



STEM CELL LABORATORY (STCL)



DOCUMENT NUMBER: STCL-EQUIP-023 JA2

DOCUMENT TITLE:

Sysmex XN-450 Hematology Analyzer Reagent Replacement

DOCUMENT NOTES:

Document Information

Revision: 01

Vault: STCL-Equipment-rel

Status: Release

Document Type: STCL

Date Information

Creation Date: 19 Mar 2025

Release Date: 20 Mar 2025

Effective Date: 20 Mar 2025

Expiration Date:

Control Information

Author: WATER002

Owner: WATER002

Previous Number: None

Change Number: STCL-CCR-562

STCL-Equip-023 JA2

Sysmex XN-450 Hematology Analyzer Reagent Replacement

1. When the replacement of reagent is required, an error message appears. Promptly acknowledge the error message by clicking execute to enter the reagent replace dialog box and proceed to replace the indicated reagent. Verify that “CAPS LOCK is off.

2. Replacing a new diluent / hemolytic agent
 - a. Touch the name of the reagent to be replaced.
 - b. Place a check-mark next to ‘Replace the reagent,’ then place the cursor in the reagent code text box.
 - c. Using the hand-held reader, scan the reagent code on the new reagent container.
NOTE: Scan Reagent Code 2 when available on the reagent container.
 - d. Remove the cap from the expired/empty container and carefully remove the spout.
 - e. Pull out the dispensing, set straight up.
 - f. Insert the dispensing set straight into the new reagent container and close the cap.
 - g. Select [Execute]
 - a. Reagent replacement starts. When complete, the dialog box closes automatically.

3. Replacing Dye
 - a. Display the [Reagent Replacement] dialog box.
 - b. Prepare the new reagent cartridge.
 1. Confirm the reagent has not expired.
 - c. Pull out the dye holder.
 - d. Slowly remove the dye cover, taking care that dye does not drip.
 - e. Remove the entire dye holder.
 1. When the dye holder is removed, a Help dialog box appears in the IPU screen.
 - f. Remove the old reagent cartridge from its holder.
 - g. Install the new reagent cartridge into the holder.
 1. Make sure the color of the label on the new reagent cartridge matches the color of the dye cover and install. Analyzer will beep as confirmation of new reagent installation.
 2. If the wrong reagent is installed, the analyzer beeps repeatedly and the Help dialog box appears in the IPU screen.
 - h. Place the dye cover.
 1. Place into dye holder.
 2. The ID of the new reagent is read automatically, and the information is registered.
 - i. Close the dye holder.
 1. Reagent replacement starts.
 2. When complete, the reagent replacement window closes automatically

4. Upon successful completion of a reagent replacement, reagent information is automatically stored in the **Reagent Replacement Log** located in the **History icon** on the Main Menu.

STCL-EQUIP-023 JA2 Sysmex XN-450 Hematology Analyzer Reagent Replacement
 Stem Cell Laboratory, DUMC
 Durham, NC

CAUTION:

- Do not use the reagent outside of the written intended use, or not according to the written directions for use.
- When replacing this reagent, do not refill and use the same container.
- Handle the reagent with care to prevent air bubbles from foaming.
- Do not use expired reagents.
- If the reagent is removed after it has been connected, (i.e. opened), it may become contaminated with bacteria causing its performance to deteriorate. Therefore, reconnecting an open reagent is not recommended.
- NEVER allow contact of the reagent with the human body. Avoid contact with skin and eyes and avoid ingestion. If it encounters the skin, rinse skin thoroughly. If it gets in the eye, rinse with large amounts of water and seek immediate medical attention. If swallowed, seek medical advice immediately.
- Before use, please read the safety data sheet carefully.

NOTE: Reagent Verification: Several Systems are used together to verify reagent consistency from cube to cube and from lot # to lot #. Reagent verification is not a stand-alone documented process. The following programs validate the reagent/instrument system: 1) daily background checks (reflected maintenance log sheet), 2) the IPU reagent log, 3) the moving average QC file (selected parameters used primarily by the service representative, 4) the commercial control files (three levels) which are compared across peer groups using ILQC and Insight Programs, 5) the XN-450 problem log).

Signature Manifest**Document Number:** STCL-EQUIP-023 JA2**Revision:** 01**Title:** Sysmex XN-450 Hematology Analyzer Reagent Replacement**Effective Date:** 20 Mar 2025

All dates and times are in Eastern Time.

STCL-EQUIP-023 JA2 Sysmex XN-450 Hematology Analyzer Reagent Replacement**Author**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATER002)		19 Mar 2025, 11:21:34 AM	Approved

Management

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATER002)		19 Mar 2025, 11:21:47 AM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		19 Mar 2025, 12:11:06 PM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Bing Shen (BS76)	Associate Director, Quality Assurance	20 Mar 2025, 12:55:21 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Amy McKoy (ACM93)	Document Control Specialist	20 Mar 2025, 01:43:39 PM	Approved