

Performance Verification for New Shipments/Lot Numbers of Reagents for the SYSMEX Analyzers

Policy

Reagents from each shipment and each new lot number will be tested to verify their performance before being used to process patients.

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

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. Refer to: Policy and Procedures Safety Manual Infection Control and Procedures 11-085-01

Get lifting assistance and use the cubicart together with the pull rod to move heavy reagent cubes. Use appropriate lifting technique, bending at the knees and lifting with legs whenever possible.

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 to complete the verification testing for new shipments of reagents or new lot numbers of reagents before using for patient testing.

DILUENTS: REQUIRE BACKGROUND CHECK ONLY

1. CELLPACK DCL
2. CELLPACK DST (DST): Concentrated DCL. For use with the RU-20 ONLY.
3. CELLPACK DFL (DFL)

LYSING REAGENTS: REQUIRE QC TESTING OR PATIENT CORRELATION

1. SULFOLYSER (SLS)
2. Lysercell WNR
3. Lysercell WDF

STAINING REAGENTS: REQUIRE QC TESTING OR PATIENT CORRELATION

1. Fluorocell WNR
2. Fluorocell WDF
3. Fluorocell RET
4. Fluorocell PLT

CLEANING REAGENTS: NO ACTION REQUIRED

1. CELLCLEAN AUTO

Reference

1. Sysmex XN-9000 *Instructions for Use* (North American Edition), Sysmex Corporation, Kobe, Japan.
2. Sysmex XN series *Administrator's Guide* (North American Edition), Sysmex Corporation, Kobe, Japan
3. Sysmex SP-10 *Instructions for Use* (North American Edition), Sysmex Corporation, Kobe, Japan.
4. Sysmex Reagents of America, Inc. MSDS sheets and reagent product inserts.
5. College of American Pathologists (CAP) Hematology-Coagulation Checklist, July 2012.

Document History Page

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Name of responsible person/date	Med. Dir. Reviewed/ Date	Lab Manager reviewed/ date	Date change Implemented
New	New procedure to verify new shipments/lot numbers of reagents for the XN Sysmex analyzers.	Julius Salomon, 7/1/17			