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GST Reg. No: 27AADCS1551J1ZC Co. Reg. No: ABC



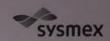
CSR No.: WO-100251484 Revision No.:

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=600 mm	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 Avilable
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 evalution regarding installation requirement and process flow			Dr Choukimath HOD
Site ready for installation	Completed		

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CSR No.: WO-100251322 Revision No.:

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
Check environmental requirements are satisfied (temp, humidity, atmosp. pres., etc)	NA		
2. Check there is enough space to install instrument	NA		
Check installation surface strength is enough	NA		
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		
<ol> <li>Check there is clearance of 500 mm or more on the left and right sides and at the rear</li> </ol>	NA		
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	NA		
Tr. Check Fluorocell WDF and Fluorocell RET are placed in Dye holder position correctly	NA		
8. Connect keyboard, mouse, handy bar code reader	NA		
9. Connect touch panel monitor for XN-550	NA		

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CSR No.: WO-100251322 Revision No.:

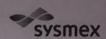
	Custome	r Service Report	
Customer Name	SUMUKH PRAYOGALAYA	SRINIKA MOLECULAR DIAGNOST	ics
Contact Person	Dr Choukimath		
Installation Date		Login Date/Time	
Equipment ID	10155698	FSR Name	Nazeeb Mulla
Model	XN-550	From Date/Time	17/10/2022 04:58:09 PM
Serial No.	23306	To Date/Time	17/10/2022 05:12:00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

Total Cycle Count Ca		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			
	NA			
18. Check levelling of the instruments	NA			
39. Check the program version and upgrade if needed	NA			
40. Check instrument ID Card is attached	100			

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Remarks



CSR No.: WO-100251484 Revision No.:

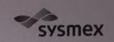
#### **Customer Service Report**

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.	

Items Consumed UOM QTY **Product Description** 

Product ID VPN Acknowledged By : Dr Choukimath Name:- Nazeeb Mulla Sign : Sign: UGF, Shreenath Complex, NeeligIn Road, N.C.M. HUBLI-29 Date: 12/10/2022 01:14:50 PM A Date: 12/10/2022 01:14:50 PM

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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.		

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

Items Consumed

Product ID VPN Product Description

Acknowledged By: Dr Choukimath

Sign:

Sign:

Sumukh Azayogalaya
UGF, Shreenath Complex,
Neeligin 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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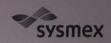
CSR No.: WO-100256605 Revision No.:

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 Code	Agine perore	Value After
Action Taken		Adjustment	Adjustment
Check environmental requirements are satisfied (temp, humidity, atmosp. pres., etc)	Checked		
2. Check there is enough space to install instrument	Checked		
Check installation surface strength is enough	Checked		
. Confirm power supply (capacity and quantity) and earth grounding	Checked		
5. Check all necessary parts (equipment, consumables and options) are available	Checked		
5. Check all accessories are supplied	Checked		
7. Confirm there are no damage on instrument	Checked		
<ol><li>Check there is clearance of 500 mm or more on the left and right sides and</li></ol>	Checked		
at the rear  Remove all transportation fixing tapes	Completed		
Remove dip and tie wraps for drive mechanism in right side cover	Completed		
Remove dup and to     Remove fixture for sampler mechanism (Fixture No. 1657) for XN-550	Completed		
Remove include to sample and waste tank     Connect waste tube between waste nipple and waste tank	Completed		
Connect waste tube between the state of	Checked		
position	Checked		
14. Secure waste tubes	Completed		
15. Connect all reagents correctly	State		
16. Check reagent containers are placed lower than instrument and in	Checked		
17 Check Fluorocell WDF and Fluorocell RE I are placed in bys house	Checked	WDF fluroscence Available	RET Fluorescence Available
position correctly  18. Connect keyboard, mouse, handy bar code reader	Completed	1	
19. Connect touch panel monitor for XN-550	Checked		

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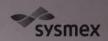


CSR No.: WO-100256605 Revision No.:

	Custon	ner Service Rep	ort			
Customer Name	SUMUKH PRAYOGALAYA SRINIKA MOLECULAR DIAGNOSTICS					
Contact Person	Dr Choukimath	Dr Choukimath				
Installation Date	17/10/2022		Login Date	Time		
Equipment ID	10155698	FSR Name		Nazeeb N	3000	
Model	IXN-550		20/10/2022 01:13:20 PM			
Serial No.	23306 To Date/Time		ne	20/10/202	22 09:44:00 PM	
Total Cycle Count	80		Case No.			THE RESERVE THE PARTY OF THE PA
Action Taken	4 (2. 17.3)	Act	ion Code	Value B		Value After Adjustment
20. Connect electric cord to the	ne main unit	Cor	mpleted			

