SYSMEX CARESPHERE

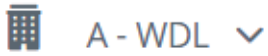
A. Double click on the Caresphere icon on the desktop or in the Citrix Applications icon

1. 

2. Log on using network email and password

a. **Note**: There will be multiple log in screens

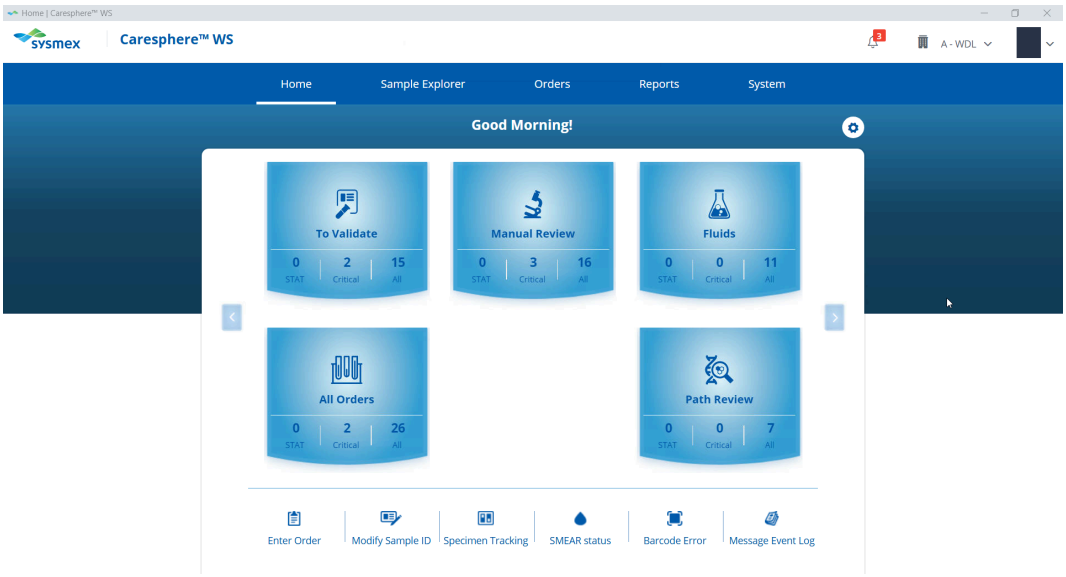
3. Change testing using drop down is applicable:

4. 

    a. (A) WDL Core Lab
    b. (B) WDL Cancer Center
    c. (D) Drexel Town Square Health Center
    d. (F) Menomonee Falls Hospital
    e. (G) Holy Family Memorial Hospital
    f. (H) Harbor Town Medical Center
    g. (J) West Bend Hospital
    h. (M) Moorland Reserve Health Center
    i. (N) North Hills Health Center
    j. (Q) Mequon Health Center
    k. (S) Tosa Health Center
    l. (T) Town Hall Health Center
    m. (W) West Bend Health Center
        i. **Notes**:
            a. Sites assignments are made by system administrators based on work location(s)
            b. Technologists will see every site listed above in the drop down menu, but work up/validation of results can only occur from their assigned working location(s)
            c. If the technologist is not logged into the correct location a read only view is available
            d. After log in, Caresphere will always default to site A, please change to correct site before testing

HOME SCREEN

A. **Note:** Tile layout varies by site

1. 

B. Home:
    1. Takes user back to main tile screen shown above

C. Sample Explorer:
    1. Sample Look up:
        a. Search by Instrument ID, Sample ID, MRN, or Patient Name
        b. Advanced search features available for instrument, date/time, and status of order

D. Orders:
    1. Drop down menu options:
        a. Enter Order
            i. Enter orders directly into Caresphere during downtimes
        b. Modify Sample ID
            i. Modify Sample/Instruemnt ID
        c. Transfer Order Log
            i. Tracking orders that have been transferred to other testing sites

E. Reports
    1. Specimen Reports

F. System
    1. Cycle analyzer interfaces (see directions below)
    2. Most other tabs will be used by System Administrators

G. To Validate:
    1. All peripheral blood specimens awaiting validation

H. Manual Review:

1. All Specimens awaiting manual review/validation

I. Fluids:
    1. All fluids specimens awaiting validation

J. All Orders:
    1. All orders in Caresphere

K. Path Review:
    1. All specimens with path reviews ordered

L. Enter Order and Modify Sample ID
    1. Same tab under enter orders

M. Specimen Tracking
    1. Specimen look up to see last scan on any XN analyzer

N. Smear Status
    1. Sites with SP-50, specimen look up of smear status

O. Barcode Error

P. Message Event Log
    1. Log of analyzer actions

VALIDATION SCREEN(S)

