

## CALIBRATION CERTIFICATE

This is to certify that Fully **Automated Haematology Analyser XN-550**, Serial No: 26205, **Calibrated**  
at **Smita Memorial Hospital & Research Centre, Thodupuzha**

Calibration Done on: 26 June 2023  
Calibration Validity: 26 June 2023 to 25 June 2024  
Calibration Due on: 26 June 2024 on or Before

### Calibration Information:

Calibration Material	Calibrated Date	Lot no	Exp
XN CAL	26 June 2023	31632101	2023-07-16

For Sysmex India Pvt. Ltd.,



Authorised Signatory

**Sysmex India Pvt. Ltd.**

1002, Damji Shamji Business Galleria,  
 10th Floor, LBS Marg,  
 Kanjurmarg (West),  
 India, 400078  
 Tel. (+91) 22 6112 6666 Fax. (+91) 22 2577 6790  
 Email: [sysmex@sysmex.co.in](mailto:sysmex@sysmex.co.in)  
 Web: <https://www.sysmex.co.in>  
 GST Reg. No: 27AADCS1551J1ZC Co. Reg. No: ABC



CSR No.: WO-100314828  
 Revision No.:

**Customer Service Report**

<b>Customer Name</b>	Smita Memorial Hospital & Research Centre		
<b>Contact Person</b>	SHYAM		
<b>Installation Date</b>		<b>Login Date/Time</b>	
<b>Equipment ID</b>	10181350	<b>FSR Name</b>	John Mathew
<b>Model</b>	XN-550	<b>From Date/Time</b>	26/06/2023 11:13:33 AM
<b>Serial No.</b>	26205	<b>To Date/Time</b>	26/06/2023 06:14:00 PM
<b>Total Cycle Count</b>	27	<b>Case No.</b>	

Defect Analysis	
Issue Code	Cause Code
Issue	Cause

Action Taken	Action Code	Value Before Adjustment	Value After Adjustment
1. Check environmental requirements are satisfied (temp, humidity, atmp. pres., etc)	Checked		
2. Check there is enough space to install instrument	Checked		
3. Check installation surface strength is enough	Checked		
4. Confirm power supply (capacity and quantity) and earth grounding	Completed		
5. Check all necessary parts (equipment, consumables and options) are available	Checked		
6. Check all accessories are supplied	Checked		
7. Confirm there are no damage on instrument	Completed		
8. Check there is clearance of 500 mm or more on the left and right sides and at the rear	Checked		
9. Remove all transportation fixing tapes	Completed		
10. Remove clip and tie wraps for drive mechanism in right side cover	Completed		
11. Remove fixture for sampler mechanism (Fixture No. 1657) for XN-550	Completed		
12. Connect waste tube between waste nipple and waste tank	Completed		
13. Check waste tank is placed lower than instrument and in replaceable position	Checked		
14. Secure waste tubes	Completed		
15. Connect all reagents correctly	Completed		
16. Check reagent containers are placed lower than instrument and in replaceable position	Checked		
17. Check Fluorocell WDF and Fluorocell RET are placed in Dye holder position correctly	Checked	Fluorocell RET NA	
18. Connect keyboard, mouse, handy bar code reader	Completed		
19. Connect touch panel monitor for XN-550	Completed		

**Sysmex India Pvt. Ltd.**

1002, Damji Shamji Business Galleria,  
 10th Floor, LBS Marg,  
 Kanjurmarg (West),  
 India, 400078  
 Tel. (+91) 22 6112 6666 Fax. (+91) 22 2577 6790  
 Email: [sysmex@sysmex.co.in](mailto:sysmex@sysmex.co.in)  
 Web: <https://www.sysmex.co.in>  
 GST Reg. No: 27AADCS1551J1ZC Co. Reg. No: ABC



CSR No.: WO-100314828  
 Revision No.:

**Customer Service Report**

<b>Customer Name</b>	Smita Memorial Hospital & Research Centre		
<b>Contact Person</b>	SHYAM		
<b>Installation Date</b>		<b>Login Date/Time</b>	
<b>Equipment ID</b>	10181350	<b>FSR Name</b>	John Mathew
<b>Model</b>	XN-550	<b>From Date/Time</b>	26/06/2023 11:13:33 AM
<b>Serial No.</b>	26205	<b>To Date/Time</b>	26/06/2023 06:14:00 PM
<b>Total Cycle Count</b>	27	<b>Case No.</b>	
<b>Action Taken</b>	<b>Action Code</b>	<b>Value Before Adjustment</b>	<b>Value After Adjustment</b>
20. Connect electric cord to the main unit	Completed		
21. Check the necessary devices are connected	Checked		
22. Connect and check tubes and wiring cords	Checked		
23. Check IPU start up properly	Checked		
24. Check system configuration been set correctly using System Configurator	Checked		
25. Check SysmexCustomShell setting is performed	Checked		
26. Check system locale is performed	Checked		
27. Check keyboard setting is performed	Checked		
28. Check McAfee Embedded setting is performed	Checked		
29. Check GP Printer setting is performed	Checked		
30. Check touch panel setting is performed	Checked		
31. Check the instruments are started properly	Checked		
32. Check setting sequence is performed	Checked		
33. Check reagents are primed and check for any leakage in main unit	Checked		
34. Check and confirm there is no problem with adjustment	Checked		
35. Check JIG_Assy No. 407 is removed and original wiring is connected	Checked		
36. Check all covers are installed	Checked		
37. Check there is no dust or dirt on the instruments	Checked		
38. Check levelling of the instruments	Checked		
39. Check the program version and upgrade if needed	Checked		
40. Check instrument ID Card is attached	Checked		
41. All local interfaces (i.e. USB port) that are not required for the intended use of the device are disabled, except during equipment servicing, maintenance, or customer request.	Completed		

