PROGRAM Standard Operating Procedure – Laboratory Services	
Title: HEM20200 XN 1000 Running Quality Control	Policy Number: 15-204-V1
Program Name: Laboratory Services	
Applicable Domain: Lab, DI and Pharmacy Services	
Additional Domain(s): NA	
Effective Date:	Effective Date:
Issuing Authority: Director, Laboratory and Diagnostic Imaging Services	Issuing Authority:
Accreditation Canada Applicable Standard: Biomedical Laboratory Services	

GUIDING PRINCIPLE:
Quality control is the routine monitoring of the analyzer's performance using commercial controls. Using statistical methods, controls are analyzed and results are compared to known characteristics.. This allows for changes to performance to be detected so action can be taken if needed.

PURPOSE/RATIONALE:
This procedure gives instructions on how to perform quality control on the Sysmex XN-1000.

DEFINITIONS:
QC- Quality Control
LIS- Laboratory Information System

SCOPE/APPLICABILITY:
This procedure applies to Medical Laboratory Technologists (MLT's) who will be performing this procedure.

EQUIPMENT
Sysmex XN-1000

EQUIPMENT CALIBRATION AND MAINTENANCE:
- Preventative Maintenance (PM) is performed annually by the Sysmex Field Service Agent (FSA).
- Daily Maintenance is performed by laboratory staff. Refer to **HEM20100 XN-1000 Daily Maintenance**.

SPECIAL SAFETY PRECAUTIONS:

- Ensure proper PPE is used such as gloves, lab gowns and eye protection when possible exposure to splashes.
- Ensure all samples are treated following universal precautions and assume all products as potentially infectious.

QUALITY CONTROL:

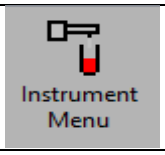
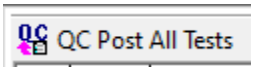
- Whole Blood
  - XN Check, Levels 1,2 and 3
  - Storage requirements- 2-8°C
  - Manufacturer Stability- 84 days
  - Open Stability- 7 days
  - Performed daily, once per shift

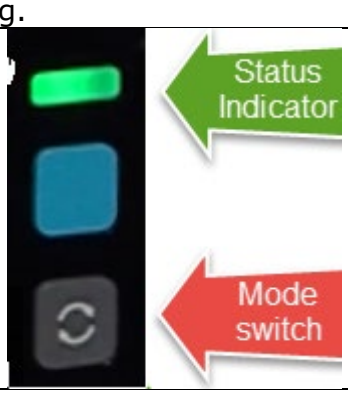
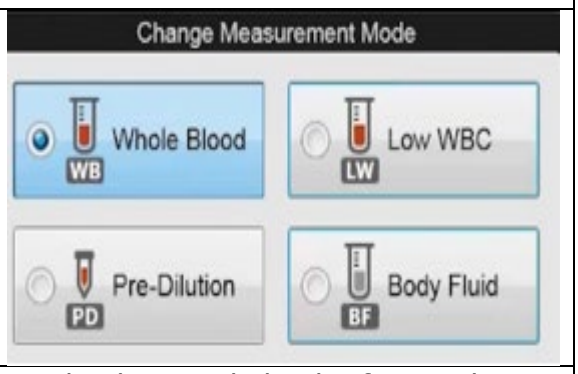
- Body Fluid
  - XN Check BF, Level 1 and 2
  - Storage requirements- 2-8°C
  - Manufacturer Stability- 84 days
  - Open Stability- 30 days
  - Performed once every 24 hours

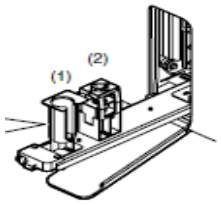
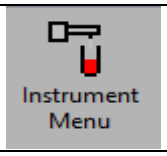
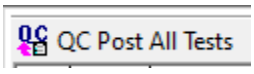
PROCEDURE INSTRUCTIONS:

