**Complete Blood Count: Whole Blood and Body Fluids on the Sysmex XN-9000 Automated Hematology System**

1. **PRINCIPLE**

The Sysmex XN-9000 is an integrated system that incorporates hematology analytical modules as well as automated slidemaker/stainer(s).

The analytical module is a quantitative automated hematology analyzer for *in vitro* diagnostic use in determining 31 whole blood diagnostic parameters and 7 body fluid diagnostic parameters. Examination of the numerical and/or morphological findings of the complete blood count by the physician are useful in the diagnosis of disease states such as anemias, leukemias, allergic reactions, viral, bacterial, and parasitic infections.

The analyzer performs hematology analysis according to the hydrodynamic focusing (DC Detection), flow cytometry method (semiconductor laser), and SLS-hemoglobin method.

The device counts and sizes red blood cells (RBC) and platelets (PLT) using electronic resistance detection. Hematocrit (HCT) is measured as a ratio of the total RBC volume to whole blood using cumulative pulse height detection. Hemoglobin (HGB) is converted to SLS-hemoglobin and read photometrically.

The white blood cell (WBC) count, differential (DIFF), reticulocytes (RET), nucleated red blood cells (NRBC) and fluorescent platelets (PLT-F) are all evaluated using flow cytometry with a semiconductor laser exploiting the differences in cell size, complexity and RNA / DNA content. Forward scattered light provides information on blood cell size and Lateral scattered light provides information on the cell interior such as the size of the nucleus. Lateral fluorescent light intensity increases as the concentration of the stain becomes higher. By measuring the intensity of the fluorescence emitted, information is obtained on the degree of blood cell staining. Fluorescent light is emitted in all directions. The XN detects the fluorescent light that is emitted sideways.

The Sysmex SP-10 is a fully automated hematology slide preparation and staining system. Whole blood specimens are mixed and aspirated and a wedge type blood smear is prepared using hematocrit information from the Sysmex XN to determine optimum smearing criteria. The dried smear is automatically loaded into an individual slide cassette and is then advanced to the staining area. In the staining area, stain and buffer are dispensed into the cassette at operator-defined intervals.

The system also provides a manual mode operation where pre-made smears may be added to be stained. The unit is self-monitoring and alarms when operation is interrupted.

Slides prepared by the Sysmex SP-10 are used for differentiation and morphologic evaluation of cellular elements of whole blood.

**II SPECIMEN**

* 1. Required specimen
		1. Whole blood should be collected in EDTA-2K or EDTA-3K anticoagulant.
		2. Serous and synovial fluids should be collected in EDTA-2K anticoagulant.
		3. The use of anticoagulant with CSF specimens is neither required nor recommended.
	2. Specimen volumes required
		1. Optimal draw is a 12 x 75 mm tube filled to capacity
		2. A minimum of 1 mL of whole blood is required for sampler analysis.
		3. Manual analysis whole blood mode
			1. Closed tube – 1 mL
			2. Open tube – 300 μL
			3. Open microtube – 160 μL
		4. Manual analysis body fluid mode
			1. Closed tube – 1 mL
			2. Open tube – 300 μL
			3. Open microtube – 160 μL
		5. Manual analysis – SP-10
			1. Closed tube smear and staining – 1 mL is optimal, 200 μL is aspirated.
			2. Microtainer mode – 300 μL minimum volume, 60 μL is aspirated.
	3. Unacceptable specimens including those listed below must be redrawn:
		1. Clotted samples or those containing clots, fibrin strands, or platelet clumps. All specimens should be checked visually for obvious clots prior to sampling by the analyzer.
		2. Grossly hemolyzed samples
		3. Samples drawn above an IV line
	4. Characteristics that may affect test results: lipemia, icterus, and cold agglutinins.
	5. Stored Specimen Stability
		1. Stored at 4-8oC, EDTA blood samples with normal results may be analyzed up to 48 hours without significant loss of differential stability.
		2. Sample stability at room temperature is 24 hours. Samples stored at room temperature may exhibit an increase in MCV after 24 hours, which may be minimized by refrigeration.
		3. Allow refrigerated samples to come to room temperature and mix well before analysis.
	6. Do not place CBC and Diff samples on a mechanical rocker. Constant rocking may alter white cell membranes, resulting in false interpretive messages.

**WARNING**: All patient specimens should be considered potentially infectious and must be handled with precautions used for human blood, as described in CDC recommendations and in compliance with the Federal OSHA Bloodborne Pathogen Standard, 29CFR part 1910.1030. Follow specimen handling as outlined by laboratory safety policy.

**Recommended**: Wear gloves and a lab coat. Wear safety glasses if there is a risk of splashing.

1. **SUPPLIES & REAGENTS**
	1. Supplies
		1. Deionized water
		2. Lint-free plastic lined lab wipes
		3. Gauze
		4. Test tubes
		5. Plastic squeeze bottles
		6. CELLCLEAN® AUTO
		7. Sysmex reagents
		8. Commercial controls; XN CHECKTM, XN CHECKTM BF
		9. Alcohol prep pads, isopropyl. Used to clean SP-10 spreader glass
		10. Microscope slides, frosted with rounded / clipped corners
			1. 76 x 26 mm; 0.9 – 1.2 mm thick
	2. Sysmex Reagents
		1. Sysmex reagents and CELLCLEAN AUTO are used on the Sysmex XN-Series modules.
		2. All reagents are used at room temperature and are to be used within the manufacturer’s expiration date on each container.
		3. Record date received and date opened on container.
		4. All reagents are azide free and are intended for *in vitro* diagnostic use only. **Do not** ingest.

XN REAGENTS OPEN EXPIRATION

CELLPACKDCL 60 Days

CELLPACK DST 60 Days

CELLPACKDFL 60 Days

SULFOLYSER 60 Days (1.5L)

 90 Days (5.0L)

Lysercell WNR 60 Days

Fluorocell WNR 90 Days

Lysercell WDF 90 Days

Fluorocell WDF 90 Days

Fluorocell RET 90 Days

Fluorocell PLT 90 Days

SP REAGENTS

Stain – Wright or Wright Giemsa Exp. Date on Bottle

[Harleco Wright Stain]

Buffer – pH 6.6 – 7.2

[Sysmex ColorWright Phosphate Buffer Solution, pH 7.2]

Methyl Alcohol Exp. Date on Bottle

[ThermoScientific Methyl Alcohol High Purity]

CELLPACK DCL 60 Days

* 1. Diluents
		1. CELLPACK DCL: Whole blood diluent for use in hematology analyzers and for use as a rinsing agent for the spreader glass, sample pipette, and piercer on the SP-10.

CELLPACK DCL Storage

1. Store at 2o-35oC away from direct sunlight.
2. If frozen, thaw and mix thoroughly before using.
3. CELLPACK DCL is clear and colorless. If it is showing signs of contamination or instability such as cloudiness or discoloration, replace.

