

Operational Qualification

Automated Haematology Analyzer
XN-L Series

Author: Chew Kui Jien

Last Edited: 08 Mar 2018

Version: 1.0

Date: 01ST FEB. 2022

Calibration Certificate

This is to certify that Automated Hematology Analyzer XN-550 Serial No: 17581 installed at **ARPAN DIAGNOSTIC CENTRE** has been calibrated.

Calibration Done on: 01ST FEB. 2022
Calibration Validity: 01ST FEB. 2022 to 31th MAY. 2022
Calibration Due on: 30th MAY. 2022.

Parameter	WBC	RBC	HGB	HCT	PLT	RET(%)	RBC-O	PLT-O
CV %	1.2	0.4	0.4	0.3	2.2			
Acceptable Range	3.0	1.5	1.0	1.5	4.0			

For Sysmex India Pvt. Ltd.


Authorized Signatory

	WBC	RBC	HGB	HCT	PLT
Target	7.130	4.420	12.42	35.58	250.5
No. 2	7.06	4.53	12.6	37.5	250
No. 3	7.15	4.50	12.5	37.3	253
No. 4	6.88	4.50	12.6	37.3	248
No. 5	7.14	4.55	12.5	37.6	244
No. 6	7.09	4.52	12.6	37.4	263
No. 7	7.06	4.55	12.6	37.6	250
No. 8	7.14	4.53	12.6	37.4	249
No. 9	7.17	4.50	12.6	37.2	247
No. 10	7.10	4.53	12.5	37.4	246
No. 11	7.08	4.50	12.6	37.3	254

Mean Value	7.087	4.521	12.57	37.40	250.4
SD	0.082	0.020	0.05	0.13	5.4
CV (%)	1.2	0.4	0.4	0.3	2.2
Limit (%)	3.0	1.5	1.0	1.5	4.0

Document Properties

Document information

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Project Name	Operational Qualification
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File Name	XN-L Series

Document history

(Add one line for each new release or review version).

Version	Date	Author	Comments
1.0	08 Mar 2018	Chew Kui Jien	None

Document distribution

Sysmex Asia Pacific Pte Ltd

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Operational Qualification**1. General Outline****1-1 Performer**

The following person shall perform Operational Qualification (OQ) procedures as the person in charge of validation of the equipment in terms of calibration and testing.

Name: Satish Rajak


Company: Sysmex India Pvt. Ltd.

Date (day/month/year): 28/02/2020

Signature/Initial: 

1-2 Reviewer

People in charge of reviewing installation procedures and being representatives of the customer shall fill out the following blanks:

Name: DR ANIL SAVALIYA
Institution or company: ARPAN DIAGNOSTIC CENTRE
Title: PATHOLOGIST
Date (day/month/year): 28/02/2020
Signature/Initial: 

Name:
Institution or company:
Title:
Date (month/day/year):
Signature/Initial:

3-1 Equipment

The scope of this procedure is limited to the Operational Qualification (OQ) of the following equipment:

Customer: Arpan Diagnostic Centre

Department: Laboratory

Installation Site:

Address: 150 Feet Ring Road, Indira Circle, Near Raj Bank, Rajkot-360005

(Equipment Details)

Model Number: XN-550

Model Serial Number: 17581

Software Version Number: 00-18

2. Operational Qualification

2-1 List of Qualification Tests

Items listed in the table 1 below "List and Order of Qualification Tests" shall be checked by the performed.

Table 1: List and Order of Qualification Tests

Check Item No.	Scope of Tests
1	Program startup
2	Self-Diagnostics Tests
3	Sensor
4	Counter
5	Operation of sampler unit (if applicable)
6	Operation of drive motor
7	Operation of pipette/piercer
8	Running of QC result
9	Printing of sample result
10	Save as CSV format
11	Backup of sample result
12	Restore of sample result
13	Shutdown of whole system
14	Power Failure Test
15	Alarm Test
16	Set User
17	Audit Log

2-2 Equipment to be tested

Model Number: XN 550
Model Serial Number: 17581

2-3 Qualification Procedures and Records**(1) Check Item No. 1**

Check item: Program startup

Description: Check that the program runs normally at startup.

