Sysmex XN550 Hematology Analyzer Validation Plan

Purpose

Before reporting patient test results, the new Sysmex XN550 Hematology Analyzer must demonstrate that it can obtain performance specification comparable to those established by the manufacturer for the following performance characteristics:

- Accuracy or Systematic Error Experiment.
- Precision or Random Error Experiment.
- Reportable Range of test results for the test system.
- Verify that the current regionally established reference ranges are appropriate for the laboratory's patient population.

Policy

All laboratories (per CLIA regulation) are required to verify or establish performance specifications for any test system introduced by the laboratory before reporting patient test results.

Scope of the Study

The tests will be performed by the Clinical Laboratory Scientist (CLS) at Harbor Mac Arthur and Mission Viejo Urgent Care Laboratory

Assays will be validated using the Sysmex XN Hematology Analyzers for the following measured parameters:

- WBC
- RBC
- Hemoglobin
- Hematocrit
- Platelets Count
- Automated Differential Count:
  - Neutrophil (%)
  - Lymphocyte (%)
  - Monocyte (%)
  - Eosinophils (%)
  - Basophils (%)
  - IG (%)

Specimen Type:
Whole Blood collected on BD EDTA Vacutainer Tube following Kaiser Permanente Laboratory-approved blood collection procedures.

Validation Process:
The laboratory will demonstrate that it can obtain performance specifications comparable to those established for the current methodology being replaced. The following performance characteristics will be used:

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Scope of the study continued

Precision

Within-Run Precision: Three levels of controls will be tested in 10 replicates for all Hematology parameters that will be evaluated.

Between-Run Precision: For each parameter, three levels of controls will be tested. Each level will be tested over 20 different runs. Discrete runs must be separated by at least 4-hour intervals.

Accuracy/Method Comparison:

For Hemogram: Correlate Sysmex XN550 Hematology Analyzer with the existing Beckman Coulter HmX Hematology Analyzer. Test at least 40 split samples for both normal and abnormal patients.

For WBC Differential Count: Compare Sysmex XN550 Diff Count with Manual Diff Count Method for at least 20 samples for both normal and abnormal patients.

Linearity/Reportable Range Verification

Reportable range identifies the range of patient values that can be reported. The laboratory must verify the range that is relevant for the laboratory's patient population. This range is established through calibration/linearity verification. A linearity verification material is used for this study, provided with 5 levels of specimens with known or assigned values and should be analyzed in 4 measurements on each specimen.

Carryover:

Run low and high levels of controls using the values for H3, L1, L3 and calculate % Carryover using the following formula: (L1-L3)/(H3-L3)x100. Acceptable Carryover for all parameter is ≤1.0%.

Reference Range Verification

Run at least 30 normal patient samples, adult patients >18 years old, to verify the current established reference ranges.

Sensitivity and Interferences:

Refer to manufacturer's published data in the XN550 IFU document.

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Acceptance Criteria

Study	Description	Goal
Precision	Within-run: 10 samples of each control level in a single run. Between-run: Each level controls, at least every four hours apart for twenty runs.	• RBC ± 1.5 % • HCT ± 1.5 % • HGB ± 1.0 % • WBC ± 3.0 % • Platelet ± 10.0 % • WBC Differential ± 3SD/± 25% • Other Parameters ± 25%
Accuracy/ Method Comparison	Perform split sample study on at least 40 samples (normal and abnormal) using specimens tested on the Sysmex XN550 and Beckman Coulter DxH	Acceptance criteria for the main CBC parameters: hemoglobin, hematocrit, RBC, WBC, platelets, MCV, RDW: R>0.900 Slope 0.900-1.100 Average bias <10% Absolute bias (%) at clinical decision points (LLN and ULN) <1.5% for the differential parameters
Linearity/ Reportable Range Verification	Use manufacturer recommended Linearity Material	R > 0.9 ≤ 10% bias from any point on line, except for the lowest level ≤ 15%
Carryover	Run with alternating sequences of low and high concentration samples. The percent carryover is calculated using the values for H3, L1, L3 and the following formula L1-L3)/(H3-L3) x100	Acceptable Carryover for all parameter is ≤1.0%.
Reference Range Verification	Run 30 normal patient samples, >18 years old.	> or = to 90% of results must be within the established Reference Range.
Interferences	Use manufacturer's data or perform manufacturer's recommendations.	Use manufacturer's published criteria for acceptability.