CELLPACK DCL Stability

1. Unopened, it is stable until expiration date printed on the container.
2. Opened, stable for 60 Days.

CELLPACK DCL Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. CELLPACK DCL does not have ingredients with those characteristics.

* + 1. CELLPACK DST (DST): Concentrated diluent of reagent for use in hematology analyzers.

CELLPACK DST Storage

1. Store at 2o-35oC away from direct sunlight.
2. If frozen, thaw and mix thoroughly before using.
3. CELLPACK DST is clear and colorless. If it is showing signs of contamination or instability such as cloudiness or discoloration, replace.

CELLPACK DST Stability

1. Unopened, it is stable until expiration date printed on the container.
2. Opened, stable for 60 Days.

CELLPACK DST Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. CELLPACK DST does not have ingredients with those characteristics.

* + 1. CELLPACK DFL (DFL): Whole blood diluent for use in hematology analyzers; used in combination with Fluorocell™ RET for the analysis of reticulocytes, or with Fluorocell PLT for the analysis of platelets by flow cytometry method using a semiconductor laser.

CELLPACK DFL Storage

1. Store at 2o-35oC away from direct sunlight.
2. Do not use the reagent if it is suspected to have frozen.
3. Replace the reagent if it is showing signs of contamination or instability such as cloudiness or discoloration.

CELLPACK DFL Stability

1. Unopened, it is stable until expiration date printed on the container.
2. Opened, stable for 60 Days.

CELLPACK DFL Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. CELLPACK DFL does not have ingredients with those characteristics.

* 1. Lysing Reagents
		1. SULFOLYSER (SLS): Reagent for the automated determination of hemoglobin concentration of blood. Sulfolyser is a lysing reagent that releases the hemoglobin to be measured by the SLS hemoglobin method.

SULFOLYSER Storage

1. Store at 1o-30oC away from direct sunlight.
2. Allow the container to equilibrate to environmental temperature (15-30o) prior to use.
3. Do not use the reagent if it is suspected to have frozen.
4. Replace the reagent if it is showing signs of contamination or instability such as cloudiness or discoloration.

SULFOLYSER Stability

1. Unopened, it is stable until expiration date printed on the container.
2. Opened, stable for 60 Days (1.5L) or 90 Days (5L).

SULFOLYSER Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. SULFOLYSER does not have ingredients with those characteristics.

* + 1. Lysercell WNR: Reagent product to be combined and used with Fluorocell WNR. By hemolyzing red blood cells with Lysercell WNR and by differentiating white blood cells (non-basophil), basophils, and nucleated red blood cells with Lysercell WNR and Fluorocell WNR, the white blood cell count, basophil count, basophil percentage, nucleated red blood cell count, and nucleated red blood cell percentage are analyzed.

Lysercell WNR Storage

1. Store at 2o-35oC away from direct sunlight.
2. Allow the container to equilibrate to environmental temperature (15-30o) prior to use.
3. Do not use the reagent if it is suspected to have frozen.
4. Replace the reagent if it is showing signs of contamination or instability such as cloudiness or discoloration.

Lysercell WNR Stability

1. Unopened, it is stable until expiration date printed on the container.
2. Opened, stable for 60 Days.

Lysercell WNR Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. Lysercell WNR does not have ingredients with those characteristics.

* + 1. Lysercell WDF: Reagent product to be combined and used with Fluorocell WDF. By hemolyzing red blood cells with Lysercell WDF and dying the white blood cell component with Fluorocell WDF, the counts and percentages of neutrophils, immature granulocytes, lymphocytes, monocytes, and eosinophils are analyzed.

Lysercell WDF Storage

1. Store at 2o-35oC away from direct sunlight.
2. Allow the container to equilibrate to environmental temperature (15-30o) prior to use.
3. Do not use the reagent if it is suspected to have frozen.
4. Replace the reagent if it is showing signs of contamination or instability such as cloudiness or discoloration.

Lysercell WDF Stability

1. Unopened, it is stable until expiration date printed on the container.
2. Opened, stable for 90 Days.

Lysercell WDF Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. Lysercell WDF does not have ingredients with those characteristics.

* 1. Staining Reagents
		1. Fluorocell WNR: Used to stain the nucleated cells in diluted and lysed blood samples for determination of white blood cell count, nucleated red blood cell count and basophil count in blood.

Fluorocell WNR Storage

1. Store at 2o-35oC in a dark place.
2. Do not use the reagent if it is suspected to have frozen.

Fluorocell WNR Stability

1. Unopened, it is stable until expiration date printed on the container.
2. Opened, stable for 90 Days.

Fluorocell WNR Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. Refer to the MSDS.

* + 1. Fluorocell WDF: Used to stain the leukocytes in diluted and lysed blood samples for determination of differential count in blood.

Fluorocell WDF Storage

1. Store at 2o-35oC in a dark place.
2. Do not use the reagent if it is suspected to have frozen.

Fluorocell WDF Stability

1. Unopened, it is stable until expiration date printed on the container.
2. Opened, stable for 90 Days.

Fluorocell WDF Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. Refer to the MSDS.

* + 1. Fluorocell RET: Used to stain the reticulocytes in diluted blood samples for the assay of reticulocyte count, reticulocyte percent in blood.

Fluorocell RET Storage

1. Store at 2o-35oC in a dark place.
2. Do not use the reagent if it is suspected to have frozen.

Fluorocell RET Stability

1. Unopened, it is stable until expiration date printed on the container.
2. Opened, stable for 90 Days.

Fluorocell RET Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. Refer to the MSDS.

* + 1. Fluorocell PLT: Used to stain the platelets in diluted blood samples for the assay of platelet counts in blood.

Fluorocell PLT Storage

1. Store at 2o-35oC in a dark place.
2. Do not use the reagent if it is suspected to have frozen.

Fluorocell PLT Stability

1. Unopened, it is stable until expiration date printed on the container.
2. Opened, stable for 90 Days.

Fluorocell PLT Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. Refer to the MSDS.

* 1. Cleaning Agent
		1. CELLCLEAN AUTO: Detergent for fully automated hematology analyzers. To be used as a strong alkaline detergent to remove lysing reagents, cellular residuals, and blood proteins remaining in the hydraulics of the analyzer. For use as a cleaning fluid for the hematology analyzers and the SP-10.

CELLCLEAN AUTO Storage

1. Store at 1-25oC, away from direct sunlight.
2. Do not use the reagent if it is suspected to have frozen.

CELLCLEAN AUTO Stability

1. Unopened, it is stable until expiration date printed on the container.

CELLCLEAN AUTO Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. Refer to the MSDS; CELLCLEAN AUTO is corrosive and may cause burns to skin.

