Date: 10-09-2023
Effective Date: 10-09-2023

Certificate of Calibration

Customer Name: REDCLIFFE LIFTECH PVT LTD.

Model : Automated Hematology Analyzer Elite 580

Serial No. : K11052132052

Calibration Done Date: 10.9.23

Next Calibration Due Date On or Before: 09-09-2024

Lab In-charge: . PAVAN KUSHWAHA

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.

BIO-MEDICALS LIMITED

Calibration at site performed by
Engineer Name Pushpendra Singh
Designation Area manager
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: 10-09-2023
Effective Date: 00-01-1900

Certificate of Inspection

1. Model: Automated Hematology Analyzer Elite 580

2. Serial No.: K11052132052

3. Calibration Date: 10-09-2023

4. Material used: H Cal (Lot No. PLUS0123, Expiry date: 10-Feb-2023)

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.

TRANSASIA BIO-MEDICALS LIMITED

Technical Service Department
Transasia Bio-Medicals Ltd

5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.0	0.3 x 10^3 UI or Less
RBC	0.00	0.02 x 10^6/uL or Less
HGB	0.0	0.1 g/dL or Less
PLT	0	10 x 10^3/uL or Less

Technical Service Department
Transasia Bio-Medicals Ltd

ELite H CAL

Hematology Calibrator / Hematologický kalibrátor / Calibrador de hematología

Assay values
Atestované hodnoty / Valores de la media

LOT PLUS0123

2023-02-10

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

CE IVD

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	$x10^9$/L	9.20	± 0.20
	RBC	$x10^{12}$/L	4.52	± 0.08
	HGB	g/L	135	± 2
		g/dL	13.5	± 0.2
	MCV	fL	85.3	± 2.0
	PLT	$x10^9$/L	250	± 12
H560 (SW A12.2 or higher; version A only)	WBC	$x10^9$/L	8.96	± 0.20
	RBC	$x10^{12}$/L	4.62	± 0.08
	HGB	g/L	134	± 2
		g/dL	13.4	± 0.2
	MCV	fL	88.4	± 2.0
	PLT	$x10^9$/L	256	± 12
H560 (SW B1.0 or higher)	WBC	$x10^9$/L	9.18	± 0.20
	RBC	$x10^{12}$/L	4.56	± 0.08
	HGB	g/L	133	± 2
		g/dL	13.3	± 0.2
	MCV	fL	85.4	± 2.0
	PLT	$x10^9$/L	262	± 12
H360	WBC	$x10^9$/L	9.23	± 0.20
	RBC	$x10^{12}$/L	4.90	± 0.08
	HGB	g/L	137	± 2
		g/dL	13.7	± 0.2
	MCV	fL	88.5	± 2.0
	PLT	$x10^9$/L	249	± 12

10020492

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

Date of issue / Datum vydání / Fecha de emisión: 3. 1. 2023
HEMA/PI/28-A/22/EN1

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	9.23	4.90	137	88.5	249
	Relative expansion Uncertainty %	2.2	0.1	0.3	0.5	4.4
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
H560 (SW A12.2 or higher; version A only)	Calibrator	8.96	4.62	134	88.4	256
	Relative expansion Uncertainty %	2.4	0.2	0.6	0.3	4.1
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
H560 (SW B1.0 or higher)	Calibrator	9.18	4.56	133	85.4	262
	Relative expansion Uncertainty %	2.3	0.6	0.5	0.4	4.2
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
ELite 580 (SW A10.4 or higher)	Calibrator	9.20	4.52	135	85.3	250
	Relative expansion Uncertainty %	2.1	0.5	0.4	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.

