CALIBRATION CERTIFICATE

NAME OF THE CUSTOMER	MAKE
Global diagnostics, OPP: THE BIKE AFFAIR, HT Road, Hyderabad, Telangana, 500084	Sysmex Corporation Sysmex India Pvt. Ltd. 1002, Damji Shamji Business Galleria, 10th Floor, LBS Marg Kanjurmarg (West), Mumbai 400 078, India Tel: +91 (22) 6112 6666 Fax: +91 (22) 2577 6790

PRODUCT NAME	SERIAL NO
XN-330 HEAMATOLOGY ANALYZER	13575

This is to certify that the XN-330 Hematology Analyzer has been calibrated with XN CAL Calibrator (Lot No. 33032101, Exp. Date 03-12-2023)

S.NO	TEST PARAMETERS	MEASURED/CALIBRATED	REMARKS
1.	Start up	WBC/RBC/HGB/PLT	PASS
2.	Reproducibility	WBC/RBC/HGB/MCV/HCT/PLT	PASS
3.	QC	WBC/RBC/HGB/HCT/PLT	PASS
4.	Calibration (Lot No. 33032101)	WBC/RBC/HGB/HCT/PLT	PASS

Date of Calibration: 18/11/2023	Due date for Calibration: 17/11/2024

NAME OF THE ENGINEER **SIGNATURE**

M. Prathik M Prathik

< XN CAL ™ ASSAY SHEET >

For XN-L series

Lot No. **33032101** Exp. Date **2023-12-03**

	RBC	HGB		HCT	PLT
	$10^6/\mu L$	g/dL	mmol/L	%	$10^3/\mu L$
TARGET	4.402	12.30	7.63	35.79	247.9

	WBC-C	WBC-D	RET%	RBC-O	PLT-O
	$10^3/\mu L$	$10^3/\mu L$	%	$10^6/\mu L$	$10^3/\mu L$
TARGET	7.593	7.100	2.788	4.261	246.9

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.

Calibrator Calibration History

Instrument Nickname: XN-L
Material: XN CAL

Calibration Date: 2023/07/28 20:08:40
Lot No.: 31912101

Logon Name: sysmex

	WBC	RBC	HGB	HCT	PLT
Target	7.001	4.408	12.01	35.00	253.6
No. 2	6.94	4.41	12.0	35.0	268
No. 3	7.19	4.42	12.1	35.1	259
No. 4	7.09	4.42	12.1	35.1	253
No. 5	7.05	4.42	12.1	35.1	252
No. 6	7.06	4.39	12.0	34.9	258
No. 7	7.20	4.45	12.2	35.3	258
No. 8	7.14	4.40	12.0	35.0	249
No. 9	7.04	4.42	12.1	35.1	257
No. 10	7.11	4.46	12.1	35.4	254
No. 11	7.07	4.41	12.2	35.0	250
Range Value	0.26	0.07	0.2	0.5	19
Max Range	0.54	0.13	0.2	1.0	27
Mean Value	7.089	4.420	12.09	35.10	255.8
Delta Percent (%)	1.24	0.27	0.66	0.28	0.86
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 (%)	106.7	102.1	97.6	100.7	120.0
New Rate (%)	105.4	101.8	97.0	100.7	119.0

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Traceability and Uncertainty

XN CAL Sysmex Calibrator System

XN-L Series Automated Hematology Analyzer

LOT NO: **3191 2101**
EXP. DATE: **13-Aug-2023**

Parameter	Reference Method	Reference Material	Assigned Value	Uncertainty*	Unit
WBC-C	*1	-	7.491	0.18	10^9/L
WBC-D	*1	-	7.001	0.18	10^9/L
RBC	*1	-	4.408	0.049	10^{12}/L
RBC-O	*1	-	4.294	0.070	10^{12}/L
PLT	*2	-	253.6	11	10^9/L
PLT-O	*2	-	250.7	12	10^9/L
HGB	*3, *4	-	12.01	0.19	g / dL
HCT	*5	-	35.00	0.63	%

* : 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 standard"

*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 haemiglobincyanide reference preparation (4th ed.)"

*5: CLSI H7-A3
"Procedure for Determining Packed Cell Volume by the Microhematcrit Method – 3rd edition; Approved Standard"