



Date: 08-06-2023
Effective Date: 08-06-2023

Certificate of Calibration

Customer Name: Redcliffe lifetech Pvt. Ltd. Ratlam

Model : Automated Hematology Analyzer Elite 580

Serial No. :K110522110C

Calibration Done Date: 8.6.23

Next Calibration Due Date On or Before: 7.6.24

Lab In-charge: . Mr. Narendra Singh Jadav

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
Designation
Transasia Bio-Medicals Ltd
Location

Encl:

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



Date: 08-06-2023

Effective Date: 08-06-2023

Certificate of Inspection

1. Model: Automated Hematology Analyzer ELITE 580
2. Serial No.: K11052211008
3. Calibration Date: 08-06-2023
4. Material used: H Cal (Lot No. PLUS0523, Expiry date: 10-June-2023)

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.

Technical Service Department
Transasia Bio-Medicals Ltd




16-2023

16-2023

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


Technical Service Department
Transasia Bio-Medicals Ltd

Hematology Analysis Report

First Name:
Last Name:
Gender:
Age:

Sample Type:
Department:
Patient ID:

Sample ID: background
Run Time: 08-06-2023 08:15
Diagnosis:

Parameter	Result	Ref. Range	Unit	Parameter	Result	Ref. Range	Unit
1 WBC	0.00 ↓		10 ³ /uL	16 P-LCC	****		10 ⁹ /L
2 RBC	0.00 ↓		10 ⁶ /uL				
3 HGB	0.0 ↓		g/dL				
4 HCT	0.0 ↓		%				
5 MCV	****		fL				
6 MCH	****		pg				
7 MCHC	****		g/dL				
8 RDW-CV	***		%				
9 RDW-SD	****		fL				
10 PLT	0 ↓		10 ³ /uL				
11 MPV	***		fL				
12 PDW-SD	***		fL				
13 PDW-CV	***		%				
14 PCT	***		%				
15 P-LCR	***		%				

Sample Type:
Description:

Microscopic exam. Time:

Submitter:

Operator: admin

Approver:

Sampling Time: 08-06-2023 08:15

Delivery Time: 08-06-2023 08:15

Validated Time:

Report Time: 2023/06/08 13:00

Remarks:

***The Report is responsible for this sample only. If you have any questions, please contact us in 24 hours.**



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

SMP NO	WBC	RBC	HGB	MCV	PLT
PRECISION1	9.68	5.35	11	65.5	281
PRECISION2	9.96	5.34	11.1	65.4	280
PRECISION3	9.8	5.29	11.1	65.4	289
PRECISION4	9.53	5.32	11	65.4	279
PRECISION5	9.54	5.30	11	65.4	292
PRECISION6	9.72	5.31	11.1	65.4	276
PRECISION7	9.84	5.33	11.1	65.7	278
PRECISION8	9.54	5.33	11	65.7	271
PRECISION9	9.73	5.35	11.1	65.3	282
PRECISION10	9.59	5.28	11	65.5	275
Mean	9.69	5.32	11.05	65.47	280.30
SD	0.15	0.02	0.05	0.13	6.29
CV%	1.50	0.46	0.48	0.20	2.24
Acceptable CV%	Within 3.5%	Within 2.0%	Within 1.5%	Within 2.0%	Within 6.0%
Result	PASS	PASS	PASS	PASS	PASS

[Signature]
 Technical Service Department
 Transasia Bio Medicals Ltd

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	9.44	4.61	130	91.4	258
	Relative expansion Uncertainty %	2.1	0.3	0.5	0.4	4.2
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
H560 (SW A12.2 or higher; version A only)	Calibrator	9.17	4.50	130	90.8	263
	Relative expansion Uncertainty %	2.2	0.6	0.3	0.1	4.4
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
H560 (SW B1.0 or higher)	Calibrator	9.27	4.52	129	87.0	269
	Relative expansion Uncertainty %	2.6	0.5	0.4	0.2	4.3
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
ELite 580 (SW A10.4 or higher)	Calibrator	9.42	4.39	131	88.0	250
	Relative expansion Uncertainty %	2.5	0.4	0.2	0.3	4.1
	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 26.05.2023