Procedures: 1. Switch on power of Information Processing Unit (IPU)
Check that the XN-L Series program runs normally after Windows operating system runs.
2. Perform log on by entering user and password.
3. Ensure that the Main menu screen is displayed.

(2) Check Item No. 2

Check item: Self Diagnostics Test

Description: Check the self-diagnostic test.

Procedures: 1. Switch on of Main Unit.
2. Ensure that the self-diagnostic test is performed successfully.

(3) Check Item No. 3

Check item: Sensor

Description: Check sensor on the Maintenance Menu screen to ensure that each item is within rated value.

Procedures: 1. Click on Controller Icon. From the Maintenance Menu screen click to open the sensor icon.
2. Check that the pressure of each unit is within the rated value
3. Check that the temperature of each unit is within the normal operating range.
4. Check that the convert value for HGB is within the rated value.
5. Check that the converted value for ASP SENSOR is within the rated value.
6. Check that the laser current is within the rated value (<195mA) by reviewing the service tab of the last measurement performed.

(4) Check Item No. 4

Check item: Counter

Description: Check that the counter works normally.

Procedures: 1. From the Maintenance Menu screen click to open the counter icon.
2. Run the blank measurement to see if the counter is running properly.

(5) Check Item No. 5

Check item: Operation of sampler unit

Description: Check that the sampler unit works normally.

Procedures: From sample analysis in sampler mode, verify:
- Tube pick-up
- Tube mixing
- Tube insert to tube holder

Operational Qualification

- Barcode Reading
- Cap piercing
- Tube returning

(6) Check Item No. 6

Check item: Operation of drive motor

Description: Check to see if *there is any abnormality occurring with the operation of the drive motor.*

Procedures: From the Maintenance Menu screen execute the following tests:

- Pipette/Piercer motor
- Sheath syringe
- Whole blood aspiration motor
- Tube holder motor
- Hand unit motor
- Tube mixing motor

(7) Check Item No. 7

Check item: Operation of piercer/pipette

Description: Check to see if there is any abnormality occurring with the operation of the pipette/piercer.

Procedures: Perform manual mode and sampler mode analysis.

(8) Check Item No. 8

Check item: Running of QC result

Description: Perform running of QC result.

Procedures:

1. Click the QC analysis icon on the controller
2. Select the QC file
3. Run the control.
4. Display of the QC analysis result.

(9) Check Item No. 9

Check item: Printing of sample result

Description: Perform test print of sample result.

Procedures: From the Sample Explorer screen, highlight the selected sample for printing. Click 'Report', 'Report (GP)'.

(10) Check Item No. 10

Check item: Save as CSV format.

Description: Export of sample result to CSV file.

Procedures: From the Sample Explorer screen, highlight the selected sample. Click 'Output' (CSV format) and save to a location.

(11) Check Item No. 11

Check item: Backup of sample result

Description: Print a report before backup. Delete/modify sample after backup.

Procedures: From the Sample Explorer screen, highlight the selected sample for back up. Click 'File', 'Backup' and save to a location.

(12) Check Item No. 12

Check item: Restore of sample result

Description: Perform restore of sample result.

Procedures:

1. Click 'File', 'Restore' and select from a location.
2. Print the sample result after restoration.

(13) Check Item No. 13

Check item: Shutdown of whole system
Description: Perform shutdown of whole system.
Procedures: 1. Click the Shutdown icon.
2. Set the Cell Clean on the manual aspiration probe or tube holder and press the Start switch.
3. Remove the Cell Clean when the ready LED turns off and the beeping stops.
4. Wait till the power off dialog box appear

(14) Check Item No. 14

Check item: Power Failure Test
Description: Perform power failure test.
Procedures: 1. Perform a sample run.
2. Power off the IPU and Main Unit.
3. Re-start the IPU and Main Unit. Ensure the last run sample result is still stored in the IPU.
4. Perform another sample run.

