

Date: 23-02-2024

Calibration Certificate

This is to certify that Automated Haematology Analyser XN-330
Serial No: 15454 installed at Agilus Pathlabs Pvt Ltd 1st Floor, Sector-
17, Mahavir Centre, Above Golden Punjab hotel, Navi-Mumbai 400703. been
calibrated.

Calibration Done on: 23-02-2024

Calibration Validity: 23-02-2024 to 22-02-2025

Calibration Due on: 22-02-2025.

Parameter	WBC	RBC	HGB	HCT	PLT
CV %	1.1	0.8	0.5	0.7	1.6
Acceptable Range	3	1.5	1	1.5	4

For Sysmex India Pvt. Ltd.



Authorized Signatory

Confidential

< XN CAL™ ASSAY SHEET for service staff >

For XN-L series

Lot No. **40222101**

Exp. Date **2024-02-25**

Use between * **2024-02-19** and **2024-02-25**

	RBC 10 ⁶ /μL	HGB		HCT %	PLT 10 ³ /μL	MPV fL
		g/dL	mmol/L			
TARGET	4.384	12.17	7.55	35.25	240.2	10.4

	WBC-C 10 ³ /μL	WBC-D 10 ³ /μL	RET% %	RBC-O 10 ⁶ /μL	PLT-O 10 ³ /μL
TARGET	8.057	7.537	3.157	4.264	242.6

	MCV fL	MCH **		MCHC **		RBC-He		RET-He	
		pg	fmol	g/dL	mmol/L	pg	fmol	pg	fmol
TARGET	80.4	27.8	1.723	34.5	21.4	27.5	1.707	23.4	1.452

	RET# ** 10 ⁶ /μL	HFR ** %	MFR ** %	LFR ** %	IRF ** %
TARGET	0.138	3.8	21.7	74.5	25.5

	WDF-X (SSC) ch	WDF-Y (SFL) ch	WDF-Z (FSC) ch	RET- RBC-X (SFL) ch	RET- RBC-Y (FSC) ch	RET- RBC-Z (SSC) ch
TARGET	162.4	103.0	118.1	22.3	161.3	22.1

There are some parameters which is not displayed on IPU according to the instrument.

Please refer to the package insert for the handling of the XN CAL.

Do not leave caribrator in the room temperature over an hour.

Please store it in a refrigerator (2-8°C) immediately after use.

* : This refers to the validity of the assay values for service palameters.

** : Don't calibrate ** marked palameters.



Traceability and Uncertainty

XN CAL Sysmex Calibrator System

XN-L Series Automated Hematology Analyzer

LOT NO: 4022 2101

EXP. DATE: 25-Feb-2024

Parameter	Reference Method	Reference Material	Assigned Value	Uncertainty*	Unit
WBC-C	*1	-	8.057	0.19	10 ⁹ /L
WBC-D	*1	-	7.537	0.19	10 ⁹ /L
RBC	*1	-	4.384	0.049	10 ¹² /L
RBC-O	*1	-	4.264	0.060	10 ¹² /L
PLT	*2	-	240.2	10	10 ⁹ /L
PLT-O	*2	-	242.6	11	10 ⁹ /L
HGB	*3, *4	-	12.17	0.19	g / dL
HCT	*5	-	35.25	0.64	%

* : This uncertainty (expanded uncertainty; k=2 was calculated in accordance with the "Guide to the expression of uncertainty in measurement" (GUM: 1995).

*1: ICSH Expert Panel on Cytometry, Clinical Laboratory Haematology, 16, 131-138, 1994

"Reference method for the enumeration of erythrocytes and leucocytes"

*2: ICSH Expert Panel on Cytometry and International Society of Laboratory Hematology Task Force on Platelet Counting, American Journal of Clinical Pathology, 115, 460-464, 2001

"Platelet Counting by the RBC/Platelet Ratio method – A reference Method"

*3: CLSI, H15-A3

"Reference and selected procedures for the quantitative determination of hemoglobin in blood – 3rd edition; Approved standard"

*4: Journal of Clinical Pathology, 49, 271-274, 1996

"Recommendation for reference method for haemoglobinometry in human blood (ICSH standard 1995) and specification for international haemoglobinocyanide reference preparation (4th ed.)"

*5: CLSI H7-A3

"Procedure for Determining Packed Cell Volume by the Microhematrit Method – 3rd edition; Approved Standard"



Date : 06th April'2024

TO WHOMSOEVER IT MAY CONCERN

We Sysmex India Pvt Ltd, have placed our fully automated Hematology analyzer model XN-30 Sr no 15454 at Agilus Pathlabs Pvt Ltd (Vashi – 400703) on Reagent Rental in the year 2023.

Add : 1st Floor, Mahavir Centre, Above Golden Punjab hotel, Sector-17, Vashi - 400703

The instrument is under warranty and service for the same will be provided till the tenure of the agreement.

Thanks & Regards,

A handwritten signature in black ink, appearing to read "Hardik", written over a horizontal line.

