

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

Certificate of Calibration

Customer Name: Shree Mata Sheetla devi swarn jyanti Daignostic Center,Gurgaon

Model : Automated Hematology Analyzer Elite 580

Serial No. : K11051912047

Calibration Done Date: 5.8.21

Next Calibration Due Date On or Before: 04/08/2022

Lab In-charge: . Dr. Deepika

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
Dileep Kumar Yadav
Area Service Manager
Transasia Bio-Medicals Ltd
New Delhi

Encl:

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

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

Certificate of Inspection

1. Model: Automated Hematology Analyzer Elite 580
2. Serial No.: K11051912047
3. Calibration Date: 05/08/2021
4. Material used: H Cal (Lot No. PLUS0821, Expiry date: 10-Sep-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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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	13.92	4.75	14.4	94.5	143
2	13.7	4.7	14.2	94.9	139
3	14.08	4.74	14.3	94.3	140
4	14.3	4.72	14.3	94.5	139
5	14.09	4.74	14.4	94.9	137
6	14.46	4.74	14.5	94.5	137
7	14.44	4.76	14.4	94.6	142
8	14.05	4.75	14.3	94.6	134
9	14.06	4.72	14.3	94.5	134
10	14.25	4.7	14.4	94.3	144
Mean	14.14	4.73	14.35	94.56	138.90
SD	0.23	0.02	0.08	0.21	3.48
CV%	1.65	0.44	0.59	0.22	2.50
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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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.

Table 1: Assignment results and uncertainty of reference method

	Reference	WBC (10 ⁹ /L)	RBC (10 ¹² /L)	HGB (g/L)	MCV (fL)	PLT (10 ⁹ /L)
H360	Calibrator	9.05	4.93	143	93.5	253
	Relative expansion Uncertainty %	2.1	0.9	0.3	0.1	3.9
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
H560	Calibrator	8.92	4.71	141	92.7	253
	Relative expansion Uncertainty %	2.1	1.1	0.2	0.1	3.7
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
ELite 580 (SW A10.4)	Calibrator	9.23	4.53	141	89.1	254
	Relative expansion Uncertainty %	2.3	1.1	0.2	0.1	3.9
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified

The reported expanded uncertainty in Table 1 is based on a standard uncertainty multiplied by a coverage factor of $k=2$ providing a level of confidence of approximately 95%.

Technical Product Management

Erba Lachema s.r.o.

Brno 5. 8. 2021