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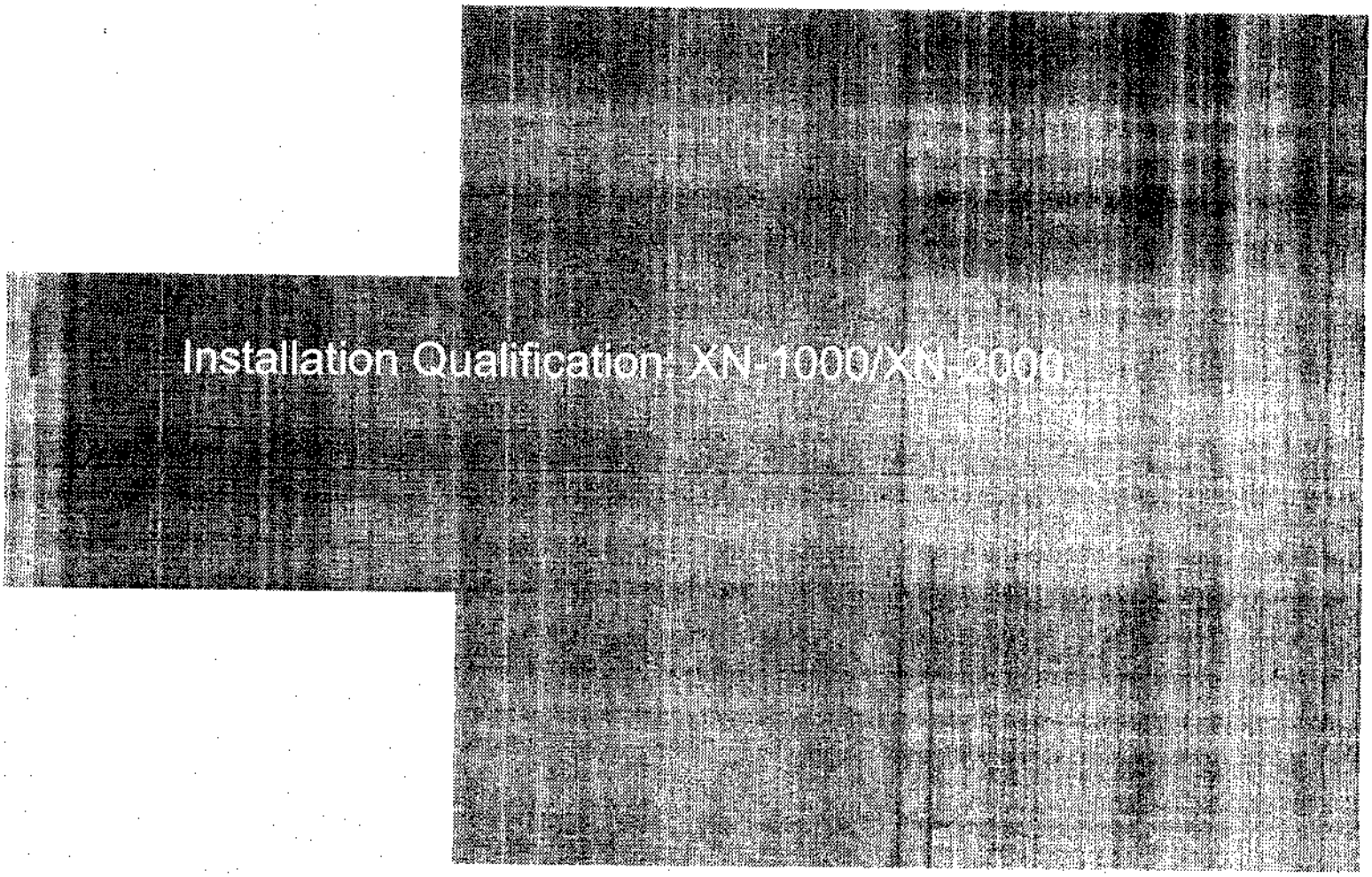
Lighting the way with diagnostics

Installation Qualification: XN-1000/XN-2000



Author(s): Nick Lee

Organization: SAS

Last Updated: 17-Oct-2013

Version: 1.0

Copyright

Document Properties

Document information

Document type	Installation Qualification
Version	1.0
Status	Approved
Last edited	17-Oct-2019
Author	Koh Kian Sing
Organization Name	SAP
Validator	
Organization Name	Muljibhai Patel Urological Hospital, Nadiad
Instrument Model	XN-10
Instrument Serial No.	47791

Document history

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

Version	Date	Author	Comments
1.0	17-Oct-19	Koh Kian Sing	None

Document distribution

Sysmex Asia Pacific Pte Ltd
Sysmex Corporation

Contents

1.General Outline

1-1 Performer

The following person shall perform Installation Qualification (IQ) 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): 23-03-2022

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:

Institution or company: Dr. Amitkumar Jojera
Consultant Pathologist
M.P.U.H. Emp. No.:- 728
Reg. No. 37297

Title:

Date (day/month/year): 23/03/2022

Signature/Initial:

Name:

Institution or company: Dr. Amitkumar Jojera
Consultant Pathologist
M.P.U.H. Emp. No.:- 728
Reg. No. 37297

Title:

Date (day/month/year): 23/03/2022

Signature/Initial:

Equipment

The scope of this procedure is limited to the Installation Qualification (IQ) of the following equipment:

Customer: Muljibhai Patel Urological Hospital

Department: Laboratory

Installation Site:

Address: Dr. Virendra Desai Road, Kheda. Nadiad-387001

(Equipment Details)

Model Number: XN-10

Model Serial Number: 47791

Software Version Number: 00-22(176)

1-4 Terms and Acquisition

☐ **Leased**

☐ **Reagent Rental**

☐ **Purchased**

2. Pre-Installation Check

2-1 Packing List

Check the serial and version number of each component for the XN-1000/2000 system and fill out table 1, "Packing and Accessories List".

Table 1: Packing and Accessories List

No	Components	Manufacturer	Model	Max. Power Consumption (VA or W)	S/N	Initial/Date
1	Analyzer(s) (Main Unit)	Sysmex Corporation	XN-10/20	270VA or lower	47991	
2	Pneumatic Unit	Sysmex Corporation	PU-17	250VA or lower	65673	
3	Sampler unit	Sysmex Corporation	SA-10/20	110VA or lower	21168	23-03-2022
4	XN-1000/2000 Series Supply Parts	Sysmex Corporation	XN-series Supply Parts package as part of the system		NA	

2-2 Certificates and Operation Manuals

Check if the equipment supplied is accompanied by the following document and fill out table 2, "List of Documents".

Table2: List of Documents

Certificates, Manuals					
No.	Descriptions	Part No.	Revision	Location	Initial/Date

2-3 Software List

Check if the equipment supplied is accompanied by the following document and fill out table 3, "Software List".

Table3: Software List

No.	Part Code	Descriptions	Version No.	Location	Initial/Date
1	NA	XN Series Software CD	22.15-00	Installed in PC	23-03-2022
2	NA	McAfee Antivirus Software CD	7.0.1	Installed in PC	23-03-2022

2-4 Computer System

Check if the equipment supplied is accompanied by the following document and fill out table 4, "Computer System".

Table4: Computer System

No.	Item Checked	As required	As found	Acceptable? [Yes/No]	Initial/Date
1.	Operating System	Windows 7 Professional (32 bits)	**Windows 10 LTSB (64 bits)**	**Yes**	
2.	Processor	2.0 GHz or higher. Dual Core or Quad Core	**3.2 GHZ Intel Core 7**	**Yes**	
3.	Memory	4.00GB	**16GB**	**Yes**	
4.	Hard disk space	160 GB or bigger	**1TB**	**Yes**	**23-03-2022**
5.	Application Requirement	USB ports, DVD ROM	**8 USB Ports & 1 DVD ROM**	**Yes**	
6.	Network Connection	2 network adaptor cards	**2**	**Yes**	
7.	Monitor	22"-inch or larger (Support 1920x1080 resolution)	**32"-Inch**	**Yes**	
8.	Printer connection	Network or USB	**USB**	**Yes**	

Remarks:

3. Location

3-1 Instrument Location

Instrument Location: Muljibhai Patel Urological Hospital

Department: Laboratory

Address: Dr. Virendra Desai Road, Kheda. Nadiad-387001

3-2 Installation Site Requirements

(1) Environmental Requirements

Temperature Range:	15°C ~ 30°C
Installation Clearance:	Minimum 50cm at the rear of the equipment for heat exhaust
	Other Requirements: Install the equipment in a well ventilated place with no direct sunlight. Avoid placing the equipment near centrifuges or communication facilities to prevent possible radio interference caused by any other high frequency equipment.

(2) Power Requirements

Rated Voltage:	AC 230V ±10%
Frequency:	50/60Hz
Type of Protection against Electric Shock:	Class I
Grounding:	Third level protection or higher (Always connect the ground wire to a proper ground to prevent the risk of electric shock.)

