

Sysmex India Pvt. Ltd.
 1002, Damji Shamji Business Galleria,
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 Web: https://www.sysmex.co.in
 GST Reg. No: 27AADCS1551J1ZC Co. Reg. No: ABC



CSR No.: WO-100251484
 Revision No.:

Customer Service Report

Customer Name	SUMUKH PRAYOGALAYA SRINIKA MOLECULAR DIAGNOSTICS		
Contact Person	Dr Choukimath		
Installation Date		Login Date/Time	
Equipment ID	10155698	FSR Name	Nazeeb Mulla
Model	XN-550	From Date/Time	12/10/2022 12:30:03 PM
Serial No.	23306	To Date/Time	12/10/2022 01:11:00 PM
Total Cycle Count		Case No.	

Defect Analysis	
Issue Code	Cause Code
Issue	Cause

Action Taken	Action Code	Value Before Adjustment	Value After Adjustment
Check the availability of door, dimension to take the instrument at installation location	Completed		
Check the space and leveling table	Checked	L=1800mm/ D=12000mm/W=600mm	L=1800mm/ D=12000mm/W=600mm
Check the availability of ups & voltages.(P-N=230V, P-E=230V, N-E: >=4 Volts)	Checked		UPS Capacity-10 KVA Centralised, P-N=227, P-E=228V,N-E=1Volt
Check the availability of power points	Checked		2 points Available
Check the room temperature & Humidity	Checked		Temp=23 deg celcius, Humidity=53%
LIS(Interface with host) required	Completed		Required
Email interface protocol to customer(If LIS is required)	Completed		
Meeting with HOD/Person for evaluation regarding installation requirement and process flow	Completed		Dr Choukimath HOD
Site ready for installation	Completed		

System India Pvt. Ltd.
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CSR No.: WO-100251322
 Revision No.:

Customer Service Report

Customer Name	SUMUKH PRAYOGALAYA SRINIKA MOLECULAR DIAGNOSTICS		
Contact Person	Dr Choukimath		
Installation Date		Login Date/Time	
Equipment ID	10155698	FSR Name	Nazeeb Mulla
Model	XN-550	From Date/Time	17/10/2022 04:58:09 PM
Serial No.	23306	To Date/Time	17/10/2022 05:12:00 PM
Total Cycle Count		Case No.	

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

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Serial No.	23306	To Date/Time	17/10/2022 05:12:00 PM
Total Cycle Count		Case No.	
Action Taken	Action Code	Value Before Adjustment	Value After Adjustment
20. Connect electric cord to the main unit	NA		
21. Check the necessary devices are connected	NA		
22. Connect and check tubes and wiring cords	NA		
23. Check IPU start up properly	NA		
24. Check system configuration been set correctly using System Configurator	NA		
25. Check SysmexCustomShell setting is performed	NA		
26. Check system locale is performed	NA		
27. Check keyboard setting is performed	NA		
28. Check McAfee Embedded setting is performed	NA		
29. Check GP Printer setting is performed	NA		
30. Check touch panel setting is performed	NA		
31. Check the instruments are started properly	NA		
32. Check setting sequence is performed	NA		
33. Check reagents are primed and check for any leakage in main unit	NA		
34. Check and confirm there is no problem with adjustment	NA		
35. Check JIG_Assy No. 407 is removed and original wiring is connected	NA		
36. Check all covers are installed	NA		
37. Check there is no dust or dirt on the instruments	NA		
38. Check levelling of the instruments	NA		
39. Check the program version and upgrade if needed	NA		
40. Check instrument ID Card is attached	NA		

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
CSR No.: WO-100251484
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Model	XN-550	From Date/Time	12/10/2022 12:30:03 PM
Serial No.	23306	To Date/Time	12/10/2022 01:11:00 PM
Total Cycle Count		Case No.	

Remarks

Items Consumed			
Product ID	VPN	Product Description	QTY UOM

Name:- Nazeeb Mulla	Acknowledged By : Dr Choukimath
Sign: A	Sign :  Sumukh Prayogalaya UGF, Shreenath Complex, Neelign Road, N.C.M. HUBLI-29 Ph: 2254477, 2254499
Date: 12/10/2022 01:14:50 PM	Date: 12/10/2022 01:14:50 PM

Customer Confidential

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Serial No.	23306	To Date/Time	17/10/2022 05:12:00 PM
Total Cycle Count		Case No.	