(15) Check Item No. 15

Check item: Alarm Test
Description: Perform alarm test.
Procedures: 1. Click Alarm sound selecting tab.
2. Click alarm sound 'Test'.
3. Click 'Reset Alarm' to stop the alarm sound.

(16) Check Item No. 16

Check item: Set user
Description: Perform set user.
Procedures: 1. Log in as an administrator and create a normal operator account
2. Uncheck the 'Modify the QC'.
3. Log off and log in as a normal operator and the password.
4. Click 'QC'.



(17) Check Item No. 17

Check item: Audit log
Description: Perform audit log check.
Procedures: 1. Log in as an administrator and create a normal operator account.
2. Log off and log as a normal operator.
3. Perform a sample analysis.
4. Log off and log in as an administrator, open the audit log.
5. Print the audit log.






Perform the qualification procedures stated in this document, fill out the appropriate row in the table2 "Operational Qualification Check Sheet" below.

2-3 Table 2. Operational Qualification Check Sheet

No.	Descriptions	Expected Results	Actual Results	Acceptable? [Yes/No]	Initial/Date
1	Operation of program startup	The program runs normally, and Main Menu screen is displayed.	OK	YES	<i>R. S. T.</i> 28/02/2022
2	Self-Diagnostic Test	Self-diagnostic test is performed successfully.	OK	YES	<i>R. S. T.</i> 28/02/2022
3	Sensor				
	Pressure 0.06MPa	0.06 ± 0.012	0.0607	YES	
	Pressure -0.03MPa	> 0.024, < 0.045	-0.0312	YES	
	Temperature: Reaction chamber	41 ± 3 °C	41 °C		
	Temperature: Reagent heater	41 ± 3°C	41.3 °C		<i>R. S. T.</i>
	Temperature: FCM analyzer unit	from 30°C to 40°C	37.5 °C		28/02/2022
	Temperature: FCM sheath	from 15°C to 35°C	31.6 °C		
	Temperature: Ambient temp.	from 5°C to 40°C	23°C		
	Convert value for HGB	5000 ± 200	5040	YES	
	Convert value for ASP SENSOR	5000 ± 200	5036	YES	
	Laser current	<195mA	118.7	YES	

	Descriptions	Rated value	Value checked	Acceptable? [Yes/No]	Initial/Date
4.	Counter				
	WB pump	-			NA
	Sheath syringe	-			NA
	Piercer	-			NA
5.	Operation of sampler unit (if applicable)				
	Tube pick up	Tube is picked up from the sampler adaptor in sampler unit	OK	YES	 28/02/2022
	Tube mixing	Tube is mixed by mixing motor	OK	YES	
	Tube inserts into sample tube holder	Tube is inserted into manual tube holder	OK	YES	
	Barcode Reading	Tube sample ID is read successfully	OK	YES	
	Cap piercer	Tube cap is piercer near the centre of the rubber area	OK	YES	
	Tube returning	Tube is returned to sampler adaptor	OK	YES	
6.	Operation of drive motor				
	Pipette/piercer motor	Pipette/piercer is moving up and down	OK	YES	 28/02/2022
	Whole blood suction motor	WB Aspiration pump is moving up and down.	OK	YES	
	Sheath syringe	Sheath syringe moving up and down.	OK	YES	
	Tube Holder motor	Manual tube holder moving front and back	OK	YES	
	Hand unit motor	Hand unit moving front-back and left-right	OK	YES	

