



UNMATCHED SERVICE  
SINCE 1979...

Date:  
Effective Date:

## Certificate of Calibration

**Customer Name: Regional Ayurveda Research Institute**

**Model : Automated Hematology Analyzer Sysmex XP-100**

**Serial No. : A1143**

**Calibration Done Date: 17.06.2022**

**Next Calibration Due Date On or Before: 16.06.2023**

**Lab In-charge: . Sangeeta Ramteke**

*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  
Designation  
Transasia Bio-Medicals Ltd  
Location

Encl:

1. Certificate of Inspection
2. Assay Sheet of Calibrator SCS-1000
3. Printouts
4. Traceability & Uncertainty document



Date: 00-01-1900  
Effective Date: 00-01-1900

## Certificate of Inspection

1. Model: Automated Hematology Analyzer Sysmex XP – 100
2. Serial No.: A1143
3. Calibration Date: 17.06.2022
4. Material used: SCS-1000 (Lot No. 21370525, Expiry date: 19-June-2022)

By comparing your data to the results of the standard counters in Sysmex Corporation, the calibration for CBC 5 parameters using the measurement standard material (SCS-1000) was completed. The calibration result of 5 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	0.0	$0.3 \times 10^3$ /U1 or Less
RBC	0.01	$0.02 \times 10^6$ /uL or Less
HGB	0.0	0.1 g/dL or Less
PLT	0	$10 \times 10^3$ /uL 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	7.8	4.80	12.9	38.4	321
2	7.9	4.85	12.9	38.8	296
3	7.7	4.85	12.9	38.6	302
4	8.2	4.86	13.0	38.8	315
5	8.10	4.90	12.9	39.1	304
6	7.9	4.90	13.0	39.0	301
7	8.2	4.89	13.0	39.1	329
8	8	4.83	13.0	38.5	306
9	8.1	4.87	13.0	38.8	308
10	8.10	4.88	13.0	39.0	304
Mean	8.00	4.86	12.96	38.81	308.60
SD	0.170	0.032	0.052	0.247	10.113
CV%	2.125	0.658	0.398	0.636	3.277
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
01	7.20	4.29	12.2	34.10	258
02	7.30	4.25	12.2	33.00	256
03	7.10	4.19	12.2	32.50	240
04	6.90	4.21	12.2	32.60	269
05	7.00	4.19	12.2	32.50	261
<b>MEAN</b>	<b>7.10</b>	<b>4.226</b>	<b>12.20</b>	<b>32.94</b>	<b>256.8</b>
Acceptable Limits	6.72 - 7.32	4.200 - 4.371	12.04 - 12.28	32.35 - 33.81	243.5 - 269.1
<b>Result</b>	<b>PASS</b>	<b>PASS</b>	<b>PASS</b>	<b>PASS</b>	<b>PASS</b>

## 8. (Traceability System ) :

The traceability system of Sysmex Hematology analyzers are shown in attached sheet.



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CE

# SCS-1000



For Asian Pacific

## Sysmex Calibrator System Assay Sheet

Lot 21370525  
19-Jun-2022

Parameter	XE-Series		XT-Series		XS-Series*	
	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits
WBC K/uL	7.819	7.510 - 8.127	8.039	7.722 - 8.357	7.343	7.053 - 7.633
RBC M/uL	4.426	4.358 - 4.494	4.294	4.228 - 4.360	4.414	4.346 - 4.482
HGB g/dL	12.73	12.63 - 12.83	12.46	12.36 - 12.55	12.56	12.46 - 12.65
HCT %	36.28	35.48 - 37.08	34.90	34.13 - 35.67	36.86	36.05 - 37.68
MCV fL	81.97	80.93 - 83.01	81.28	80.25 - 82.31	83.52	82.46 - 84.58
PLT K/uL	245.8	237.1 - 254.5	239.9	231.5 - 248.4	243.1	234.5 - 251.7

Parameter	K-4500 / K-1000 / K-800		pocH-100i**		KX-21		XP-Series	
	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits
WBC K/uL	7.97	7.63 - 8.31	7.53	7.20 - 7.85	7.80	7.47 - 8.14	7.02	6.72 - 7.32
RBC M/uL	4.341	4.255 - 4.428	4.430	4.341 - 4.519	4.315	4.229 - 4.401	4.286	4.200 - 4.371
HGB g/dL	12.56	12.43 - 12.68	12.49	12.37 - 12.62	12.64	12.51 - 12.76	12.16	12.04 - 12.28
HCT %	33.52	32.78 - 34.26	35.79	35.00 - 36.58	33.36	32.62 - 34.09	33.08	32.35 - 33.81
MCV fL	77.20	76.35 - 78.05	80.79	79.90 - 81.68	77.30	76.45 - 78.15	77.19	76.34 - 78.04
PLT K/uL	245.5	233.2 - 257.8	240.3	228.3 - 252.3	268.9	255.5 - 282.4	256.3	243.5 - 269.1

**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-1000i/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