A. **Demographic Area:** Displays patient name and demographics

B. **Operator Alert (OP Alert) Area:** Displays instructions related to the rules that are triggered by the sample results. Scroll down to view all OP alerts

C. **Order Comment Area:** allows user to place internal or external comments, Internal comments are not chartable and stay in Caresphere

D. **Flags**: Area displays any flags by the analyzer

E. **Details Button Functions**:
    1. Cancel entire test order
    2. Remove a test from the order
    3. Resend results to LIS
    4. Transfer the order to another site
    5. See the message event log
    6. Go to Sample Explorer
    7. Go to Specimen Tracking
    8. See the sample Audit Trail
    9. See the Rules Executed on sample

F. **Action Button:** The action box allows the user to manually add test requests and reruns at the discretion of the technologist

G. **Sample List:** The samples ready for validation are listed in sample list. The list will refresh automatically and add new samples that have been completed since first accessing the validation screen

H. **Images:** This area will display analyzer scatter grams

I. **Manual**: This area indicates any slides that are being made/made by a slide maker stainer or manually, pathology reviews, and tube sorter locations (if applicable)

J. **Validation Functions**

1. Validate All: Allows the user to validate all the displayed results
2. Validate Selection: Allows the user to validate only the selected parameters
3. Validate CBC: Allows the user to validate the CBC component
4. Save: Saves work

PERIPHERAL BLOOD VALIDATION PROCEDURE AND WORK FLOW

A. Home Screen- To Validate

1. Samples that appear here are samples that need work up and did not Auto-Verify

B. Sample list will be on the right hand side of the screen

C. Sample list symbols/colors:

1. Bold Red C- Critical result
2. White background Sample ID- Routine
3. Red Background Sample ID- Stat
4. Blue background Sample ID- Unregistered
5. Lock next to Sample ID- Specimen is being worked on/locked by another user

D. Click on sample you are going to work on, sample will display a bold dark blue line on the left hand side

1. 

2. Note: If you cannot find the sample you are looking for on the sample list use Sample Explorer to search for sample

E. Sample ID and demographics will populate at the top of the display screen with results underneath

F. Results display symbols/colors:

1. Results Box Blue: Critical Result Low
2. Results Box Red: Critical Result High
3. Results Box Green: Delta Check
4. Results Box Orange: MCHC >38
5. Asterick*- Results not trusted
6. Dash- - Result below reference range

7. Plus sign + - results above reference range
8. &F- PLT-F run on sample

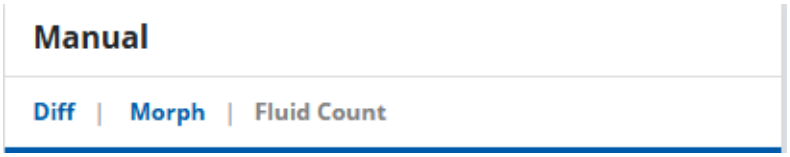
G. Review results and OP Alerts

H. Follow site specific SOPs to resolve OP Alerts to verify results

DIFFERENTIALS AND MORPHOLOGY

A. Samples in need of a differential or morphology will have codes appear in the Manual Box

B. To access the manual differential keyboard and morphology click on the blue hyper links in the Manual Box:

1. 

C. Perform differential

D. Click save

E. Follow site specific SOP for completing manual differentials/reviews

SELECTING RERUNS

A. To look at and select results from a rerun select double arrow button

1. 

B. On next screen select results you are going to report and hit ok

C. Follow site specific SOP for selecting and resulting reruns

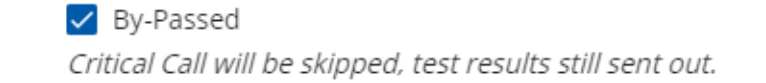
CRITICAL CALL DOCUMENTATION

A. Selecting Validate CBC/ALL/SEL will generate the critical all pop up box

B. Document critical call information

C. Select Save

D. **Note:** If you have Closed Loop Critical Calling or Follow-Up Worklist Criticals you will need to check the By-Passed box in the upper left corner to send out results without call documentation

1. 

