



Date:  
Effective Date:

## Certificate of Calibration

**Customer Name: Central Ayurveda Research Institute**

**Model : Automated Hematology Analyzer Elite 580**

**Serial No. : 11051903050**

**Calibration Done Date: 7.9.22**

**Next Calibration Due Date On or Before: 06/09/2023**

**Lab In-charge: . Dr. Reetika Saini**

*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  
Navin Kumar  
Service Engineer  
Transasia Bio-Medicals Ltd  
Delhi

Encl:

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





UNMATCHED SERVICE

SINCE 1979/2022

Date:

Effective Date: 07/09/2022

## Certificate of Inspection

1. Model: Automated Hematology Analyzer Elite 580
2. Serial No.: k11051903056
3. Calibration Date: 07/09/2022
4. Material used: H Cal (Lot No. PLUS0822, Expiry date: 10-Sep-2022)

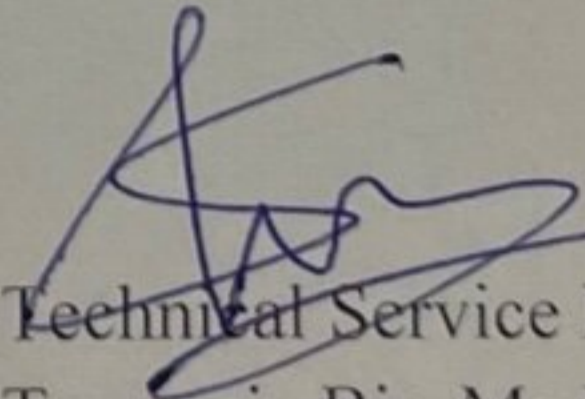
By comparing your data to the results of the standard counters in Erba Lachema, the calibration for CBC 5 parameters using the measurement standard material (H Cal) was completed. The calibration result of 5 runs is summarized in the following table. Please refer to the attached sheets for the details.

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## 5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.0	$0.3 \times 10^3/\text{UI}$ 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

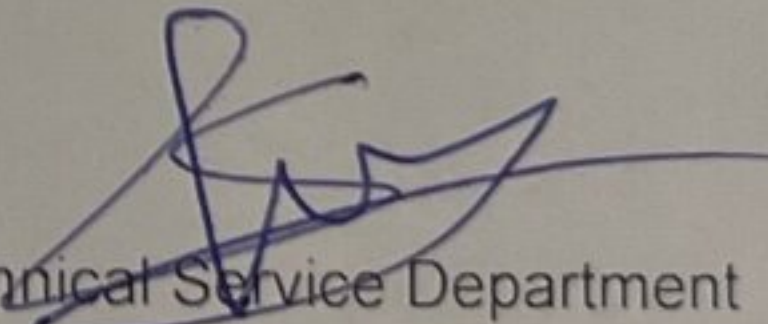
  
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## 6. PRECISION STUDY PERFORMED ON THE ANALYSER USING A BLOOD SAMPLE (ORIGINAL ATTACHED)

SMP NO	WBC	RBC	HGB	MCV	PLT
1	6.64	4.13	12.8	87.9	170
2	6.71	4.21	12.8	88	164
3	6.75	4.23	12.8	87.8	164
4	6.64	4.23	12.9	87.3	163
5	6.62	4.24	12.8	88	161
6	6.82	4.22	12.9	87.4	161
7	6.54	4.23	12.8	88	155
8	6.79	4.2	12.8	87.7	158
9	6.62	4.27	13	87.4	159
10	6.9	4.28	12.9	87.5	164
Mean	6.70	4.22	12.85	87.70	161.90
SD	0.11	0.04	0.07	0.28	4.12
CV%	1.65	0.97	0.55	0.32	2.55
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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### L-J QC Table

Editor: service  
 Existing / Total: 20/500  
 QC Sample ID: QC10

QC Mode: Whole Blood-CBC+DIFF File No.: 15  
 Level: Normal  
 Date Range: 07/09/2022-07/09/2022  
 Exp. Date: 30/09/2022

Lot No.: EH2207N  
 Print Time: 07/09/2022 15:11:20

Date	Time	Operator	WBC	Neu%	Lym%	Mon%	Eos%	Bas%	Neu#	Lym#	Mon#	Eos#	Bas#	RBC	HGB	HCT	MCV	MCH	MCHC	RDW-CV	RDW-SD	PLT	MPV	PDW-SD	PDW-CV	PCT	P-LCR	P-LCC	GRAN-X	GRAN-Y	GRAN-ZW	MCV	
TARGET	/	/	7.73	55.8	29.8	6.9	7.5	7.1	4.31	2.3	0.53	0.58	5.49	4.49	12.9	38.3	85.4	28.3	33.1	17.5	53.3	240	10.1	12.5	16	0.244	27.5	67					
LIMITS(±)	/	/	1	8	8	5	6	8	0.7	0.7	0.5	0.5	0.7	0.24	0.6	3	5	2.5	3	3	10	40	3	3	3	0.1	8	25					
1	07/09/2022	15:01:30	service	7.53	60.2	30.0	8.2	1.6	70.5	4.54	2.26	0.61	0.12	5.31	4.59	12.9	41.2	89.9	28.0	31.2	17.0	56.2	227	10.1	12.4	16.4	0.230	28.2	64	76	88	66	102.5

## 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<sup>(1)</sup>. Readings are made at 540 nm in a colorimeter/spectrophotometer calibrated according to CLSI H15-A3 and ICSH recommendations<sup>(1)</sup>.

