

Date: 25.01.2023  
Effective Date: 25.01.2023

## Certificate of Calibration

**Customer Name: Redcliffe Lifetech Pvt. Ltd. Bhopal M.P.**

**Model : Automated Hematology Analyzer Elite 580**

**Serial No. : K11052211031**

**Calibration Done Date: 25.01.2023**

**Next Calibration Due Date On or Before: 24.01.2024**

**Lab In-charge: . Dr. Sakar Saxena**

*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 Sudhir Ahirwar  
Designation Sr. Service Engineer  
Transasia Bio-Medicals Ltd  
Location Bhopal M.P.

Encl:

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

Date: 25.01.2023

Effective Date: 25.01.2023

## Certificate of Inspection

1. Model: Automated Hematology Analyzer Elite 580
2. Serial No.: K11052211031
3. Calibration Date: 25.01.2023
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.



Technical Service Department  
Transasia Bio-Medicals Ltd

Transasia Bio-Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai- 400 072  
Tel: +91 22 4030 9000 Fax: +91 22 2857 3030

## 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 (ORIGINALS ATTACHED)

SMP NO	WBC	RBC	HGB	MCV	PLT
1	9.01	4.49	13.4	87	246
2	9.26	4.5	13.6	87	251
3	9.01	4.45	13.5	86.8	243
4	9.13	4.56	13.6	87.2	238
5	9.21	4.45	13.6	87.1	242
6	9.26	4.47	13.6	87.1	252
7	9.03	4.48	13.6	87.2	243
8	9.16	4.47	13.6	86.9	249
9	9.08	4.5	13.5	86.9	235
10	9.36	4.57	13.6	87.2	239
Mean	9.15	4.49	13.56	87.04	243.80
SD	0.12	0.04	0.07	0.14	5.67
CV%	1.32	0.92	0.52	0.16	2.33
Acceptable CV%	Within 3.5%	Within 2.0%	Within 1.5%	Within 2.0%	Within 6.0%
Result	PASS	PASS	PASS	PASS	PASS



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<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	9.23	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

## History

Cal. Operator : admin

Cal. Method : Calibrator

Cal. Mode : Whole Blood

Cal. Time : 2023/01/25 14:22:33

Description : PLUS0123(Lot No.) 2023/02/10(Exp. Date)

Print Time : 2023/05/29 11:34:13

### Details

Para.	WBC	RBC	HGB	MCV	PLT
Target	9.2	4.52	13.5	85.3	250
1	9.01	4.49	13.4	87	246
2	9.26	4.5	13.6	87	251
3	9.01	4.45	13.5	86.8	243
4	9.13	4.56	13.6	87.2	238
5	9.21	4.45	13.6	87.1	242
6	9.26	4.47	13.6	87.1	252
7	9.03	4.48	13.6	87.2	243
8	9.16	4.47	13.6	86.9	249
9	9.08	4.5	13.5	86.9	235
10	9.36	4.57	13.6	87.2	239
New Calibration Coefficient (%)	100.54	100.58	99.56	98.00	102.54
Original Calibration Coefficient (%)	100.00	100.00	100.00	100.00	100.00

# Calibration Coefficient

Print Time: 2023/05/29 11:43:00

Whole Blood Mode

PARA.	CAL. COEFFICIENT (%)	CAL. DATE
WBC	100.54	2023/01/25
RBC	100.58	2023/01/25
HGB	99.56	2023/01/25
MCV	98.00	2023/01/25
PLT	102.54	2023/01/25

Predilute Mode

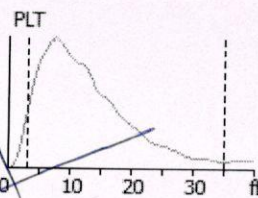
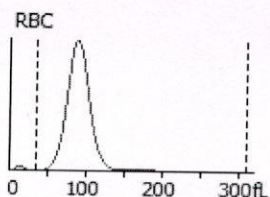
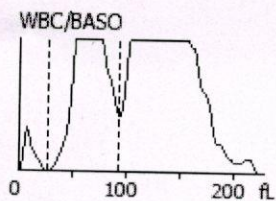
PARA.	CAL. COEFFICIENT (%)	CAL. DATE
WBC	100.00	2022/03/20
RBC	100.00	2022/03/20
HGB	100.00	2022/03/20
MCV	100.00	2022/03/20
PLT	100.00	2022/03/20



# L-J QC Analysis

File No.: 5      Lot No.: Elite H5 con N      Level: Normal  
 Operator: admin      Exp. Date: 2023/03/10      Run Time: 2023/01/25 15:35  
 Print Time: 2023/01/25 15:36      QC Mode: Whole Blood-CBC+DIFF      QC Sample ID: 2301

