



Certificate of Calibration

Customer Name: IMPULSE DIAGNOSTICS,

Model : Automated Hematology Analyzer Sysmex XY 300

Serial No B6923

Calibration Done Date: 18/08/2021

Next Calibration Due Date On or Before: 17/08/2022

Lab In-charge: . DR RATANDEEP NATH

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
BHOJRAJ SINGH
AREA SERVICE MANAGER
Transasia Bio-Medicals Ltd
Silchar, Assam

Encl:

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



Date: 18/08/2021

Effective Date: 18/08/2021

UNMATCHED SERVICE
SINCE 1979...

Certificate of Calibration

1. Model: Automated Hematology Analyzer Sysmex XP – 300
2. Serial No.: B6923
3. Calibration Date: 18/08/2021
4. Material used: SCS-1000 (Lot No. 6257 0525, Expiry date: -21-AUG-2021)

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	0.2	0.3×10^3 /UI or Less
RBC	0.00	0.02×10^6 /uL or Less
HGB	0.0	0.1 g/dL or Less
PLT	0	10×10^3 /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	7.1	3.45	10.3	30.5	387
2	7.1	3.43	10.3	30.6	382
3	7.1	3.43	10.3	30.7	385
4	7.1	3.47	10.3	30.7	392
5	7.10	3.44	10.2	30.4	384
6	7.1	3.47	10.4	30.6	383
7	7	3.45	10.4	30.5	385
8	7.2	3.51	10.4	31.0	381
9	7.2	3.49	10.4	30.8	377
10	7.10	3.50	10.4	31.0	374
Mean	7.11	3.46	10.34	30.68	383.00
SD	0.057	0.029	0.070	0.204	5.033
CV%	0.798	0.830	0.676	0.666	1.314
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
2	7.20	4.48	12.8	34.20	272
3	7.40	4.50	12.8	34.40	265
4	7.40	4.54	12.9	34.80	261
5	7.40	4.53	12.9	34.50	273
6	7.40	4.44	12.7	34.00	262
MEAN	7.36	4.498	12.82	34.38	266.6
Acceptable Limits	7.11-7.75	4.407 - 4.587	12.65 - 12.91	33.68 - 35.20	254.6- 281.4
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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