(Product Details)

Model:	XN-1000/2000
Manufacturer:	Sysmex Corporation
Dimensions (XN-1000):	645(W) x 855(H) x 755(D) mm
(XN-2000):	960(W) x 855(H) x 880(D) mm
(PU-17):	280(W) x 400(H) x 355(D) mm
Weight (XN-1000):	Approximately 78kg
(XN-2000):	Approximately 143kg
(PU-17):	Approximately 17kg
Power Supply:	AC 230V within 10% (50/60Hz)

3-3 Installation Checklist for Environment Requirements and Equipment Configuration

Check Items	Specified Value	Actual Value	Acceptance? [Yes/No]	Initial/Date
Installation Environment				
Ambient temperature	15℃~30℃	23 ℃	Yes	
Power supply (Input)	230V ± 10%	230 V	Yes	
Avoid direct sunlight	No direct Sunlight	NA	Yes	23-03-2022
Well ventilated	At least 50 cm behind the instrument	NA	Yes	
Appearance	No dent	NA	Yes	
Connections	No loose connection	NA	Yes	
Software Installation	Program start up	NA	Yes	

3-4 Test Equipment

No.	Tools	Model	S/No.	Calibration Date	Calibration Due Date	Location	Initial/Date
	Mastec Multimeter	**MS 8217**	**MBIJ016541**	**21-07-2021**	**20-07-2022**	Mumbai	23-03-**2024**

Installation Qualification

Model Number: XN-10
Serial Number: 47991
Software Version: 00-22(176)
Installation Site: Muljibhai Patel Urological Hospital, Nadiad

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

-Performer

Name: Satish Rajak

Signature: 

Date (day/month/year): 23-03-2022

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

-Reviewer

Name: Dr Amit Jojera

Signature: Amit

Date (day/month/year): 23/03/2022

-Reviewer

Name: Dr Amit Jojera

Signature: Amit

Date (day/month/year): 23/03/2022

End of Document

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End of Document

sysmex

Lighting the way with diagnostics

Operation Qualification: XN-1000/2000

Author: Koh Kian Sing

Organization: SAP

Last Updated: 17-Jan-2020

Version: 1.0

Copyright

Document Properties

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Document type	Operation Qualification
Version	1.0
Status	Approved
Last edited	17-Jan-2020
Author	Koh Kian Sing
Organization Name	SAP
Validator	...
Organization Name	Muljibhai Patel Urological Hospital, Nadiad
Instrument Model	XN 10
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Date (day/month/year): 24-03-2022

Signature/Initial:

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Name:

Institution or company:

Title:

Dr. Amitkumar Jojera
Consultant Pathologist
M.P.U.H. Emp. No.:- 728
Reg. No. 37297

Date (day/month/year): 24-03-2022

Signature/Initial: Amit

Name:

Institution or company:

Title:

Dr. Amitkumar Jojera
Consultant Pathologist
M.P.U.H. Emp. No.:- 728
Reg. No. 37297

Date (day/month/year): 24-03-2022

Signature/Initial: Amit

1-3 Equipment

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

Customer: Muljibhai Patel Urological Hospital

Department: Laboratory

Installation Site:

Address: Dr. Virendra Desai Road, Kheda. Nadiad-387001

(Equipment Details)

Model Number: XN-10

Serial Number: 47991

Software Version: 00-22(176)

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.

Table1: 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
6.	Operation of drive motor
7.	Operation of 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 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-1000/2000 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 convert value for ASP SENSOR is within the rated value 6. Check that the laser current is within the rated value by making sure there was no laser output error or laser life error in maintenance log

(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 - Barcode Reading - Tube returning - Rack Feed-in

- Rack Feed-out

(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:
- Piercer motor
- RBC Sheath syringe
- FCM 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

Description: Check to see if there is any abnormality occurring with the operation of the 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 administration 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

2-3 Operational Qualification Check Sheet

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

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	The program runs normally, and Main Menu screen is displayed	Yes	24-03-2022
2.	**Self Diagnostic Test**	Self-diagnostic test is performed successfully	Self-diagnostic test is performed successfully	Yes	
3.	**Sensor**				
	Pressure 0.25MPa	0.25 ± 0.04	0.2528	Yes	24-03-2022
	Pressure 0.16MPa	0.16 ± 0.016	0.1611	Yes	
	Pressure 0.07MPa	0.07 ± 0.01	0.0714	Yes	
	Pressure -0.04MPa	>0.04, < 0.05	-0.0475	Yes	
	Temperature: Reaction chamber	41 ± 3 ℃	41.2	Yes	
	Temperature: Reagent heater	41 ± 3℃	42.5	Yes	
	Temperature: FCM analyzer unit	from 30℃ to 40℃	41.2	Yes	
	Temperature: FCM sheath	from 15℃ to 35℃	26.1	Yes	
	Temperature: Ambient temp.	from 5℃ to 40℃	24	Yes	
	Convert value for HGB	5000 ± 200	4939	Yes	

	Convert value for ASP SENSOR	5000 ± 200	4862	Yes	
No.	Descriptions	Rated value	Value checked	Acceptable? [Yes/No]	Initial/Date
4.	**Counter**				
	WB pump	< 120,000	120	Yes	24-03-2022
	FCM Sheath syringe	< 120,000	147	Yes	
	RBC Sheath syringe	< 120,000	91	Yes	
	Piercer	< 120,000	49	Yes	
5.	**Operation of sampler unit**				
	Tube pick up	Tube is picked up from the sample rack	Tube is picked up from the sample rack	Yes	24-03-2022
	Barcode Reading	Tube sample ID is read successfully	Tube sample ID is read successfully	Yes	
	Tube returning	Tube is returned to sample rack	Tube is returned to sample rack	Yes	
	Rack Feed-in	Verify racks feed in smoothly	Verified racks feed in smoothly	Yes	
	Rack Feed-out	Verify racks feed out smoothly	Verified racks feed out smoothly	Yes	
6.	**Operation of drive motor**				
	Pipette/piercer motor	Piercer is moving up and down	Piercer is moving up and down	Yes	24-03-2022
	Whole blood suction motor	WB Aspiration pump is moving up and down.	WB Aspiration pump is moving up and down.	Yes	
	FCM & RBC Sheath syringes	Sheath syringes moving up and down.	Sheath syringes moving up and down.	Yes	
	Tube Holder motor	Manual tube holder moving front and back	Manual tube holder moving front and back	Yes	
	Hand unit motor	Hand unit moving front-back and left-right	Hand unit moving front-back and left-right	Yes	
	Tube mixing motor	Tube is mixed correctly	Tube is mixed correctly	Yes	
7.	**Operation of**	Sample is	Sample is	Yes	

	piercer	aspirated properly	aspirated properly		24-03-2022
No.	Descriptions	Rated value	Value checked	Acceptable? [Yes/No]	Initial/Date
8.	**Running of QC result**	- QC analysis results are displayed - All parameters are within QC assay ranges	- QC analysis results are displayed - Allparameters are within QC assay ranges	Yes	
9.	**Printing of sample result**	-A Report can be printed -Printed report is identical as displayed on IPU	-A Report can be printed -Printed report is identical as displayed on IPU	Yes	
10.	**Output of CSV(sample result)**	-Sample result can be save in CSV format. -Data saved in CSV file is correct	-Sample result can be save in CSV format. -Data saved in CSV file is correct	Yes	24-03-2022
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	- A sample report is printed prior to backup - Backup of sample result is performed successfully - Sample file is deleted/modified	Yes	
12.	**Restore of sample result**	- Data restoration is performed successfully - The report printout is identical to the one before backup	- Data restoration is performed successfully - The report printout is identical to the one before backup	Yes	

13.	**Shutdown of Main Unit**	Shutdown procedure is performed without any errors	Shutdown procedure is performed	Yes	
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	- The IPU and main unit restart normally after power is resumed - Last sample result is still in IPU -Sample analysis is performed successfull y after the power is restored	Yes	
15	**Alarm Test**	Alarm sounds at step 2, and stops at step 3.	Alarm sounds at step 2, and stops at step 3.	Yes	
16	**Set User**	User is not able to deleting QC results.	User is not able to deleting QC results.	Yes	24-03-2022
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	- All entries with corresponding user, time, and date in the audit log are accurate. - Audit log is printed and attached to this protocol	Yes	

Remarks:

3. Attachments

Attach the additional attachments to this page

Attachment No.	Description	No. of pages	Initial/Date

Remarks:

Operational Qualification

Model Number	XN-10
Serial Number(s)	47991
Software Version	00-22(176)
Installation Site	Muljibhai Patel Urological Hospital, Nadiad

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): 24-03-2022

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 Amit Tojera

Signature: Amit

Date (day/month/year): 24-03-2022

-Reviewer

Name: Dr Amit Tojera

Signature: Amit

Date (day/month/year): 24-03-2022.

End of Document

PQ

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PERFORMANCE QUALIFICATION

Instrument	:	XN-10 Hematology Analyzer Sr. No. 47791
Laboratory	:	Muljibhai Patel Urological Hospital, Dr Virendra Desai Road, Yogiraj Society, Nadiad, Gujarat 387001
Manufacturer	:	Sysmex Corporation
Supported by	:	1002, Damji Shamji Business Galleria, 10th Floor, LBS Marg Kanjurmarg (West), Mumbai 400 078, India Tel: +91 (22) 6112 6666 Fax: +91 (22) 2577 6790

PERFORMANCE QUALIFICATION PROTOCOL

This Performance Qualification protocol will be performed on the installation located at

Muljibhai Patel Urological Hospital,
Dr Virendra Desai Road, Yogiraj Society, Nadiad, Gujarat - 387001

This protocol will define the documentation that will be used to evaluate the instrument and documented in accordance with the user specification requirements. Successful completion of this protocol will verify that the instrument performance consistently meets pre-determined specifications under normal conditions.

Performance checks will be carried out by repeatedly running the system on its intended schedule and record the information/data to demonstrate that it consistently meets the required performance, as expected.

Department personnel along with the trained personnel from Sysmex will perform qualification studies as mentioned in this protocol. Department personnel will record the information and write the report. The technical person from Sysmex will verify the records. The reports will be reviewed by head of the department and approved by QA person. This protocol is to be reviewed and approved by the head of the department and QA.

Any exceptional conditions encountered during the qualification studies will be identified for review and documented in deviation report. Exceptional conditions will be investigated, and appropriate course of action will be determined.

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Report Sign Off:

Prepared by:	Mr Hardik Trivedi	
Title: Sr. Application Specialist	Sign: Hardik	Date: 25/03/2022
Checked By: Ms Vinaya Mhaskar Application Manager - West	Sign: Vinaya	Date: 25/03/2022
Approved by:	Muljibhai Patel Urological Hospital, Nadiad	
Name:	Dr. Shailesh Soni	
Title: H O D M. D. Pathologist Dr. Shailesh Soni Consultant Pathologist M.P.U.H. Emo. No.-733 Reg. No. 15631	Sign: 25/02/2022	Date: 25/03/2022

PQ SCHEDULE

The following activities mentioned below must be performed to complete the performance qualification.

