

DATE –



Effective Date – 05.10.2020

UNMATCHED SERVICE
SINCE 1979...

Certificate of Calibration

Customer Name VINAMRA SWARAJ HOSPITAL

Model : Automated Hematology Analyser Sysmex XNL 350

Serial Number : 11359

Calibration done Date 05.10.2020

Next Calibration Due Date on or Before : 04.10.2021

Lab In-Charge: DR.S.D.TECKCHANDANI

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.

A handwritten signature in black ink, appearing to read 'Abhishek Kalekar', is positioned above the printed name.

Calibration at site performed by
Abhishek Kalekar
Service Engineer
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

Date: 05.10.2020
Effective Date: 05.10.2020

Certificate of Inspection

1. Model: Automated Hematology Analyzer Sysmex XNL-350
2. Serial No.: 11359
3. Calibration Date: 05.10.2020
4. Material used: XN-CAL (Lot No. 0251 2101, Expiry date:11-OCT-2020)

By comparing your data to the results of the standard counters in Sysmex Corporation, the calibration for XN Analyzer parameters using the measurement standard material (XN-CAL) was completed. The calibration result of 10 runs is summarized in the following table. Please refer to the attached sheets for the details.

Technical Service Department
Transasia Bio-Medicals Ltd



UNMATCHED SERVICE
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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	0.1 g/dl or less
PLT	0	$10 \times 10^6 / \mu\text{L}$ or less



Technical Service Department
Transasia Bio-Medicals Ltd

Sample No.: BACKGROUNDCHECK

Patient ID: [Redacted] Adapter: [Redacted] Pos: [Redacted]
 Name: [Redacted] Ward: [Redacted] Birth: [Redacted]

2020/10/05 13:10:43 WB

Phone: +91 22 4030 9000 Fax: +91 22 2857 3030 Email: transasia@transasia.co.in CIN: U33110MH1985PLC036190

Doctor: [Redacted]

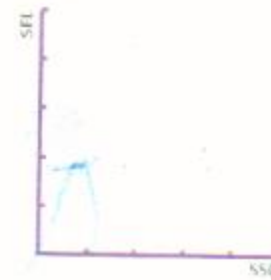


Nickname: [Redacted]

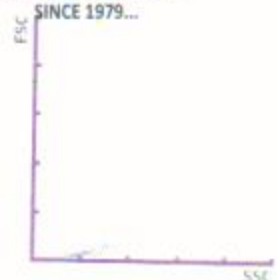
Sample Comment:

WBC	0.00	[10 ³ /uL]		
RBC	0.00	[10 ⁶ /uL]		
HGB	0.0	[g/dL]		
HCT	0.0	[%]		
MCV	----	[fL]		
MCH	----	[pg]		
MCHC	----	[g/dL]		
PLT	0	[10 ³ /uL]		
RDW-SD	----	[fL]		
RDW-CV	----	[%]		
PDW	----	[+L]		
MPV	----	[fL]		
P-LCR	----	[%]		
PCT	----	[%]		
NEUT	----	[10 ³ /uL]	----	[%]
LYMPH	----	[10 ³ /uL]	----	[%]
MONO	----	[10 ³ /uL]	----	[%]
EO	----	[10 ³ /uL]	----	[%]
BASO	----	[10 ³ /uL]	----	[%]
IG	----	[10 ³ /uL]	----	[%]

WDF



WDF-GBC



RBC



PLT



WBC IP Message

RBC IP Message

PLT IP Message

[Handwritten Signature]

Transasia Bio-Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (East), Mumbai - 400 072
 Tel: +91 22 4030 9000 Fax: +91 22 2857 3030 Email : transasia@transasia.com CIN : U3310MH1985PLC036198



UNMATCHED SERVICE
SINCE 1979...