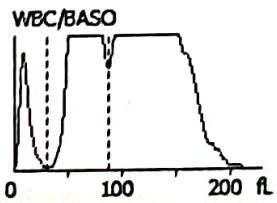
Brno 03.01.2023

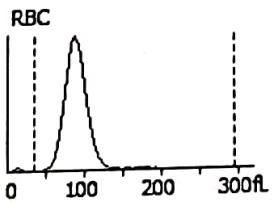
L-J QC Analysis

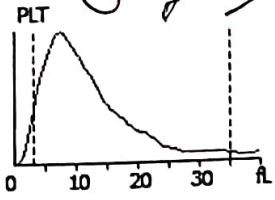
File No.:	20	Lot No.:	EH2405N	Level:	Normal
Operator:	admin	Exp. Date:	2024/07/10	Run Time:	25/05/2024 09:23
Print Time:	2024/05/25 09:25	QC Mode:	Whole Blood-CBC+DIFF	QC Sample ID:	

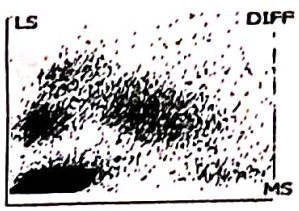
	Parameter	Result	Ref. Range	Unit
1	**WBC**	**8.42**	**7.30-9.30**	**10^3/uL**
2	Neu%	60.3	47.4-63.4	%
3	Lym%	28.7	21.4-37.4	%
4	Mon%	7.9	2.8-12.8	%
5	Eos%	3.1	0.0-11.4	%
6	Bas%	71.4	63.5-79.5	%
7	Neu#	5.08	3.90-5.30	10^3/uL
8	Lym#	2.42	1.44-2.84	10^3/uL
9	Mon#	0.66	0.15-1.15	10^3/uL
10	Eos#	0.26	0.11-1.11	10^3/uL
11	Bas#	6.02	5.24-6.64	10^3/uL
12	**RBC**	**4.62**	**4.46-4.94**	**10^6/uL**
13	HGB	13.9	13.0-14.2	g/dL
14	HCT	40.9	39.3-45.3	%
15	MCV	88.4	85.0-95.0	fL
16	MCH	30.1	26.3-31.3	pg
17	MCHC	34.1	29.1-35.1	g/dL
18	RDW-CV	15.5	13.3-19.3	%
19	RDW-SD	50.5	42.6-62.6	fL
20	**PLT**	**265**	**231-311**	**10^3/uL**
21	MPV	9.5	6.8-12.8	fL
22	PDW-SD	10.2	8.8-14.8	fL
23	PDW-CV	15.0	13.0-19.0	%
24	PCT	0.252	0.166-0.366	%
25	P-LCR	23.5	17.4-33.4	%
26	P-LCC	62	44-94	10^9/L

25/05/24









L-J QC Analysis

File No.:	21	Lot No.:	EH2405H	Level:	High
Operator:	admin	Exp. Date:	2024/07/10	Run Time:	25/05/2024 09:57
Print Time:	2024/05/25 10:09	QC Mode:	Whole Blood-CBC+DIFF	QC Sample ID:	

	Parameter	Result	Ref. Range	Unit
1	**WBC**	**18.74**	**16.38-21.38**	**10^3/uL**
2	Neu%	65.9	57.5-71.5	%
3	Lym%	21.1	14.5-26.5	%
4	Mon%	6.9	1.0-13.0	%
5	Eos%	6.1	1.0-15.0	%
6	Bas%	73.6	72.8-88.8	%
7	Neu#	12.35	10.77-13.57	10^3/uL
8	Lym#	3.96	2.77-4.97	10^3/uL
9	Mon#	1.29	0.22-2.42	10^3/uL
10	Eos#	1.14	0.21-2.81	10^3/uL
11	Bas#	13.79	11.75-14.75	10^3/uL
12	**RBC**	**5.47**	**5.06-6.06**	**10^6/uL**
13	HGB	17.8	16.6-18.2	g/dL
14	HCT	52.1	49.6-57.6	%
15	MCV	95.3	90.5-102.5	fL
16	MCH	32.6	28.6-33.6	pg
17	MCHC	34.2	29.4-35.4	g/dL
18	RDW-CV	15.0	13.1-19.1	%
19	RDW-SD	52.2	43.6-67.6	fL
20	**PLT**	**574**	**528-648**	**10^3/uL**
21	MPV	9.3	6.4-12.4	fL
22	PDW-SD	10.4	8.2-14.2	fL
23	PDW-CV	15.3	12.8-18.8	%
24	PCT	0.533	0.352-0.752	%
25	P-LCR	21.8	14.9-30.9	%
26	P-LCC	125	96-166	10^9/L

25/05/24