**Systemex India Pvt. Ltd.**

1002, Damji Shamji Business Galleria,  
 10th Floor, LBS Marg,  
 Kanjurmarg (West),  
 India, 400078  
 Tel. (+91) 22 6112 6666 Fax. (+91) 22 2577 6790  
 Email: [systemex@systemex.co.in](mailto:systemex@systemex.co.in)  
 Web: <https://www.systemex.co.in>  
 GST Reg. No: 27AADCS1551J1ZC Co. Reg. No: ABC



CSR No.: WO-100314828  
 Revision No.:

**Customer Service Report**



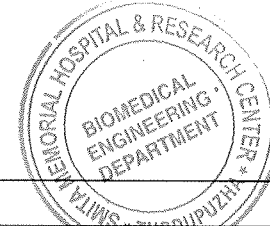
<b>Customer Name</b>	Smita Memorial Hospital & Research Centre		
<b>Contact Person</b>	SHYAM		
<b>Installation Date</b>		<b>Login Date/Time</b>	
<b>Equipment ID</b>	10181350	<b>FSR Name</b>	John Mathew
<b>Model</b>	XN-550	<b>From Date/Time</b>	26/06/2023 11:13:33 AM
<b>Serial No.</b>	26205	<b>To Date/Time</b>	26/06/2023 06:14:00 PM
<b>Total Cycle Count</b>	27	<b>Case No.</b>	

**Remarks**

Installation of XN 550, SI no: 26205 equipment completed successfully.

**Items Consumed**

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

<b>Name:-</b> John Mathew	<b>Acknowledged By :</b> SHYAM
<b>Sign:</b> 	<b>Sign :</b>  
<b>Date:</b> 26/06/2023 06:16:36 PM	<b>Date:</b> 26/06/2023 06:16:36 PM

**Customer Confidential**



## XN-L Series Commissioning Report

Customer : Smita Memorial Hospital & Research Centre  
Model: XN 550

Date: 26-06-2023  
Serial No: 26205

### 1 MECHANICAL ADJUSTMENTS

Positions	Perform
Piercer/Pipette Position	Completed
Tube Holder Position	Completed
Hand Position	Completed
BCR Position	Completed

### 2 BACKGROUND VERIFICATION

Parameters	Results	Acceptable Range	Status
WBC	0.00	$\leq 0.10 \times 10^3/\mu\text{L}$	PASS
RBC	0.00	$\leq 0.02 \times 10^6/\mu\text{L}$	PASS
HGB	0.0	$\leq 0.1 \text{ g/dL}$	PASS
PLT-I	0	$\leq 10 \times 10^3/\mu\text{L}$	PASS
RBC-O*	NA	$\leq 0.02 \times 10^6/\mu\text{L}$	NA
PLT-O*	NA	$\leq 10 \times 10^3/\mu\text{L}$	NA

\* Only applicable when RET license is activated

### 3 OPTICAL AXIS VERIFICATION

3.1 **CELLPACK DFL 10ml + DUKE 4207A 5 Drops.** The diluted latex was analyzed to determine the Optical Axis of the FSC (Rough). The results are as below :

Parameters	Results	Acceptable Range	Status
FSC (X) Rough	NA	70 - 130	NA
FSC (W) Rough	NA	Less than 0.15	NA

3.2 **CELLPACK DCL 10ml + DUKE 4207A 5 Drops.** The diluted latex was analyzed to determine the Optical Axis of the FSC (Fine). The results are as below :

Parameters	Results	Acceptable Range	Status
FSC (X) Fine	86.9	70 - 130	PASS
FSC (W) Fine	0.173	Less than 0.35	PASS

3.3 **CELLPACK DCL 10ml + PS-FLUORED-L2830-4 2 Drops.** The diluted latex was analyzed to determine the Optical Axis of the SFL(Fine) & SSC(Fine). The results are as below :

Parameters	Results	Acceptable Range	Status
SFL (X)	116.7	For Record Purpose	
SFL (W)	0.171	lower than 0.20	PASS
SSC (X)	73.9	50 - 100	PASS
SSC (W)	0.19	For Record Purpose	

NOTE: Please attach FSC(X) rough, FSC(X) fine, SFL(X) fine, SSC(X) fine peaks screenshots.



