



UNMATCHED SERVICE
SINCE 1979...

Date: 08/05/2021
Effective Date: 08/05/2021

Certificate of Calibration

Customer Name: Dr. B Lal Laboratory, Alwar.

Model : Automated Hematology Analyzer Elite 580

Serial No. : 1105190301

Calibration Done Date: 8.5.21

Next Calibration Due Date On or Before: 07/05/2022

Lab In-charge: . Dr. Saroj Gupta

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 :- Manish Kumar Saini
Designation :- Service Engineer
Transasia Bio-Medicals Ltd
Alwar.

Encl:

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



Date: 08/05/2021
Effective Date: 08/05/2021

Certificate of Inspection

1. Model: Automated Hematology Analyzer Elite 580
2. Serial No.: K11051903014
3. Calibration Date: 08/05/2021
4. Material used: H Cal (Lot No. PLUS0421, Expiry date: 10-May-2021)

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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Transasia Bio-Medicals Ltd



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5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.0	$0.3 \times 10^3/\text{UI}$ or Less
RBC	0.00	$0.02 \times 10^6/\text{uL}$ or Less
HGB	0.0	0.1 g/dL or Less
PLT	0	$10 \times 10^3/\text{uL}$ or Less



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

SMP NO	WBC	RBC	HGB	MCV	PLT
T-1	5.9	4.51	12.2	84	308
T-2	5.89	4.52	12.3	84.1	310
T-3	5.88	4.51	12.2	84.2	312
T-4	5.9	4.49	12.2	84.1	314
T-5	5.8	4.4	12.2	84.1	312
T-6	5.85	4.49	12.3	84.1	310
T-7	5.95	4.45	12.2	83.7	315
T-8	5.9	4.46	12.3	83.9	310
T-9	5.95	4.43	12.2	84.3	309
T-10	5.98	4.5	12.3	83.8	310
Mean	5.90	4.48	12.24	84.03	311.00
SD	0.05	0.04	0.05	0.18	2.21
CV%	0.88	0.88	0.42	0.22	0.71
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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History

Cal. Operator	Service engineer	Cal. Method	Calibrator
Cal Mode	Whole Blood-Factory	Cal Date	2021/05/08
Description	PLUS0421(Lot No) 2021/05/08 (Exp Date) 2021/05/10		

Details

Para.	WBC	RBC	HGB	MCV	PLT	MPV
Target	9.13	4.47	13.7	89.6	254	
1	9.14	4.49	13.7	91.9	247	
2	9.07	4.45	13.5	91.8	258	
3	9.39	4.46	13.7	91.9	256	
4	9.15	4.48	13.6	91.9	256	
5	9.14	4.51	13.7	91.5	261	
6	9.43	4.55	13.6	91.8	266	
7	9.06	4.53	13.6	92.1	244	
8	9.2	4.52	13.7	91.7	239	
9	9.49	4.5	13.6	91.4	236	
10	9.28	4.51	13.8	91.7	244	
11	9.13	4.51	13.7	91.6	242	
12	9.28	4.42	13.7	91.8	249	
New CBC+ DIFF Cal Coefficient (%)	98.81	99.38	100.15	97.69	104.83	
Original CBC+DIFF Cal. Coefficient (%)	106.45	97.75	102.86	102.3	100.08	100.00
New Transfer Coefficient	1.0021	1.0017	1.0036	0.9991	0.9417	
Original Transfer Coefficient	1.0195	1.0143	1.0086	0.9977	0.9450	1.0000



PRECISION HISTORY

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Acceptable CV%	Within 3.5%	Within 2.0%	Within 1.5%	Within 2.0%	Within 6.0%
Result	PASS	PASS	PASS	PASS	PASS



TRACEABILITY

Erba Lachema s.r.o., Karásek 1d, 621 00 Brno hereby certifies the traceability of the assigned values of the product listed below to a reference material.

Assignment of Reference Values to Fresh Whole Blood

Hematology Calibrator values are traceable to standard reference methods.

Hematology analyzers in the Quality Assurance Laboratory of the Supplier are whole blood calibrated to values obtained using the following standard reference methods. Whole blood samples drawn from normal, healthy donors are collected in EDTA anticoagulant and analyzed within six hours of collection.

The **White Blood Cell (WBC)** and **Red Blood Cell (RBC)** are analyzed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.

Hemoglobin is measured using the Clinical Laboratory Standards Institute (CLSI) recommended reagent for the hemoglobincyanide (cyanmethemoglobin) method⁽¹⁾. Readings are made at 540 nm in a colorimeter/spectrophotometer calibrated according to CLSI H15-A3 and ICSH recommendations⁽¹⁾.

The **hematocrit** (packed cell volume) is measured using plain glass microhematocrit tubes (not coated with anticoagulant) centrifuged for 5 minutes in a microhematocrit centrifuge according to the CLSI H7-A3 document⁽²⁾. No correction is made for trapped plasma.

Platelets are assayed using a hemocytometer and phase contrast optics.

Determination of uncertainty

Uncertainty is an estimate of the range in which the true value of a reported result may occur.

The uncertainty associated with the calibration of the H360, H560 and ELite 580 analyzer using the ELite H CAL calibrator has been estimated by adding the following sources of uncertainty:

- Uncertainty of the equipment used to determine the reference values: flask, pipette, single aperture impedance counter (WBC, RBC), Hemocytometer by phase-contrast (PLT), spectrophotometer (HGB), and ruler (HCT).
- Uncertainty of the hematology analyzer when calibrating with the ELite H CAL.