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Study Outcome (refer to Validation binder)

Study	Goal	Outcome
Precision	• RBC ± 1.5 % • HCT ± 1.5 % • HGB ± 1.0 % • WBC ± 3.0 % • Platelet ± 10.0 % • WBC Differential ± 3SD/± 25% • Other Parameters ± 25%	**Within-run:** ☒ **Pass** ☐ **Fail** **Between-run:** ☒ **Pass** ☐ **Fail**
Accuracy/ Method Comparison	Acceptance criteria for the main CBC parameters: Hemoglobin, Hematocrit, RBC, WBC, platelets, MCV, RDW: R>0.900 Slope 0.900-1.100 Average bias <10% Absolute bias (%) at clinical decision points (LLN and ULN) <1.5% for the differential parameters	☒ **Pass** ☐ **Fail**
Linearity/ Reportable Range Verification	R > 0.9 ≤ 10% bias from any point on line, except for the lowest level ≤ 15%	☒ **Pass** ☐ **Fail**
Carryover	Acceptable Carryover for all parameter is ≤1.0%.	☒ **Pass** ☐ **Fail**
Reference Range Verification	> or = to 90% of results must be within the established Reference Range.	☒ **Pass** ☐ **Fail**
Interferences	Use manufacturer's published criteria for acceptability.	**Based on Manufacturer's data:** **WBC** If any of the following conditions are present, the system may erroneously report a low white blood cell count. • White blood cell aggregation If any of the following conditions are present, the system may erroneously report a high white blood cell count.

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Study Outcome continued

Study	**Outcome**
Interferences Data from: *Sysmex XN-L Series Flagging Guide Document Number: 1399-LSS, Rev. 2, February 2019*	**Based on Manufacturer's data:** • Platelet aggregation • Poor lysing of red blood cells during analysis • Erythroblasts • Red blood cell aggregation (cold agglutinin) • Chylemia • Cryoprotein • Cryoglobulin • Fibrin • Giant platelets **RBC** If any of the following conditions are present, the system may erroneously report a low red blood cell count. • Red blood cell aggregation (cold agglutinin) • Microcytic red blood cells • Fragmented red blood cells If any of the following conditions are present, the system may erroneously report a high red blood cell count. • Leukocytosis (>100,000/µL) • Giant platelets **HGB** If any of the following conditions are present, the system may erroneously report a high hemoglobin value. • Leukocytosis (>100,000/µL) • Lipemia • Abnormal protein **HCT** If any of the following conditions are present, the system may erroneously report a low hematocrit value. • Red blood cell aggregation (cold agglutinin) • Microcytic red blood cells • Fragmented red blood cells If any of the following conditions are present, the system may erroneously report a high hematocrit value. • Leukocytosis (> 100,000/µL) • Hyperglycemia • Uremia • Spherocytes **PLT** If any of the following conditions are present, the system may erroneously report a low platelet count. • Platelet aggregation • Pseudothrombocytopenia • Giant platelets If any of the following conditions are present, the system may erroneously report a high platelet count. • Microcytic red blood cells • Fragmented red blood cells • Fragmented white blood cells • Cryoprotein • Cryoglobulin

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The verification data for precisions, accuracy, correlation, linearity, carryover and reference range verification studies on the Sysmex XN 550 Hematology analyzer have been reviewed, and the performance of the method is considered acceptable for patient testing.

Controlled Documents

The following controlled documents support this policy.

References
Sysmex XN-L Series Flagging Guide Document Number: 1399-LSS, Rev. 2, February 2019
Sysmex XN-L Automated Hematology Analyzer Method Verification Guide Document Number: 1251-LSS, Rev 2
Clinical and Laboratory Standards Institute (CLSI). Laboratory Documents: Development and Control; Approved Guideline; Fifth Edition. (GP2-A5, 2006).

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Document History Page

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Name of responsible person/date	Med. Dir. Reviewed/ Date	Director of Lab Ops. reviewed/ date	Date change Implemented
New	Procedure for new XN instruments.	Yvette Lingat 4/15/2020		Mary Lou Beaumont	4/28/2020