Total Cycle Count	80	Case No.		
Action Taken		Action Code	Value Before Adjustment	Value After Adjustment
20. Connect electric cord to th	e main unit	Completed		
21. Check the necessary devi	ces are connected	Checked		
22. Connect and check tubes	and wiring cords	Checked		
23. Check IPU start up prope	rly	Checked		
24. Check system configuration	on been set correctly using System Configurator	Checked		
25. Check SysmexCustomSh		Checked		
26. Check system locale is pe		Checked		
27. Check keyboard setting is	- 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1	Checked		
28. Check McAfee Embedde		Checked		
29. Check GP Printer setting		Completed		
30. Check touch panel setting		Checked		
31. Check the instruments ar		Checked		
32. Check setting sequence		Checked		
33 Check reagents are prim	ed and check for any leakage in main unit	Checked		
24 Check and confirm there	is no problem with adjustment	Checked		
as Chack IIG Assy No. 407	is removed and original wiring is connected	Checked		
36. Check all covers are inst		Checked		
37. Check there is no dust o		Checked		
38. Check levelling of the ins		Checked		
39. Check the program vers	ion and upgrade if needed	Checked	00-24	00-24
40. Check instrument ID Car		Checked		
40. Check instrument in Car	U lo discourse			

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CSR No.: WO-100256605 Revision No.:

#### **Customer Service Report**

Customer Name	SUMUKH PRAYOGALAYA	SRINIKA MOLECULAR DIAGNOSTI	cs
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.	

Remarks
Completed

Items Consumed
Product ID VPN Product Description

Acknowledged By : Dr Choukimath

Sign:

Sign:

Sign:

Sign:

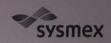
Sign:

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

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

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CSR No.: WO-100256605 Revision No.:

	Custon	ner Service Rep	ort			
Customer Name	SUMUKH PRAYOGALAYA SRINIKA MOLECULAR DIAGNOSTICS					
Contact Person	Dr Choukimath	Dr Choukimath				
Installation Date	17/10/2022		Login Date	Time		
Equipment ID	10155698	FSR Name		Nazeeb N	3000	
Model	IXN-550		20/10/2022 01:13:20 PM			
Serial No.	23306 To Date/Time		ne	20/10/202	22 09:44:00 PM	
Total Cycle Count	80		Case No.			THE RESERVE THE PARTY OF THE PA
Action Taken	4 (2. 17.3)	Act	ion Code	Value B		Value After Adjustment
20. Connect electric cord to the	ne main unit	Cor	mpleted			

Total Cycle Count	80	Case No.		
Action Taken		Action Code	Value Before Adjustment	Value After Adjustment
20. Connect electric cord to th	e main unit	Completed		
21. Check the necessary devi	ces are connected	Checked		
22. Connect and check tubes	and wiring cords	Checked		
23. Check IPU start up prope	rly	Checked		
24. Check system configuration	on been set correctly using System Configurator	Checked		
25. Check SysmexCustomSh		Checked		
26. Check system locale is pe		Checked		
27. Check keyboard setting is	- 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1	Checked		
28. Check McAfee Embedde		Checked		
29. Check GP Printer setting		Completed		
30. Check touch panel setting		Checked		
31. Check the instruments ar		Checked		
32. Check setting sequence		Checked		
33 Check reagents are prim	ed and check for any leakage in main unit	Checked		
24 Check and confirm there	is no problem with adjustment	Checked		
as Chack IIG Assy No. 407	is removed and original wiring is connected	Checked		
36. Check all covers are inst		Checked		
37. Check there is no dust o		Checked		
38. Check levelling of the ins		Checked		
39. Check the program vers	ion and upgrade if needed	Checked	00-24	00-24
40. Check instrument ID Car		Checked		
40. Check instrument in Car	U lo discourse			



