

## Performance Verification of Reagents for the SYSMEX Analyzers

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### Policy

Since we do not perform parallel testing on reagents, **ALL** reagents will be tested to verify their performance before XN analyzer is used to process patients.

The Reagent Verification Log will be used to record the reagent lot numbers, their in-use date and an indication that **Background Check or QC** has been performed, reviewed and determined acceptable by the CLS.

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### Safety

All specimens, reagents and controls should be handled as though capable of transmitting infectious diseases. Wear appropriate personal protective equipment when running patient samples or performing scheduled maintenance.

Get lifting assistance. Use appropriate lifting technique, bending at the knees and lifting with legs whenever possible.

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### Supplies Needed

To test the integrity of the reagents, a material with a known value must be tested. The following materials can be used:

- Previously tested patient sample to perform a comparison study
  - XN Check Controls
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### Procedure

Follow the guidelines below whenever replacing a reagent to complete the verification testing of **ALL** reagents before using the XN analyzer for patient testing.

**DILUENTS:** REQUIRE BACKGROUND CHECK ONLY

1. CELLPACK DCL

**LYSING REAGENTS:** REQUIRE QC TESTING OR PATIENT CORRELATION

1. SULFOLYSER (SLS)
2. LYSERCELL WDF

**STAINING REAGENTS:** REQUIRE QC TESTING OR PATIENT CORRELATION

1. FLUOROCCELL WDF

**CLEANING REAGENTS:** NO ACTION REQUIRED

1. CLEANCELL AUTO

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### Controlled Documents

The following controlled documents support this procedure.

Reference
1. Sysmex XN-L Series XN-550/XN-450/XN-350 Basic Operation (North American Edition), Sysmex Corporation, Kobe, Japan.
2. Sysmex XN-L Series XN-550/XN-450/XN-350 General Information (North American Edition), Sysmex Corporation, Kobe, Japan.
3. Sysmex XN-L Series XN-550/XN-450/XN-350 Troubleshooting (North American Edition), Sysmex Corporation, Kobe, Japan.
4. Sysmex Reagents of America Inc., Mundelein, IL. XN CAL, Hematology Calibrators: Calibrators for Sysmex Hematology XN-L Series Analyzers, package insert.
5. Sysmex America Inc., Lincolnshire, IL. XN-L CHECK Hematology Control for Sysmex XN-L Series Analyzers package insert.
6. Sysmex Reagents of America, Inc. SDS sheets and reagent product inserts.
7. College of American Pathologists (CAP) Hematology-Coagulation Checklist, July 2012.