Contents

Evaluation methods for Whole Blood Mode

1. Precision
2. Accuracy
3. Carryover
4. Limit of Blank
5. Limit of Detection and Limit of Quantitation

PERFORMANCE QUALIFICATION PROCEDURE

Performance Qualification

1. **Precision Check**

   Procedure for Precision Testing

   Requirements: - 2 Peripheral Blood samples

   1. Set the analyser to WB Mode, analyse Peripheral Blood for 11 consecutive times. The coefficient of variation of counting for each analysing parameter should meet the following condition.
   2. Input the data into the provided table. Calculate Mean, SD and CV%.
   3. Compare these values with the performance criteria for Within-run Precision Table.
   4. Acceptable Variation are as follows:

Precision Check Limit

Parameters	Performance
WBC-N ($10^3/\mu L$)	3.0 % or less
WBC-D ($10^3/\mu L$)	3.0 % or less
RBC ($10^6/\mu L$)	1.5 % or less
HGB (g/dL)	1.5 % or less
HCT (%)	1.5 % or less
MCV (fL)	1.0 % or less
MCH (pg)	2.0 % or less
MCHC (g/dL)	2.0 % or less
RDW-SD (fL)	2.0 % or less
RDW-CV (%)	2.0 % or less
PLT-I ($10^3/\mu L$)	4.0 % or less
PDW (fL)	10.0 % or less
MPV (fL)	4.0 % or less
P-LCR (%)	15 % or less
PCT (%)	6 % or less
NEUT% (%)	8 % or less
LYMPH% (%)	8 % or less
MONO% (%)	20 % or less
EO% (%)	25 % or less
BASO% (%)	40 % or less
NEUT# ($10^3/\mu L$)	8 % or less
LYMP# ($10^3/\mu L$)	8 % or less
MON# ($10^3/\mu L$)	20 % or less
EO# ($10^3/\mu L$)	25 % or less
BASO# ($10^3/\mu L$)	40 % or less

5. Attach the ledger report of the result in the final report.

2. **Accuracy Check**

Procedure for Accuracy Check Testing

XN Cal / XN Check Level 2

1. Set the analyser to WB Mode, analyse XN CAL/XN Check Level 2 for 10 consecutive times.
2. Input the data into the provided table. Calculate Mean and Calculate % difference from Target mentioned in Lot Assay sheet.
3. Acceptable Variation are as follows:

Accuracy Check Limit

Parameters	Performance
WBC-N ($10^3/\mu L$)	± 3.0 % or less
WBC-D ($10^3/\mu L$)	± 3.0 % or less
RBC ($10^6/\mu L$)	± 4.0 % or less
HGB (g/dL)	± 2.0 % or less
HCT (%)	± 3.0 % or less
PLT-I ($10^3/\mu L$)	± 5.0 % or less

4. Attach the ledger report of the result in the final report.

3. **Linearity Check**

Procedure for Testing Linearity Check

Requirements: - WRP Check/ High value peripheral Blood sample/ XN Check Level 3

1. Prepare a series of dilution of patient 'sample with high cell counts using DCL Cellpack.
2. Analyze each diluted sample in duplicates and calculate the average.
3. Plot Actual Values against Expected values.
4. Calculate verify R2 & Slope Value.
5. Attach the ledger report of the result in the final report.

4. **Carryover – Analysis Results & Calculation**

Procedure for Carryover Check testing

Requirements: - XN Check Level 3 & DCL Cellpack

1. Analyze high peripheral blood for 3 times consecutively to obtain high concentrations of cells to get 3 values (H1, H2, H3).
2. Then analyse CELLPACK DCL for 3 times consecutively to obtain low concentrations of cells to get 3 values (L1, L2, L3)
3. Calculate the carryover rate using the following formula.
   % Carryover = [(L1- L3)/ (H3 – L3)] x 100 (%)
4. Compare this value with the performance criteria for carryover rate.
5. Acceptable Variation are as follows:

Carryover check Limit

Parameters	Performance
WBC-N (10^3/µL)	1.0 % or less
RBC (10^6/µL)	1.0 % or less
HGB (g/dL)	1.0 % or less
HCT (%)	1.0 % or less
PLT-I (10^3/µL)	1.0 % or less

6. Attach the ledger report of the result in the final report.

5. LoB

1. Cellpack DCL was analyzed 11 times and LoB was Calculated as follows
2. LoB (Limit of Blank) = Average + 1.645 X SDb

6. LoD & LoQ

1. Peripheral blood was diluted with CELL PACK DCL to the following Target consistencies

Target Consistencies

Parameter	WBC (x10^3/µL)	RBC (x10^6/µL)	HGB (g/dL)	HCT(%)	PLT (x10^3/µL)
Sample 1	0.02	0.01	0.0	0.10	1
Sample 2	0.05	0.02	0.0	0.20	2

2. Each diluted Blood was analyzed 10 times consecutively and LoD & LoQ were calculated as follows

LoDi = LoB + 1.645 X SDdi

Where,

SDdi = Standard Deviation in the consecutive measurement of the sample

LoD (Limit of Detection) = Average of LoDi

LoQ (Limit of Quantitation) = Maximum Value of LoDi

1. Precision (Whole Blood Mode)

Peripheral blood is analysed 11x. The first run was excluded and the Average, SD, and CV% were calculated. Judgement is applicable only if the condition is satisfied.

XN-10 SN: 47791								
Run	WBC-N (x10^3/µL)		WBC-D (x10^3/µL)		RBC (x10^6/µL)		HGB (g/dL)	
	Sample 1	Sample 2	Sample 1	Sample 2	Sample 1	Sample 2	Sample 1	Sample 2
~~1~~	~~9.82~~	~~13.67~~	~~9.93~~	~~13.66~~	~~4.22~~	~~4.44~~	~~11.6~~	~~12.1~~
2	10.05	13.86	10.10	13.57	4.25	4.40	11.8	12.1
3	9.83	13.66	9.90	13.78	4.20	4.46	11.7	12.2
4	9.94	13.86	9.60	13.91	4.21	4.43	11.7	12.2
5	10.11	13.86	10.00	13.95	4.21	4.45	11.7	12.1
6	9.93	14.20	9.90	13.92	4.20	4.43	11.6	12.2
7	10.06	13.68	10.20	14.11	4.22	4.42	11.7	12.1
8	9.90	13.91	10.08	13.91	4.24	4.44	11.8	12.2
9	9.91	13.82	10.28	13.95	4.25	4.42	11.8	12.2
10	9.94	13.87	10.35	14.09	4.18	4.46	11.7	12.0
11	9.85	13.77	10.20	14.13	4.18	4.38	11.7	12.1
Average	9.95	13.85	10.06	13.93	4.21	4.43	11.7	12.1
SD	0.09	0.15	0.22	0.17	0.03	0.03	0.1	0.1
CV%	0.9	1.1	2.2	1.2	0.6	0.6	0.5	0.6
Criteria	≤ 3.0 %		≤ 3.0 %		≤ 1.5 %		≤ 1.0 %	
Condition	WBC ≥ 4.00x10^3/µL		WBC ≥ 4.00x10^3/µL		RBC ≥ 4.00x10^6/µL		NA	
Judgement	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

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XN-10 SN: 47791								
Run	HCT (%)		MCV (fL)		MCH (pg)		MCHC(%)	
	Sample 1	Sample 2	Sample 1	Sample 2	Sample 1	Sample 2	Sample 1	Sample 2
~~1~~	~~39.5~~	~~40.2~~	~~93.6~~	~~90.5~~	~~27.5~~	~~27.3~~	~~29.4~~	~~30.1~~
2	39.7	39.8	93.4	90.5	27.8	27.5	29.7	30.4
3	39.3	40.4	93.6	90.6	27.9	27.4	29.8	30.2
4	39.4	40.0	93.6	90.3	27.8	27.5	29.7	30.5
5	39.4	40.2	93.6	90.3	27.8	27.2	29.7	30.1
6	39.2	40.0	93.3	90.3	27.6	27.5	29.6	30.5
7	39.4	40.0	93.4	90.5	27.7	27.4	29.7	30.3
8	39.7	40.2	93.6	90.5	27.8	27.5	29.7	30.3
9	39.6	39.9	93.2	90.3	27.8	27.6	29.8	30.6
10	39.2	40.2	93.8	90.1	28.0	26.9	29.8	29.9
11	39.1	39.6	93.5	90.4	28.0	27.6	29.9	30.6
Average	39.4	40.0	93.5	90.4	27.8	27.4	29.7	30.3
SD	0.2	0.2	0.2	0.1	0.1	0.2	0.1	0.2
CV%	0.5	0.6	0.2	0.2	0.4	0.8	0.3	0.7
Criteria	≤ 1.5 %		≤ 1.0 %		≤ 2.0 %		≤ 2.0 %	
Condition	NA		NA		NA		NA	
Judgement	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

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XN-10 SN: 47791								
Run	HCT (%)		MCV (fL)		MCH (pg)		MCHC(%)	
	Sample 1	Sample 2	Sample 1	Sample 2	Sample 1	Sample 2	Sample 1	Sample 2
~~1~~	~~39.5~~	~~40.2~~	~~93.6~~	~~90.5~~	~~27.5~~	~~27.3~~	~~29.4~~	~~30.1~~
2	39.7	39.8	93.4	90.5	27.8	27.5	29.7	30.4
3	39.3	40.4	93.6	90.6	27.9	27.4	29.8	30.2
4	39.4	40.0	93.6	90.3	27.8	27.5	29.7	30.5
5	39.4	40.2	93.6	90.3	27.8	27.2	29.7	30.1
6	39.2	40.0	93.3	90.3	27.6	27.5	29.6	30.5
7	39.4	40.0	93.4	90.5	27.7	27.4	29.7	30.3
8	39.7	40.2	93.6	90.5	27.8	27.5	29.7	30.3
9	39.6	39.9	93.2	90.3	27.8	27.6	29.8	30.6
10	39.2	40.2	93.8	90.1	28.0	26.9	29.8	29.9
11	39.1	39.6	93.5	90.4	28.0	27.6	29.9	30.6
Average	39.4	40.0	93.5	90.4	27.8	27.4	29.7	30.3
SD	0.2	0.2	0.2	0.1	0.1	0.2	0.1	0.2
CV%	0.5	0.6	0.2	0.2	0.4	0.8	0.3	0.7
Criteria	≤ 1.5 %		≤ 1.0 %		≤ 2.0 %		≤ 2.0 %	
Condition	NA		NA		NA		NA	
Judgement	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

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XN-10 SN: 47791						
Run	RDW-SD (fL)		RDW-CV (%)		PLT-I (x10^3/µL)	
	Sample 1	Sample 2	Sample 1	Sample 2	Sample 1	Sample 2
~~1~~	~~52.2~~	~~48.5~~	~~15.3~~	~~14.6~~	~~375~~	~~325~~
2	52.4	48.8	15.4	14.6	368	336
3	52.3	48.5	15.3	14.6	374	332
4	52.4	49.0	15.3	14.6	370	329
5	52.5	48.5	15.3	14.6	380	335
6	52.3	48.8	15.3	14.6	359	336
7	52.1	49.0	15.3	14.6	371	329
8	52.0	48.5	15.2	14.6	372	337
9	52.5	47.8	15.3	14.5	375	328
10	53.1	48.3	15.4	14.6	361	343
11	52.1	48.3	15.3	14.5	385	335
Average	52.4	48.6	15.3	14.6	371.50	334.00
SD	0.3	0.4	0.1	0.0	7.85	4.59
CV%	0.6	0.8	0.4	0.3	2.1	1.4
Criteria	≤ 2.0 %		≤ 2.0 %		≤ 4.0 %	
Condition	NA		NA		PLT ≥ 100x10^3/µL	
Judgement	Pass	Pass	Pass	Pass	Pass	Pass