* 1. Stain / Buffer for SP-10
		1. Romanowsky stain (Wright or Wright-Giemsa)
			1. Used to fix and stain blood cells for the purpose of differentiation and morphologic evaluation

[Harleco Wright Stain]

* + 1. Phosphate Buffer pH 6.6 – 7.2

[Sysmex ColorWrightPhosphate Buffer Solution, pH 7.2]

**WARNING:** Stain contains methanol. Methanol is flammable and poisonous. Potential human carcinogen. May be fatal if ingested. Harmful if inhaled. Causes irritation to eyes, skin and respiratory tract.

* 1. Methyl Alcohol (Methanol), anhydrous for SP-10
		1. Used for cleaning of the staining system and cassettes. Also may be used for optional staining pre-fix.

[Thermo Scientific Methyl Alcohol High Purity]

**WARNING:** Methanol is flammable and poisonous. Potential human carcinogen. May be fatal if ingested. Harmful if inhaled. Causes irritation to eyes, skin and respiratory tract.

* 1. Deionized water, pH ~7.0 – Lab system
	2. Commercial Control Material for XN analyzers
		1. XN CHECK
1. Manufactured by Streck, available as a tri-level package.
2. Whole blood commercial control used to monitor performance of the XN analyzers.
3. Formulation
	1. Consists of human red and white blood cells with a platelet component suspended in fluid medium.
	2. Each vial contains 3 mL of control material.
4. Storage
	1. Store vials at 2-8oC
	2. Do not freeze or expose to excessive heat.
5. Stability
	1. Unopened and properly stored, XN CHECK is stable until the expiration date printed on the unopened vial.
	2. Open vial stability is 7 days when promptly refrigerated after each use.
	3. Record the date on each vial upon opening or cap piercing.
	4. Heat or freezing can damage XN CHECK without gross visible changes. Moderate hemolysis can be normal. Deterioration is suspected when the mean of the control results is not within the assay expected ranges after appropriate troubleshooting.
	5. If deterioration is suspected, call the Sysmex Technical Assistance Center.
	1-888-879-7639 (1-888-8SYSMEX)

**WARNING: POTENTIALLY INFECTIOUS MATERIAL.**

The human blood used in XN CHECK is non-reactive for Hepatitis B Surface Antigen and negative for antibodies to HIV-1, HIV-2, and Hepatitis C Virus using FDA specified techniques. However, no current tests can assure the absence of these pathogens. XN CHECK should be considered potentially infectious and must be handled with precautions used for human blood as described in CDC recommendations and in compliance with the Federal OSHA Bloodborne Pathogen Standard, 29CFR, 1910.1030.

* + 1. XN CHECK BF
1. Manufactured by Streck, available as a bi-level package.
2. Body Fluid commercial control used to monitor performance of the XN analyzer body fluid analysis mode.
3. Formulation
4. Each vial contains 3 mL of control material
5. Storage
	1. Store vials at 2-8oC
	2. Do not freeze or expose to excessive heat.
6. Stability
	1. Unopened and properly stored, XN CHECK BF is stable until the expiration date printed on the unopened vial.
	2. Open vial stability is 30 days when promptly refrigerated after each use.
	3. Record the date on each vial upon opening or cap piercing.
	4. Heat or freezing can damage XN CHECK BF without gross visible changes. Deterioration is suspected when the mean of the control results is not within the assay expected ranges after appropriate troubleshooting.
	5. If deterioration is suspected, call the Sysmex Technical Assistance Center. 1-888-879-7639 (1-888-8SYSMEX)

**WARNING: POTENTIALLY INFECTIOUS MATERIAL.**

The human blood used in XN CHECK BF is non-reactive for Hepatitis B Surface Antigen and negative for antibodies to HIV-1, HIV-2, and Hepatitis C Virus using FDA specified techniques. However, no current tests can assure the absence of these pathogens. XN CHECK BF should be considered potentially infectious and must be handled with precautions used for human blood as described in CDC recommendations and in compliance with the Federal OSHA Bloodborne Pathogen Standard, 29CFR, 1910.1030.

* 1. SP-10 Quality Control
		1. Daily, examine a stained smear from the routine workload for smear and stain quality. This is incorporated in the daily DI-60 (Cellavision) QC.
	2. Calibrators
		1. XN CALTM: for use in calibrating the analyzer for WBC, RBC, HGB, HCT, PLT, and RET

XN CAL Storage

* 1. Store the calibrator in a dark refrigerator at 2-8oC

XN CAL Stability

* + - 1. Unopened and properly stored, XN CAL is stable until the expiration date printed on the unopened vial.

b. Open vial stability is 4 hours.

**WARNING: POTENTIALLY INFECTIOUS MATERIAL.**

The human blood used in XN CAL is non-reactive for Hepatitis B Surface Antigen and negative for antibodies to HIV-1, HIV-2, and Hepatitis C Virus using FDA specified techniques. However, no current tests can assure the absence of these pathogens. XN CAL should be considered potentially infectious and must be handled with precautions used for human blood as described in CDC recommendations and in compliance with the Federal OSHA Bloodborne Pathogen Standard, 29CFR, 1910.1030.

2. XN CALTM PF: for use in calibrating the analyzer for PLT-F (platelet count obtained from the PLT-F channel)

XN CAL PF Storage

* 1. Store the calibrator in a dark refrigerator at 2-8oC

XN CAL PF Stability

a. Unopened and properly stored, XN CAL PF is stable until the expiration date printed on the unopened vial.

b. Open vial stability is 4 hours.

**WARNING: POTENTIALLY INFECTIOUS MATERIAL.**

The human blood used in XN CAL PF is non-reactive for Hepatitis B Surface Antigen and negative for antibodies to HIV-1, HIV-2, and Hepatitis C Virus using FDA specified techniques. However, no current tests can assure the absence of these pathogens. XN CAL PF should be considered potentially infectious and must be handled with precautions used for human blood as described in CDC recommendations and in compliance with the Federal OSHA Bloodborne Pathogen Standard, 29CFR, 1910.1030.

* 1. XN Reagent Replacement
		1. When the reagent runs out during analysis, the analysis is paused and an error message appears in the analyzer area of the Control menu.
		2. Display the [Reagent Replacement] dialog box to replace the reagent.
			1. Select the help button on the control menu
			2. Select [Execute]
				1. Remaining Reagent Volume indicator appears
		3. Replacing a new diluent / hemolytic agent
			1. Display the [Reagent Replacement] dialog box
			2. Remove the cap from the new reagent container
				1. Confirm the reagent has not expired
			3. Input the reagent code (barcode)
				1. Place the cursor in the reagent code field
				2. Scan the reagent code on the outer box of the new reagent with the hand-held barcode reader or manually enter the reagent code
				3. Select [OK]
			4. Remove the cap from the old reagent container.
			5. Pull out the dispensing set straight up.
			6. Insert the dispensing set straight into the new container.
			7. Close the cap.
			8. Select [Execute]
				1. Reagent replacement starts. When complete, the dialog box closes automatically.
		4. Replacing CELLPACK DST with an RU-20
			1. Display the RU-20 Maintenance menu.
			2. Select [Replace Reagent]
			3. Remove the cap from the new reagent container.
				1. Confirm that reagent has not expired
			4. Input the reagent code (barcode)
				1. Place the cursor in the reagent code field.
				2. Scan the reagent code on the outer box of the new reagent with the hand-held barcode reader or manually enter the reagent code.
				3. Select [OK]
				4. Remove the cap from the old reagent container
				5. Pull out the dispensing set straight up.
				6. Insert the dispensing set straight into the new reagent container.
				7. Close the cap
				8. Select [Execute]

Reagent replacement starts. When complete, the dialog box closes automatically.