No.	Descriptions	Rated value	Value checked	Acceptable? [Yes/No]	Initial/Date
	Tube mixing motor	Tube is mixed correctly	OK	YES	
7	Operation of pipette/piercer	Sample is aspirated properly	OK	YES	<i>R. S. K.</i> 28/02/2022
8	Running of QC result	- QC analysis results are displayed. - All parameters are within QC assay ranges.	YES	YES	<i>R. S. K.</i> 28/02/2022
9	Printing of sample result	-A Report can be printed. -Printed report is identical as displayed on IPU.	YES	YES	<i>R. S. K.</i> 28/02/2022
10	Output of CSV(sample result)	-Sample result can be save in CSV format. -Data saved in CSV file is correct.	YES	YES	<i>R. S. K.</i> 28/02/2022
11	Backup of sample result	- A sample report is printed prior to backup - Backup of sample result is performed successfully - Sample file is deleted/modified.	YES	YES	<i>R. S. K.</i> 28/02/2022
12	Restore of sample result	- Data restoration is performed successfully - The report printout is identical to the one before backup	YES	YES	<i>R. S. K.</i> 28/02/2022

13	Shutdown of Main Unit	Shutdown procedure is performed without any errors.	YES	YES	 28/02/2022
14	Power failure test	- The IPU and main unit restart normally after power is resumed. - Last sample result is still in IPU - Sample analysis is performed successfully after the power is restored.	YES	YES	 28/02/2022
15	Alarm Test	Alarm sounds at step 2, and stops at step 3.	YES	YES	 28/02/2022
16	Set User	User is not able to deleting QC results.	YES	YES	 28/02/2022
17	Audit Log	- All entries with corresponding user, time, and date in the audit log are accurate. - Audit log is printed and attached to this protocol	YES	YES	 28/02/2022

Remarks:

3-1 Attachment List

Attach the additional attachments to this page

Attachment No.	Description	No. of pages	Initial/Date
1	QC LEVEL 1(220110801)	3	1/2/22

Remarks:


Operational Qualification

Model Number XN 550
Serial Number 17581
Software Version Number 00-18
Installation Site

By the subsequent signature it becomes evident that all validation procedures for Operational Qualification (OQ) of the above stated equipment are completed by the performer.

-Performer

Name: Satish Rajak

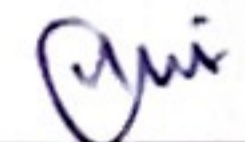
Signature: 

Date (day/month/year): 28/02/2022

By the subsequent signature the reviewer witnesses that all validation procedures for Operational Qualification (OQ) of the above stated equipment are completed by the performer.

-Reviewer

Name: DR ANIL SAVALIYA

Signature: 

Date (day/month/year): 28/02/22

-Reviewer

Name:

Signature:

Date (day/month/year):

End of Document



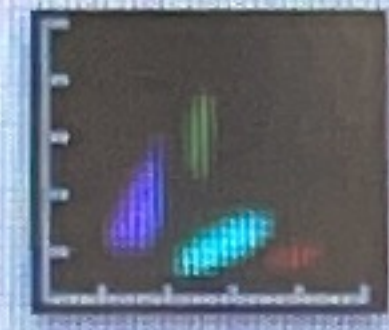
Menu



QC File



Explorer



Browser



Regist.