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XN-10 SN: 47791								
Run	PDW (fL)		MPV (fL)		P-LCR (%)		PCT (%)	
	Sample 1	Sample 2	Sample 1	Sample 2	Sample 1	Sample 2	Sample 1	Sample 2
~~1~~	~~11.5~~	~~17.1~~	~~10.5~~	~~12.8~~	~~28.0~~	~~46.9~~	~~0.39~~	~~0.41~~
2	11.2	17.3	10.4	12.7	27.0	47.5	0.38	0.43
3	11.4	18.5	10.5	12.7	27.9	46.6	0.39	0.42
4	11.3	16.8	10.5	12.7	28.1	46.2	0.39	0.42
5	11.1	16.9	10.4	12.7	27.5	46.9	0.40	0.43
6	11.8	17.6	10.5	12.7	27.8	46.4	0.38	0.43
7	11.4	17.6	10.5	12.9	27.7	48.1	0.39	0.42
8	11.7	17.3	10.2	12.6	26.8	47.0	0.38	0.43
9	12.0	16.9	10.6	12.6	28.2	46.2	0.40	0.41
10	11.5	17.6	10.4	12.8	28.2	47.1	0.38	0.44
11	11.1	18.5	10.5	12.9	27.6	48.2	0.41	0.43
Average	11.5	17.5	10.5	12.7	27.7	47.0	0.39	0.43
SD	0.3	0.6	0.1	0.1	0.5	0.7	0.01	0.01
CV%	2.6	3.5	1.0	0.8	1.7	1.5	2.7	2.0
Criteria	≤ 10.0 %		≤ 4.0 %		≤ 15.0 %		≤ 6.0 %	
Condition	NA		NA		NA		NA	
Judgement	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

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XN-10 SN: 47791								
Run	NEUT# (x10^3/μL)		NEUT% (%)		LYMPH# (x10^3/μL)		LYMPH% (%)	
	Sample 1	Sample 2	Sample 1	Sample 2	Sample 1	Sample 2	Sample 1	Sample 2
~~1~~	~~8.17~~	~~8.88~~	~~83.2~~	~~64.9~~	~~0.88~~	~~3.85~~	~~9.0~~	~~28.2~~
2	8.32	9.02	82.7	65.0	0.91	3.89	9.1	28.1
3	8.08	8.98	82.2	65.7	0.94	3.69	9.6	27.0
4	8.22	9.14	82.7	65.9	0.89	3.70	9.0	26.7
5	8.40	9.04	83.1	65.2	0.89	3.82	8.8	27.6
6	8.11	9.38	81.6	66.1	0.93	3.82	9.4	26.9
7	8.34	8.84	82.9	64.6	0.89	3.81	8.8	27.9
8	8.21	9.10	82.9	65.4	0.83	3.79	8.4	27.2
9	8.25	9.18	83.2	66.4	0.89	3.64	9.0	26.3
10	8.22	9.09	82.7	65.5	0.83	3.73	8.4	26.9
11	8.13	9.15	82.6	66.4	0.81	3.62	8.2	26.3
Average	8.23	9.09	82.7	65.6	0.88	3.75	8.9	27.1
SD	0.10	0.14	0.5	0.6	0.04	0.09	0.4	0.6
CV%	1.3	1.6	0.6	0.9	5.0	2.4	5.0	2.3
Criteria	≤ 8.0 %		≤ 8.0 %		≤ 8.0 %		≤ 8.0 %	
Condition	NEUT# ≥ 1.20x10^3/μL		NEUT% ≥ 30.0%		LYMP# ≥ 0.60x10^3/μL		LYMP% ≥ 15.0%	
Judgement	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

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XN-10 SN: 47791								
Run	MONO# (x10^3/µL)		MONO% (%)		EO# (x10^3/µL)		EO% (%)	
	Sample 1	Sample 2	Sample 1	Sample 2	Sample 1	Sample 2	Sample 1	Sample 2
~~1~~	~~0.69~~	~~0.77~~	~~7.0~~	~~5.6~~	~~0.04~~	~~0.13~~	~~0.4~~	~~1.0~~
2	0.74	0.79	7.4	5.7	0.06	0.12	0.6	0.9
3	0.74	0.81	7.5	5.9	0.04	0.13	0.4	1.0
4	0.73	0.84	7.3	6.1	0.06	0.14	0.6	1.0
5	0.72	0.81	7.1	5.8	0.05	0.14	0.5	1.0
6	0.79	0.83	8.0	5.8	0.08	0.13	0.8	0.9
7	0.72	0.81	7.2	5.9	0.07	0.17	0.7	1.2
8	0.76	0.83	7.7	6.0	0.07	0.14	0.7	1.0
9	0.65	0.81	6.6	5.9	0.09	0.15	0.9	1.1
10	0.75	0.79	7.5	5.7	0.11	0.21	1.1	1.5
11	0.78	0.77	7.9	5.6	0.10	0.18	1.0	1.3
Average	0.74	0.81	7.4	5.8	0.07	0.15	0.7	1.1
SD	0.04	0.02	0.4	0.2	0.02	0.03	0.2	0.2
CV%	5.3	2.6	5.5	2.6	30.3	18.3	30.3	17.5
Criteria	≤ 20.0 %		≤ 20.0 %		≤ 25.0 % or ± 0.12 x 10^3/µL		≤ 25.0 % or ± 1.5 EO%	
Condition	MONO# ≥ 0.20x10^3/µL		MONO% ≥ 5.0%		NA		WBC ≥ 4.00x10^3/µL	
Judgement	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

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XN-10 SN: 47791								
Run	BASO# (x10^3/µL)		BASO% (%)		IG# (x10^3/µL)		IG% (%)	
	Sample 1	Sample 2	Sample 1	Sample 2	Sample 1	Sample 2	Sample 1	Sample 2
~~1~~	~~0.04~~	~~0.04~~	~~0.4~~	~~0.3~~	~~0.20~~	~~0.08~~	~~2.0~~	~~0.6~~
2	0.02	0.04	0.2	0.3	0.17	0.11	1.7	0.8
3	0.03	0.05	0.3	0.4	0.19	0.10	1.9	0.7
4	0.04	0.04	0.4	0.3	0.17	0.08	1.7	0.6
5	0.05	0.05	0.5	0.4	0.20	0.12	2.0	0.9
6	0.02	0.04	0.2	0.3	0.18	0.08	1.8	0.6
7	0.04	0.05	0.4	0.4	0.20	0.12	2.0	0.9
8	0.03	0.05	0.3	0.4	0.19	0.13	1.9	0.9
9	0.03	0.04	0.3	0.3	0.22	0.13	2.2	0.9
10	0.03	0.05	0.3	0.4	0.24	0.13	2.4	0.9
11	0.03	0.05	0.3	0.4	0.19	0.15	1.9	1.1
Average	0.03	0.05	0.3	0.4	0.20	0.12	2.0	0.8
SD	0.01	0.01	0.1	0.1	0.02	0.02	0.2	0.2
CV%	28.7	11.2	28.7	14.3	11.1	19.8	11.1	18.9
Criteria	≤ 40.0 % or ± 0.06 x 10^3/µL		≤ 40.0 % or ± 1.0 BASO%		≤ 25.0 % or ± 0.12 x 10^3/µL		≤ 25.0 % or ± 1.5 IG%	
Condition	NA		WBC ≥ 4.00x10^3/µL		IG# ≥ 0.10x10^3/µL		IG% ≥ 2.0%	
Judgement	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

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XN-10 SN: 47791				
Run	NRBC# (x10^3/µL)		NRBC% (%)	
	Sample 1	Sample 2	Sample 1	Sample 2
~~1~~	~~0.01~~	~~0.00~~	~~0.1~~	~~0.0~~
2	0.02	0.00	0.2	0.0
3	0.01	0.01	0.1	0.1
4	0.03	0.01	0.3	0.1
5	0.03	0.01	0.3	0.1
6	0.03	0.01	0.3	0.1
7	0.02	0.02	0.2	0.1
8	0.03	0.03	0.3	0.2
9	0.05	0.06	0.5	0.4
10	0.06	0.08	0.6	0.6
11	0.10	0.08	1.0	0.6
Average	0.04	0.03	0.4	0.2
SD	0.03	0.03	0.3	0.2
CV%	68.8	99.1	68.8	96.2
Criteria	≤ 25.0 % or ± 0.12 x 10^3/µL		≤ 25.0 % or ± 1.5 NRBC%	
Condition	NA		WBC ≥ 4.00x10^3/µL	
Judgement	Pass	Pass	Pass	Pass

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2. Accuracy (Whole Blood Mode)

XN CAL / XN Check Level 2 is analysed 11x. The first run is excluded and the Average, % Difference, and Difference from target values are calculated.

