



Date: 24-11-2023  
Effective Date: 24-11-2023

## Certificate of Calibration

**Customer Name:** Vinamra Swaraj Hospital

**Model :** Automated Hematology Analyzer Sysmex XN-350

**Serial No. :** 11359

**Calibration Done Date:** 24-11-2023

**Next Calibration Due Date On or Before:** 23-11-2024

**Lab In-charge: .** Dr.S.D.Teckchandai

*This is to certify that the above-mentioned product has been verified of calibration according to the standard procedures provided by Sysmex Corporation, Japan.*

*The reference instruments used for value-assignment are managed by the traceability system in Sysmex Corporation and these are traceable to the International Standards, such as ICSH.*

*Suraj*

Calibration at site performed by  
Suraj Chandak  
ASM  
Transasia Bio-Medicals Ltd  
Mumbai

Encl:

1. Certificate of Inspection
2. Assay Sheet of Calibrator XN
3. Printouts
4. Traceability & Uncertainty document



UNMATCHED SERVICE  
SINCE 1979...

## 5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC-N	0	$0.1 \times 10^3 / \mu\text{L}$ or less
WBC-D	0	$0.1 \times 10^3 / \mu\text{L}$ or less
RBC	0	$0.02 \times 10^6 / \mu\text{L}$ or less
HGB	0	0.1g/dl or less
PLT	0	$10 \times 10^6 / \mu\text{L}$ or less

*SyngJ*

Technical Service Department  
Transasia Bio-Medicals Ltd

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

Ward: Adapter:

Pos.: 2023/11/24 12:04:15 WB  
 Doctor:  
 Birth: Sex: XN-L  
 Nickname: XN-L

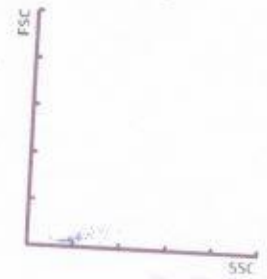
XN-L xn1

WBC	0.00	[10 <sup>3</sup> /uL]		
RBC	0.00	[10 <sup>6</sup> /uL]		
HGB	0.0	[g/dL]		
HCT	0.0	[%]		
MCV	----	[fL]		
MCH	----	[pg]		
MCHC	----	[g/dL]		
PLT	0	[10 <sup>3</sup> /uL]		
RDW-SD	----	[fL]		
RDW-CV	----	[%]		
PDW	----	[fL]		
MPV	----	[fL]		
P-LCR	----	[%]		
PCT	----	[%]		
NEUT	----	[10 <sup>3</sup> /uL]	----	[%]
LYMPH	----	[10 <sup>3</sup> /uL]	----	[%]
MONO	----	[10 <sup>3</sup> /uL]	----	[%]
EO	----	[10 <sup>3</sup> /uL]	----	[%]
BASO	----	[10 <sup>3</sup> /uL]	----	[%]
IG	----	[10 <sup>3</sup> /uL]	----	[%]
HFLC	----	[10 <sup>3</sup> /uL]	----	[%]
NRBC	----	[10 <sup>3</sup> /uL]	----	[%]
WBC-C	0.00	[10 <sup>3</sup> /uL]	----	[/100WBC]
WBC-D	0.00	[10 <sup>3</sup> /uL]		
MicroR	----	[%]		
MacroR	----	[%]		

WDF



WDF-CBC



RBC



PLT



BC IP Message

RBC IP Message

PLT IP Message

Precision Check Log

XN-L xnl

Instrument Nickname: XN-L

Execution Date: 2023/11/24 12:18:27

Logon Name: xnl

	WBC	RBC	HGB	HCT	PLT
No. 2	7.30	4.67	14.1	39.8	333
No. 3	7.30	4.68	14.0	39.9	324
No. 4	7.17	4.68	14.1	39.7	333
No. 5	7.28	4.67	14.1	39.7	336
No. 6	7.13	4.67	14.1	39.7	343
No. 7	7.21	4.63	14.1	39.4	330
No. 8	7.24	4.68	14.2	39.7	331
No. 9	7.26	4.69	14.1	39.7	333
No. 10	7.25	4.68	14.1	39.6	328
No. 11	7.24	4.68	14.2	39.5	341
Mean Value	7.238	4.673	14.11	39.67	333.2
SD	0.055	0.016	0.06	0.14	5.7
CV (%)	0.8	0.3	0.4	0.4	1.7
Limit (%)	3.0	1.5	1.0	1.5	4.0

