

Date: 19/06/2021
Effective Date: 19/06/2021

Certificate of Calibration

Customer Name: Narayan Pathology

Model : Automated Hematology Analyzer Sysmex XP-100

Serial No. : A5525

Calibration Done Date: 19.6.21

Next Calibration Due Date On or Before: 18/06/2022

Lab In-charge: .

This is to certify that the above-mentioned product has been verified of calibration for CBC 5 parameters (WBC, RBC, HGB, HCT and PLT) 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

Engineer Name SAURABH JIRIBATHI

Designation ASJM

Transasia Bio-Medicals Ltd

Location KANPUR

TRANSASIA BIO-MEDICALS LTD.



Encl:

1. Certificate of Inspection
2. Assay Sheet of Calibrator SCS-1000

ISO 13485 & ISO 9001 Certified

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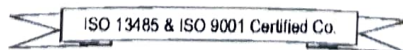
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5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.0	0.3 x 10 ³ /µl or Less
RBC	0.00	0.02 x 10 ⁶ /µL or Less
HGB	0.0	0.1 g/dL or Less
PLT	0	10 x 10 ³ /µL or Less

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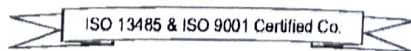
6. PRECISION STUDY PERFORMED ON THE ANALYZER USING A BLOOD SAMPLE (ORIGINALS ATTACHED)

SMP NO	WBC	RBC	HGB	HCT	PLT
1	8.3	5.10	12.6	40.2	264
2	8.3	5.08	12.7	40.2	265
3	8.3	5.09	12.7	40.2	267
4	8.30	5.14	12.7	40.5	268
5	8.5	5.09	12.7	40.0	260
6	8.3	5.09	12.7	40.0	265
7	8.5	5.15	12.8	40.5	259
8	8.33	5.13	12.8	40.2	239
9	8.30	5.19	12.9	40.6	255
10	8.4	5.17	12.9	40.6	236
Mean	8.35	5.12	12.75	40.30	257.80
SD	0.084	0.039	0.097	0.231	11.419
CV%	1.000	0.753	0.762	0.573	4.430
Acceptable CV%	Within 3.5%	Within 2.0%	Within 1.5%	Within 2.0%	Within 6.0%
Result	PASS	PASS	PASS	PASS	PASS


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7. CALIBRATION DATA

SMP NO/TIME	WBC	RBC	HGB	HCT	PLT
1	7.10	4.33	11.2	31.00	270
2	7.00	4.32	11.2	31.50	271
3	7.00	4.29	11.2	31.00	268
4	7.20	4.28	11.2	31.06	265
5	7.00	4.34	11.1	31.11	267
MEAN	7.06	4.312	11.18	31.13	268.2
Acceptable Limits	6.69 - 7.29	4.272 - 4.447	11.09 - 11.32	30.67 - 32.05	252.3 - 278.8
Result	PASS	PASS	PASS	PASS	PASS

8. (Traceability System) :
The traceability system of Sysmex Hematology analyzers are shown in attached sheet.



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Traceability and Uncertainty

SCS-1000 Sysmex Calibrator System

XP-Series, Automated Hematology Analyzer



LOT NO: 11380525

EXP. DATE: 20-Jun-2021

Paramter	Reference Method	Reference Material	Assigned Value	Uncertainty*	Unit
WBC	*1	-	6.992	0.18	10 ⁹ /L
RBC	*1	-	4.360	0.051	10 ¹² /L
PLT	*2	-	265.5	14	10 ⁹ /L
HGB	*3, *4	-	11.20	0.12	g / dL
HCT	*5, *6	-	31.36	0.77	%

* : 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 Microhematcrit Method – 3rd edition; Approved Standard"

*6: Laboratory Hematology, 7, 148-170, 2001

"Recommendations for reference method for the packed cell volume (ICSH Standard 2001)"



SCS-1000



For Asian Pacific

Sysmex Calibrator System Assay Sheet

11380525
20-Jun-2021

LOT

Parameter	XE-Series		XT-Series		XS-Series*	
	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits
WBC K/uL	7.804	7.496 - 8.113	7.828	7.519 - 8.137	7.249	6.963 - 7.536
RBC M/uL	4.483	4.414 - 4.552	4.373	4.305 - 4.440	4.450	4.382 - 4.519
HGB g/dL	11.68	11.59 - 11.77	11.50	11.41 - 11.59	11.53	11.44 - 11.62
HCT %	33.75	33.00 - 34.49	32.24	31.53 - 32.95	34.11	33.36 - 34.87
MCV fL	75.29	74.33 - 76.24	73.73	72.80 - 74.67	76.65	75.68 - 77.63
PLT K/uL	248.3	239.5 - 257.1	246.8	238.0 - 255.5	244.4	235.8 - 253.1

Parameter	K-4500 / K-1000 / K-800		pocH-100j**		KX-21		XP-Series	
	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits
WBC K/uL	7.76	7.43 - 8.10	7.43	7.11 - 7.75	7.76	7.42 - 8.09	6.99	6.69 - 7.29
RBC M/uL	4.396	4.308 - 4.484	4.428	4.339 - 4.516	4.387	4.299 - 4.474	4.360	4.272 - 4.447
HGB g/dL	11.55	11.43 - 11.66	11.19	11.07 - 11.30	11.66	11.55 - 11.78	11.20	11.09 - 11.32
HCT %	31.33	30.63 - 32.02	33.30	32.57 - 34.04	31.51	30.82 - 32.21	31.36	30.67 - 32.05
MCV fL	71.26	70.48 - 72.04	75.21	74.39 - 76.04	71.84	71.05 - 72.63	71.93	71.14 - 72.72
PLT K/uL	255.9	243.1 - 268.7	246.0	233.7 - 258.3	275.7	261.9 - 289.5	265.5	252.3 - 278.8

SCS-1000 ASSAY TERM DEFINED

Assay Target - This is the assigned value for calibration.

Acceptable Limits - These limits represent the interval around the Assay Target that can be attributed to the expanded uncertainty of the total traceability chain.
A calibrator mean (n=5) that falls within these limits indicates an accurately calibrated instrument.

* XS-1000/XS-800I - Assay target for WBC only for operation in CBC+Diff mode

** pocH-100I - Assay Target for WBC only for systems operating under software version 00-18 and following