* + 1. Replacing Dye
			1. Display the [Reagent Replacement] dialog box.
			2. Prepare the new reagent cartridge.
				1. Confirm the reagent has not expired.
			3. Open the top front cover.
			4. Pull up the cover from the reagent that is to be replaced.
				1. When the dye solution cover is pulled up, a Help dialog box appears in the IPU screen.
			5. Remove the old reagent cartridge from its holder
			6. 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.
			7. Pull down the cover on the reagent until you hear a click.
				1. When the cover is pulled down, the Help dialog box closes automatically.
				2. The ID of the new reagent is read automatically and the information is registered.
			8. Close the top front cover.
				1. Reagent replacement starts.
				2. When complete, the reagent replacement window closes automatically.
		2. SP-10 Reagent Replacement

The following is a list of replacement messages and the reagent requiring replacement:

 **Message** **Reagent**

\*DCL not filled CELLPACK DCL

\*Stain 1 not filled in Chamber 1 Stain

\*Stain 1 not filled in Chamber 2 Stain

\*Stain 2 not filled 2nd stain (if using 2 stain method)

\*Rinse water not filled Deionized water

 (internal chamber not filled)

Replace Rinse water Deionized water

 (external container empty)

Replace buffer Buffer

Replace methanol Methanol

\* Reagents with internal chambers. Other reagents use bottle sensors.

1. When a reagent container is empty, an alarm sounds and a dialogue box displays. Press **[OK]** to silence the alarm and close the dialogue box.
2. Press **[Help]** icon and follow the corrective action message.
3. When replacing a reagent with an internal chamber, press **[OK]** to clear the action message and reset. For reagents with bottle sensors, the error clears when the reagent is replaced or filled.
4. Replace reagent using clean technique. Avoid placing spout kit or sensor on a contaminated surface.

**Document all reagent changes on the appropriate log.**

1. **CALIBRATION and PRECISION**

Initial calibration is performed during installation by the Sysmex Field Service Engineer (FSE). Per the XN-Series IFU, calibration should be performed only when indicated. The calibration of Sysmex hematology analyzers does not expire and is not reagent lot dependent.

It is not recommended to make time-based adjustments to the analyzer calibration as this can decrease the quality of the results over time. Sysmex instead recommends the use of **BCQM*h***, an evidenced-based approach that will detect deterioration of analyzer quality in real time and allow immediate corrective action to be taken.

The **BCQM*h*** program provides a calibration verification system that may detect issues earlier than with traditional quality control methods. Because the XN CHECK and XN CHECK BF controls are cleared by the U.S. Food and Drug Administration (FDA) for use as control and calibration verification materials, calibration status is confirmed every time the controls are analyzed.

The laboratory must verify calibration if one or more of the following occur:

* Critical parts or assemblies are replaced.
* Calibration Verification fails (QC values are outside of acceptable limits) and troubleshooting indicates that there is no major underlying problem with the analyzer, reagents or quality control materials.
* When advised by Sysmex Service Representative.

Calibration verification is performed by:

* Following manufacturer’s instruction for instrument operation.
* Testing at least two levels of control materials each day, whereby the controls meet the laboratory’s criteria of acceptability.
* Review and documentation of commercial QC and X-BarM QC data.

If indicated, the calibration procedure may be done by a Sysmex SE on-site or remotely through the Sysmex Network Communications System (SNCS™) with the Sysmex Calibration Specialist.

|  |  |  |
| --- | --- | --- |
| **Remote Calibration Procedure** | **Step** | **Action** |
| 1 | A Sysmex representative will contact the laboratory to schedule the Managed Calibration event. |
|  | 2 | Sysmex will ship the calibrator to arrive before the scheduled Managed Calibration event. |
|  | 3 | Sysmex will send a reminder email to the Hematology Mgr or laboratory representative (CLS) prior to the scheduled event. The email contains the schedule date, time and instructions for the Managed Calibration event. Follow the instructions in the email to prepare. |
|  | 4 | On the pre-arranged day, a Sysmex representative will contact the designated laboratory representative. SNCS is used to remotely connect with the analyzer. |
|  | 5 | Sysmex will ask the CLS to log off the Information Processing Unit (IPU). Sysmex will then remotely log into the IPU with a username and password that prevents viewing or access to patient data. |
|  | 6 | Sysmex will review the analyzer’s historical and current QC recovery with the CLS. During this analysis, if indicated by abnormal QC recovery, Sysmex may discontinue the Managed Calibration event and schedule an on-site service visit for analyzer troubleshooting and calibration verification. |
|  | 7 | Using SNCS, Sysmex will prepare the IPU and analyzer for calibration verification. |
|  | 8 | Prepare the calibrator as described in the calibrator package insert when instructed by the Sysmex representative. |
|  | 9 | Analyze the calibrator when instructed by the Sysmex representative. Data is captured automatically and analyzed by Sysmex.  |
|  | 10 | Sysmex will compare the recovery of the initial analyses to the calibrator package insert ranges and discuss the recovery with the CLS. Sysmex will instruct the operator to analyze the calibrator up to four additional times. This entire process verifies analyzer accuracy and precision. |
|  | 11 | If the calibrator and QC recovery indicate a calibration adjustment is required, Sysmex will recommend adjusting the calibration using SNCS. During this analysis, if indicated by abnormal calibrator recovery, Sysmex may discontinue the Managed Calibration event and schedule an on-site service visit for analyzer troubleshooting and calibration verification. |
|  | 12 | If an adjustment is made, Sysmex will prepare the IPU and analyzer to verify the calibration adjustment using SNCS. Sysmex will instruct the operator to analyze the calibrator six times. |
|  | 13 | After calibration verification passes, Sysmex will prepare the IPU and analyzer to run at least two levels of QC. |
|  | 14 | Mix and analyze the QC material when instructed by the Sysmex representative. |
|  | 15 | Once the calibration verification and QC recovery meets manufacturer specifications, Sysmex will retrieve data from the IPU using SNCS to prepare a certificate of calibration verification. Sysmex will send the completed certificate of calibration verification to automatically print on the IPU printer. This certificate contains information about reagent and calibrator lot numbers, expiration dates, precision data, calibrator and QC recovery and acceptable ranges for calibrator recovery. |
|  | 16 | Sysmex will review the certificate and post-calibration QC recovery with the operator and log off the IPU. The SNCS remote event will be terminated and Sysmex will instruct the operator to log onto the IPU. |
|  | 17 | Sign the certificate of calibration verification to document review and acceptance of calibration and post-calibration QC recovery and retain it in XN Calibration binder. |
|  |  |
| **Important** **Procedure Notes** | * If calibration fails the first time, notify your supervisor or the Sysmex Field Service Representative. Recalibrate with the same or new lot of calibrators and perform the following:
1. Select at least 10 different fresh blood samples whose values have been determined by duplicate analysis in another instrument known to be accurately calibrated.
2. If all specimens have less than 15% difference, then the instrument is ready to run.
3. Run the specific level of controls for your shift.
4. If controls are IN, then you can begin processing patient samples.
5. If controls are NOT IN, notify your supervisor, Sysmex Field Service Representative/IR Dept. or call tech support.
* Critical dilution or analytical parts and assemblies include:
* Pipettor assembly
* Flow Cytometry Module (FCM) Detector Block
* RBC Detector Assembly
* Hemoglobin Detector Assembly
 |