XN-10 SN: 47791				
XN CAL	LOT NO. 20522101		Expiry Date - 27-03-2022	
Run	RBC (x10^6/µL)	HGB (g/dL)	HCT (%)	PLT-I (x10^3/µL)
~~1~~	~~4.46~~	~~11.8~~	~~35.4~~	~~259~~
2	4.41	11.7	35.1	252
3	4.42	11.7	35.0	260
4	4.45	11.7	35.3	254
5	4.36	11.7	34.7	261
6	4.41	11.7	35.1	255
7	4.41	11.7	35.0	260
8	4.39	11.7	34.8	265
9	4.42	11.7	35.1	261
10	4.43	11.7	35.2	255
11	4.36	11.7	34.5	253
Average	4.406	11.70	34.98	257.60
Target	4.426	11.80	35.10	253.30
% Difference	-0.5	-0.9	-0.3	1.7
Difference	-0.02	-0.10	-0.1	4.3
Criteria	± 2 % or ± 0.03 x 10^6/µL	± 2 % or ± 0.2 g/dL	± 3 % or ± 1.0 HCT	± 5 % or ± 10 x 10^3/µL
Judgement	Pass	Pass	Pass	Pass

XN-10 SN: 47791		
XN CAL	Lot No. 20522101	EXP: 27-03-2022
Run	WBC-N (x10^3/µL)	WBC-D (x10^3/µL)
1	7.09	7.17
2	7.11	7.28
3	6.99	7.24
4	7.13	7.20
5	7.19	7.17
6	7.26	7.26
7	6.98	7.18
8	7.05	7.09
9	7.15	7.18
10	7.12	7.36
11	7.00	7.23
Average	7.098	7.219
Target	7.155	7.281
% Difference	-0.8	-0.9
Difference	-0.1	0
Criteria	± 3 % or ± 0.20 x 10^3/µL	± 3 % or ± 0.20 x 10^3/µL
Judgement	Pass	Pass

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CIN :U33120MH1998PTC115943

3. Carryover (Whole Blood Mode)

Control blood is analysed 3x consecutively to obtain high concentrations (H1-H3). Then CELLPACK DCL is analysed 3x consecutively to obtain low concentrations (L1-L3). The % Carryover is calculated as follows:

$$\% \text{ Carryover} = \frac{L1 - L3}{H3 - L3} \times 100$$

XN-1000 SN: 47791					
Sample 1	**WBC (x10^3/µL)**	**RBC (x10^6/µL)**	**HGB (g/dL)**	**HCT (%)**	**PLT (x10^3/µL)**
H1	16.06	5.05	15.2	43.3	592
H2	16	5.11	15.2	43.6	590
H3	16.24	5.09	15.1	43.5	598
L1	0	0	0	0	1
L2	0.01	0	0	0	0
L3	0	0	0	0	0
% Carryover	0.00	0.0	0.0	0.0	0.2
Criteria	≤ 1.0 %	≤ 1.0 %	≤ 1.0 %	≤ 1.0 %	≤ 1.0 %
Judgement	Pass	Pass	Pass	Pass	Pass

4. Limit of Blank (Whole Blood Mode)

CELLPACK DCL is analysed 11x consecutively. The first run is excluded, and the LoB is calculated as follows:

LoB (Limit of Blank) = Average + 1.645 x SDb
SDb = Standard deviation in the consecutive measurement of the sample

XN-1000 SN: 47791					
Run	WBC (x10^3/µL)	RBC (x10^6/µL)	HGB (g/dL)	HCT (%)	PLT-I (x10^3/µL)
~~1~~	~~0.00~~	~~0.00~~	~~0.0~~	~~0.00~~	~~0~~
2	0.00	0.00	0.0	0.00	0
3	0.00	0.00	0.0	0.00	0
4	0.00	0.00	0.0	0.00	0
5	0.00	0.00	0.0	0.00	0
6	0.00	0.00	0.0	0.00	1
7	0.00	0.00	0.0	0.00	0
8	0.00	0.00	0.0	0.00	0
9	0.00	0.00	0.0	0.00	0
10	0.00	0.00	0.0	0.00	0
11	0.00	0.00	0.0	0.00	1
Average	0.00	0.00	0.0	0.00	0
SDb	0.00	0.00	0.0	0.00	0

5. Limit of Detection and Limit of Quantitation (Whole Blood Mode)

Peripheral blood is diluted with CELLPACK DCL to the following target consistencies:

Parameter	WBC (x10^3/µL)	RBC (x10^6/µL)	HGB (g/dL)	HCT (%)	PLT (x10^3/µL)
Sample 1	0.02	0.01	0.0	0.10	1
Sample 2	0.05	0.02	0.0	0.20	2

Each diluted sample is analyzed 11x consecutively. The first run is excluded and the LoD and LoQ are calculated as follows:

LoDi = LoB + 1.645 x SDdi

SDdi = Standard deviation in the consecutive measurement of the sample

LoD (Limit of Detection) = Average of LoDi

LoQ (Limit of Quantitation) = Maximum value of LoDi

XN-10 SN: 47791						
Run	WBC (x10^3/µL)		RBC (x10^6/µL)		HGB (g/dL)	
	Sample 1	Sample 2	Sample 1	Sample 2	Sample 1	Sample 2
~~1~~	~~0.02~~	~~0.05~~	~~0.01~~	~~0.02~~	~~0~~	~~0~~
2	0.03	0.05	0.01	0.02	0	0
3	0.02	0.04	0.01	0.02	0	0
4	0.03	0.05	0.01	0.02	0	0
5	0.02	0.04	0.01	0.02	0	0
6	0.02	0.05	0.01	0.02	0	0
7	0.02	0.06	0.01	0.02	0	0
8	0.02	0.05	0.01	0.02	0	0
9	0.01	0.06	0.01	0.02	0	0
10	0.03	0.04	0.01	0.02	0	0
11	0.03	0.04	0.01	0.02	0	0
Average	0.02	0.05	0.01	0.02	0.0	0.0
SDd_i	0.01	0.01	0.00	0.00	0.0	0.0
LoD_i	0.01	0.01	0.00	0.00	0.00	0.00
LoD	0.01		0.01		0.0	
LoQ	0.01		0.00		0.0	

XN-1000 SN: 47791				
Run	HCT (%)		PLT-I (x10^3/µL)	
	Sample 1	Sample 2	Sample 1	Sample 2
~~1~~	~~0.1~~	~~0.2~~	~~1~~	~~2~~
2	0.1	0.2	2	3
3	0.1	0.2	1	2
4	0.1	0.2	1	2
5	0.1	0.2	2	2
6	0.1	0.2	1	2
7	0.1	0.2	1	3
8	0.1	0.2	1	2
9	0.1	0.2	1	2
10	0.1	0.2	1	2
11	0.1	0.2	1	2
Average	0.10	0.20	1	2
SDd_i	0.00	0.00	0	0
LoD_i	0.00	0.00	0.69	0.69
LoD	0.04		0.7	
LoQ	0.08		0.69	

ISO 9001 & ISO 13485

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CIN :U33120MH1998PTC115943

The Final Conclusion and deviation verified by:

Prepared by:	**Mr. Hardik Trivedi**	
Title: Sr. Application Specialist	**Sign:**	**Date: 25/03/2022**
Checked By: Ms Vinaya Mhaskar **Application Manager - West**	**Sign:**	**Date: 25/03/2022**
Approved by:	**Muljibhai Patel Urological Hospital, Nadiad**	
Name:	**Dr. Shailesh Soni**	
Title: **H O D** **M. D. Pathologist** Dr. Shailesh Soni Consultant Pathologist M.P.U.H. Regn. No.- 774 Reg. No. 35191	**Sign:** 25/03/2022	**Date: 25/03/2022**

Deviation: None

Conclusion: This report certifies that the instrument XN-10 Fully Automated Hematology Analyzer **S. No: 47791** is qualified to perform as per manufacturer's specifications.

PC Rao Lab

47791 XN-1 XN series sysmex

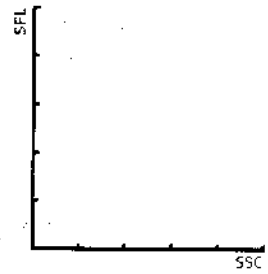
Sample No.: BACKGROUNDCHECK
Patient ID:
Name:
Sample Comment:

Rack:
Ward:

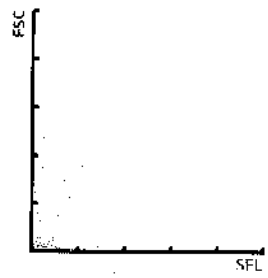
Position: 25/03/2022 08:55:08 WB
Doctor:
Birth:
Sex:
Nickname: XN-1000-1-A

WBC	0.00	[10^3/uL]		
RBC	0.00	[10^6/uL]		
HGB	0.0	[g/dL]		
HCT	0.0	[%]		
MCV	----	[fL]		
MCH	----	[pg]		
MCHC	----	[g/dL]		
PLT	1	[10^3/uL]		
RDW-SD	----	[fL]		
RDW-CV	----	[%]		
PDW	----	[fL]		
MPV	----	[fL]		
P-LCR	----	[%]		
CT	----	[%]		
NRBC	----	[10^3/uL]	----	[%]
NEUT	----	[10^3/uL]	----	[%]
LYMPH	----	[10^3/uL]	----	[%]
MONO	----	[10^3/uL]	----	[%]
EO	----	[10^3/uL]	----	[%]
BASO	----	[10^3/uL]	----	[%]
IG	----	[10^3/uL]	----	[%]

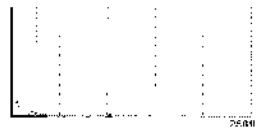
WDF



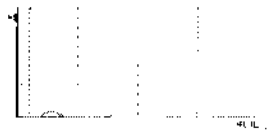
WNR



RBC



PLT



WBC IP Message

RBC IP Message

PLT IP Message

Analysis Data(WB,LW,PD)

Date	Time	Measurement Mode	Order Type	PC	Sample No.	Nickname			Judgment
WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	NEUT#	LYMPH#	MONO#	EO#	BASO#
RDW-SD	RDW-CV	PDW	MPV	P-LCR	PCT	NRBC#	NRBC%	NEUT%	LYMPH%	MONO%	EO%	BASO%
								IG#	IG%	MicroR	MacroR	
25/03/2022	09:55:15	WB		Initial				QC-20171103 B		XN-1000-1-A		
16.11	5.10	15.1	43.8	85.9	29.6	34.5	593	7.80	3.91	1.93	1.68	0.79
47.4	15.2	9.1	9.6	18.6	0.57	1.09	6.8	48.4	24.3	12.0	10.4	4.9
								2.01	12.5			
										3.1	4.3	
25/03/2022	09:54:03	WB		Initial				QC-20191101 B		XN-1000-1-A		
2.81	2.41	5.3	16.1	66.8	22.0	32.9	79	1.13	0.88	0.37	0.30	0.13
45.8	19.3	7.4	8.7	12.1	0.07	0.15	5.3	40.2	31.3	13.2	10.7	4.6
								0.30	10.7			
										38.9	1.6	
25/03/2022	09:54:39	WB		Initial				QC-20201102 B		XN-1000-1-A		
6.89	4.40	11.9	35.5	80.7	27.0	33.5	242	2.93	2.07	0.83	0.72	0.34
48.4	16.8	8.0	9.7	17.2	0.23	0.41	6.0	42.7	30.0	12.0	10.4	4.9
								0.75	10.9			
										8.1	4.1	