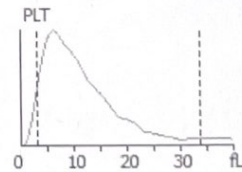
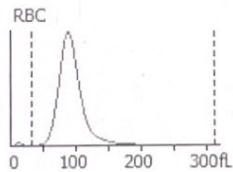
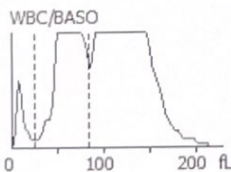


L-J QC Analysis

File No.: 13 Lot No.: EH2305 Level: Normal
 Operator: admin Exp. Date: 2023/07/10 Run Time: 08-06-2023 15:07
 Print Time: 2023/06/08 16:13 QC Mode: Whole Blood-CBC+DIFF QC Sample ID:

Parameter	Result	Ref. Range	Unit
1 WBC	8.54	7.20-9.20	10³/uL
2 Neu%	59.6	49.3-65.3	%
3 Lym%	30.9	22.4-38.4	%
4 Mon%	6.3	0.6-10.6	%
5 Eos%	3.2	0.7-12.7	%
6 Bas%	70.2	62.1-78.1	%
7 Neu#	5.09	3.97-5.43	10 ³ /uL
8 Lym#	2.64	1.79-3.19	10 ³ /uL
9 Mon#	0.54	0.00-0.92	10 ³ /uL
● Eos#	0.27	0.05-1.05	10 ³ /uL
11 Bas#	5.99	5.05-6.45	10 ³ /uL
12 RBC	4.54	4.39-4.87	10⁶/uL
13 HGB	13.3	12.4-14.0	g/dL
14 HCT	41.2	37.6-43.6	%
15 MCV	90.8	83.2-94.2	fL
16 MCH	29.3	26.1-31.1	pg
17 MCHC	32.2	29.6-35.6	g/dL
18 RDW-CV	18.4	13.4-21.4	%
19 RDW-SD	61.5	45.9-74.3	fL
20 PLT	259	216-296	10³/uL
21 MPV	9.0	6.7-12.7	fL
22 PDW-SD	10.5	9.0-15.0	fL
23 PDW-CV	15.7	13.1-19.1	%
● PCT	0.232	0.149-0.349	%
25 P-LCR	20.7	17.7-33.7	%
26 P-LCC	54	41-91	10 ⁹ /L

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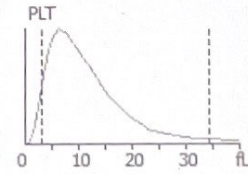
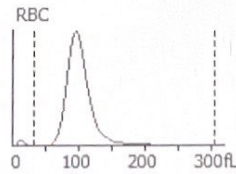
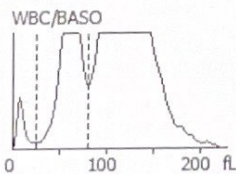


L-J QC Analysis

File No.: 15 Lot No.: EH2305 Level: High
 Operator: admin Exp. Date: 2023/07/10 Run Time: 08-06-2023 15:05
 Print Time: 2023/06/08 16:12 QC Mode: Whole Blood-CBC+DIFF QC Sample ID:

Parameter	Result	Ref. Range	Unit
1 WBC	17.98	16.02-21.02	10³/uL
2 Neu%	68.2	56.3-70.3	%
3 Lym%	21.2	15.6-27.6	%
4 Mon%	6.6	0.1-12.1	%
5 Eos%	4.0	2.0-16.0	%
6 Bas%	81.1	71.0-87.0	%
7 Neu#	12.27	10.58-13.38	10 ³ /uL
8 Lym#	3.82	2.90-5.10	10 ³ /uL
9 Mon#	1.18	0.03-2.23	10 ³ /uL
● Eos#	0.71	0.37-2.97	10 ³ /uL
11 Bas#	14.57	13.13-16.13	10 ³ /uL
12 RBC	5.03	4.76-5.76	10⁶/uL
13 HGB	16.2	15.7-17.3	g/dL
14 HCT	49.4	46.0-54.0	%
15 MCV	98.3	88.2-102.2	fL
16 MCH	32.2	28.9-33.9	pg
17 MCHC	32.8	30.1-36.1	g/dL
18 RDW-CV	16.6	13.4-19.4	%
19 RDW-SD	60.0	41.9-71.9	fL
20 PLT	445	419-539	10³/uL
21 MPV	9.0	7.0-13.0	fL
22 PDW-SD	10.5	9.6-15.6	fL
23 PDW-CV	15.6	13.4-19.4	%
● PCT	0.402	0.279-0.679	%
25 P-LCR	20.9	18.1-34.1	%
26 P-LCC	93	86-164	10 ⁹ /L