Modify



Manage



Display



Output



Range



File



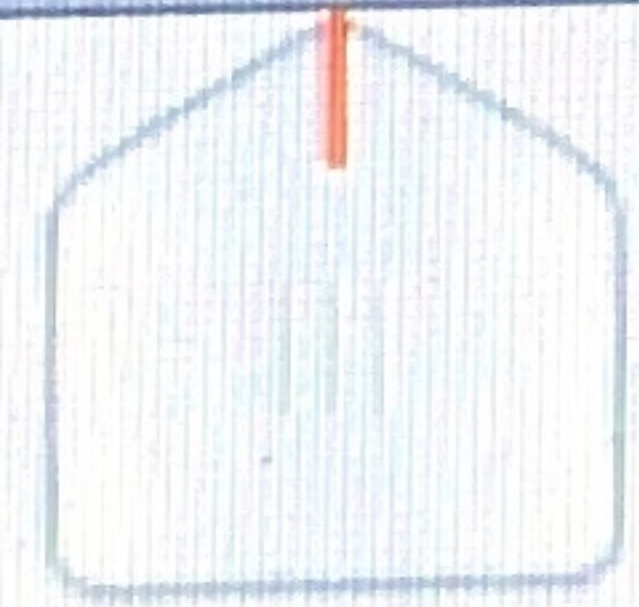
Delete

QC06 20/05/2022

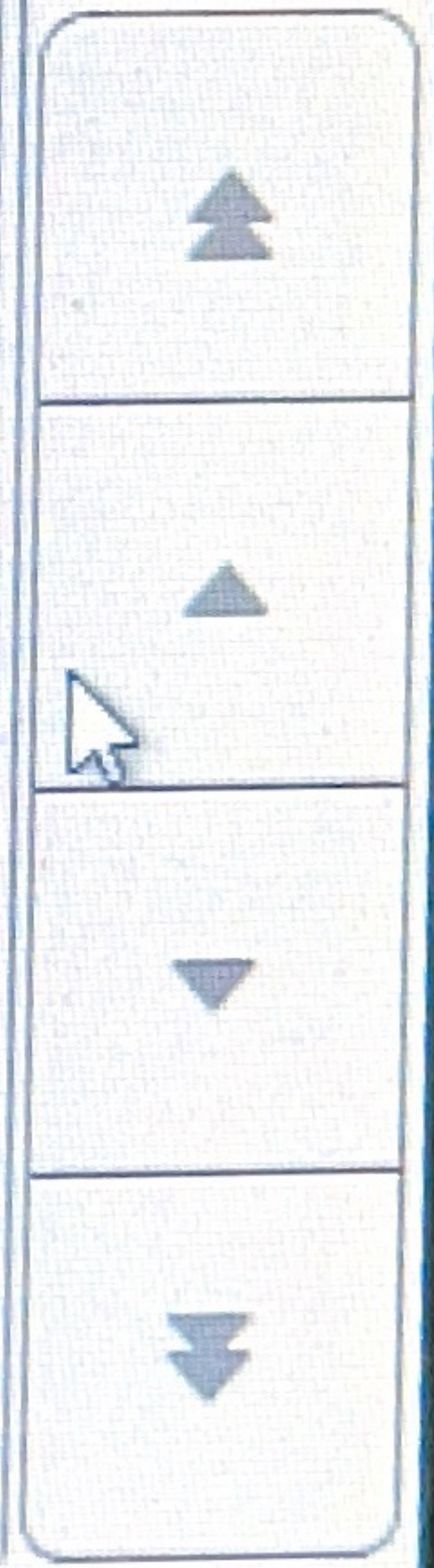
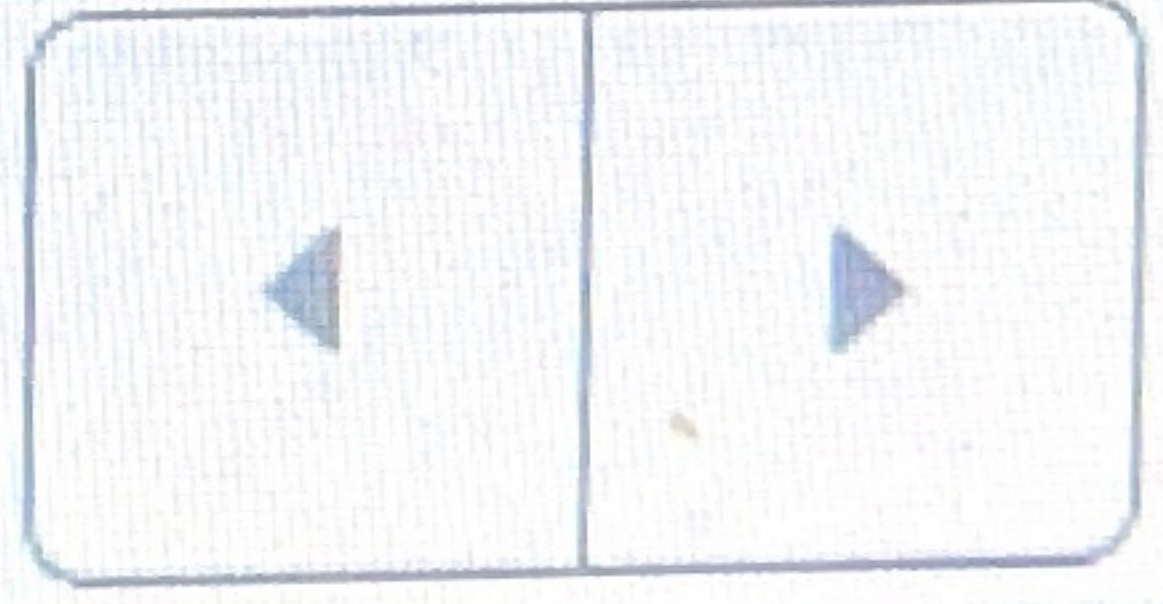
XN Control Level1 QC-22010801

