

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

Policy

Reagents 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.

Get lifting assistance and use the pushcart together 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 or
 - 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

Perform XN Check Level 2 QC and evaluate control results before proceeding with patient testing.

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

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Procedure,
continued

STAINING REAGENTS: REQUIRE QC TESTING

Perform XN Check Level 2 QC and evaluate control results before proceeding with patient testing.

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

CLEANING REAGENTS: NO ACTION REQUIRED

1. CELLCLEAN AUTO

NOTE: Print the background check or QC (whichever applies), then write the reagent and lot # information and file in the appropriate tab in the Hematology reagent binder.

Reference

1. Sysmex XN-3100 *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-50 *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.
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