



UnityPoint Health

PROCTOR

HEMATOLOGY
LABORATORY

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Section: UPP HEMO

Policy #:

Approved by: see signature block at end of document

Date 06/28/18

Review by: 6/28/20

Policy Created:

Supersedes:

Primary Responsible Parties: Sheanea LaCock

Secondary Responsible Parties: Ron Fitzgerald

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 twice a year.

II. PURPOSE:

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

III. SCOPE:

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

IV. SPECIMEN:

A. Required specimen

1. 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.

2. Samples should be kept at room temperature during the analysis.

3. Samples should be run on both analyzers within 4 hours.

4. Do not place samples on a mechanical blood mixer.

V. PROCEDURE:

A. Analyzer 31876 will be considered the "reference" analyzer. Analyzer 31878 will be considered a test analyzer and will be compared to 31876.

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:

$$\frac{\text{Reference Analyzer mean} - \text{Comparison analyzer mean}}{\text{Reference analyzer mean}} \times 100$$

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%		

REFERENCES:

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

MAINTENANCE AND STORAGE:

1. All policies and procedures are reviewed every two years by Laboratory Administration and or the Medical Director of the Laboratory or designee.
2. The Laboratory Administration and Medical Director review policies and procedures when there are changes in practice standards, or requirements.
3. All policies and procedures are reviewed every two years by staff or at the time new or revised ones are put in effect.
4. All policies are retained 8 years after being discontinued or revised.
5. All procedures are retained 2 years after being discontinued or revised.

UnityPoint Proctor Laboratory is a CAP accredited facility. As of 7/1/11, the responsibility of new and/or substantially revised policies and procedures will be restricted the Laboratory Director whose name appears on the CLIA certificate, whose signature appears below. The biennial review will be completed by the Administrative Director.

POLICY CREATION :

Author: Sheanea LaCock

Date 6/28/18

Medical Director:

Date

REVISION HISTORY (began tracking 2011)			
Rev	Description of Change	Author	Effective Date
1	Initial Release	S. LaCock	5/23/18

Lead	Date	Coordinator/ Manager	Date	Medical Director	Date
Sheanea LaCock	6/28/18				