xnl

	WBC	RBC	HGB	HCT	PLT
No. 2	8.71	4.99	14.0	43.1	376
No. 3	8.74	4.98	14.0	42.9	377
No. 4	8.45	4.95	14.1	42.8	383
No. 5	8.45	5.01	14.1	43.1	378
No. 6	8.74	5.01	14.1	43.0	379
No. 7	8.54	4.98	14.0	42.6	377
No. 8	8.76	5.03	14.2	42.9	394
No. 9	8.37	4.95	14.1	42.2	377
No. 10	8.67	4.99	14.1	42.5	386
No. 11	8.50	5.02	14.2	42.7	385
Mean Value	8.593	4.991	14.09	42.78	381.2
SD	0.146	0.027	0.07	0.29	5.8
CV (%)	1.7	0.5	0.5	0.7	1.5
Limit (%)	3.0	1.5	1.0	1.5	4.0

Transasia

Calibrator Calibration History

Transasia Biomedicals Ltd, Transasia House, 8 Chandivali Studio Road, Andheri (East), Mumbai - 400 072
 Tel: +91 22 40319000 Fax: +91 22 2857 3030 Email: transasia@transasia.co.in CIN: U33110MH1985PLC036198

Lot No.: 02512101



Target	WBC	RBC	HGB	HCT	PLT
No. 2	7.048	4.228	12.40	35.05	251.1
No. 3	6.82	4.27	12.5	36.2	256
No. 4	6.77	4.32	12.4	36.6	257
No. 5	7.15	4.32	12.4	36.5	251
No. 6	7.02	4.31	12.5	36.5	257
No. 7	6.83	4.28	12.4	36.2	262
No. 8	7.03	4.30	12.5	36.2	260
No. 9	6.80	4.32	12.4	36.4	255
No. 10	6.84	4.30	12.4	36.2	264
No. 11	7.01	4.29	12.5	36.2	256
	6.94	4.31	12.6	36.4	261
Range Value	0.38	0.05	0.2	0.4	13
Max Range	0.54	0.12	0.2	1.0	27
Mean Value	6.921	4.302	12.46	36.34	257.9
Delta Percent (%)	1.83	1.72	0.48	3.55	2.64
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	99.0	101.6	101.1	99.8
New Rate (%)	101.3	97.3	101.6	99.2	99.8

[Handwritten Signature]

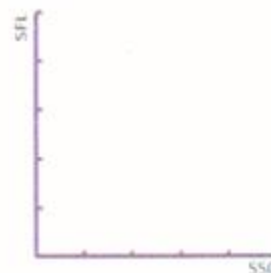
Sample No.: BACKGROUNDCHECK
 Patient ID:
 Name:
 Sample Comment:

Adapter:
 Ward:

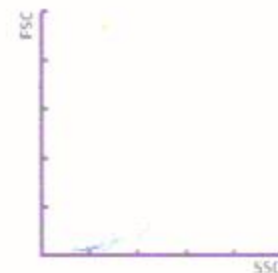
Pos.: 2020/10/05 13:10:43 WB
 Doctor:
 Birth: Sex:
 Nickname: XN-L

WBC	0.00	[10 ³ /uL]		
RBC	0.00	[10 ⁶ /uL]		
HGB	0.0	[g/dL]		
HCT	0.0	[%]		
MCV	----	[fL]		
MCH	----	[pg]		
MCHC	----	[g/dL]		
PLT	0	[10 ³ /uL]		
RDW-SD	----	[fL]		
RDW-CV	----	[%]		
PDW	----	[fL]		
MPV	----	[fL]		
P-LCR	----	[%]		
PCT	----	[%]		
NEUT	----	[10 ³ /uL]	----	[%]
LYMPH	----	[10 ³ /uL]	----	[%]
MONO	----	[10 ³ /uL]	----	[%]
EO	----	[10 ³ /uL]	----	[%]
BASO	----	[10 ³ /uL]	----	[%]
IG	----	[10 ³ /uL]	----	[%]

