

Certificate of Calibration

Customer Name: SURE DIAGNOSTIC LAB

Model : Automated Hematology Analyzer Sysmex XP-100

Serial No. : B7428

Calibration Done Date: 27.7.20

Next Calibration Due Date On or Before: 27.7.2021

Lab In-charge: . DR SUMEDHA MENGI

This is to certify that the above-mentioned product has been verified of CBC 5 parameters (WBC, RBC, HGB, HCT and PLT) according to the procedures provided by Sysmex Corporation, Japan.

The reference instruments used for value-assignment are managed by the system in Sysmex Corporation and these are traceable to the International System of Units such as ICSH.

Calibration at site performed by
Engineer Name: SUNNY BHAT/ AJAY SINGH
Designation: APP SPECIALIST / ENGINEER
Transasia Bio-Medicals Ltd
Location: JAMMU

Encl:

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

Date: 27/07/2020
Effective Date: 27/07/2020

Certificate of Inspection

1. Model: Automated Hematology Analyzer Sysmex XP – 100
2. Serial No.: B7428
3. Calibration Date: 27/07/2020
4. Material used: SCS-1000 (Lot No. 0196 0525, Expiry date: -16-Aug-2020)

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

SMP NO	WBC	RBC	HGB	HCT	PLT
1	6.9	4.55	12.7	34.9	248
2	7.1	4.47	12.7	34.9	248
3	6.8	4.62	12.6	35.2	245
4	7	4.62	12.6	35.4	248
5	7.10	4.57	12.8	34.6	253
NA					
NA					
NA					
NA					
NA					
Mean	6.98	4.57	12.68	35.00	248.40
SD	0.130	0.062	0.084	0.308	2.881
CV%	1.868	1.355	0.660	0.881	1.160
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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5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.0	$0.3 \times 10^3/\text{UL}$ 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	0	$10 \times 10^3/\mu\text{L}$ or Less

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7. CALIBRATION DATA

SMP NO/TIME	WBC	RBC	HGB	HCT	PLT
1	6.40	4.40	11.9	32.10	267
2	6.50	4.41	11.9	32.10	273
3	6.50	4.35	12.0	32.30	259
4	6.50	4.35	12.0	32.50	256
5	6.40	4.37	12.0	32.40	247
MEAN	6.46	4.376	11.96	32.28	260.4
Acceptable Limits	6.34 - 6.91	4.209 - 4.380	11.91 - 12.15	32.09 - 33.54	240.4 - 265.7
Result	PASS	PASS	PASS	PASS	PASS

Traceability System) :

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

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