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| Origination | N/A |
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| Owner | Carolyn Webb: Heme Technical Specialist |
| Area | Hematology |
| Applicability | Community Physician |

# CP Hematology Quality Assurance with Sysmex



## SCOPE

This procedure is effective at all Froedtert & Medical College of Wisconsin Community Physician laboratories that perform hematology testing on Sysmex analyzers. The procedure covers topics specific to the Hematology section of the laboratory that are not included in Quality Management Plan of Laboratory.

Effective 3/19/25 at the following laboratories:

- Drexel Town Square Health Center
- Moorland Reserve Health Center
- North Hills Health Center
- Tosa Health Center
- Town Hall Health Center
- West Bend Health Center

## PURPOSE

1. To maintain high quality patient care.

## DEFINITIONS

A. QC- Quality Control

B. CV- Coefficient of variation

C. CBC- Complete Blood Count

D. TAT- Turn around time

E. LIS - Laboratory Information System

F. XN-L Series analyzers = XN550

G. XN-Series analyzers = XN10, XN20, XN1000, XN2000

# POLICY

A. A quality control program is established to ensure test results are accurate and reliable. See individual analyzer procedures for details.

B. Quality control is monitored daily by the technologist performing the test.

C. Interlaboratory reports are utilized for ESR and CBCD/Retic test methods to ensure laboratory compares well with peer group.

D. BEYONDCARE QUALITY MONITOR (BCQM) is a Sysmex Quality Management program that provides the following:

1. Evidence based quality control ranges
    a. BCQM has the ability to synchronize the peer group driven BCQM mean and limits with the analyzer's QC L-J charts. All XN-L analyzer come with the synchronization feature enabled. XN-series analyzes have the feature enabled with IPU software version 00-22.16 or higher. When synchronization is enabled, there is no need to perform a manual synchronization procedure.
    b. If BCQM is not available, the analyzer QC files provide the same acceptable QC ranges for evaluation of QC results.
2. Standardized corrective actions when QC fails
3. Real-time peer group evaluation
4. Continuous calibration verification every time at least 2 levels of QC material is run.
    a. Calibration verification is when materials of known concentration is tested in the same manner as patient specimens to assure the test system is accurately measuring samples throughout the reportable range. Proactive QC monitoring.
5. In lieu of 6-month calibrations the CCV Certificate report will be reviewed monthly. Only when calibration specifications are not met will a calibration to be performed.
    a. CCV Certificate report is an on demand report for accuracy and precision of the test method that follows CLIA recommendations for automated cell counters verification of calibration (using approved standards for cal verification).
    b. CCV Certificate report is available in BCQM under the Calibration History Tab>Calibration Verification>Select A Report>CCV Certificate.

E. The Hematology Technical Specialist or designee will review the following Sysmex QC reports

at regular intervals.

1. Insight Report
    a. This report shows exceptions that need to be reviewed and actions needed for each individual laboratory and analyzer. Insight is generated at intervals midway through a control lot and at end of control lot. Designated personnel receive email notifications when reports are available. Follow the link provided in the email to access the Insight web site. (Note: Insight report can also be obtained through BCQM.)
    b. Access and store report
        i. Select Report Center>Customer QC Reports
        ii. Select View Report with Raw Data for the most recent report.
        iii. Click the PRINT icon, set Printer to "Microsoft Print to PDF", and click Print
        Select the appropriate QC file on Froedtert's shared I drive to save the document.
        Sign/date the report electronically.
2. Detailed Daily Verification Report
    a. The Detailed Daily Verification Report is an on-demand report that standardizes the control concentrations into noe chart for trending review. Review charts to see like performance between the control levels with P (Pass) for each day of patient testing.
    b. The Detailed Daily Verification Report is available in BCQM under the Calibration History tab>Calibration Verification>Select a Report>Detailed Daily Verification.
    c. Hematology Technical Specialist will use this report to monitor for shifts/ trends in QC results.

F. Corrective Action Documentation
1. Corrective actions do not appear on any of the Sysmex printed reports.
2. To access the corrective actions:
    a. Log-in to Sysmex Customer Resource Center
    b. Open BCQM
    c. Select the Activity Tab at bottom of screen and Activity Log at top of screen.
    d. Set the time interval to correspond with the Insight report and select Search.
    e. Any corrective actions that were recommended by BCQM will appear on the Activity Log regardless of whether they were completed or skipped. While the Activity Log is available in BCQM for a minimum of 2.5 years, there is no ability to document review of the Activity log in BCQM.
    f. Capture a screenshot of the Activity Log, paste the screenshot into a Word

document and save it to the same location as the Insight report.