1. **QUALITY CONTROL**

Quality control is performed to monitor an analyzer’s performance over time.

XN CHECK & XN CHECK BF is used to monitor the performance of the XN analyzer. Quality control should be run in accordance to licensing agency regulations and laboratory policy. It should be noted that for troubleshooting purposes, additional control runs may be necessary.

QC results must be reviewed for acceptability by CLS before reporting patient results. Document results on appropriate log.

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| --- | --- |
| **Frequency of QC Run** | **XN CHECK** control: **L1, L2, L3** will be performed daily on each shift.**XN CHECK** **BF** control: **L1, L2** will be performed on 1st and 2nd shift. **L1, L2** will be performed on 3rd shift when a patient body fluid sample is performed.SP-10 QC slide and DI-60 will be evaluated daily through the cell location test on AM shift.**Note**: Since the XN only has one sample pathway, i.e. it only has one needle for aspiration, it does not matter whether it is done in **AUTO or MANUAL** mode. |
|  |  |
| **QC Sample Preparation**  | **Step** | **Action** |
| 1 | Remove vials from refrigerator and allow them to come to room temperature (18-25°C), for approximately 15 minutes before mixing. |
|  | 2 | Mixing instructions:**NOTE: Do NOT mix mechanically or vortex** |
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|  |  |  |
| **QC Sample Processing (Auto)** | **Step** | **Action** |
| 1 | Make sure the analyzer and the sampler are in **READY** state. |
| 2 | Check that tube holder has retracted into the analyzer, press mode button if necessary. |
|  | 3 | Place QC in **RED** labelled rack in the feeder. Feeder will auto-start and send QC material to each XN module. |
|  | 4 | When analysis is done, results will be displayed in the IPU. |
|  | 5 | Results will automatically be sent to ***Insight*** and **BCQM*h*** programs, plotted on the L-J Chart and the Radar Chart for review. |

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| **QC Sample Processing (Manual)** | **Step** | **Action** |
| 1 | Check the Status indicator LED on the analyzer to confirm analyzer is in **READY** state. |
| 2 | Press the mode switch to eject the tube holder. |
|  | 3 | Properly mix the QC sample and place in the tube holder. |
|  | 4 | Press the start switch on the analyzer.* The tube holder will slide in and the sample will be aspirated
* When the analysis is complete, the tube holder slides out
 |
|  | 5 | Remove the QC sample, repeat steps for next QC sample. |
|  | 6 | Results will automatically be sent to ***Insight*** and **BCQM*h*** programs, plotted on the L-J Chart and the Radar Chart for review. |
|  |  |
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| **BF QC Sample Processing (Manual Mode Only)** | **Step** | **Action** |
| 1 | Check the Status indicator LED on the analyzer to confirm analyzer is in **READY** state. |
| 2 | If the tube holder is not ejected, press the mode switch. Tube holder will slide out. |
|  | 3 | Select the **[Change Analysis Mode]** button on the control menu. |
|  | 4 | Select **[Body Fluid]** mode. Analyzer will automatically perform an Autorinse and background count. |
|  | 5 | Select **[OK]**. |
|  | 6 | Select **[Manual Analysis]** button on the control menu. |
|  | 7 | Select **[Read ID]** (Make sure **[CAP OPEN]** is **NOT** selected). |
|  | 8 | Properly mix the QC sample and press **[start switch]** on the analyzer.* The tube holder will slide in and the sample will be aspirated
* When the analysis is complete, the tube holder slides out and results are displayed.
 |
|  | 9 | CLS will review results and either accept or cancel the run.  |
|  | 10 | Accepting the run will transfer the results to ***Insight*** and **BCQM*h*** programs, plotted on the L-J Chart and the Radar Chart for review. |
|  | 11 | Remove the QC sample, repeat steps for next QC sample. |
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| **Cell Location QC Slide** | **Step** | **Action** |
| 1 | Select a blood sample with a WBC count greater than 7x103/µl to reduce the processing time. |
| 2 | Prepare a slide in the manual mode of the SP-10 using this method:* Enter the specimen ID as [QC-[CURRENT DATE]]. Once the slide is stained it will automatically be transported to the DI-60.
 |
|  | 3 | The slide will be scanned using the same method used to collect images for patients’ samples. |
|  | 4 | Once processing is complete, click **[Tools]** on the top tool bar, select **[Cell** **Location].** Select the new slide at the top of the list. (Cell location images automatically delete after 5 days). |
|  | 5 | Review each image for any missed nucleated cells. Double-click an area for magnification if necessary.* **Green** boxes mark nucleated cells. The cell does NOT have to be completely inside the box. As long as there is a box associated with a cell it indicates the system found the cell.
* **Blue** boxes mark artifacts or other objects the number of these objects must not exceed 50%.
* **Missed** cells are those not marked with any box.
* **Black** boxes mark cells not needed in the 200 cell process for cell location.
 |
|  | 6 | Review all images by clicking the right arrow. For each image, enter the number of missed cells in the input field when all images have been examined, the result will appear as a “%”.Note: When needed, results may also be printed by clicking **[Print Result]** if analyzer is connected to a printer. |
|  | 7 | Results must be > 97%. If result is less than the acceptable percentage, dry clean the objective with lens paper and repeat QC slide. |
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| **Evaluating XN QC Results** | **Reviewing and Managing QC with BCQM*h* Program** |
| The BCQM*h* program allows the CLS to customize QC analysis preferences for QC analysis into the program. The BCQM*h* Dashboard will notify the CLS as to when QC analysis is required and if that analysis falls within the acceptable limits. The dashboard colors are:* **Green** – No issues detected. All control requirements have been met. Analyzer is **Ready** for patient analysis.
* **Yellow** – indicates additional action/information is required. Follow onscreen steps for returning to analysis ready.
* **Red** – Indicates service is required due to a detected issue not resolved by

recommended corrective action.* **Resolve** –is activated if a **QC error** has been detected.
* **QC is overdue** –end user needs to analyze QC since it exceeds the timeframe determined by the preferences screen.

