

Date: 22-04-2021

Effective Date: 22-04-2021

Certificate of Calibration

Customer Name: Christian Institute of Health Sciences and Research

Model : Automated Hematology Analyzer Sysmex XN-550

Serial No. : 14707

Calibration Done Date: 22-04-2021

Next Calibration Due Date On or Before: 21-04-2022

Lab In-charge: . Mr.K.g.Gaikhonlungpou

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
Dipankar Saikia
Service Engineer
Transasia Bio-Medicals Ltd
Jorhat

*Dipankar Saikia
29/4/2021*

Encl:

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


Date: 22-04-2021

Effective Date: 22-04-2021

Certificate of Inspection

1. Model: Automated Hematology Analyzer Sysmex XN-550
2. Serial No.: 14707
3. Calibration Date: 22-04-2021
4. Material used: XN-CAL (Lot No. 10812101, Expiry date: 25-April-2021)

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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5. BACKGROUND CHECK

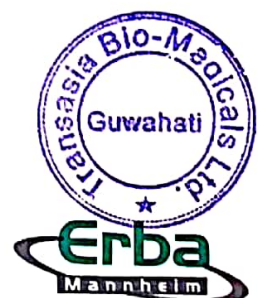
PARAMETER	RESULT	Range
WBC-N	0.0	$0.1 \times 10^3 / \mu\text{L}$ or less
WBC-D	0.0	$0.1 \times 10^3 / \mu\text{L}$ or less
RBC	0.0	$0.02 \times 10^6 / \mu\text{L}$ or less
HGB	0.0	0.1g/dl or less
PLT	0	$10 \times 10^6 / \mu\text{L}$ or less

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Instrument Nickname Instrument Execution Date Logon Name
XN-L XN-550^14 22-04-21 12:53 CIHSR

	WBC	RBC	HGB	HCT	PLT	RET%	RBC-O	PLT-O
PRE-CHK-02	9.75	4.52	14.4	43.9	267	1.44	4.46	236
PRE-CHK-03	9.73	4.51	14.5	43.7	253	1.41	4.47	238
PRE-CHK-04	9.77	4.57	14.5	44.3	259	1.5	4.41	235
PRE-CHK-05	9.65	4.49	14.5	43.6	244	1.54	4.4	227
PRE-CHK-06	9.75	4.52	14.5	43.9	255	1.55	4.48	236
PRE-CHK-07	9.67	4.53	14.4	43.9	252	1.39	4.43	231
PRE-CHK-08	9.68	4.56	14.5	44.2	263	1.48	4.39	237
PRE-CHK-09	9.51	4.53	14.4	43.9	264	1.46	4.39	238
PRE-CHK-10	9.75	4.5	14.3	43.6	268	1.55	4.41	239
PRE-CHK-11	9.72	4.45	14.2	43.2	266	1.42	4.35	243
Mean Value	96.98	45.18	144.2	438.2	2591	14.74	44.19	2360
SD	0.077	0.034	0.1	0.32	7.9	0.06	0.041	4.4
CV (%)	0.8	0.8	0.7	0.7	3	4.1	0.9	1.9
Limit (%)	3	1.5	1	1.5	4	15	2.5	6

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29/4/21
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Transasia Bio-Medicals Ltd



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Instrument Nickname Instrument ID Calibration Date Logon Nam Material Lot No.
 XN-L XN-550^14707 22-04-21 15:46 CIHSR XN CAL 10812101

	WBC	RBC	HGB	HCT	PLT	RET%	RBC-O	PLT-O
Target	7.624	4.407	12.19	35.3	252.3	2.451	4.259	260.8
No.2	7.29	4.44	12.3	35.5	236	2.39	4.18	253
No.3	7.51	4.42	12.3	35.3	247	2.37	4.18	257
No.4	7.45	4.42	12.2	35.3	249	2.34	4.19	261
No.5	7.55	4.41	12.1	35.2	252	2.28	4.17	270
No.6	7.49	4.43	12.2	35.3	237	2.26	4.17	259
No.7	7.3	4.46	12.2	35.6	244	2.21	4.17	263
No.8	7.6	4.45	12.2	35.6	251	2.33	4.16	257
No.9	7.4	4.43	12.2	35.3	263	2.24	4.14	253
No.10	7.35	4.45	12.2	35.4	250	2.34	4.17	258
No.11	7.64	4.44	12.2	35.3	250	2.34	4.17	253
Range Value	0.35	0.05	0.2	0.4	27	0.18	0.05	17
Max Range	0.59	0.13	0.2	1	27	0.37	0.23	29
Mean Value	7.458	4.435	12.21	35.38	247.9	2.31	4.17	258.4
Delta Percent (%)	2.23	0.63	0.16	0.23	1.77	6.1	2.13	0.93
Acceptable Limit (%)	2.27	1.25	0.78	2.64	4.16	8.38	3.02	5.16
Service Limit (%)	14	4	5	5	10	25	10	10
Current Rate (%)	105.1	101.3	101.4	102	117.5	100	100	100
New Rate (%)	107.4	100.7	101.2	102.4	119.6	100	102.1	100.9

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