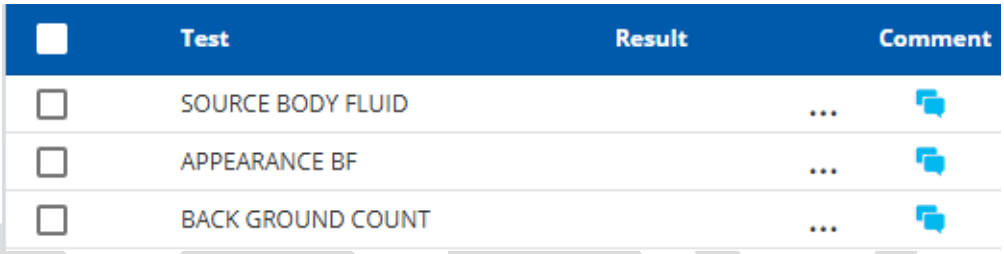
DOCUMENTING COMMENTS

A. To make an over arching Comment on specimen select the 'Comment Box' located on the left side of your screen

1. 

2. All comments that have already been placed on this sample will appear here
3. To add a new comment click the blue 'Double Comment Box'
    a. 
4. Click 'Add New Comment'
5. Select pre-made comment code or free text a commet at the bottom
6. There is a toggle for Internal and Extrenal at the top of the box
    a. Internal-Stays in Caresphere
    b. External- Will be sent to chart with results

B. 'Double Comment Box' is also seen next to every result field

1. 

2. Comments typed in or selected for these boxes are all external and will result to the chart

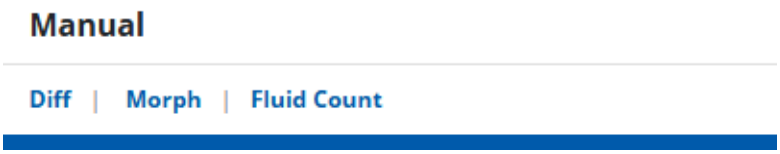
C. Follow site specific SOPs for documenting comments

BODY FLUID CELL COUNTS

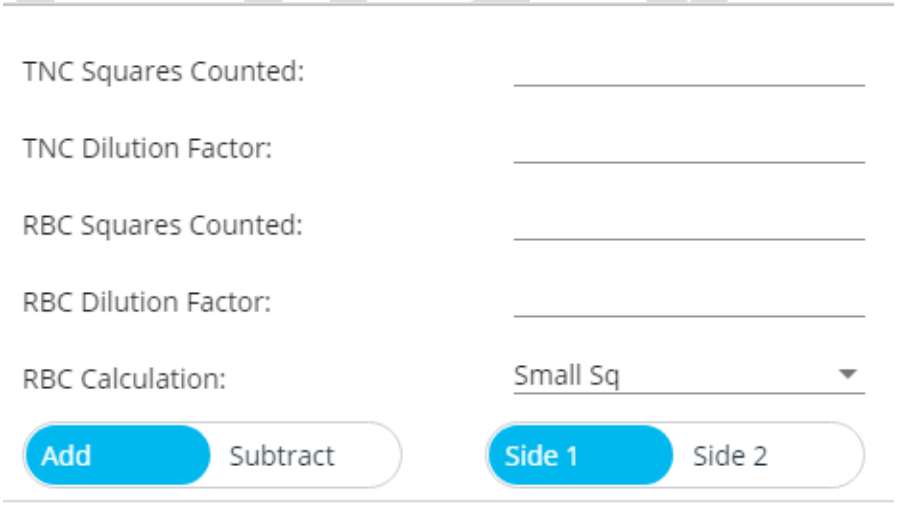
PERFORMING THE CELL COUNT

A. Find Sample using Sample Explorer
    1. Note: If sample has already had results saved by another technologist it will appear under the sample list on the fluids tile
B. Using elipsis select fluid source, appearance, color, and volume
C. Click Save
    1. Note: If Caresphere refreshes before saving data will be lost
D. RBCs will stay an aviliable field or place not measured based on fluid type entered
E. Run the body fluid on the XN or plate a hemocytometer
    1. **When running on the XN:**
        a. Fluid should be run straight without a diltuion first
        b. If Astricks are present dilute the fluid
        c. After preparing the diltion order a rerun with dilution in Caresphere
            i. Be sure to enter the correct dilution factor
        d. Rerun the sample

e. If results still have astericks- try a new dilution or plate hemocytometer for a manual body fluid count

2. **Manual count on a hemocytometer:**
   a. Select the hyperlink in the manual box 'Fluid Count'
   b. 