3. Document any necessary follow up on the Word document.
4. Sign/date the report electronically.

G. Parameter Report

1. This report is useful for evaluating warnings received on an Insight report and comparing analyzer to analyzer performance of QC materials. In addition to showing how all of the CP Labs compare to each other for each analyte on a single report, the report provides an Historical SDI which is an average of last 6 Insight period's SDI
2. To access the Parameter Report:
    a. Log-in to Sysmex Customer Resource Center
    b. Open BCQM
    c. Click no Manage QC at bottom of screen
    d. Under [QC Reporting], [Select a Report], choose "Parameter Report"
    e. [Select A Parameter], choose "All"
    f. Select "Lot to Date" or "Last Period" to correspond with the Insight report being reviewed.
    g. [Select A Level], choose control level for which warning was received.
    h. Click [Submit]
3. Click the PRINT icon > Destination = Save as PDF. Then Click Save.
4. Save to the "QC *YEAR* Parameter Reports" Folder under QC folder on Froedtert's shared I drive.
5. Review the report
    a. look for a Red X on any parameter at any location
        i. Correlate finding with site specific Insight Report
        ii. Request performing location contact Sysmex Technical Assistance Center for guidance on the flagged analyte. User performed maintenance or service call may be needed.
    b. Check the historical SDI for the parameter with warning. If greater than 2.0, have request performing location contact Sysmex Technical Assistance Center for guidance. User performed maintenance or service call may be needed.
6. Sign/date the report electronically.

H. Continuous Calibration Verification Certificate (This report shows lab mean vs target mean)

I. Storage of QC Data

1. The BeyondCare Quality Monitor application stores the last 2.5 years of QC data on demand. All QC data older than 2.5 years is archived. If data older than 2.5 years is needed, contact Sysmex Technical Assitance Center.

2. CP labs will save PDF of all reports on a shared drive on Froedtert's network and retain for a minimum of 2 years.

J. Appropriate proficiency testing is performed for all analytes currently analyzed within the Hematology Department following the sample preparation and testing instructions that are provided with the samples. See Proficiency Testing Policy for complete details.
**Note**: At no time will there be inter laboratory communication or referral of proficiency testing materials to another laboratory until after the deadline for submission of data has past.

K. Training and competency program has been established. Refer to Training and Competency Assessment policy for details.

L. The hematology laboratory at least annually assesses morphologic observations among personnel performing blood cell microscopy and body fluid cell differentials, to ensure consistency. Some methods used to cover this may include (but not limited to) circulation of blood films, use of blood or marrow photomicrographs with referee and consensus identification, use of digital images, case studies, and retained patient samples.

M. Quality Management report: A summary report is compiled each month which consists of any troubleshooting/service/calibrations performed on instrumentation and measures taken to resolve problems, along with a monthly summary of all quality control. This report is reviewed by the Hematology Technical Specialist and Pathologist.

N. Hematology is monitored by the following performance/quality indicators:
1. Turnaround time for STAT CBC and manual differential (average 45 minutes)
2. # of corrected reports sent out from the lab each month.
3. Monitor the critical values to ensure they are handled correctly 100% of the time.

O. Patient samples are tested and compared between the two Hematology analyzers at minimum twice a year. CP generally performs the comparisons using one sample on a monthly basis. Acceptability is based on the acceptability limits provided by Sysmex.

**Expectations for XN-Series, XN-L Series, XE-Series, XT-Series, XS-Series, XP-300, KX-Series and pocH-100*i***
**Analyzer-to-Analyzer Correlation (Closed to Closed or Open to Open)**

| Parameter | Bias Limit | Parameter | Bias Limit | Parameter | Bias Limit |
|---|---|---|---|---|---|
| WBC | ± 7.5% | NEUT # | within ±23% or ±0.30 | NEUT % | within ±23% or ±5.0 |
| RBC | ± 3.0% | LYMPH # | within ±16% or ±0.30 | LYMPH % | within ±16% or ±5.0 |
| HGB | ± 3.5% | MONO #[2] | within ±28% or ±0.30 | MONO %[2] | within ±28% or ±3.0 |
| HCT | ± 3.0% | EO #[2] | within ±37% or ±0.30 | EO %[2] | within ±37% or ±2.0 |
| MCV | ± 3.0% | BASO #[2] | within ±39% or ±0.30 | BASO %[2] | within ±39% or ±1.0 |
| PLT[1] | ± 12.5% | IG #[2] | within ±12% or ±0.30 | IG %[2] | within ±12% or ±1.5 |
| RET% | ± 30.0% | | | | |

[1] Platelet correlation limits apply to comparisons of results obtained using the same methodology (i.e., PLT-I to PLT-I, PLT-F to PLT-F).
[2] Does not apply to XP-300, KX-Series or pocH-100*i*

P. Automated differentials vs. Manual differential and Cellavision manual differential comparisons will be performed at minimum twice per year using patient samples in which the

Automated differential was acceptable to report.