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<sup>(2)</sup>. 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 <sup>9</sup> /L)	RBC (10 <sup>12</sup> /L)	HGB (g/L)	MCV (fL)	PLT (10 <sup>9</sup> /L)
H360	Calibrator	9.40	4.82	136	89.3	257
	Relative expansion Uncertainty %	2.1	0.4	0.5	0.4	4.1
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
H560 (SW A12.2 or higher; version A only)	Calibrator	9.10	4.57	132	87.5	264
	Relative expansion Uncertainty %	2.2	0.6	0.2	0.1	4.2
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
H560 (SW B1.0 or higher)	Calibrator	9.24	4.47	131	84.4	263
	Relative expansion Uncertainty %	2.3	0.5	0.4	0.3	4.0
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
ELite 580 (SW A10.4 or higher)	Calibrator	9.27	4.49	133	84.6	258
	Relative expansion Uncertainty %	2.5	0.3	0.3	0.2	4.3
	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 27.08.2022



Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, Czech Republic  
 Identification number: 269 18 846. Tax identification number: CZ26918846  
 Incorporated in the Commercial Register maintained by the Regional Court in Brno, Section C, insert 45458  
 Tel.: +420 517 077 111, e-mail: diagnostics@erbamannheim.com, www.erbalachema.com

# ELite H CAL



Hematology Calibrator / Hematologický kalibrátor / Calibrador de hematología

## Assay values

Atestované hodnoty / Valores de la media

LOT

PLUS0822



2022-09-10

Name Název Nombre	Cat. No. Kat.č. No.Cat.	Package volume Objem balení Volumen
ELite H CAL	HEM00027	3 ml



Before using refer to the instruction sheet for mixing directions. Calibration errors may result if instructions are not followed exactly.  
 Před použitím čtěte návod. Nepřesný postup kalibrace může způsobit chybné výsledky stanovení.  
 Lea las instrucciones de mezclado antes de usar. Los errores de calibración pueden surgir si no se siguen las instrucciones exactamente.

Instrument Analyzátor Instrumento	Parameter Analyt Analito	Unit Jednotka Unidad	Assigned Value Hodnota Valor	Deviation Odchylka Desviación
ELite 580 (SW A10.4 or higher)	WBC	$\times 10^9/L$	9.27	$\pm 0.20$
	RBC	$\times 10^{12}/L$	4.49	$\pm 0.08$
	HGB	g/L	133	$\pm 2$
		g/dL	13.3	$\pm 0.2$
	MCV	fL	84.6	$\pm 2.0$
	PLT	$\times 10^9/L$	258	$\pm 12$
H560 (SW A12.2 or higher; version A only)	WBC	$\times 10^9/L$	9.10	$\pm 0.20$
	RBC	$\times 10^{12}/L$	4.57	$\pm 0.08$
	HGB	g/L	132	$\pm 2$
		g/dL	13.2	$\pm 0.2$
	MCV	fL	87.5	$\pm 2.0$
	PLT	$\times 10^9/L$	264	$\pm 12$
H560 (SW B1.0 or higher)	WBC	$\times 10^9/L$	9.24	$\pm 0.20$
	RBC	$\times 10^{12}/L$	4.47	$\pm 0.08$
	HGB	g/L	131	$\pm 2$
		g/dL	13.1	$\pm 0.2$
	MCV	fL	84.4	$\pm 2.0$
	PLT	$\times 10^9/L$	263	$\pm 12$
H360	WBC	$\times 10^9/L$	9.40	$\pm 0.20$
	RBC	$\times 10^{12}/L$	4.82	$\pm 0.08$
	HGB	g/L	136	$\pm 2$
		g/dL	13.6	$\pm 0.2$
	MCV	fL	89.3	$\pm 2.0$
	PLT	$\times 10^9/L$	257	$\pm 12$

10020492



Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, CZ

Date of Issue / Datum vydání / Fecha de emisión: 29. 7. 2022

HEMA/PI/28-A/22/F/INT



# Calibrator

Lot No.: PLUS0822  
 Calibration Mode: Whole Blood

Exp. Date: 10/09/2022  
 Print Time: 07/09/2022 14:38:31

PARA.	WBC	RBC	HGB	MCV	PLT	MPV
Target	9.27	4.49	13.3	84.6	258	10.0
1	9.58	4.48	12.9	83.4	278	10.2
2	9.34	4.56	13.0	83.2	296	10.1
3	9.72	4.55	12.9	83.2	307	10.1
4	9.58	4.59	13.0	83.0	300	10.0
5	9.60	4.52	13.0	83.1	299	10.2
6	9.42	4.56	13.1	83.1	301	10.2
7	9.54	4.51	12.9	83.3	265	10.1
8	9.58	4.49	12.9	83.3	267	10.0
9	9.67	4.52	13.0	83.3	277	10.0
10	9.79	4.54	13.0	83.3	278	10.3
11	9.78	4.55	13.0	83.3	286	9.9
12	9.55	4.55	13.0	83.2	280	10.1
CBC-Mean	9.540	4.543	12.98	83.17	296.8	10.13
DIFF-Mean	9.652	4.527	12.97	83.28	275.5	10.07
CBC-CV(%)	1.4	0.8	0.6	0.2	3.3	0.8
DIFF-CV(%)	1.2	0.5	0.4	0.0	2.9	1.4
CBC Cal. Coefficient(%)	97.17	98.83	102.47	101.72	86.93	98.72
DIFF Cal. Coefficient (%)	96.04	99.18	102.54	101.59	93.65	99.30
Transfer Coefficient	1.0118	0.9965	0.9993	1.0013	0.9282	0.9942