For a calendar view of whether the QC passed or failed, access the Summary report which will also display background status.* + - P= Last 2 different levels of QC passed
		- F= QC failed
		- B= Background counts pass
		- X= Background counts failed
		- ?= Run QC
		- L=XNBF QC passed
		- D=XNBF QC failed
		- S= service event
		- Calibration (EBC)

**Corrective Action Process when QC fails**When CLS intervention is necessary, the BCQM*h* application provides dynamic step-by-step instructions that are easy to follow. All actions are documented in the activity log. |
|  | **Step** | **Action** |
| 1 | Once a QC issue is detected, the **[Resolve]** button becomes active for the affected analyzer**;** click **[Resolve].** |
| 2 | Follow prompts to the next course of action. The instructions button gives details on how to perform the troubleshooting action. |
|  | 3 | Once all controls have finished analysis, click **[Yes, Start Troubleshooting].**  |
|  | 4 | Perform the recommended troubleshooting task.Once a task is finished, click **[Complete]**, type your initials/NUID and add a comment before advancing to the next troubleshooting step.  |
|  | 5 | If the issue is not resolved through the series of troubleshooting tasks the program will alert the Technical Assistance Center and someone will be contacting you. |
|  |  |
|  |  |
|  | **Reviewing and Managing QC without BCQM*h* Program (downtime)** |
|  | **Step** | **Action** |
| 1 | Review QC results for acceptability by clicking on the QC file icon. This will allow you to view the files in:* 1. QC File screen
		1. Allows for review of the latest QC results in Radar Chart format for the QC file that is selected in the list.
		2. Any point exceeding the upper or lower limit is marked with a red “X”.
1. QC Chart screen
2. Allows for review of detailed graph data of all QC runs for selected file.
3. Analysis data is plotted cumulatively and displayed in the chart area as a line graph.
4. Any point exceeding the upper or lower limit is marked with a red “X”.
5. User must scroll up and down through the chart to view all parameters for each run.
 |
|  | 2 | Controls are flagged in red if the values fall outside of the established range. CLS must take the appropriate corrective actions to troubleshoot any out-of-range QC result (this may include repeating QC, using a fresh vial of QC, performing maintenance, or contacting Sysmex TAC). |
|  | 3 | After resolving the QC issue, navigate to the QC Chart and select the out-of-range QC data point. Select the **[Manage]** button on the toolbar. |
|  | 4 | Select **[Not Manage]** to exclude data from the following:1. Statistical computations (SD, Mean, CV)
2. Variable target computation
3. Number of data points = n

An open circle will be displayed on the L-J Chart when the QC run is not managed or excluded and is not connected by a line to the adjacent QC runs. |
|  | 5 | Add a comment describing the corrective actions taken by:1. Select **[Input Any Comment]** to input a free text comment.
2. Select **[OK]**
3. A comment bubble will be displayed when a comment exists for a QC run.
4. The comment will be visible in the comment display area when the cursor is placed on the QC run.
 |
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| **Reviewing Cell Location QC Slide** | **Step** | **Action** |
| 1 | **Review the blood smears macroscopically for acceptability:**1. Smears are sufficient length (greater than half the length of the unfrosted portion of the slide).
2. The feathered edge becomes gradually thinner without streaks, holes or tails.
3. Even, consistent staining of blood smear.
 |
|  | 2 | **Review the blood smears microscopically for acceptability:**1. Relatively even distribution of cellular elements.
2. Acceptable morphology within the working area.
3. None or very little artifact of the cell morphology (e. g., “punched-out” RBC’s, smashed WBC’s).
4. None, or very little stain precipitate or debris.
5. The staining is consistent and imparts the characteristic cytoplasmic color differences and distinct nuclear chromatic patterns of the whole spectrum of blood cells. Acceptable stains will display the following characteristics:
6. RBC’s should be pink to orange. There should be good differentiation between normochromic, hypochromic, and polychromatic cells.
7. Lymphocytes will display dark purple nuclei with varying shades of blue cytoplasm.
8. Neutrophils will display dark purple nuclei, with light pink cytoplasm and lilac granules.
9. Monocytes will show lighter purple nuclei. The cytoplasm of the monocytes will be gray-blue with reddish granules.
10. Eosinophils show bright orange granules in the cytoplasm.
11. Basophils display dark blue granules in the cytoplasm.
12. Platelets will be violet to purple.
 |
|  | 3 | If smear quality is unsatisfactory, clean, or if necessary, replace the spreader glass. If still unable to obtain an acceptable smear, refer to the SP-Series Implementation Manual troubleshooting section. If the troubleshooting steps do not resolve the problem, notify the supervisor / key operator when available or call the Sysmex Technical Assistance Center (TAC) 1-888-879-7639. Document all corrective action. |
|  |  |

1. **OPERATING PROCEDURE**
	1. Start-Up Procedure
		1. Checks prior to turning on
			1. Visual inspections of analyzer / system / reagents
				1. Place completed samples into final storage area for the lab
				2. Remove any items that may interfere with operations
				3. Gather and re-locate all empty racks to designated processing or sample loading area
				4. If applicable, verify waste container is empty
				5. Verify network / host connections are properly working
				6. Ensure that the towers (slide supply cassettes) have sufficient slides. Fill with glass slides.
2. Remove the tower to be filled.
3. Remove the metal insert from the end of the tower.
4. Fan the slides to prevent them from adhering to each other and place them with the frosted end up and towards the open end of the tower.
5. Replace the metal insert and replace the tower with the frosted end of the slides towards the back of the analyzer.
	* + - 1. Verify sufficient reagent supply is nearby
				2. Fill the cassette supply table with clean, dry single cassettes. The Sysmex logo should be forward and the notch at the bottom must be away from you (or to the left). The supply table holds up to 100 cassettes. A minimum of 8 cassettes are required for start-up.
		1. Turning ON the entire system
			1. Verify that all power switches for each device are in the ON position
			2. Press the green master switch on the BT to power ON the entire system
		2. Log on to the XN-IPU
			1. When the logon dialog box appears, enter user name and password
		3. Analyzers and SP-10 self-checks
			1. XN: Initialization of the mechanical parts; Rinse; Temperature stabilization; Background Check (up to 3 times)

|  |
| --- |
| **XN Acceptable Background Counts** |
| **Parameters** | **Acceptable Limit** |
| WBC-N | 0.10 x 103/ μL |
| WBC-D | 0.10 x 103/ μL |
| RBC | 0.02 x 106/μL |
| HGB | 0.1 g/dL |
| PLT-I | 10 x 103/ μL |
| PLT-F | 3 x 103/ μL |

b. SP-10: System check to evaluate internal stored data files; shutdown check to determine whether shutdown was performed properly, a mechanical initialization sequence.