Analysis Data(WB,LW,PD)

Date / Time	Measurement Mode	Order Type	PC	Sample No.	Nickname	Judgment
WBC / RBC / HGB / HCT / MCV / MCH / MCHC / PLT						
RDW-SD / RDW-CV / PDW / MPV / P-LCR / PCT / NRBC# / NRBC%				NEUT# / LYMPH# / MONO# / EO# / BASO#		
				NEUT% / LYMPH% / MONO% / EO% / BASO%		
				IG# / IG%		
					MicroR / MacroR	
25/03/2022 10:04:56	WB	Manual		PRE S1 01 M	XN-1000-1-A	Positive
9.82 / 4.22 / 11.6 / 39.5 / 93.6 / 27.5 / 29.4- / 375				8.17+ / 0.88- / 0.69 / 0.04 / 0.04		
52.2 / 15.3 / 11.5 / 10.5 / 28.0 / 0.39+ / 0.01 / 0.1				83.2+ / 9.0- / 7.0 / 0.4 / 0.4		
				0.20 / 2.0		
					1.1 / 4.7	
25/03/2022 10:06:14	WB	Manual		PRE S1 02 M	XN-1000-1-A	Positive
10.05 / 4.25 / 11.8 / 39.7 / 93.4 / 27.8 / 29.7- / 368				8.32+ / 0.91- / 0.74+ / 0.06 / 0.02		
52.4 / 15.4 / 11.2 / 10.4 / 27.0 / 0.38+ / 0.02 / 0.2				82.7+ / 9.1- / 7.4 / 0.6 / 0.2		
				0.17 / 1.7		
					1.2 / 4.8	
25/03/2022 10:06:51	WB	Manual		PRE S1 03 A	XN-1000-1-A	Positive
9.83 / 4.20 / 11.7 / 39.3 / 93.6 / 27.9 / 29.8- / 374				8.08+ / 0.94- / 0.74+ / 0.04 / 0.03		
52.3 / 15.3 / 11.4 / 10.5 / 27.9 / 0.39+ / 0.01 / 0.1				82.2+ / 9.6- / 7.5 / 0.4 / 0.3		
				0.19 / 1.9		
					1.2 / 4.6	
25/03/2022 10:07:30	WB	Manual		PRE S1 04 A	XN-1000-1-A	Positive
9.94 / 4.21 / 11.7 / 39.4 / 93.6 / 27.8 / 29.7- / 370				8.22+ / 0.89- / 0.73+ / 0.06 / 0.04		
52.4 / 15.3 / 11.3 / 10.5 / 28.1 / 0.39+ / 0.03 / 0.3				82.7+ / 9.0- / 7.3 / 0.6 / 0.4		
				0.17 / 1.7		
					1.2 / 4.9	
25/03/2022 10:08:14	WB	Manual		PRE S1 05 A	XN-1000-1-A	Positive
10.11 / 4.21 / 11.7 / 39.4 / 93.6 / 27.8 / 29.7- / 380				8.40+ / 0.89- / 0.72+ / 0.05 / 0.05		
52.5 / 15.3 / 11.1 / 10.4 / 27.5 / 0.40+ / 0.03 / 0.3				83.1+ / 8.8- / 7.1 / 0.5 / 0.5		
				0.20 / 2.0		
					1.1 / 4.8	
25/03/2022 10:09:01	WB	Manual		PRE S1 06 A	XN-1000-1-A	Positive
9.93 / 4.20 / 11.6 / 39.2 / 93.3 / 27.6 / 29.6- / 359				8.11+ / 0.93- / 0.79+ / 0.08 / 0.02		
52.3 / 15.3 / 11.8 / 10.5 / 27.8 / 0.38+ / 0.03 / 0.3				81.6+ / 9.4- / 8.0 / 0.8 / 0.2		
				0.18 / 1.8		
					1.3 / 4.4	
25/03/2022 10:09:42	WB	Manual		PRE S1 07 A	XN-1000-1-A	Positive
10.06 / 4.22 / 11.7 / 39.4 / 93.4 / 27.7 / 29.7- / 371				8.34+ / 0.89- / 0.72+ / 0.07 / 0.04		
52.1 / 15.3 / 11.4 / 10.5 / 27.7 / 0.39+ / 0.02 / 0.2				82.9+ / 8.8- / 7.2 / 0.7 / 0.4		
				0.20 / 2.0		
					1.2 / 4.6	
25/03/2022 10:10:19	WB	Manual		PRE S1 08 A	XN-1000-1-A	Positive
9.90 / 4.24 / 11.8 / 39.7 / 93.6 / 27.8 / 29.7- / 372				8.21+ / 0.83- / 0.76+ / 0.07 / 0.03		
52.0 / 15.2 / 11.7 / 10.2 / 26.8 / 0.38+ / 0.03 / 0.3				82.9+ / 8.4- / 7.7 / 0.7 / 0.3		
				0.19 / 1.9		
					1.3 / 4.7	
25/03/2022 10:10:55	WB	Manual		PRE S1 09 A	XN-1000-1-A	Positive
9.91 / 4.25 / 11.8 / 39.6 / 93.2 / 27.8 / 29.8- / 375				8.25+ / 0.89- / 0.65 / 0.09 / 0.03		
52.5 / 15.3 / 12.0 / 10.6 / 28.2 / 0.40+ / 0.05 / 0.5				83.2+ / 9.0- / 6.6 / 0.9 / 0.3		
				0.22 / 2.2		
					1.3 / 4.7	
25/03/2022 10:11:43	WB	Manual		PRE S1 10 A	XN-1000-1-A	Positive
9.94 / 4.18 / 11.7 / 39.2 / 93.8 / 28.0 / 29.8- / 361				8.22+ / 0.83- / 0.75+ / 0.11 / 0.03		
53.1 / 15.4 / 11.5 / 10.4 / 28.2 / 0.38+ / 0.06 / 0.6				82.7+ / 8.4- / 7.5 / 1.1 / 0.3		
				0.24 / 2.4		
					1.2 / 4.7	
25/03/2022 10:12:41	WB	Manual		PRE S1 11 A	XN-1000-1-A	Positive
9.85 / 4.18 / 11.7 / 39.1 / 93.5 / 28.0 / 29.9- / 385				8.13+ / 0.81- / 0.78+ / 0.10 / 0.03		
52.1 / 15.3 / 11.1 / 10.5 / 27.6 / 0.41+ / 0.10 / 1.0				82.6+ / 8.2- / 7.9 / 1.0 / 0.3		
				0.19 / 1.9		
					1.3 / 4.6	

Analysis Data(WB,LW,PD)

Date / Time	Measurement Mode	Order Type	PC	Sample No.	Nickname	Judgment
WBC / RBC / HGB / HCT / MCV / MCH / MCHC / PLT				NEUT# / LYMPH# / MONO# / EO#		BASO#
RDW-SD / RDW-CV / PDW / MPV / P-LCR / PCT / NRBC# / NRBC%				NEUT% / LYMPH% / MONO% / EO%		BASO%
				IG# / IG%	MicroR / MacroR	
25/03/2022 10:15:40	WB	Manual		PRE S2 01 M	XN-1000-1-A	Negative
13.67 / 4.44 / 12.1 / 40.2 / 90.5 / 27.3 / 30.1- / 325				8.88+ / 3.85+ / 0.77+ / 0.13		0.04
48.5 / 14.6 / 17.1+ / 12.8 / 46.9+ / 0.41+ / 0.00 / 0.0				64.9 / 28.2 / 5.6 / 1.0		0.3
				0.08 / 0.6		
					2.2 / 3.7	
25/03/2022 10:16:27	WB	Manual		PRE S2 02 A	XN-1000-1-A	Positive
13.86 / 4.40 / 12.1 / 39.8 / 90.5 / 27.5 / 30.4- / 336				9.02+ / 3.89+ / 0.79+ / 0.12		0.04
48.8 / 14.6 / 17.3+ / 12.7 / 47.5+ / 0.43+ / 0.00 / 0.0				65.0 / 28.1 / 5.7 / 0.9		0.3
				0.11 / 0.8		
					2.1 / 3.8	
25/03/2022 10:17:23	WB	Manual		PRE S2 03 A	XN-1000-1-A	Negative
13.66 / 4.46 / 12.2 / 40.4 / 90.6 / 27.4 / 30.2- / 332				8.98+ / 3.69 / 0.81+ / 0.13		0.05
48.5 / 14.6 / 18.5+ / 12.7 / 46.6+ / 0.42+ / 0.01 / 0.1				65.7 / 27.0 / 5.9 / 1.0		0.4
				0.10 / 0.7		
					2.3 / 3.8	
25/03/2022 10:18:21	WB	Manual		PRE S2 04 A	XN-1000-1-A	Negative
13.86 / 4.43 / 12.2 / 40.0 / 90.3 / 27.5 / 30.5- / 329				9.14+ / 3.70 / 0.84+ / 0.14		0.04
49.0 / 14.6 / 16.8 / 12.7 / 46.2+ / 0.42+ / 0.01 / 0.1				65.9 / 26.7 / 6.1 / 1.0		0.3
				0.08 / 0.6		
					2.2 / 3.7	
25/03/2022 10:18:59	WB	Manual		PRE S2 05 A	XN-1000-1-A	Positive
13.86 / 4.45 / 12.1 / 40.2 / 90.3 / 27.2 / 30.1- / 335				9.04* / 3.82* / 0.81* / 0.14		0.05
48.5 / 14.6 / 16.9 / 12.7 / 46.9+ / 0.43+ / 0.01 / 0.1				65.2* / 27.6* / 5.8* / 1.0		0.4
				0.12* / 0.9*		
					2.2 / 3.8	
25/03/2022 10:20:29	WB	Manual		PRE S2 06 A	XN-1000-1-A	Negative
14.20 / 4.43 / 12.2 / 40.0 / 90.3 / 27.5 / 30.5- / 336				9.38+ / 3.82+ / 0.83+ / 0.13		0.04
48.8 / 14.6 / 17.6+ / 12.7 / 46.4+ / 0.43+ / 0.01 / 0.1				66.1 / 26.9 / 5.8 / 0.9		0.3
				0.08 / 0.6		
					2.3 / 3.8	
25/03/2022 10:21:39	WB	Manual		PRE S2 07 A	XN-1000-1-A	Positive
13.68 / 4.42 / 12.1 / 40.0 / 90.5 / 27.4 / 30.3- / 329				8.84* / 3.81* / 0.81* / 0.17		0.05
49.0 / 14.6 / 17.6+ / 12.9 / 48.1+ / 0.42+ / 0.02 / 0.1				64.6* / 27.9* / 5.9* / 1.2		0.4
				0.12* / 0.9*		
					2.4 / 3.7	
25/03/2022 10:22:27	WB	Manual		PRE S2 08 A	XN-1000-1-A	Positive
13.91 / 4.44 / 12.2 / 40.2 / 90.5 / 27.5 / 30.3- / 337				9.10+ / 3.79+ / 0.83+ / 0.14		0.05
48.5 / 14.6 / 17.3+ / 12.6 / 47.0+ / 0.43+ / 0.03 / 0.2				65.4 / 27.2 / 6.0 / 1.0		0.4
				0.13 / 0.9		
					2.5 / 3.7	
25/03/2022 10:23:46	WB	Manual		PRE S2 09 A	XN-1000-1-A	Positive
13.82 / 4.42 / 12.2 / 39.9 / 90.3 / 27.6 / 30.6- / 328				9.18+ / 3.64 / 0.81+ / 0.15		0.04
47.8 / 14.5 / 16.9 / 12.6 / 46.2+ / 0.41+ / 0.06 / 0.4				66.4 / 26.3 / 5.9 / 1.1		0.3
				0.13 / 0.9		
					2.4 / 3.7	
25/03/2022 10:24:30	WB	Manual		PRE S2 10 A	XN-1000-1-A	Positive
13.87 / 4.46 / 12.0 / 40.2 / 90.1 / 26.9 / 29.9- / 343				9.09+ / 3.73+ / 0.79+ / 0.21		0.05
48.3 / 14.6 / 17.6+ / 12.8 / 47.1+ / 0.44+ / 0.08 / 0.6				65.5 / 26.9 / 5.7 / 1.5		0.4
				0.13 / 0.9		
					2.3 / 3.7	
25/03/2022 10:25:11	WB	Manual		PRE S2 11 A	XN-1000-1-A	Positive
13.77 / 4.38 / 12.1 / 39.6 / 90.4 / 27.6 / 30.6- / 335				9.15+ / 3.62 / 0.77+ / 0.18		0.05
48.3 / 14.5 / 18.5+ / 12.9 / 48.2+ / 0.43+ / 0.08 / 0.6				66.4 / 26.3 / 5.6 / 1.3		0.4
				0.15 / 1.1		
					2.3 / 3.7	