Hardik Notaria
Sr. Area Sales Manager
Sysmex India Pvt Ltd

Sysmex India Pvt. Ltd.

Unit No 05-07, 4th Floor, Newa Bhakti Knowledge City,
 Plot No. IT-06, Airoli Knowledge Park, T.T.C. Indl. Area,
 Airoli, Thane,
 India, 400708
 Tel. (+91) 22 6112 6666 Fax. (+91) 22 2577 6790
 Email: sysmex@sysmex.co.in
 Web: https://www.sysmex.co.in
 GST Reg. No: 27AADCS1551J1ZC Co. Reg. No:



CSR No.: WO-100346460
 Revision No.:

Customer Service Report

Customer Name	Agilus Pathlabs Pvt Ltd		
Contact Person	Miss.Rukaiya		
Installation Date	09/02/2023	Login Date/Time	
Equipment ID	10171723	FSR Name	Sagar Patil
Model	XN-330	From Date/Time	23/02/2024 11:46:22 AM
Serial No.	15454	To Date/Time	23/02/2024 04:01:00 PM
Total Cycle Count	11,014	Case No.	

Defect Analysis

Issue Code	Cause Code
Issue	Cause

Action Taken	Action Code	Value Before Adjustment	Value After Adjustment
1. Pre-check: Perform QC analysis with XN-L Check or XN Check at least 2 times	Completed		
2. RBC Detector Block: Open the metal cover of the RBC detector block and clean the internal surfaces with moist paper towel	Cleaned		
3. RBC Detector Block: Perform "Drain Isolation Chamber" in Maintenance Menu of IPU program	Cleaned		
4. RBC Detector Block: Clean transducer aperture using aperture brush dipped in cellclean	Cleaned		
5. RBC/HGB Mix Chamber: Activate "Drain Reaction Chamber". Dispense 2ml of cellclean auto into the RBC chamber and activate sequence again to drain cellclean. Repeat twice	Cleaned		
6. WBC Chamber: Activate "Drain Reaction Chamber". Dispense 2ml of cellclean auto into the reaction chambers and activate sequence again to drain cellclean. Repeat twice	Cleaned		
7. FCM Unit: Check laser current value in "Service Menu" of IPU program [Range: 100mA to 140 mA]	Checked	133.4	133.4
8. Vacuum Line: Clean vacuum line using ethanol or methanol (Approx 30ml)	Cleaned		
9. Shut Down: Shut down analyzer before proceeding	Completed		
10. Vacuum Line: Rinse vacuum trap chamber using DI or distilled water	Cleaned		
11. RBC/HGB Mix Chamber: Remove Filter No. 13 below RBC/HGB chamber and flush it with cellclean using syringe	Cleaned		
12. WBC Chamber: Remove Filter No. 13 below WBC reaction chamber and flush it with cellclean using syringe	Cleaned		
13. Waste Chamber: Remove waste chamber and clean the internal surface and the waste sensor with gauze dipped in diluted cellclean.	Cleaned		
14. Waste Chamber: Rinse waste chamber trap chamber with DI or distilled wter	Cleaned		

Sysmex India Pvt. Ltd.

Unit No 05-07, 4th Floor, Newa Bhakti Knowledge City,
 Plot No. IT-06, Airoli Knowledge Park, T.T.C. Indl. Area,
 Airoli, Thane,
 India, 400708
 Tel. (+91) 22 6112 6666 Fax: (+91) 22 2577 6790
 Email: sysmex@sysmex.co.in
 Web: <https://www.sysmex.co.in>
 GST Reg. No: 27AADCS1551J1ZC Co. Reg. No:



CSR No.: WO-100346460
 Revision No.:

Customer Service Report

Customer Name	Agilus Pathlabs Pvt Ltd		
Contact Person	Miss.Rukaiya		
Installation Date	09/02/2023	Login Date/Time	
Equipment ID	10171723	FSR Name	Sagar Patil
Model	XN-330	From Date/Time	23/02/2024 11:46:22 AM
Serial No.	15454	To Date/Time	23/02/2024 04:01:00 PM
Total Cycle Count	11,014	Case No.	
Action Taken	Action Code	Value Before Adjustment	Value After Adjustment
15. Waste Chamber: Replace the motorized pinch valve pharmed tubing (Total Length : 150mm) (3 Years or 60K Cycle)	Replaced		
16. FCM Unit: Clean flowcell using syringe and 3ml of cellclean in a back and forth motion at least 20 times	Cleaned		
17. Piercer: Clean exterior of pipette/piercer using gauze dipped in cellclean	Cleaned		
18. Piercer: Check piercer, replace if it is blunt. Replace piercer. Reset Piercer cycle count if it is replaced (120K Cycles)	NA		
19. Piercer: Clean rinse cup using cellclean then rinse with DI or distilled water	Cleaned		
20. Piercer: Clean pipette/piercer protector using cellclean then rinse with DI or distilled water	Cleaned		
21. Sheath syringe: Check sheath syringe for leakage. Replace if there is a leak	Checked		
22. Sheath syringe: Remove old grease and lubricate the sheath motor spindle using Kluber L60 (6 Months)	Lubricated		
23. WB pump: Check WB pump for leakage. Replace WB pump if there is a leak	Checked		
24. Sampler: Remove old grease and lubricate the sampler drive unit (XN-530/550) with Grease Molykote (6 Months)	Lubricated		
25. Pneumatic unit: Replace air pump. Reset airpump cycle count if it is replaced (2 Years or 30K Cycles)	NA		
26. Power On: Power on analyzer in service mode and ensure there are no errors. Run auto rinse once and ensure background check pass	Completed		
27. Pneumatic unit: Check 0.06 Mpa pressure from IPU software [Target: $\geq 0.06\text{MPa}$]	Checked	0.0596	0.0596
28. Pneumatic unit: Check -0.03 Mpa pressure from IPU software [Target: $\geq -0.03\text{MPa}$]	Checked	-0.0316	-0.0316
29. Mechanical Adjustment: Check pipette/piercer position. Adjust if it is out of alignment	Checked		
30. Mechanical Adjustment: Check sampler hand and tube holder position for XN-550. Adjust if it is out of alignment	NA		
31. Mechanical Adjustment: Check Barcode Reader functionality. Adjust barcode reading position if it is out of alignment. (XN-530/550)	NA		
32. Electronics Adjustment: Check blood aspiration sensor blank. Adjust if it is out of range [Range: 4800 to 5200]	Adjusted	5682	4990

Sysmex India Pvt. Ltd.

Unit No 05-07, 4th Floor, Newa Bhakti Knowledge City,
 Plot No. IT-06, Airoli Knowledge Park, T.T.C. Indl. Area,
 Airoli, Thane,
 India, 400708
 Tel. (+91) 22 6112 6666 Fax. (+91) 22 2577 6790
 Email: sysmex@sysmex.co.in
 Web: https://www.sysmex.co.in
 GST Reg. No: 27AADCS1551J1ZC Co. Reg. No:

CSR No.: WO-100346460
 Revision No.:

Customer Service Report

Customer Name	Agilus Pathlabs Pvt Ltd		
Contact Person	Miss.Rukaiya		
Installation Date	09/02/2023	Login Date/Time	
Equipment ID	10171723	FSR Name	Sagar Patil
Model	XN-330	From Date/Time	23/02/2024 11:46:22 AM
Serial No.	15454	To Date/Time	23/02/2024 04:01:00 PM
Total Cycle Count	11,014	Case No.	
Action Taken	Action Code	Value Before Adjustment	Value After Adjustment
33. Electronics Adjustment: Check blood aspiration sensor span using XN-L Check or XN Check Level 2. Adjust if it is out of range [Range: 12,500 to 13,500]	Adjusted	11972	13116
34. Electronics Adjustment: Check RBC Clog Level. Adjust if it is out of range [Range: 99 to 101]	Adjusted	100	100
35. Electronics Adjustment: Check HGB Blank. Adjust if it is out of range [Range: 4800 to 5200]	Adjusted	6622	4993
36. Operation check: Test the host communication	Checked		
37. Operation check: Perform QC analysis with XN-L Check or XN Check at least 3 times	Completed		
38. Operation check: Perform full backup and copy mmb files to desktop	Completed		
39. General Cleaning: Clean Main Unit covers	Cleaned		
40. General Cleaning: Clean IPU touch panel	Cleaned		
41. General Cleaning: Clean peripheral device (printer, etc.)	Cleaned		
42. General Cleaning: Clean the interior of sampler for XN-550	NA		

Sysmex India Pvt. Ltd.

Unit No 05-07, 4th Floor, Newa Bhakti Knowledge City,
 Plot No. IT-06, Airoli Knowledge Park, T.T.C. Indl. Area,
 Airoli, Thane,
 India, 400708
 Tel. (+91) 22 6112 6666 Fax. (+91) 22 2577 6790
 Email: sysmex@sysmex.co.in
 Web: https://www.sysmex.co.in
 GST Reg. No: 27AADCS1551J1ZC Co. Reg. No:



CSR No.: WO-100346460
 Revision No.:

Customer Service Report



Customer Name	Agilus Pathlabs Pvt Ltd		
Contact Person	Miss.Rukaiya		
Installation Date	09/02/2023	Login Date/Time	
Equipment ID	10171723	FSR Name	Sagar Patil
Model	XN-330	From Date/Time	23/02/2024 11:46:22 AM
Serial No.	15454	To Date/Time	23/02/2024 04:01:00 PM
Total Cycle Count	11,014	Case No.	

Remarks

Preventive Maintenance

Items Consumed

Product ID	VPN	Product Description	QTY	UOM
------------	-----	---------------------	-----	-----

Name:- Sagar Patil	Acknowledged By : Miss.Rukaiya
Sign: 	Sign : 
Date: 23/02/2024 11:13:16 PM	Date: 23/02/2024 11:13:16 PM

Customer Confidential