* + 1. Analyze Quality Control Material
	1. Patient Sample Processing
		1. System Analysis (sampler analysis)
			1. Make sure the analyzer and the sampler are in READY state
			2. Check that tube holder has retracted into the analyzer, press mode button if necessary
			3. Place barcoded sample(s) in rack(s) in the feeder.
			4. Rack(s) will be automatically pushed forward and routed to BT.
			5. Samples will run, results will be displayed in the IPU.
			6. On-Board IPU rules or Sysmex WAM will determine repeat or reflex testing
			7. Rack will run in reverse to perform repeat or reflex testing on the same XN.
			8. If smear is required, rack will be transported to SP-10 via feeder line and samples will be aspirated by SP-10.
			9. If no smears are required, rack will be transported via collector line to the collector and will not be routed to SP-10.
			10. Remove the rack(s) when analysis in completed.
		2. Manual Analysis - XN
			1. Check the status of the analyzer. Confirm the analyzer is ready.
			2. Press the mode switch to eject the tube holder.
			3. Select the Change Analysis Mode button on the control menu
			4. Select analysis mode
				1. [Whole blood] is selected when whole blood is being analyzed
				2. [Low WBC] Select this to perform low WBC analysis on whole blood
				3. [Pre-Dilution] select when running 1:7 pre-diluted blood.
			5. Select [OK]
			6. Select Manual Analysis button on the control menu
			7. Input sample ID or select [Read ID]
			8. Select [OK]
			9. Properly mix the specimen and place in the tube holder
				1. If running microtainer, remove the cap using caution to avoid splattering.
			10. Press the start switch on the analyzer
				1. The tube holder will slide in and the sample will be aspirated
				2. When the analysis is complete, the tube holder slides out
			11. Remove the sample, repeat steps for additional samples
			12. Review results in IPU to determine whether repeat or reflex testing is required. Rerun sample if required. Make smear if required.
		3. Body Fluid Analysis - XN
			1. Check the status of the analyzer. Confirm the analyzer is ready.
			2. Press the mode switch to eject the tube holder.
			3. Select the Change Analysis Mode button on the control menu.
			4. Select [Body Fluid]
			5. Select [OK]
				1. The analyzer will automatically perform a background check up to three times
			6. Select the Manual Analysis button on the control menu
			7. Input the sample ID or select [Read ID]
			8. Select [OK]
			9. Properly mix the specimen and place in tube holder.
				1. If running microtainer, remove the cap using caution to avoid splattering
			10. Press the start switch on the analyzer
				1. The tube holder will slide in and the sample will be aspirated
				2. When the analysis is complete, the tube holder slides out
			11. Remove the sample
			12. Perform Background check prior to running additional samples if indicated
			13. Return analyzer to Whole Blood mode prior to running whole blood samples.
		4. Off-line analysis: The conveyor for the analyzer, or the conveyor for the SP-10 is separated from the transport line of the overall system and operated as a standalone device
			1. Press mode switch on the conveyor
			2. Verify conveyor is in READY state
			3. Place the rack in the designated area in the right pool of the conveyor for the analyzer that you wish to use.
			4. Transport begins automatically
			5. Remove the rack after analysis is complete
			6. Press the mode switch on the conveyor.
		5. SP-10 Manual Mode – Smear and Stain
			1. Press [Conv. Int.] on the SP-10 main menu screen
			2. Press [Interrupt]
			3. Select [Return]
			4. Select [Manual] on the SP-10 main menu screen
			5. Op Mode is set to [Smr + Sta], Smpl. Tube is set to [Closed]
			6. Input Specimen information, Sample ID, HCT, select number of slides to be made
			7. Thoroughly mix the sample and place in 10th rack position
			8. Place the rack so that the sample aligns with the tube gripper and that the left end of the rack fits the label on the sampler
			9. Select [Start]
				1. Analysis will begin
				2. When the tube is returned to the rack, remove the rack
			10. Press [Return] [Conv. Int.] [Stop Int.]
		6. SP-10 Manual Mode – Stain Only
			1. Select [Manual] mode
			2. Select [Op. Mode], [Stain]. Do not proceed until [START] button is green.
			3. Place labeled, unstained blood films into cassettes at the front of the cassette supply table on the right side of the analyzer. If multiple slides are to be stained, place them in consecutive cassettes.
			4. Press [Start]
			5. The cassettes will be fed to the stain table and the smears will be stained. An empty cassette will follow to indicate the end of the run.
		7. SP-10 Micro Mode
			1. Select [Manual]
			2. Choose [Op. Mode], [Smr.+Stain] and set [Smpl. Tube] to [micro]
			3. Input Specimen information, Sample ID, HCT
			4. Place the thoroughly mixed uncapped microtainer in the micro collection sample tube holder.
			5. Select [Start]
			6. Micro tube will be lowered into position and sample will be aspirated.
			7. When aspiration is complete, micro tube will be returned to home position and should be removed.
		8. SP-10 Smear Only – No staining occurs

Smear mode may be used in System, Single, or Manual Modes. To access Smear Mode:

* 1. Press **[Settings]** on the main screen. (A password may be required.)
	2. Press **[Select]**, **[Cond.]**, **[Mode]**.
	3. Press **[Op. Mode]** and select **[Smear]**. Press **[RETURN]** and **[YES]** to accept the settings.
	4. To use Smear Only in System Mode:
		1. Place bar coded samples in a Sysmex rack.
		2. Place the rack in the feeder.
		3. Racks will auto-start.
		4. Racks are transported to the XN analyzer and then to the SP-10 where a smear will be prepared when appropriate criteria are met.
	5. To use Smear Only in Off Line Mode: The conveyor for the SP-10 is separated from the transport line of the overall system and operated as a standalone device
		1. Press mode switch on the conveyor
		2. Verify conveyor is in READY state
		3. Place the rack in the designated area of the right pool of the sampler for the SP-10.
		4. Transport begins automatically
		5. Remove the rack after analysis is complete
		6. Press the mode switch on the conveyor.
	6. To use Smear Only in Manual Closed Mode:
		1. Press [Conv. Int.] on the SP-10 main menu screen
		2. Press [Interrupt]
		3. Select [Return]
		4. Select [Manual] on the SP-10 main menu screen
		5. Op Mode is set to [Smear], Smpl. Tube is set to [Closed]
		6. Input Specimen information, Sample ID, HCT, select number of slides to be made
		7. Thoroughly mix the sample and place in 10th rack position
		8. Place the rack so that the sample aligns with the tube gripper and that the left end of the rack fits the label on the sampler
		9. Select [Start]
			+ 1. Analysis will begin
				2. When the tube is returned to the rack, remove the rack
		10. Press [Return] [Conv. Int.] [Stop Int.]
			1. Remove the rack when sampling is complete.

