

Date: 09/03/2022
Effective Date: 09/03/2022

Certificate of Calibration

Customer Name: SHANKAR DIAGNOSTICS CENTRE

Model : Automated Hematology Analyzer H560

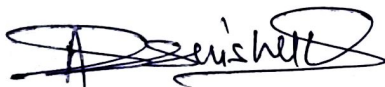
Serial No. : 1104B214709

Calibration Done Date: 9.3.22

Next Calibration Due Date On or Before: 03/08/2023

Lab In-charge: . MR SADDAM

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
Engineer Name ANUBHISHEK KASHYAP
Designation SERVICE ENG.
Transasia Bio-Medicals Ltd
Location AGRA

Encl:

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

Date: 09/03/2022
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Certificate of Inspection

1. Model: Automated Hematology Analyzer H560
2. Serial No.: 1104B214709
3. Calibration Date: 09/03/2022
4. Material used: H Cal (Lot No. PLUS0822, Expiry date: 10-Sep-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.

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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

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

SMP NO	WBC	RBC	HGB	MCV	PLT
1	9.34	4.59	13.3	90.6	284
2	9.17	4.57	13.3	90.8	290
3	9.29	4.6	13.4	90.8	280
4	9.39	4.54	13.3	90.7	286
5	9.52	4.57	13.4	90.7	283
6	9.29	4.54	13.4	90.9	278
7	9.56	4.61	13.5	91.1	283
8	9.52	4.58	13.4	90.8	285
9	9.53	4.58	13.5	90.6	284
10	9.49	4.63	13.5	90.7	274
Mean	9.41	4.58	13.40	90.77	282.70
SD	0.13	0.03	0.08	0.15	4.45
CV%	1.41	0.62	0.61	0.16	1.57
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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