



Date: 22.04.2024
Meters No: 22.04.2024

Certificate of Calibration

Customer Name: Alva's Healthcare Centre

Model: Automated Hematology Analyzer Sysmex XE-550/350/1050/2050/3050

Serial No.: 11547

Calibration Done Date: 22.4.23

Next Calibration Due Date On or Before: 21-04-2024

Lab In-charge: Dr. Shankar Shetty

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.



Calibration at site performed by
Sanjay Unnikrishnan PK
Service Engineer
Transasia Bio-Medicals Ltd
Mumbai

Encl:

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

Shankar Shetty
Manager





Date: 22-04-2023
Effective Date: 22-04-2023

Certificate of Inspection

1. Model: Automated Hematology Analyzer Sysmex XN-350/550/1000/2000/3000
2. Serial No.: 11547
3. Calibration Date: 22-04-2023
4. Material used: XN-CAL (Lot No. 30792101, Expiry date: 23-Apr-2023)

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.



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Transasia Bio-Medicals Ltd

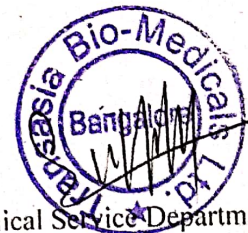


*Shri to
verified*



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	4	$10 \times 10^6/\mu\text{L}$ or less



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Traceability and Uncertainty

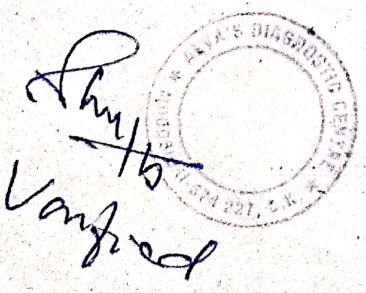
XN CAL/XN CAL PF Sysmex Calibrator System

XN Series Automated Hematology Analyzer

LOT NO: 3079 2101/3079 2102
 EXP. DATE: 23-Apr-2023

Parameter	Reference Method	Reference Material	Assigned Value	Uncertainty*	Unit
WBC-N	*1	-	7.010	0.22	10 ⁹ /L
WBC-D	*1	-	7.133	0.23	10 ⁹ /L
WBC-P	*1	-	7.283	0.27	10 ⁹ /L
RBC	*1	-	4.387	0.071	10 ¹² /L
RBC-O	*1	-	4.325	0.12	10 ¹² /L
PLT	*2	-	251.4	12	10 ⁹ /L
PLT-O	*2	-	242.4	15	10 ⁹ /L
PLT-F	*2	-	233.9	11	10 ⁹ /L
HGB	*3, *4	-	12.07	0.23	g / dL
HCT	*5	-	35.75	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 (CSH 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. 30792101

Exp. Date 2023-04-23

	RBC 10 ⁶ /μL	HGB		HCT %	PLT 10 ³ /μL
		g/dL	mmol/L		
TARGET	4.381	12.13	7.53	35.53	253.4

	WBC-C 10 ³ /μL	WBC-D 10 ³ /μL	RET% %	RBC-O 10 ⁶ /μL	PLT-O 10 ³ /μL
TARGET	7.762	7.297	2.946	4.286	256.7

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.

*Shylo
Varghese*



Precision Check Log

Instrument Nickname: XN-L

Execution Date: 22/04/2023 02:40:24

Logon Name: sysmex

	WBC	RBC	HGB	HCT	PLT
No. 2	6.26	4.22	13.2	37.8	211
No. 3	6.34	4.29	13.3	38.3	204
No. 4	6.23	4.29	13.2	38.3	204
No. 5	6.35	4.30	13.3	38.4	209
No. 6	6.16	4.26	13.3	37.9	202
No. 7	6.32	4.27	13.2	37.8	199
No. 8	6.18	4.28	13.3	38.0	207
No. 9	6.27	4.28	13.2	37.9	205
No. 10	6.32	4.32	13.3	38.2	210
No. 11	6.19	4.34	13.4	38.4	201
Mean Value	6.262	4.285	13.27	38.10	205.2
SD	0.070	0.033	0.07	0.24	4.0
CV (%)	1.1	0.8	0.5	0.6	1.9
Limit (%)	3.0	1.5	1.0	1.5	4.0

Verified.
[Signature]



Calibrator Calibration History

Instrument Nickname: XN-L
Material: XN CAL

Calibration Date: 22/04/2023 03:27:28
Lot No.: 30792101

Logon Name: sysmex

	WBC	RBC	HGB	HCT	PLT
Target	7.297	4.381	12.13	35.53	253.4
No. 2	7.20	4.42	12.1	35.6	265
No. 3	7.24	4.39	12.1	35.4	261
No. 4	7.29	4.40	12.1	35.6	258
No. 5	7.01	4.35	12.1	35.1	267
No. 6	7.38	4.40	12.2	35.5	261
No. 7	7.42	4.37	12.3	35.3	268
No. 8	7.26	4.38	12.2	35.4	264
No. 9	7.38	4.37	12.2	35.3	268
No. 10	7.22	4.41	12.1	35.6	271
No. 11	7.42	4.42	12.2	35.6	272
Range Value	0.41	0.07	0.2	0.5	14
Max Range	0.56	0.13	0.2	1.0	27
Mean Value	7.282	4.391	12.16	35.44	265.5
Delta Percent (%)	0.21	0.23	0.25	0.25	4.56
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 (%)	102.9	98.6	99.6	101.7	110.0
New Rate (%)	103.1	98.4	99.4	102.2	105.0

*Amey To
Vandret*