Follow the steps in the table below

Step	Action
Performing Quality Control- Whole Blood	
1	Ensure QC vials are not expired then allow them to reach room temperature for 15 minutes before processing.
2	Ensure the analyzer and sampler are in "Ready" state, indicated by a green light on the Status Indicator LED display. 
3	Mix the XN Check by holding the vials vertically and roll each vial between the palms of the hands for 15-20 seconds. Continue to mix by holding the vial by the ends between the thumb and finger, rapidly inverting the vials 20 times end-over-end using a very quick turning motion of the wrist. **Note:** Do not use a mechanical mixer to mix the QC vials.
4	Place the 3 levels of XN Check QC vials on a sample rack and place on the right side of the sampler section. Slide the groove on the rack into the metal ridge on the right side (when facing the analyzer).
5	Once the rack is set in place, the analyzer will automatically start processing the QC material.
6	Once the sampling is completed the rack will be moved to the left-hand side of the sampler section. Remove the racks.
7	Log into SoftLab to verify results.

8	In the LIS open the Hematology Instrument Menu: Instrument Menu>SXN1(XN-1000-1-A)/SXN2(XN-1000-1-B)	
9	From your worksheet, locate the QC file you wish to verify and highlight it. Click on **QC Post All Tests.** When the prompt appears "Do you want to verify results with posting?" select **Yes.** Click **OK**	

Step	Action	
Performing Quality Control- Body Fluids		
1	Ensure QC vials are not expired then allow them to reach room temperature for 15 minutes before processing.	
2	Ensure the analyzer and sampler are in "Ready" state, indicated by a green light on the Status Indicator LED. Place the analyzer in Manual Analysis by pressing the **Mode Switch** button on the front of the analyzer.	
3	Click the **Change Analysis Mode** icon on the control menu.	
4	When the Change Measurement Mode screen appears select **Body Fluid** and hit **OK**.	
5	The analyzer will automatically perform a background check after Body Fluid analysis is selected. If the background values are below the acceptable values, the Status Indicator LED light will turn green and the anlayzer enters "Ready" state for body fluid analysis. If the background checks fail after 3 attempts it is considered an Error, refer to the XN Series Instructions For Use Manual for troubleshooting.	

6	Click the **Manual Analysis** icon in the analyzer area. • Confirm that "Read ID" is checked • Confirm that "Cap Open" is unchecked Click **OK**	
7	Mix the XN Check BF by holding the vial vertically and roll the vial between the palms of the hands for 15-20 seconds. Continue to mix by holding the vial by the ends between the thumb and finger, rapidly inverting the vials 20 times end-over-end using a very quick turning motion of the wrist. **Note:** Do not use a mechanical mixer to mix the QC vials.	
8	Place the XN Check BF vial in the manual tube holder (1). Press the blue start button on the front of the analyzer. After aspiration the tube holder slides out and you are able to remove the sample.	
9	Once the Status Indicator LED turns green, the analzer is in "Ready" state and the next level of XN Check BF can be run. Go to step 7.	
10	Once all QC vials are run press the **Mode Switch** button to switch back to Sampler Analysis.	
11	Log into SoftLab to verify results.	
12	In the LIS open the Hematology Instrument Menu: Instrument Menu>SXN1(XN-1000-1-A)/SXN2(XN-1000-1-B)	
13	From your worksheet, locate the QC file you wish to verify and highlight it. Click on **QC Post All Tests.** When the prompt appears "Do you want to verify results with posting?" select **Yes.** Click **OK**	

TROUBLESHOOTING:
Refer to the Sysmex XN Series Instructions for Use Manual for general troubleshooting guidance.

CROSS-REFERENCES:
HEM20100 XN-1000 Daily Maintenance

REFERENCES:
XN Series (XN-1000) Instructions for Use, (North American Edition, XN-11/XN-21), Kobe, Japan, November 2015

Running Quality Control, Stanton Territorial Hospital, November 2018

RELATED DOCUMENTS:
NA

APPROVAL:

April 17, 2025
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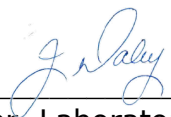
Date



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Director, Laboratory and Diagnostic Imaging Services

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	30 Nov 2018	Initial Release	K. Wilson
2.0	10 Mar 2025	Transferred to NTHSSA Template, Procedure reviewed	L. Howlett