Remarks

Presently Accessories, printer is missing. Once all accessories available, will proceed for installation

Items Consumed

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

Name:- Nazeeb Mulla	Acknowledged By : Dr Choukimath
Sign: A	Sign : Sumukh Prayogalaya UGF, Shreenath Complex, Neelgin Road, N.C.M. HUBLI-29 Ph: 2254477, 2254499
Date: 17/10/2022 05:15:33 PM	Date: 17/10/2022 05:15:33 PM

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Systemx India Pvt. Ltd.
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CSR No.: WO-100256605
 Revision No.:

Customer Service Report

Customer Name	SUMUKH PRAYOGALAYA SRINIKA MOLECULAR DIAGNOSTICS		
Contact Person	Dr Choukimath		
Installation Date	17/10/2022	Login Date/Time	
Equipment ID	10155698	FSR Name	Nazeeb Mulla
Model	XN-550	From Date/Time	20/10/2022 01:13:20 PM
Serial No.	23306	To Date/Time	20/10/2022 09:44:00 PM
Total Cycle Count	80	Case No.	

Defect Analysis	
Issue Code	Cause Code
Issue	Cause
Installation XNL 550	

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	Checked		
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	Checked		
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	Checked		
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	WDF fluorescence Available	RET Fluorescence Available
18. Connect keyboard, mouse, handy bar code reader	Completed		
19. Connect touch panel monitor for XN-550	Checked		

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Serial No.	23306	To Date/Time	20/10/2022 09:44:00 PM
Total Cycle Count	80	Case No.	
Action Taken	Action Code	Value Before Adjustment	Value After Adjustment
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	Completed		
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	00-24	00-24
40. Check instrument ID Card is attached	Checked		

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Serial No.	23306	To Date/Time	20/10/2022 09:44:00 PM
Total Cycle Count	80	Case No.	

Remarks

Completed

Items Consumed

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

Name:- Nazeeb Mulla

Acknowledged By : Dr Choukimath

Sign:

Sign :

Sumukh Prayogalaya
 UGF, Shreenath Complex,
 Neelign Road, N.C.M. HUBLI-29
 Ph: 2254477, 2254499

Date: 20/10/2022 10:58:38 PM

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Serial No.	23306	To Date/Time	20/10/2022 09:44:00 PM
Total Cycle Count	80	Case No.	
Action Taken	Action Code	Value Before Adjustment	Value After Adjustment
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	Completed		
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	00-24	00-24
40. Check instrument ID Card is attached	Checked		



XN-L Series Commissioning Report

Customer : Samukha prayogalaya Lab -Hubli
Model: XN-550

Date: 20-10-22
Serial No: 23306

1 MECHANICAL ADJUSTMENTS

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

2 BACKGROUND VERIFICATION

Parameters	Results	Acceptable Range	Status
WBC	0	$\leq 0.10 \times 10^3/\mu\text{L}$	PASS
RBC	0	$\leq 0.02 \times 10^6/\mu\text{L}$	PASS
HGB	0	$\leq 0.1 \text{ g/dL}$	PASS
PLT-I	1	$\leq 10 \times 10^3/\mu\text{L}$	PASS
RBC-O*	0	$\leq 0.02 \times 10^6/\mu\text{L}$	PASS
PLT-O*	0	$\leq 10 \times 10^3/\mu\text{L}$	PASS

* 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	102.5	70 - 130	PASS
FSC (W) Rough	0.117	Less than 0.15	PASS

- 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	92.7	70 - 130	PASS
FSC (W) Fine	0.119	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	For Record Purpose	
SFL (W)	0.121	lower than 0.20	PASS
SSC (X)	63	50 - 100	PASS
SSC (W)	0.175	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	99	100 ± 1	PASS

5 HGB BLANK ADJUSTMENT

Parameters	Results	Acceptable Range	Status
HB Blank Gain	4965	5000 ± 200	PASS

6 ASPIRATION SENSOR BLANK ADJUSTMENT

Parameters	Results	Acceptable Range	Status
Aspiration Sensor	4968	5000 ± 200	PASS

7 ASPIRATION SENSOR SPAN ADJUSTMENT

7.1 *Material : XN-CHECK / XN CAL

Lot : 22661402

Expiry : 03-01-2023

* Cross whichever not applicable

Parameters	Results	Acceptable Range	Status
Aspiration Sensor Span	12988	13000 ± 500	PASS

8 SENSITIVITY ADJUSTMENTS

8.1 Material :XN-CAL

Lot :22762101

Expiry :06/11/2022

Parameters	Results	Assay Value	Acceptable Range	Status	Scattergram normal?
WDF-X	161.5	160.5	± 3 ch	PASS	Normal
WDF-Y	93.2	94.1	± 3 ch	PASS	
WDF-Z / WDF-FSC	114.5	114.6	± 2.5 ch	PASS	

Parameters	Results	Assay Value	Acceptable Range	Status	Scattergram normal?
RBC-X	21.3	21.1	± 1 ch	PASS	Normal
RBC-Y	160.1	159.6	± 3 ch	PASS	
RBC-Z	23.1	22.5	± 2 ch	PASS	