Item	UL		Data	SD	
	Target	LL			Mean
RBC	2.38		2.18	----	
	2.23			2.18	2.18
	2.08			----	----
HGB	6.4		5.7	----	
	6.0			5.7	5.7
	5.6			----	----
HCT	20.5		17.2	----	
	18.5			17.2	17.2
	16.5			----	----
MCV	84.0		78.9	----	
	79.0			78.9	78.9
	74.0			----	----

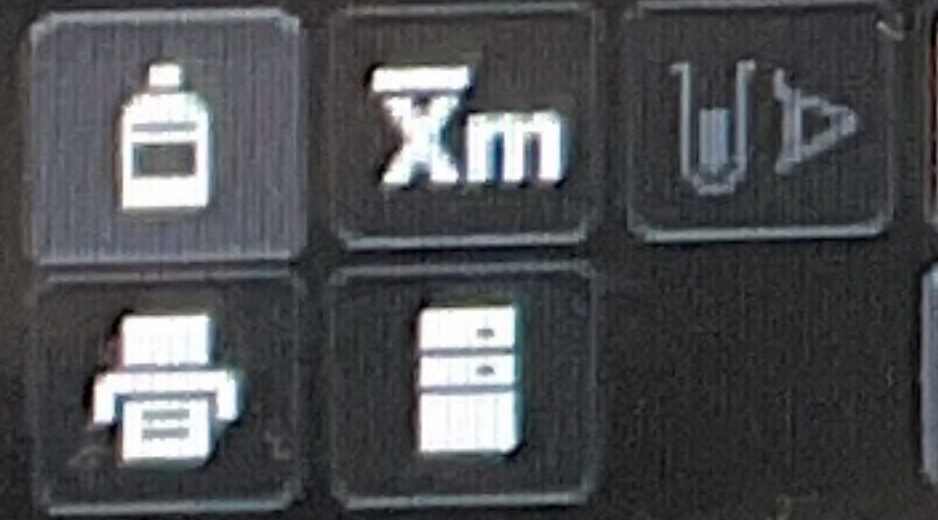
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01/02/2022
09:33