# XN-L Series Commissioning Report

Customer	Samukha prayogalaya Lab -Hubli	Date:	20-10-22
Model:	XN-550	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	≤ 0.10 x 10*3/uL	PASS
RBC	0	≤ 0.02 x 10*6/uL	PASS
HGB	0	≤ 0.1 g/dL	PASS
PLT-I	1	≤ 10 x 10*3/µL	PASS
RBC-O*	0	≤ 0.02 x 10*6/uL	PASS
PLT-O*	0	≤ 10 x 10*3/µL	PASS

<sup>\*</sup> 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
A	spiration Sensor Span	12988	13000 ± 500	PASS

# 8 SENSITIVITY ADJUSTMENTS

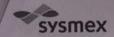
8.1 Material :XN-CAL Lot :22762101 Expiry :06/11/2022

Results	Assay Value	Acceptable Range	Status	Scattergram normal?
161.5	160.5	±3 ch	PASS	
	94.1	±3ch	PASS	Normal
114.5	114.6	± 2.5 ch	PASS	
	161.5 93.2	161.5 160.5 93.2 94.1	161.5 160.5 ± 3 ch 93.2 94.1 ± 3 ch	161.5 160.5 ±3 ch PASS 93.2 94.1 ±3 ch PASS

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

Descriptions	Results	Assay Value	Acceptable Range	Status
Parameters	82.3	82.8	± 1 ch	PASS
MCV	10	10.2	± 0.3 ch	PASS
MPV	12.4	12.48	± 0.2g/dl	PASS
HGB	16.0			

NOTE: Please attach sensitivity adjustment screenshots.



#### 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	4	2	2	Ta	15	Average	Assay Value	Old Cal	New Cal	% Diff	Status
RBC PD CAL	4.34	_	4.30	4.35	4.38	4.34	4.425	1014	1034	-1.96	PASS
PLT PD CAL	251	269	0.00	253	266	261	257.2	953	940	1.38	PASS
HGB PD CAL	12.1		12.0	12.1	12.1	12.1	12.48	976	1008	-3.31	PASS
WBC PD CAL	8.06	8.18		8.37	8.17	8.17	8.206	1000	1004	-0.42	PASS
WBC-D/WDF PD	7.92	8.06		8.19	8.10	8.05	7.693	1026	981	4.41	PASS
RET PD CAL*	7.02	0.00	7.07	0.10	0.10	#DIV/0!		958	#DIV/0!	#DIV/0!	#DIV/0!
RBCO PD CAL*		8 1				#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 Expir 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
WRC BE CAL*	7.66	-			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.



# 12 Certification

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

23306 has been

Report and Commissioning Performed By :

	1	
Signature (En	gineer 1)	
Name:	May	ers
Date:	1	1

Signature (I	Engineer 2)	
Name:		
Date:	-	

Report Reviewed and Accepted By :

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

Signature (Customer)

Name:

Date:

De chaubinate

# Calibrator Calibration History

Instrument Nickname: XN-L Material: XN CAL			Cal:	ibration D	Logon Name:sysmex				
	WBC	RBC	HGB	нст	PLT	RET%	RBC-0	PLT-0	
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		
No. 6	7.77	4.46	12.3	36.7	261	3.12		263	
No. 7	7.77	4.45	12.4	36.7	262		4.27	273	7
No. 8	7.68	4.43	12.4	36.5		3.02	4.26	264	
No. 9	7.85	4.44	12.4		260	2.91	4.25	258	
No. 10	7.73	4.45		36.6	262	2.88	4.28	259	
No. 11	7.72	4.43	12.4	36.7	254	2.83	4.28	261	
	1.12	4.43	12.3	36.8	262	2.93	4.29	268	
Range Value	0.17	0.07	0.1	0.4	14	0.24	0.05		
Max Range	0.59	0.13	0.2			0.34	0.06	16	
Mean Value	7.738	4.430		1.0	27	0.44	0.23	29	
Delta Percent (%)	0.58		12.35	36.65	260.3	2.925	4.278	265.2	
Acceptable Limit (%)	2.27	0.11	1.05	0.85	1.19	0.96	0.16	3.09	
Service Limit (%)		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: 20<sup>th</sup> 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: 20<sup>th</sup> Oct 2022

Calibration Validity: 20<sup>th</sup> Oct 2022 to 19<sup>th</sup> Oct 2023

Next Calibration Date: ON or Before 19<sup>th</sup> Oct 2023

For Sysmex India Pvt. Ltd.,

**Authorized Signatory**