



HEMATOLOGY
LABORATORY

Approved by: see signature block at end of document

Date 11/16/18

Review by:

Policy Created: 11/16/18

Supersedes:

Primary Responsible Parties: Kelly Hall, MLS

CAP Standard: NA

SUBJECT: XN 2000 Analyzer to Analyzer Correlation

I. POLICY STATEMENT:

Standard Operating Procedure for Sysmex XN-2000 Automated Hematology Analyzer Cross Check. Comparison will be performed every 6 months.

II. PURPOSE:

To ensure multiple analyzers within the laboratory are calibrated and ensure reproducibility of patient data across all analyzers.

III. POLICY SCOPE:

All Hematology technologists will follow this policy when performing patient testing.

IV. SPECIMEN:

- A. Whole blood collected in K2 EDTA drawn per manufacturer's specifications for correct blood to anticoagulant ratio with a total volume of 3.0 ml available as needed to complete this study.
- B. Samples should be kept at room temperature during the analysis.
- C. Samples should be run on both analyzers within 4 hours.
- D. Do not place samples on a mechanical blood mixer.

V. PROCEDURE:

- A. Analyzer 31851 (Left side) will be considered the "reference" analyzer. Analyzer 31847 (Right Side) will be considered a test analyzer and will be compared to 31851.
- B. Run 10 samples on the reference analyzer and record results for WBC, RBC, HGB, PLT, and RET%. Average the results from all ten samples for each parameter.
- C. Run the same ten samples on the test analyzer and record results for WBC, RBC, HGB, HCT, MCV, PLT, and RET%. Average the results from all ten samples for each parameter and record this value. Samples must be run within four hours of being run on the reference analyzer.
- D. Calculate the percent difference between analyzers using the following formula:

$$\left(\frac{[\text{Reference Analyzer Mean} - \text{Comparison Analyzer Mean}]}{\text{Reference Analyzer Mean}} \right) * 100$$

- E. Evaluate the results. Compare the calculated mean percent difference for each parameter and ensure they are within the recommended limits
- a. Expectations for XN-Series Analyzer-to-Analyzer Correlation
(Closed to Closed or Open to Open)

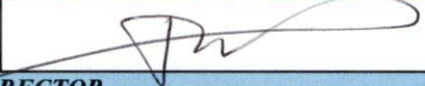
WBC	+/- 7.5%	MCV	+/- 3.0%
RBC	+/- 3.0%	PLT*	+/- 12.5%
HGB	+/- 3.5 %	RET	+/- 30%
HCT	+/- 3.0%		

*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).

VI. REFERENCES:

- A. Analyzer-to Analyzer Correlation (Whole Blood Cross-Check Procedure). Product Notification: Document Number 62-1457. 04/2018. Sysmex America Inc., Lincolnshire, IL.

POLICY CREATION :	Date
Author: Kelly Hall, MLS (ASCP)	11/16/18
Medical Director: Kathryn Kramer, MD	11/16/18

MEDICAL DIRECTOR		
DATE	NAME	SIGNATURE
11-19-18	Kathryn O. Kramer MD	
SECTION MEDICAL DIRECTOR		

REVISION HISTORY (began tracking 2011)			
Rev	Description of Change	Author	Effective Date

Reviewed by:

Lead	Date	Coordinator/ Manager	Date	Medical Director	Date
.1 Kelly Del	11-23-18				