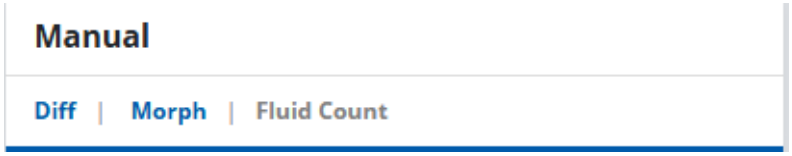
   c. This will bring up a hemocytometer counting page
   d. On the left hand side of the screen there is a toggle for side 1 and side 2
      i. When you have finished counting side 1 toggle this switch to side 2
      ii. 

      iii. Follow site specific SOP for any hemocytometer count acceptability
   e. After both side have been counted, enter in number of squares counted and the dilution factor on the left hand side of the screen
      i. Note: If RBCs are not counted based on fluid type this counter can be used for TNC only
   f. 

      i. When entering in squares counted you will want to do it for 1 side of the hemocytometer only
         a. Ex. 8 large squares were counted for TNC, 4 on side one, 4 on side two, 4 should be entered in the TNC Squares Counted
      ii. TNC is large squares only
      iii. RBCs have the option to toggle between the large squares or small squares in the center

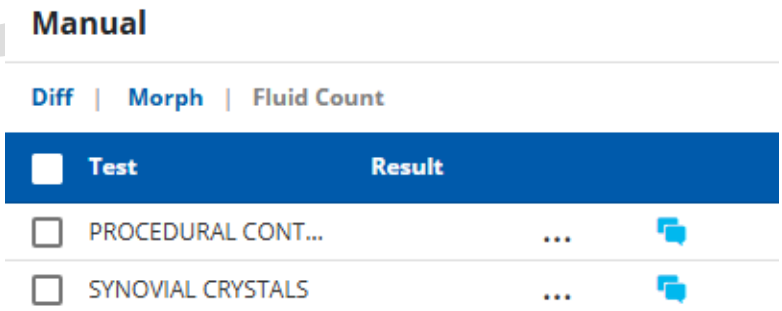
g. Hit Calculate
h. Hit Save
i. Caresphere will enter results into the TNC and RBC fields based on the averge count of both sides

PERFORMING THE DIFFERENTIAL

A. If a fluid differential was ordered 'Fluid Neutrophil' will be present in the morphology box and must be completed to validate specimen
B. Follow site specifc SOP for need of differential
C. In the manul box select the Diff hyperlink
D. 

E. Be sure to change your counter in the bottom left corner to FDIFF
    1. Note: Cell types will be missing if this if counter is not changed
F. Perform differential
G. Click Save
H. Mark procedural control as acceptable per site SOP

BODY FLUID CRYSTAL ANALYSIS

A. If crystals are ordered a Synovial Crystals field will appear under the Manaul Box
    1. 

B. Selelct Elipsis
C. Select Present or None Seen
D. If Present:
    1. Click on the double comment box in the Synovial Crystals field
    2. Click add coded comment
    3. Select crystal type
    4. Click Ok
    5. Click Save
E. Place a procedural control per site specific SOP

BARCODE ERRORS AND UNREGISTERED SAMPLES

A. For any Barcode errors and unregistered samples follow site specific SOP to resolve

INTERFACES

A. When results are not crossing to Caresphere, check to see that everything is connected properly:
    1. System
    2. Monitoring
    3. Interface Status

B. If your site does not say connected/if you are still having issues please call Froedtert IT and Sysmex TAC if needed

REFERENCES

A. Carespehe Workflow Solution (WS) Quick Guide

B. Caresphere Workflow Solution User Manual

Attachments

- Caresphere Rule Definition List.xlsx
- Caresphere Smear Codes.docx
- Caresphere WS Quick Guide.pdf
- Caresphere WS User Manual.pdf

Approval Signatures

Step Description	Approver	Date
	Maria Hintzke: MCW Assistant Professor	Pending
	Chuck Schur: Manager-Heme & Flow	03/2025
	Meagan Seeger	02/2025
	McKenzie Stahl (Konitzer)	02/2025

Standards

No standards are associated with this document