**4 RBC CLOG LEVEL ADJUSTMENT**

4.1 The RBC clog adjustment is monitored after the background check. The result is as below :

Parameters	Results	Acceptable Range	Status
RBC CLOG	100	100 ± 1	PASS

**5 HGB BLANK ADJUSTMENT**

Parameters	Results	Acceptable Range	Status
HB Blank Gain	5016	5000 ± 200	PASS

**6 ASPIRATION SENSOR BLANK ADJUSTMENT**

Parameters	Results	Acceptable Range	Status
Aspiration Sensor	4889	5000 ± 200	PASS

**7 ASPIRATION SENSOR SPAN ADJUSTMENT**

7.1 \*Material : XN-CHECK /XN-CAL

Lot : 31531402

Expiry : 2023-09-12

\* Cross whichever not applicable

Parameters	Results	Acceptable Range	Status
Aspiration Sensor Span	13090	13000 ± 500	PASS

**8 SENSITIVITY ADJUSTMENTS**

8.1 Material :XN-CAL

Lot : 31632101

Expiry : 2023-07-16

Parameters	Results	Assay Value	Acceptable Range	Status	Scattergram normal?
WDF-X	163.7	163.4	± 3 ch	PASS	YES
WDF-Y	101.7	101.2	± 3 ch	PASS	
WDF-Z / WDF-FSC	120.3	119.6	± 2.5 ch	PASS	

Parameters	Results	Assay Value	Acceptable Range	Status	Scattergram normal?
RBC-X	NA	NA	± 1 ch	NA	RET Not activated
RBC-Y	NA	NA	± 3 ch	NA	
RBC-Z	NA	NA	± 2 ch	NA	

Parameters	Results	Assay Value	Acceptable Range	Status
MCV	79.8	79.9	± 1 ch	PASS
MPV	9.5	9.5	± 0.3 ch	PASS
HGB	11.9	11.9	± 0.2g/dl	PASS

NOTE: Please attach sensitivity adjustment screenshots.



**9 Calibration**

**9.1 Please refer to Whole Blood Calibration Report Attached**

**9.2 PD Mode Calibration** (NOTE: If Applicable)

**Material: XN CAL (1:7 Dilution)**

**Lot: 31632101**

**Expiry: 2023-07-16**

Parameters	1	2	3	4	5	Average	Assay Value	Old Cal	New Cal	% Diff	Status
RBC_PD_CAL	4.57	4.40	4.38	4.37	4.39	4.42	4.348	1025	1008	1.67	PASS
PLT_PD_CAL	264	251	257	245	250	253	247.9	959	938	2.17	PASS
HGB_PD_CAL	12.7	11.9	11.8	11.9	11.9	12.0	11.94	1005	997	0.83	PASS
WBC_PD_CAL	7.89	7.69	7.68	7.50	7.69	7.69	7.548	1000	982	1.85	PASS
WBC-D/WDF_P	7.31	7.11	7.20	6.96	7.22	7.16	7.056	1029	1014	1.45	PASS
RET_PD_CAL*	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RBCO_PD_CAL	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
PLTO_PD_CAL	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

\*NOTE: Only Applicable when RET license has been activated

NOTE: Please attach PD Mode Calibration results screenshots

**9.3 Body Fluid Calibration** (NOTE: If Applicable)

**Material: XN CAL**

**Lot:**

**Expiry:**

Parameters	1	2	3	4	5	Average	Assay Value	Old Cal	New Cal	% Diff	Status
RBC_BF_CAL*	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
WBC_BF_CAL*	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

\*NOTE: Only Applicable when BF license has been activated

NOTE: Please attach BF Mode Calibration results screenshots

**10 QC Verification**

**10.1** Please attach QC radar charts print outs for QC runs after the calibration.

**11** Pipetors/Dilutors reproducibility and accuracy checked.



**12 Certification**

We certify that the **XN 550** Automated Hematology Analyzer S/N: **26205** has been successfully commissioned in accordance with the manufacturer's recommendations.

**Report and Commissioning Performed By :**

\_\_\_\_\_  
**Signature (Engineer 1)**

**Name: John Mathew**  
\_\_\_\_\_  
**Date: 26-06-2023**  
\_\_\_\_\_

\_\_\_\_\_  
**Signature (Engineer 2)**

**Name: Nikhiljith A K**  
\_\_\_\_\_  
**Date: 26-06-2023**  
\_\_\_\_\_

**Report Reviewed and Accepted By :**

\_\_\_\_\_  
**Signature (Customer)**

**Name:** Jejanthara S  
**Date:** 26/6/2023

26/6/2023