42-1

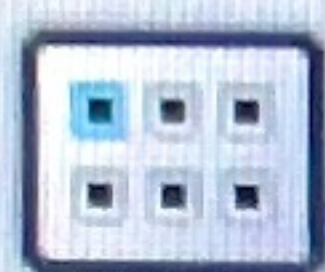


WB CBC DIFF

>411



Sampler



Menu



QC File



Explorer



Browser



Regist



Modify



Manage



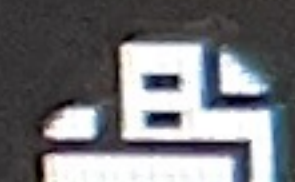
Display



Output



Range



File



Delete

QC06

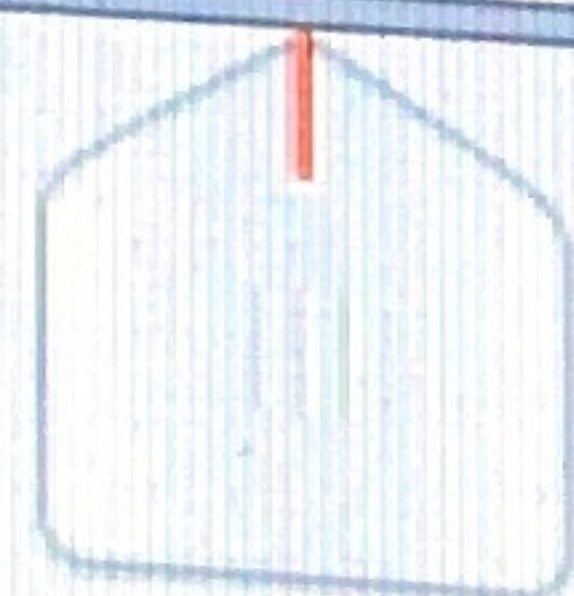
20/05/2022

XN Control Level1

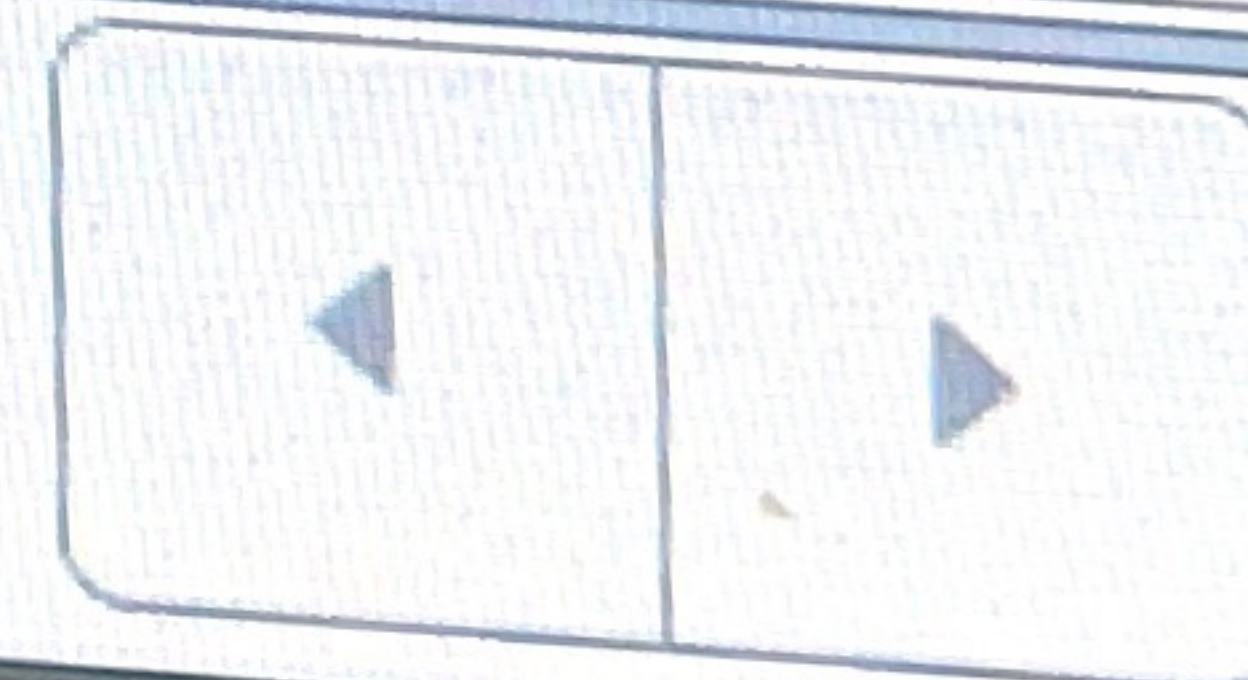
QC-22010801

Item	UL Target		Data	SD Mean CV
		LL		
MCH	28.1	25.6	26.1	26.1
MCHC	35.5	32.5	33.1	33.1
PCT	0.07	0.04	0.05	0.05
WBC-D	4.50	3.30	3.13	3.13