Analysis Data(WB,LW,PD)

Date	Time	Measurement Mode	Order Type	PC	Sample No.	Nickname	Judgment
WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	NEUT#	LYMPH#	MONO#	EO#	BASO#
RDW-SD	RDW-CV	PDW	MPV	P-LCR	PCT	NRBC#	NRBC%	NEUT%	LYMPH%	MONO%	EO%	BASO%
								IG#	IG%			
										MicroR	MacroR	
24/03/2022 10:44:39		WB		Manual				CAL-CAL-01 A		XN-1000-1-A		
7.09	4.46	11.8	35.4	79.4	26.5	33.3	259	3.03	2.06	0.96	0.70	0.34
48.5	17.1	9.5	10.0	22.0	0.26	0.43	6.1	42.7	29.1	13.5	9.9	4.8
								0.77	10.9			
										9.6	4.0	
24/03/2022 10:45:29		WB		Manual				CAL-CAL-02 A		XN-1000-1-A		
7.11	4.41	11.7	35.1	79.6	26.5	33.3	252	3.00	2.02	0.96	0.78	0.35
48.6	16.9	9.6	9.9	21.3	0.25	0.41	5.8	42.2	28.4	13.5	11.0	4.9
								0.78	11.0			
										9.4	3.9	
24/03/2022 10:55:23		WB		Manual				CAL-CAL-03 A		XN-1000-1-A		
6.99	4.42	11.7	35.0	79.2	26.5	33.4	260	3.01	2.10	0.82	0.74	0.32
48.5	17.0	9.7	10.1	23.3	0.26	0.42	6.0	43.1	30.0	11.7	10.6	4.6
								0.76	10.9			
										9.8	3.8	
24/03/2022 10:47:08		WB		Manual				CAL-CAL-04 A		XN-1000-1-A		
7.13	4.45	11.7	35.3	79.3	26.3	33.1	254	2.98	2.10	0.96	0.74	0.35
48.2	17.1	9.6	10.2	23.0	0.26	0.42	5.9	41.7	29.5	13.5	10.4	4.9
								0.74	10.4			
										9.6	3.9	
24/03/2022 10:47:57		WB		Manual				CAL-CAL-05 A		XN-1000-1-A		
7.19	4.36	11.7	34.7	79.6	26.8	33.7	261	3.10	2.10	0.92	0.71	0.36
48.2	17.0	9.4	10.1	22.4	0.26	0.41	5.7	43.1	29.2	12.8	9.9	5.0
								0.84	11.7			
										9.5	4.0	
24/03/2022 10:48:46		WB		Manual				CAL-CAL-06 A		XN-1000-1-A		
7.26	4.41	11.7	35.1	79.6	26.5	33.3	255	3.14	2.07	0.93	0.78	0.34
48.6	17.1	9.6	10.0	22.6	0.25	0.39	5.4	43.3	28.5	12.8	10.7	4.7
								0.78	10.7			
										9.6	3.9	
24/03/2022 10:49:36		WB		Manual				CAL-CAL-07 A		XN-1000-1-A		
6.98	4.41	11.7	35.0	79.4	26.5	33.4	260	2.96	1.99	0.97	0.72	0.34
48.5	17.0	9.2	10.0	21.3	0.26	0.40	5.7	42.4	28.5	13.9	10.3	4.9
								0.79	11.3			
										9.7	3.9	
24/03/2022 10:56:40		WB		Manual				CAL-CAL-08 A		XN-1000-1-A		
7.05	4.39	11.7	34.8	79.3	26.7	33.6	265	2.97	2.09	0.90	0.75	0.34
48.3	17.0	9.0	9.9	20.6	0.26	0.38	5.4	42.2	29.6	12.8	10.6	4.8
								0.76	10.8			
										9.9	3.9	
24/03/2022 10:51:15		WB		Manual				CAL-CAL-09 A		XN-1000-1-A		
7.15	4.42	11.7	35.1	79.4	26.5	33.3	261	3.03	2.06	0.99	0.73	0.34
48.6	17.0	9.6	10.0	22.8	0.26	0.37	5.2	42.4	28.8	13.8	10.2	4.8
								0.74	10.3			
										9.6	3.8	
24/03/2022 10:52:04		WB		Manual				CAL-CAL-10 A		XN-1000-1-A		
7.12	4.43	11.7	35.2	79.5	26.4	33.2	255	3.14	2.02	0.87	0.75	0.34
48.5	16.9	8.9	9.8	19.4	0.25	0.43	6.0	44.1	28.4	12.2	10.5	4.8
								0.82	11.5			
										9.5	3.8	
24/03/2022 10:58:04		WB		Manual				CAL-CAL-11 A		XN-1000-1-A		
7.00	4.36	11.7	34.5	79.1	26.8	33.9	253	2.94	2.03	0.91	0.77	0.35
48.2	17.1	9.5	10.0	21.4	0.25	0.39	5.6	42.0	29.0	13.0	11.0	5.0
								0.77	11.0			
										9.8	3.7	

Analysis Data(WB,LW,PD)

Date / Time	Measurement Mode	Order Type	PC	Sample No.	Nickname	Judgment
WBC / RBC / HGB / HCT / MCV / MCH / MCHC / PLT / NEUT# / LYMPH# / MONO# / EO# / BASO#						
RDW-SD / RDW-CV / PDW / MPV / P-LCR / PCT / NRBC# / NRBC% / NEUT% / LYMPH% / MONO% / EO% / BASO%						
				IG# / IG% / MicroR / MacroR		
25/03/2022 09:58:59	WB	Manual		H 01 M	XN-1000-1-A	Positive
16.06+ / 5.05 / 15.2 / 43.3 / 85.7- / 30.1 / 35.1 / 592+ / 11.24* / 3.55* / 1.15* / 0.04* / 0.08*						
43.9 / 14.3 / 9.0 / 9.6 / 18.4 / 0.57+ / 0.37 / 2.3 / 70.0* / 22.1* / 7.2* / 0.2* / 0.5*						
				0.45* / 2.8* / 3.4 / 4.6		
25/03/2022 09:59:35	WB	Manual		H 02 A	XN-1000-1-A	Positive
16.00+ / 5.11 / 15.2 / 43.6 / 85.3- / 29.7 / 34.9 / 590+ / 10.84* / 3.49* / 1.54* / 0.03* / 0.10*						
43.4 / 14.3 / 8.9- / 9.6 / 18.1 / 0.57+ / 0.38 / 2.4 / 67.8* / 21.8* / 9.6* / 0.2* / 0.6*						
				0.38* / 2.4* / 3.6 / 4.7		
25/03/2022 10:00:11	WB	Manual		H 03 A	XN-1000-1-A	Positive
16.24+ / 5.09 / 15.1 / 43.5 / 85.5- / 29.7 / 34.7 / 598+ / 11.09* / 3.79* / 1.17* / 0.04* / 0.15*						
43.7 / 14.3 / 9.0 / 9.7 / 18.7 / 0.58+ / 0.34 / 2.1 / 68.4* / 23.3* / 7.2* / 0.2* / 0.9*						
				0.45* / 2.8* / 3.6 / 4.5		
25/03/2022 10:01:21	WB	Manual		L 01 M	XN-1000-1-A	
0.00 / 0.00 / 0.0 / 0.0 / ---- / ---- / ---- / 1 / ---- / ---- / ---- / ---- / ----						
---- / ---- / ---- / ---- / ---- / ---- / ---- / ---- / ---- / ---- / ---- / ---- / ----						
				---- / ---- / ---- / ----		
25/03/2022 10:03:10	WB	Manual		L 02 A	XN-1000-1-A	
0.01 / 0.00 / 0.0 / 0.0 / ---- / ---- / ---- / 0 / ---- / ---- / ---- / ---- / ----						
---- / ---- / ---- / ---- / ---- / ---- / ---- / ---- / ---- / ---- / ---- / ---- / ----						
				---- / ---- / ---- / ----		
25/03/2022 10:03:46	WB	Manual		L 03 A	XN-1000-1-A	
0.00 / 0.00 / 0.0 / 0.0 / ---- / ---- / ---- / 0 / ---- / ---- / ---- / ---- / ----						
---- / ---- / ---- / ---- / ---- / ---- / ---- / ---- / ---- / ---- / ---- / ---- / ----						
				---- / ---- / ---- / ----		

