

Date: 23.12.20
Effective Date: 23.12.20

Certificate of Calibration

Customer Name: POLO LABS PVT. LTD.

Model : Automated Hematology Analyzer Sysmex XS-800i

Serial No. : 67677

Calibration Done Date: 23.12.20

Next Calibration Due Date On or Before: 22.12.21

Lab In-charge: . Dr. SUKSHAM SAMIR

This is to certify that the above-mentioned product has been verified of calibration for CBC 6 parameters (WBC, RBC, HGB, HCT, MCV 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.

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Calibration at site performed by
GIAN CHAND
Designation : SR.SERVICE ENGG.
Transasia Bio-Medicals Ltd
Location : JALANDHAR

Encl:

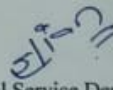
1. Certificate of Inspection
2. Assay Sheet of Calibrator SCS-1000
3. Printouts
4. Traceability & Uncertainty document

Date: 23.12.2020
Effective Date: 23.12.20

Certificate of Inspection

1. Model: Automated Hematology Analyzer Sysmex XS-800i
2. Serial No.: 67677
3. Calibration Date: 23.12.20
4. Material used: SCS-1000 (Lot No. 0336 0525, Expiry date: 03-Jan-2021)

By comparing your data to the results of the standard counters in Sysmex Corporation, the calibration for CBC 6 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	$0.3 \times 10^3 / \mu\text{L}$ or less
RBC	0.00	$0.02 \times 10^6 / \mu\text{L}$ or less
HGB	0.0	0.1 g /dL or less
PLT	3	$10 \times 10^3 / \mu\text{L}$ or less

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

SMP NO	WBC	RBC	HGB	HCT	MCV	PLT
102	7.92	4.60	12.10	36.6	79.6	248
103	7.66	4.64	12.10	36.80	79.3	245
104	7.72	4.64	12.20	36.8	79.3	251
105	7.75	4.61	12.20	36.4	79.0	248
106	8.00	4.61	12.10	36.3	78.7	254
107	7.77	4.65	12.30	36.5	78.5	257
108	7.6	4.65	12.20	36.4	78.3	243
109	7.67	4.57	12.20	35.7	78.1	243
110	7.48	4.68	12.10	36.5	78.0	249
111	7.61	4.66	12.20	36.2	77.7	253
Mean	7.72	4.63	12.17	36.42	78.65	249.10
SD	0.153	0.033	0.067	0.319	0.636	4.701
CV%	1.988	0.709	0.555	0.876	0.809	1.887
Acceptable CV%	Within 3.0%	Within 1.5%	Within 1.5%	Within 1.5%	Within 1.5%	Within 4.0%
Result	PASS	PASS	PASS	PASS	PASS	PASS

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7. CALIBRATION DATA

SMP NO/TIME	WBC	RBC	HGB	HCT	MCV	PLT
203	6.59	4.39	12.5	36.1	82.2	244
204	6.66	4.40	12.5	36.1	82.0	254
205	6.58	4.36	12.3	35.8	82.1	237
2.06	6.76	4.42	12.2	36.3	82.1	254
207	6.58	4.38	12.4	36.0	82.2	256
MEAN	6.63	4.390	12.38	36.06	82.12	249.0
Acceptable Limits	6.472 - 7.005	4.328 - 4.464	12.30 - 12.49	35.42 - 37.02	81.35 - 83.45	239.3 - 256.8
Result	PASS	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
XS-1000i, XS-800i, XS-500i Automated Hematology Analyzer



LOT NO: 03360525
 EXP. DATE: 3-Jan-2021

Parameter	Reference Method	Reference Material	Assigned Value	Uncertainty*	Unit
WBC	*1	-	6.739	0.20	10 ⁹ /L
RBC	*1	-	4.396	0.072	10 ¹² /L
PLT	*2	-	248.1	11	10 ⁹ /L
HGB	*3, *4	-	12.40	0.15	g / dL
HCT	*5, *6	-	36.22	0.88	%

- * : 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 Microhematocrit 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



LOT

03360525
3-Jan-2021

Sysmex Calibrator System Assay Sheet

For Asian Pacific

Parameter	XE-Series		XT-Series		XS-Series*	
	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits
WBC K/uL	7.139	6.857 - 7.421	7.145	6.862 - 7.427	6.739	6.472 - 7.005
RBC M/uL	4.445	4.377 - 4.514	4.345	4.278 - 4.412	4.396	4.328 - 4.464
HGB g/dL	12.54	12.44 - 12.63	12.30	12.21 - 12.39	12.40	12.30 - 12.49
HCT %	35.86	35.07 - 36.66	34.59	33.82 - 35.35	36.22	35.42 - 37.02
MCV fL	80.67	79.65 - 81.70	79.59	78.58 - 80.61	82.40	81.35 - 83.45
PLT K/uL	251.4	242.5 - 260.3	249.3	240.5 - 258.1	248.1	239.3 - 256.8

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	7.06	6.75 - 7.36	6.88	6.58 - 7.18	7.08	6.78 - 7.38	6.54	6.26 - 6.82
RBC M/uL	4.358	4.271 - 4.446	4.387	4.299 - 4.475	4.306	4.220 - 4.393	4.325	4.238 - 4.411
HGB g/dL	12.45	12.33 - 12.58	12.02	11.90 - 12.14	12.43	12.31 - 12.56	12.08	11.96 - 12.20
HCT %	33.05	32.32 - 33.78	34.97	34.20 - 35.74	32.96	32.23 - 33.69	33.09	32.36 - 33.82
MCV fL	75.84	75.00 - 76.67	79.71	78.84 - 80.59	76.54	75.70 - 77.38	76.51	75.67 - 77.35
PLT K/uL	253.7	241.0 - 266.3	246.8	234.5 - 259.2	273.3	259.6 - 286.9	263.4	250.2 - 276.5

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

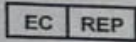
SYMBOL EXPLANATIONS



Biological risks



In Vitro Diagnostic Medical Device



Authorized Representative in the European Community



Consult Instructions for Use



Batch code



Use by ...



Temperature limitation



Manufacturer