Palmer

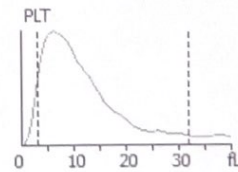
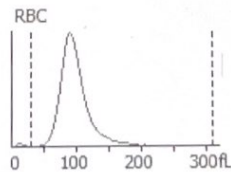
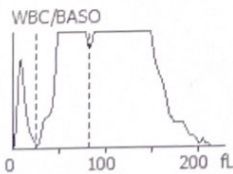


L-J QC Analysis

File No.: 13 Lot No.: EH2305 Level: Normal
 Operator: admin Exp. Date: 2023/07/10 Run Time: 26-06-2023 08:59
 Print Time: 2023/06/26 11:25 QC Mode: Whole Blood-CBC+DIFF QC Sample ID:

Parameter	Result	Ref. Range	Unit
1 WBC	8.74	7.20-9.20	10³/uL
2 Neu%	58.9	49.3-65.3	%
3 Lym%	31.7	22.4-38.4	%
4 Mon%	6.5	0.6-10.6	%
5 Eos%	2.9	0.7-12.7	%
6 Bas%	70.5	62.1-78.1	%
7 Neu#	5.15	3.97-5.43	10 ³ /uL
8 Lym#	2.78	1.79-3.19	10 ³ /uL
9 Mon#	0.56	0.00-0.92	10 ³ /uL
10 Eos#	0.25	0.05-1.05	10 ³ /uL
11 Bas#	6.16	5.05-6.45	10 ³ /uL
12 RBC	4.59	4.39-4.87	10⁶/uL
13 HGB	13.6	12.4-14.0	g/dL
14 HCT	43.2	37.6-43.6	%
15 MCV	94.1	83.2-94.2	fL
16 MCH	29.5	26.1-31.1	pg
17 MCHC	31.4	29.6-35.6	g/dL
18 RDW-CV	21.1	13.4-21.4	%
19 RDW-SD	74.0	45.9-74.3	fL
20 PLT	252	216-296	10³/uL
21 MPV	9.0	6.7-12.7	fL
22 PDW-SD	10.5	9.0-15.0	fL
23 PDW-CV	15.8	13.1-19.1	%
24 PCT	0.227	0.149-0.349	%
25 P-LCR	20.9	17.7-33.7	%
26 P-LCC	53	41-91	10 ⁹ /L

Admin



L-J QC Analysis

File No.: 15 Lot No.: EH2305 Level: High
 Operator: admin Exp. Date: 2023/07/10 Run Time: 26-06-2023 09:05
 Print Time: 2023/06/26 11:22 QC Mode: Whole Blood-CBC+DIFF QC Sample ID:

Parameter	Result	Ref. Range	Unit
1 WBC	19.20	16.02-21.02	10³/uL
2 Neu%	68.0	56.3-70.3	%
3 Lym%	21.1	15.6-27.6	%
4 Mon%	7.3	0.1-12.1	%
5 Eos%	3.6	2.0-16.0	%
6 Bas%	80.1	71.0-87.0	%
7 Neu#	13.06	10.58-13.38	10 ³ /uL
8 Lym#	4.05	2.90-5.10	10 ³ /uL
9 Mon#	1.40	0.03-2.23	10 ³ /uL
10 Eos#	0.69	0.37-2.97	10 ³ /uL
11 Bas#	15.38	13.13-16.13	10 ³ /uL
12 RBC	5.20	4.76-5.76	10⁶/uL
13 HGB	16.7	15.7-17.3	g/dL
14 HCT	52.8	46.0-54.0	%
15 MCV	101.4	88.2-102.2	fL
16 MCH	32.1	28.9-33.9	pg
17 MCHC	31.6	30.1-36.1	g/dL
18 RDW-CV	18.8	13.4-19.4	%
19 RDW-SD	71.0	41.9-71.9	fL
20 PLT	472	419-539	10³/uL
21 MPV	8.9	7.0-13.0	fL
22 PDW-SD	10.0	9.6-15.6	fL
23 PDW-CV	15.4	13.4-19.4	%
24 PCT	0.418	0.279-0.679	%
25 P-LCR	19.2	18.1-34.1	%
26 P-LCC	91	86-164	10 ⁹ /L

Admin