WDF



WDF-CBC



RBC



PLT



WBC IP Message

RBC IP Message

PLT IP Message

Precision Check Log

Instrument Nickname: XN-L

Execution Date: 2020/10/05 13:25:41

Logon Name: xnl

	WBC	RBC	HGB	HCT	PLT
No. 2	8.71	4.99	14.0	43.1	376
No. 3	8.74	4.98	14.0	42.9	377
No. 4	8.45	4.95	14.1	42.8	383
No. 5	8.45	5.01	14.1	43.1	378
No. 6	8.74	5.01	14.1	43.0	379
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No. 8	8.76	5.03	14.2	42.9	394
No. 9	8.37	4.95	14.1	42.2	377
No. 10	8.67	4.99	14.1	42.5	386
No. 11	8.50	5.02	14.2	42.7	385
Mean Value	8.593	4.991	14.09	42.78	381.2
SD	0.146	0.027	0.07	0.29	5.8
CV (%)	1.7	0.5	0.5	0.7	1.5
Limit (%)	3.0	1.5	1.0	1.5	4.0

Calibrator Calibration History

Instrument Nickname: XN-L
Material: XN CAL

Calibration Date: 2020/10/05 13:46:35
Lot No.: 02512101

Logon Name: xnl

	WBC	RBC	HGB	HCT	PLT
Target	7.048	4.228	12.40	35.05	251.1
No. 2	6.82	4.27	12.5	36.2	256
No. 3	6.77	4.32	12.4	36.6	257
No. 4	7.15	4.32	12.4	36.5	251
No. 5	7.02	4.31	12.5	36.5	257
No. 6	6.83	4.28	12.4	36.2	262
No. 7	7.03	4.30	12.5	36.2	260
No. 8	6.80	4.32	12.4	36.4	255
No. 9	6.84	4.30	12.4	36.2	264
No. 10	7.01	4.29	12.5	36.2	256
No. 11	6.94	4.31	12.6	36.4	261
Range Value	0.38	0.05	0.2	0.4	13
Max Range	0.54	0.12	0.2	1.0	27
Mean Value	6.921	4.302	12.46	36.34	257.9
Delta Percent (%)	1.83	1.72	0.48	3.55	2.64
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	99.0	101.6	101.1	99.8
New Rate (%)	101.3	97.3	101.6	99.2	99.8

Traceability and Uncertainty

XN CAL Sysmex Calibrator System

XN-L Series Automated Hematology Analyzer

LOT NO: 0251 2101
 EXP. DATE: 11-Oct-2020

Parameter	Reference Method	Reference Material	Assigned Value	Uncertainty*	Unit
WBC-C	*1	-	7.487	0.19	10 ⁹ /L
WBC-D	*1	-	7.048	0.18	10 ⁹ /L
RBC	*1	-	4.228	0.064	10 ¹² /L
RBC-O	*1	-	4.079	0.086	10 ¹² /L
PLT	*2	-	251.1	9.8	10 ⁹ /L
PLT-O	*2	-	265.3	12	10 ⁹ /L
HGB	*3, *4	-	12.40	0.19	g / dL
HCT	*5	-	35.05	0.60	%

* : 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 haemoglobin cyanide reference preparation (4th ed.)"

*5: CLSI H7-A3

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

< XN CAL™ ASSAY SHEET >

For XN-L series

Lot No. 02512101

Exp. Date 2020-10-11

	RBC 10 ⁶ /μL	HGB		HCT %	PLT 10 ³ /μL
		g/dL	mmol/L		
TARGET	4.228	12.40	7.70	35.05	251.1

	WBC-C	WBC-D	RET%	RBC-O	PLT-O
	10 ³ /μL	10 ³ /μL	%	10 ⁶ /μL	10 ³ /μL
TARGET	7.487	7.048	2.469	4.079	265.3

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.

Date : 21/04/2021

To whomsoever it may concern

The 6 Part Differential Hematology Analyser XNL350 Sr. No. 11359 placed at
Vinamra Swaraj Hospital, Sector 11, Vashi on Reagent Rental is
under CMC Contract of Transasia Biomedicals Ltd.

Contract End Date : 18/12/2021

Thanks & Regards,

Rahul Turambekar,
Sales Executive
07700907402.

