

Date: 19-02-2022
Effective Date: 19-02-2022

Certificate of Calibration

Customer Name: MEDICENTER SONOGRAPHY AND CLINICAL LAB, DUNGARPUR

Model : Automated Hematology Analyzer H360

Serial No. : K10011914125-RR

Calibration Done Date: 19.2.22

Next Calibration Due Date On or Before: 18-02-2023

Lab In-charge: . DR. MAYANKA SETH

This is to certify that the above-mentioned product has been verified of calibration for CBC 5 parameters (WBC, RBC, HGB, MCV and PLT) according to the standard procedures provided by Erba Lachema s.r.o, Karasek.

Calibration at site performed by
MR. GUNJAN KUMAR PAHAD
SR. SERVICE ENGINEER
Transasia Bio-Medicals Ltd
DUNGARPUR RAJASTHAN

Encl:

1. Certificate of Inspection
2. Assay Sheet of Hematology Calibrator (H Cal)
3. Printouts
4. Traceability Document

Date: 19.02.2022
Effective Date: 19.02.2022

Certificate of Inspection

1. Model: Automated Hematology Analyzer H360
2. Serial No.: K10011914125-RR
3. Calibration Date: 19-02-2022
4. Material used: H Cal (Lot No. PLUS0222, Expiry date: 10-Mar-2022)

By comparing your data to the results of the standard counters in Erba Lachema, the calibration for CBC 5 parameters using the measurement standard material (H Cal) was completed. The calibration result of 5 runs is summarized in the following table. Please refer to the attached sheets for the details.

Technical Service Department
Transasia Bio-Medicals Ltd

Transasia Bio-Medicals Ltd . Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai- 400 072
Tel: +91 22 4030 9000 Fax +91 22 2857 3030

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

SMP NO	WBC	RBC	HGB	MCV	PLT
PRI 1	12.06	3.55	10.2	79.9	279
PRI 2	12.09	3.57	10.1	80.1	279
PRI 3	11.98	3.58	10.2	80.2	286
PRI 4	12.09	3.58	10.2	79.9	279
PRI 5	11.84	3.53	10.1	80	285
PRI 6	12.42	3.57	10.2	79.8	283
PRI 7	12.40	3.57	10	80	272
PRI 8	12.4	3.58	10.3	80	283
PRI 9	12.18	3.53	10.2	79.9	279
PRI 10	12.11	3.55	10.2	79.8	280
Mean	12.16	3.56	10.17	79.96	280.50
SD	0.20	0.02	0.08	0.13	4.01
CV%	1.67	0.55	0.81	0.16	1.43
Acceptable CV%	Within 3.5%	Within 2.0%	Within 1.5%	Within 2.0%	Within 6.0%
Result	PASS	PASS	PASS	PASS	PASS

Technical Service Department
Transasia Bio Medicals Ltd

5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.0	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

Technical Service Department
Transasia Bio-Medicals Ltd