Parameters	Results	Assay Value	Acceptable Range	Status
MCV	82.3	82.8	± 1 ch	PASS
MPV	10	10.2	± 0.3 ch	PASS
HGB	12.4	12.48	± 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: 22762101
 Expiry: 06-11-2022

Parameters	1	2	3	4	5	Average	Assay Value	Old Cal	New Cal	% Diff	Status
RBC_PD_CAL	4.34	4.33	4.30	4.35	4.38	4.34	4.425	1014	1034	-1.96	PASS
PLT_PD_CAL	251	269	265	253	266	261	257.2	953	940	1.38	PASS
HGB_PD_CAL	12.1	12.1	12.0	12.1	12.1	12.1	12.48	976	1008	-3.31	PASS
WBC_PD_CAL	8.06	8.18	8.08	8.37	8.17	8.17	8.206	1000	1004	-0.42	PASS
WBC-D/WDF_PD	7.92	8.06	7.97	8.19	8.10	8.05	7.693	1026	981	4.41	PASS
RET_PD_CAL*						#DIV/0!		958	#DIV/0!	#DIV/0!	#DIV/0!
RBCO_PD_CAL*						#DIV/0!		1085	#DIV/0!	#DIV/0!	#DIV/0!
PLTO_PD_CAL*						#DIV/0!		1059	#DIV/0!	#DIV/0!	#DIV/0!

*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: 22762101
 Expi: 06-11-2022

Parameters	1	2	3	4	5	Average	Assay Value	Old Cal	New Cal	% Diff	Status
RBC_BF_CAL*	4.353	4.37	4.36	4.34	4.34	4.354	4.425	1031	1048	-1.63	PASS
WBC_BF_CAL*	7.66	7.77	7.72	7.78	7.72	7.727	7.693	975	971	0.43	PASS

*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.

Calibrator Calibration History

Instrument Nickname: XN-L
Material: XN CAL

Calibration Date: 2022/10/20 18:53:23
Lot No.: 22762101

Logon Name: sysmex

	WBC	RBC	HGB	HCT	PLT	RET%	RBC-O	PLT-O
Target	7.693	4.425	12.48	36.34	257.2	2.897	4.285	257.0
No. 2	7.72	4.44	12.3	36.9	265	3.02	4.27	274
No. 3	7.69	4.40	12.3	36.5	263	2.91	4.28	268
No. 4	7.71	4.41	12.3	36.6	251	2.85	4.29	264
No. 5	7.74	4.39	12.4	36.5	263	2.78	4.31	263
No. 6	7.77	4.46	12.3	36.7	261	3.12	4.27	273
No. 7	7.77	4.45	12.4	36.7	262	3.02	4.26	264
No. 8	7.68	4.43	12.4	36.5	260	2.91	4.25	258
No. 9	7.85	4.44	12.4	36.6	262	2.88	4.28	259
No. 10	7.73	4.45	12.4	36.7	254	2.83	4.28	261
No. 11	7.72	4.43	12.3	36.8	262	2.93	4.29	268
Range Value	0.17	0.07	0.1	0.4	14	0.34	0.06	16
Max Range	0.59	0.13	0.2	1.0	27	0.44	0.23	29
Mean Value	7.738	4.430	12.35	36.65	260.3	2.925	4.278	265.2
Delta Percent (%)	0.58	0.11	1.05	0.85	1.19	0.96	0.16	3.09
Acceptable Limit (%)	2.27	1.25	0.78	2.64	4.16	8.38	3.02	5.16
Service Limit (%)	14.00	4.00	5.00	5.00	10.00	25.00	10.00	10.00
Current Rate (%)	104.4	101.4	100.0	101.8	100.0	100.0	100.0	100.0
New Rate (%)	104.4	101.4	101.1	101.8	100.0	100.0	100.0	100.0



Date: 20th October 2022

CALIBRATION CERTIFICATE

This is to Certify that **Sysmex Hematology Analyser XN-550 bearing** Serial No:23306 is
Calibrated at

Sumukha Prayogalaya Srinika

Molecular Diagnostics

Shrinath Complex 2nd Floor,

Neeligin Road Despande Nagar,

Hubli-Karnataka 580029.

With Calibrator **XN CAL** baring **LOT 22762101 with Exp Date: 06/11/2022**

Please refer attached details.

Calibration Done on: 20th Oct 2022

Calibration Validity: 20th Oct 2022 to 19th Oct 2023

Next Calibration Date: ON or Before 19th Oct 2023

For Sysmex India Pvt. Ltd.,

A handwritten signature in black ink, appearing to be a stylized 'A' or similar character.

Authorized Signatory

SYSMEX INDIA PVT. LTD.

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