n=1



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42-1

Xm

WB CBC DIFF

>411



Menu



QC File



Explorer



Browser



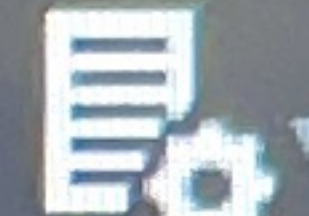
Regist



Modify



Manage



Display



Output



Range



File



Delete

QC06

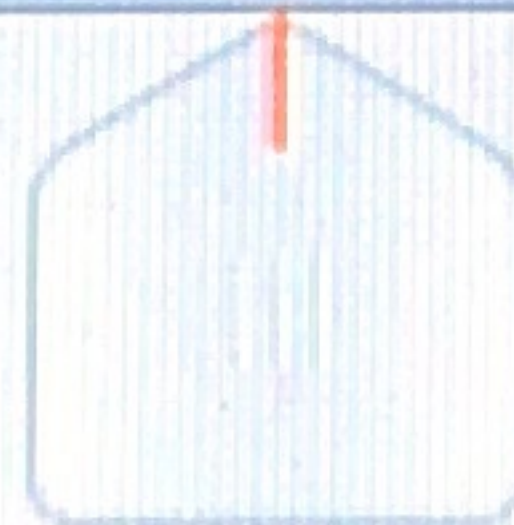
20/05/2022

XN Control Level1

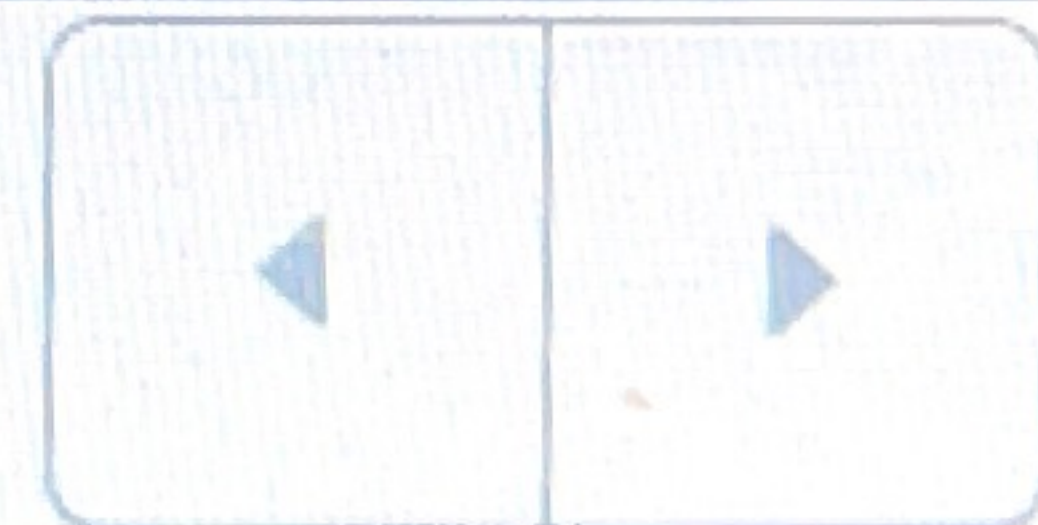
QC-22010801

Item	UL Target LL	Data	SD Mean CV
WBC-D	4.50 3.30 2.10	3.13	3.13
WBC-C	5.20 4.00 2.80	3.87	3.87
RDW-SD	57.0 47.0 37.0	49.9	49.9
RDW-CV	22.0 17.0 12.0	17.7	17.7

n=1



01/02/2022
09:33



Sampler



42-1



Xm



WB

CBC

DIFF

>411