1. Limits of agreement will be based on Rumke Limits using the automated differential as the result to which the manual diff will be compared. Any discrepancy outside of these limits will be noted and acceptability will be determined by the Medical Director, or action will be taken as necessary.
2. Hub labs will perform 5 comparisons twice per year.
3. Urgent Care labs ill perform 2 comparisons twice per year.
4. Whenever possible, each sample comparison should be performed by a different tech.
5. See attached worksheet.

Q. LIS audits are performed at least every two years or when changes are made to LIS test components, calculations, or autoverification rules. Refer to Beaker Data Transmission and Calculation Accuracy Audit procedure.

1. Calculations performed in Caresphere and Beaker are verified by technical specialist. One calculation verification applies to all sites. The calculations performed are related to the manual differential and Citrated platelet count:
    a. Band Neutrophil % = Bands counted *100 / Total Cells counted in differential
    b. Segmented Neutrophil % = Segmented neutrophils counted *100 / Total Cells counted in differential
    c. Lymphocyte % = Lymphocytes counted *100 / Total Cells counted in differential
    d. Monocyte % = Monocytes counted *100 / Total Cells counted in differential
    e. Eosinophil % = Eosinophils counted *100 / Total Cells counted in differential
    f. Basophil % = Basophils counted *100 / Total Cells counted in differential
    g. Absolute Neutrophil (segs and bands) = (Neutrophils counted + Bands counted) x WBC / Total cells counted in differential
    h. Absolute Lymphocytes = Lymphocytes counted X WBC / Total cells counted in differential
    i. Absolute Monocytes = Monocytes counted X WBC / Total cells counted in differential
    j. Absolute Eosinophils = Eosinophils counted X WBC / Total cells counted in differential
    k. Absolute Basophils = Basophils counted X WBC / Total cells counted in differential
    l. Citrated Platelet Count = analyzer PLT X 1.1
2. Verification of accurate transmission of results across interfaces is performed by

each laboratory for each interfaced analyzer.

3. Verification of Auto Validation/Auto Verification Rules is performed by each laboratory. at least every two years and when changes are made to the rules. It is not necessary to test every example within the category, but each category should be confirmed as working properly. Current hematology auto verification rules are **Auto verification stops if:**
    - If there is a suspect, definitive, or system message from the Sysmex analyzer that requires additional investigation, the results will stop in Caresphere.
    - Delta check failures stop in Caresphere
        - MCV delta plus or minus >5.0 fL compared to any result within 3 days
        - MCHC delta plus or minus >3.0 g/dL compared to any result within 3 days
    - Critical values stop in Caresphere for documentation of the critical value notification.
        - WBC ≤1.2 or ≥40.0
        - HGB ≤6.0 or ≥19.0, except Newborn <6.0 or >24.0
        - HCT ≤20.0 or ≥60.0, except Newborn <24.0 or >78.0
        - PLT ≤25 or ≥1000
    - If a patient has "PLT Clumps" FYI flag, the results will not autoverify in Beaker.
    - Result outside of linear range are changed to < or > in Caresphere and are held for review.
        - WBC = 0.03 to 440.0
        - RBC = 0.01 to 8.60
        - HGB = 0.1 to 26.0
        - HCT = 0.1 to 75.0
        - PLT = 2 to 5000
        - Diff % = 0-100.0
        - Diff # = 0.03-440.0
        - NRBC% = 0.0 to 600.0 (per 100 WBCs)
        - Retic% = 0.00-30.00
        - Retic# = 0.0100-0.7200
        - MCV, MCH, MCHC, RDW-CV, MPV = n/a

R. All identified problems are documented, and as appropriate, are reported to the Pathologist and the Quality Assurance Committee.

S. **RECORD KEEPING**
All analyzer printouts that are used as interim worksheets, quality assurance records, maintenance records, calibration records, and proficiency survey records are to be kept for 2 years. Analyzer service records and analyzer verification records are kept for the life of the analyzer plus 2 years.

# References:


Sysmex Corporation; Automated Hematology XN Series Instructions for Use; Document Number BH924846 version 03/2024.

Sysmex Corporation; BeyondCare Quality Monitor Instructions for Hematology User Manual; Document Number CF-08453; May 2024.

Sysmex Corporation; BeyondCare Quality Monitor Instructions for Hematology Inspection Guide; Document 1518-MKT, Rev 2; April 2019.

Sysmex Corporation; Analyzer to Analyzer Correlation; Product Notification 62-1457;

Froedtert Caresphere Rules: Dry Testing - All Documents

CLIA Federal Regulations




## Attachments

Automated vs Manual Diff comparison worksheet

Sysmex analyzer to analyzer comparison limits.png

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Technical Specialists | Colleen Turtenwald: Technical Specialist | Pending |
| Technical Specialists | Carolyn Webb: Heme Technical Specialist | 03/2025 |
| Policy Owner | Carolyn Webb: Heme Technical Specialist | 03/2025 |

## Applicability

Community Physician

## Standards

No standards are associated with this document