Return Setting to SMEAR + STAINING

Press **[Settings], [Select], [Cond.], [Mode], [Smr + Sta.]**.Press **[RETURN]** and **[YES]**.

 **Note:** *If setting is left at* ***Smear****, the system will perform smear only in all modes.*

* 1. Shutdown – performed daily
		1. CELLCLEAN AUTO is used to shut down the entire system. Refer to the XN-9000 *Instructions for Use* for detailed, illustrated procedures.
			1. Confirm analyzers, conveyors, and SP-10 are at ready.
			2. Confirm tube holders are retracted into the analyzers.
			3. Obtain empty blue maintenance rack labeled SRRA00
				1. Place one tube of CELLCLEAN AUTO in the rack for each module or SP-10 requiring maintenance beginning with position 10 and load backwards.
			4. Place rack on feeder unit, sampler unit will auto-start.
			5. XN on-board maintenance history will auto-populate
			6. Document shutdown on the SP maintenance log.
	2. Maintenance

Document all maintenance procedures on the appropriate log sheet for the SP-10. Maintenance performed on the XN will be automatically tracked in the maintenance history.

* + 1. SP-10
			1. Daily
				1. Clean Spreader Glass: Power must be on to perform this maintenance – may be performed prior to Shutdown, or after Start-up.

Press **[Maint.]** on the main screen. (Maintenance button is not available during routine operation.)

Press **[Spreader Glass]** and the “Spreader Glass Replace” screen displays.

Press **[OK]** to move the smear unit forward.

Remove the left tower for easier access to the spreader glass.

Wipe the spreader in one direction with an alcohol prep pad.

Replace the tower so that the frosted end of the slides are towards the back of the analyzer.

Press **[OK]** to return the smear unit to the home position.

Press **[OK]** to reset the spreader glass cycle counter or **[CANCEL]** to allow the cycle count to continue.

Press **[RETURN]**.

* + - * 1. Clean Single Cassettes

Place cassettes in a bin with open end up.

Pour methanol over the cassettes, filling them.

Swish the methanol and pour off into designated container for reuse.

Invert cleaned cassettes on absorbent material to dry.

**Note:** *Methanol may be reused for cleaning cassettes up to three (3) times. Discard when appropriate, according to laboratory policy.*

1. Weekly
	1. Perform Shutdown 2 (Weekly)
		1. Press **[SHUTDOWN]** on the main screen.
		2. Press **[Shutdown 2]** (Weekly).
		3. The shutdown screen displays the number of cassettes and amount of methanol required for the shutdown process. Ensure that required amounts are available.
		4. Place a tube of CELLCLEAN AUTO in position 10 of a Sysmex rack.
		5. Place the rack so that the tube is lined up with tube gripper.
		6. Press **[OK].**
		7. When the process completes, the SP-10 turns off automatically.
		8. To restart the SP-10, press the green button on the right side.
	2. Clean DI water/Buffer containers
		1. If re-usable containers for deionized water and/or buffer are used, empty weekly.
		2. Rinse with methanol and allow to dry.
		3. Fill with fresh deionized water or buffer.
	3. As Needed Maintenance

Refer to the XN-9000 *Instructions for Use* for detailed and illustrated instructions for performing as needed maintenance.

1. **PROCEDURAL NOTES AND CALCULATIONS**
	1. If making a dilution of a patient specimen and running in XN Whole Blood mode, multiply the parameters by the dilution factor
	2. If correcting the HGB or HCT due to interfering substances, recalculate and correct the affected indices:
		1. MCHC = HGB / HCT x 100
		2. MCH = HGB / RBC x 10
		3. MCV = HCT / RBC x 10
	3. Use the Help function on the SP-10 when errors and messages display. Use the error icon on the XN to display help menu.
	4. While slides are being processed on the SP smear table, the START key may not be available for manual mode processing
	5. During normal processing of slides on the SP-10, Maint., Settings, and Shutdown functions are not available.
	6. Current settings for XN and SP-10 should be recorded and maintained in the XN-Series Resource Manual and the SP-Series Implementation Manual.
	7. Current on-board rules must be exported and saved on external storage device each time a change is made. A printout of the rules should be inserted in the XN-Series Resource Manual each time a change is made.
	8. **Do not** place samples on a mechanical rocker. Excessive mixing may alter white cell membranes resulting in false interpretive messages.
	9. For troubleshooting specifics refer to the Sysmex XN-9000 *Instructions for Use*.
2. **LIMITATIONS OF PROCEDURE**
3. XN-Series Manufacturer Stated Linearity

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Range** | **Units** |
| WBC | 0-440.0  | x103/μL |
| RBC | 0-8.60  | x106/μL |
| HGB | 0-26.0  | g/dL |
| HCT | 0-75.0  | % |
| PLT, PLT-F | 0-5000  | x103/μL |
| RET% | 0-30 | % |
| NRBC% | 0-600 | /100 WBC |

1. Parameters that exceed these limits are flagged with @ beside the result. The sample must be diluted, rerun and multiplied by the dilution factor.
2. Note the use of dilution for linearity on the patient report.
3. Possible Sample Interferences
4. Specimens must be free of clots and fibrin strands.
5. Marked changes in plasma constituents, (e.g., low sodium, extremely elevated glucose) may cause cells to swell or shrink. The blood to anticoagulant ratio is important.
6. Red cell fragments, microcytic RBC's, or white cell cytoplasmic fragments may interfere with automated platelet counts. A fluorescent platelet may be performed to avoid this interference.
7. Cold agglutinins produce spurious macrocytosis, elevated MCH's & MCHC's, falsely decreased RBC counts and HCT's. Rare, warm agglutinins produce the same spurious results as a cold agglutinin.
8. Extremely elevated WBCs may cause turbidity and falsely increase the hemoglobin, in addition to RBC and HCT values.
9. Severely hemolyzed samples (*in vitro*) falsely decrease RBC and hematocrit. Recollect hemolyzed specimens.
10. Giant platelets and clumped platelets may falsely elevate the WBC count and falsely decrease the platelet count. Platelet clumping and/or "platelet satellitism" can occur in specimens collected in EDTA. This may falsely elevate the WBC count and falsely decrease the platelet count. There are different methods for handling samples with platelet clumping or “platelet satellitism”. These methods include vortexing of the original sample and reanalyzing or adding amikacin to the original sample and reanalyzing. Laboratories should define and validate the method(s) used by their facility.
11. Abnormal paraproteins found in Multiple Myeloma patients can falsely increase the HGB. To correct HGB perform plasma replacement.
12. Severely icteric samples may falsely elevate the HGB value and related indices. Make a 1:5 dilution with CELLPACK.
13. Rocking specimen excessively, may affect the WBC differential.
14. Megakaryocytes may falsely increase WBC counts on automated hematology analyzers.

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