Calibrator Calibration History

XN-L xnl

Instrument Nickname: XN-L  
Material: XN CAL

Calibration Date: 2023/11/24 12:37:55  
Lot No.: 33032101

Logon Name: xnl

	WBC	RBC	HGB	HCT	PLT
Target	6.930	4.397	12.18	36.06	245.0
No. 2	6.87	4.44	12.3	36.6	236
No. 3	7.03	4.43	12.3	36.5	243
No. 4	7.08	4.40	12.3	36.3	242
No. 5	7.11	4.41	12.3	36.3	237
No. 6	6.97	4.43	12.3	36.5	239
No. 7	6.97	4.42	12.3	36.4	227
No. 8	7.28	4.45	12.4	36.7	237
No. 9	7.12	4.40	12.3	36.3	238
No. 10	6.96	4.42	12.4	36.4	239
No. 11	7.22	4.48	12.3	36.9	234
Range Value	0.41	0.08	0.1	0.6	16
Max Range	0.53	0.13	0.2	1.0	26
Mean Value	7.061	4.428	12.32	36.49	237.2
Delta Percent (%)	1.86	0.70	1.14	1.18	3.29
Acceptable Limit (%)	2.27	1.25	0.78	2.64	4.16
Service Limit (%)	14.00	4.00	5.00	5.00	10.00
Current Rate (%)	101.3	99.4	101.6	100.6	99.8
New Rate (%)	101.3	99.4	100.4	100.6	99.8



# Traceability and Uncertainty

## XN CAL/XN CAL PF Sysmex Calibrator System

### XN Series Automated Hematology Analyzer

LOT NO: 3303 2101/3303 2102  
 EXP. DATE: 03-Dec-2023

Parameter	Reference Method	Reference Material	Assigned Value	Uncertainty*	Unit
WBC-N	*1	-	6.740	0.21	10 <sup>9</sup> /L
WBC-D	*1	-	6.930	0.22	10 <sup>9</sup> /L
WBC-P	*1	-	7.019	0.26	10 <sup>9</sup> /L
RBC	*1	-	4.397	0.071	10 <sup>12</sup> /L
RBC-O	*1	-	4.336	0.12	10 <sup>12</sup> /L
PLT	*2	-	245.0	12	10 <sup>9</sup> /L
PLT-O	*2	-	238.0	15	10 <sup>9</sup> /L
PLT-F	*2	-	222.7	11	10 <sup>9</sup> /L
HGB	*3, *4	-	12.18	0.24	g / dL
HCT	*5	-	36.06	0.83	%

\*: 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

\*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"



Dated – 01-Jan-24

TO,  
Dr. S.D.Teckchandani  
Navi Mumbai

Dear Sir

At the outset we thank you for your continued loyalty and trust in our Organization.  
We are pleased to hear that the XNL 350 equipment has performed well since its installation on December 19, 2016 under Reagent rental agreement with Transasia Bio-Medicals Ltd.

The XNL350 instrument bearing no.11359 was installed at address given below.

Pathology Laboratory, Vinamra Swaraj Hospital  
Plot no. 108-109, Sector 11, Vashi,  
Navi Mumbai, Thane,  
Maharashtra 400703

Please be advised that we will continue to supply the necessary reagents and maintain the instrument until further notice

We value the relationship we have with you and appreciate the opportunity to serve you.

Thank you for choosing Transasia.

Warm regards,



Yalguresh Kulkarni  
[Zonal Manager/Mumbai Division]  
Transasia Bio-Medicals Ltd.