Analysis Data(WB,LW,PD)

Date / Time	Measurement Mode	Order Type	WBC / RBC / HGB / HCT / MCV / MCH / MCHC / PLT	RDW-SD / RDW-CV / PDW / MPV / P-LCR / PCT / NRBC# / NRBC%	Sample No.	Nickname	NEUT# / NEUT% / IG#	LYMPH# / LYMPH% / IG%	MONO# / MONO%	EO# / EO%	Judgment BASO# / BASO%
25/03/2022 10:25:54	WB	Manual	0.00 0.00 0.0 0.0 ---- ---- ---- 0	---- ---- ---- ---- ---- ---- ---- ----	LOB 01 M	XN-1000-1-A	---- ---- ----	---- ---- ----	---- ----	---- ----	---- ----
25/03/2022 10:26:46	WB	Manual	0.00 0.00 0.0 0.0 ---- ---- ---- 0	---- ---- ---- ---- ---- ---- ---- ----	LOB 02 A	XN-1000-1-A	---- ---- ----	---- ---- ----	---- ----	---- ----	---- ----
25/03/2022 10:27:30	WB	Manual	0.00 0.00 0.0 0.0 ---- ---- ---- 0	---- ---- ---- ---- ---- ---- ---- ----	LOB 03 A	XN-1000-1-A	---- ---- ----	---- ---- ----	---- ----	---- ----	---- ----
25/03/2022 10:28:07	WB	Manual	0.00 0.00 0.0 0.0 ---- ---- ---- 0	---- ---- ---- ---- ---- ---- ---- ----	LOB 04 A	XN-1000-1-A	---- ---- ----	---- ---- ----	---- ----	---- ----	---- ----
25/03/2022 10:28:46	WB	Manual	0.00 0.00 0.0 0.0 ---- ---- ---- 0	---- ---- ---- ---- ---- ---- ---- ----	LOB 05 A	XN-1000-1-A	---- ---- ----	---- ---- ----	---- ----	---- ----	---- ----
25/03/2022 10:29:34	WB	Manual	0.00 0.00 0.0 0.0 ---- ---- ---- 1	---- ---- ---- ---- ---- ---- ---- ----	LOB 06 A	XN-1000-1-A	---- ---- ----	---- ---- ----	---- ----	---- ----	---- ----
25/03/2022 10:30:15	WB	Manual	0.00 0.00 0.0 0.0 ---- ---- ---- 0	---- ---- ---- ---- ---- ---- ---- ----	LOB 07 A	XN-1000-1-A	---- ---- ----	---- ---- ----	---- ----	---- ----	---- ----
25/03/2022 10:31:12	WB	Manual	0.00 0.00 0.0 0.0 ---- ---- ---- 0	---- ---- ---- ---- ---- ---- ---- ----	LOB 08 A	XN-1000-1-A	---- ---- ----	---- ---- ----	---- ----	---- ----	---- ----
25/03/2022 10:31:48	WB	Manual	0.00 0.00 0.0 0.0 ---- ---- ---- 0	---- ---- ---- ---- ---- ---- ---- ----	LOB 09 A	XN-1000-1-A	---- ---- ----	---- ---- ----	---- ----	---- ----	---- ----
25/03/2022 10:33:26	WB	Manual	0.00 0.00 0.0 0.0 ---- ---- ---- 0	---- ---- ---- ---- ---- ---- ---- ----	LOB 10 A	XN-1000-1-A	---- ---- ----	---- ---- ----	---- ----	---- ----	---- ----
25/03/2022 10:34:30	WB	Manual	0.00 0.00 0.0 0.0 ---- ---- ---- 1	---- ---- ---- ---- ---- ---- ---- ----	LOB 11 A	XN-1000-1-A	---- ---- ----	---- ---- ----	---- ----	---- ----	---- ----

Analysis Data(WB,LW,PD)

Date	Time	Measurement Mode	Order Type	PC	Sample No.	Nickname	Judgment
WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	NEUT#	LYMPH#	MONO#	EO#	BASO#
RDW-SD	RDW-CV	PDW	MPV	P-LCR	PCT	NRBC#	NRBC%	NEUT%	LYMPH%	MONO%	EO%	BASO%
								IG#	IG%			
										MicroR	MacroR	
25/03/2022	10:35:34	WB		Manual			LOD LOQ	S1 01 M	XN-1000-1-A			
0.02	0.01	0.0	0.1	100.0	0.0	0.0	1	----	----	----	----	----
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								----	----			
										----	----	
25/03/2022	10:37:07	WB		Manual			LOD LOQ	S1 02 A	XN-1000-1-A			
0.03	0.01	0.0	0.1	100.0	0.0	0.0	2	----	----	----	----	----
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								----	----			
										----	----	
25/03/2022	10:38:06	WB		Manual			LOD LOQ	S1 03 A	XN-1000-1-A			
0.02	0.01	0.0	0.1	100.0	0.0	0.0	1	----	----	----	----	----
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								----	----			
										----	----	
25/03/2022	10:39:51	WB		Manual			LOD LOQ	S1 04 A	XN-1000-1-A			
0.03	0.01	0.0	0.1	100.0	0.0	0.0	1	----	----	----	----	----
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								----	----			
										----	----	
25/03/2022	10:40:37	WB		Manual			LOD LOQ	S1 05 A	XN-1000-1-A			
0.02	0.01	0.0	0.1	100.0	0.0	0.0	2	----	----	----	----	----
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								----	----			
										----	----	
25/03/2022	10:42:02	WB		Manual			LOD LOQ	S1 06 A	XN-1000-1-A			
0.02	0.01	0.0	0.1	100.0	0.0	0.0	1	----	----	----	----	----
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								----	----			
										----	----	
25/03/2022	10:42:40	WB		Manual			LOD LOQ	S1 07 A	XN-1000-1-A			
0.02	0.01	0.0	0.1	100.0	0.0	0.0	1	----	----	----	----	----
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								----	----			
										----	----	
25/03/2022	10:43:16	WB		Manual			LOD LOQ	S1 08 A	XN-1000-1-A			
0.02	0.01	0.0	0.1	100.0	0.0	0.0	1	----	----	----	----	----
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								----	----			
										----	----	
25/03/2022	10:43:52	WB		Manual			LOD LOQ	S1 09 A	XN-1000-1-A			
0.01	0.01	0.0	0.1	100.0	0.0	0.0	1	----	----	----	----	----
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								----	----			
										----	----	
25/03/2022	10:44:32	WB		Manual			LOD LOQ	S1 10 A	XN-1000-1-A			
0.03	0.01	0.0	0.1	100.0	0.0	0.0	1	----	----	----	----	----
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								----	----			
										----	----	
25/03/2022	10:45:42	WB		Manual			LOD LOQ	S1 11 A	XN-1000-1-A			
0.03	0.01	0.0	0.1	100.0	0.0	0.0	1	----	----	----	----	----
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								----	----			
										----	----	

Analysis Data(WB,LW,PD)

Date / Time	Measurement Mode	Order Type	PC	Sample No.	Nickname	Judgment
WBC / RBC / HGB / HCT / MCV / MCH / MCHC / PLT / NEUT# / LYMPH# / MONO# / EO# / BASO#						
RDW-SD / RDW-CV / PDW / MPV / P-LCR / PCT / NRBC# / NRBC% / NEUT% / LYMPH% / MONO% / EO% / BASO%						
				IG# / IG% / MicroR / MacroR		
25/03/2022 10:47:46	WB	Manual		LOD LOQ S2 01 M	XN-1000-1-A	
0.05 0.02 0.0 0.2 100.0 0.0 0.0 2 ---- ---- ---- ---- ----						
---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ----						
25/03/2022 10:49:27	WB	Manual		LOD LOQ S2 02 A	XN-1000-1-A	
0.05 0.02 0.0 0.2 100.0 0.0 0.0 3 ---- ---- ---- ---- ----						
---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ----						
25/03/2022 10:50:10	WB	Manual		LOD LOQ S2 03 A	XN-1000-1-A	
0.04 0.02 0.0 0.2 100.0 0.0 0.0 2 ---- ---- ---- ---- ----						
---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ----						
25/03/2022 10:50:55	WB	Manual		LOD LOQ S2 04 A	XN-1000-1-A	
0.05 0.02 0.0 0.2 100.0 0.0 0.0 2 ---- ---- ---- ---- ----						
---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ----						
25/03/2022 10:51:31	WB	Manual		LOD LOQ S2 05 A	XN-1000-1-A	
0.04 0.02 0.0 0.2 100.0 0.0 0.0 2 ---- ---- ---- ---- ----						
---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ----						
25/03/2022 10:52:39	WB	Manual		LOD LOQ S2 06 A	XN-1000-1-A	
0.05 0.02 0.0 0.2 100.0 0.0 0.0 2 ---- ---- ---- ---- ----						
---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ----						
25/03/2022 10:54:02	WB	Manual		LOD LOQ S2 07 A	XN-1000-1-A	
0.06 0.02 0.0 0.2 100.0 0.0 0.0 3 ---- ---- ---- ---- ----						
---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ----						
25/03/2022 10:54:38	WB	Manual		LOD LOQ S2 08 A	XN-1000-1-A	
0.05 0.02 0.0 0.2 100.0 0.0 0.0 2 ---- ---- ---- ---- ----						
---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ---- ----						
25/03/2022 10:55:47	WB	Manual		LOD LOQ S2 09 A	XN-1000-1-A	
0.06 0.02 0.0 0.2 100.0 0.0 0.0 2 ---- ---- ---- ---- ----						
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25/03/2022 10:56:30	WB	Manual		LOD LOQ S2 10 A	XN-1000-1-A	
0.04 0.02 0.0 0.2 100.0 0.0 0.0 2 ---- ---- ---- ---- ----						
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25/03/2022 10:57:39	WB	Manual		LOD LOQ S2 11 A	XN-1000-1-A	
0.04 0.02 0.0 0.2 100.0 0.0 0.0 2 ---- ---- ---- ---- ----						
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