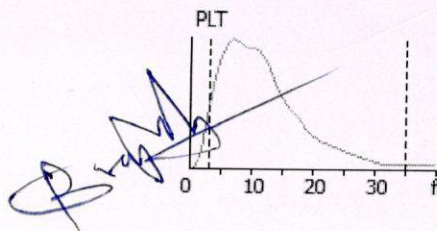
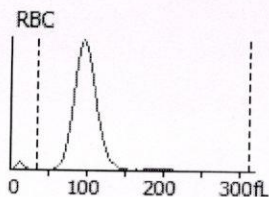
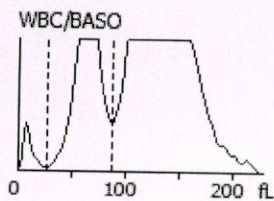
Parameter	Result	Ref. Range	Unit
<b>1 WBC</b>	<b>8.20</b>	<b>6.96-8.96</b>	<b>10<sup>3</sup>/uL</b>
2 Neu%	59.2	48.2-64.2	%
3 Lym%	30.4	23.3-39.3	%
4 Mon%	6.5	1.4-11.4	%
5 Eos%	3.9	0.1-12.1	%
6 Bas%	69.9	61.8-77.8	%
7 Neu#	4.86	3.77-5.17	10 <sup>3</sup> /uL
8 Lym#	2.50	1.79-3.19	10 <sup>3</sup> /uL
9 Mon#	0.53	0.01-1.01	10 <sup>3</sup> /uL
10 Eos#	0.31	0.00-0.98	10 <sup>3</sup> /uL
11 Bas#	5.73	4.85-6.25	10 <sup>3</sup> /uL
<b>12 RBC</b>	<b>4.63</b>	<b>4.31-4.79</b>	<b>10<sup>6</sup>/uL</b>
13 HGB	13.1	12.6-13.8	g/dL
14 HCT	39.5	36.0-42.0	%
15 MCV	85.2	80.6-90.6	fL
16 MCH	28.3	26.5-31.5	pg
17 MCHC	33.2	31.6-37.6	g/dL
18 RDW-CV	15.9	14.0-20.0	%
19 RDW-SD	50.3	41.3-61.3	fL
<b>20 PLT</b>	<b>257</b>	<b>222-302</b>	<b>10<sup>3</sup>/uL</b>
21 MPV	10.0	6.6-12.6	fL
22 PDW-SD	12.5	8.4-14.4	fL
23 PDW-CV	16.4	12.7-18.7	%
24 PCT	0.258	0.151-0.351	%
25 P-LCR	27.8	15.7-31.7	%
26 P-LCC	71	37-87	10 <sup>9</sup> /L



# L-J QC Analysis

File No.:	6	Lot No.:	Elite H5 con H	Level:	High
Operator:	admin	Exp. Date:	2023/03/10	Run Time:	2023/01/25 15:39
Print Time:	2023/01/25 15:41	QC Mode:	Whole Blood-CBC+DIFF	QC Sample ID:	2301

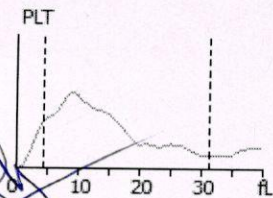
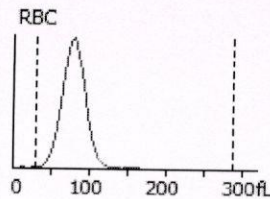
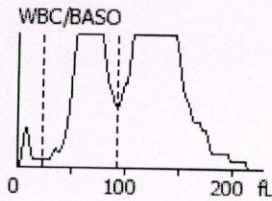
Parameter	Result	Ref. Range	Unit
<b>1 WBC</b>	<b>18.52</b>	<b>15.22-20.22</b>	<b>10<sup>3</sup>/uL</b>
2 Neu%	67.1	58.6-72.6	%
3 Lym%	20.8	14.5-26.5	%
4 Mon%	7.2	0.5-12.5	%
5 Eos%	4.9	0.0-11.0	%
6 Bas%	80.6	72.6-88.6	%
7 Neu#	12.43	10.22-13.02	10 <sup>3</sup> /uL
8 Lym#	3.86	2.53-4.73	10 <sup>3</sup> /uL
9 Mon#	1.33	0.05-2.25	10 <sup>3</sup> /uL
10 Eos#	0.90	0.00-2.30	10 <sup>3</sup> /uL
11 Bas#	14.93	12.78-15.78	10 <sup>3</sup> /uL
<b>12 RBC</b>	<b>5.25</b>	<b>4.78-5.78</b>	<b>10<sup>6</sup>/uL</b>
13 HGB	16.5	15.9-17.5	g/dL
14 HCT	49.0	45.0-53.0	%
15 MCV	93.5	86.8-98.8	fL
16 MCH	31.5	29.2-34.2	pg
17 MCHC	33.7	31.8-37.8	g/dL
18 RDW-CV	14.6	13.2-19.2	%
19 RDW-SD	50.1	40.6-64.6	fL
<b>20 PLT</b>	<b>461</b>	<b>427-547</b>	<b>10<sup>3</sup>/uL</b>
21 MPV	9.5	7.0-13.0	fL
22 PDW-SD	11.3	9.1-15.1	fL
23 PDW-CV	15.7	12.8-18.8	%
24 PCT	0.437	0.287-0.687	%
25 P-LCR	23.1	17.5-33.5	%
26 P-LCC	107	89-159	10 <sup>9</sup> /L



# L-J QC Analysis

File No.: 4      Lot No.: Elite H5 con L      Level: Low  
 Operator: admin      Exp. Date: 2023/03/10      Run Time: 2023/01/25 15:38  
 Print Time: 2023/01/25 15:39      QC Mode: Whole Blood-CBC+DIFF      QC Sample ID: 2301

Parameter	Result	Ref. Range	Unit
<b>1 WBC</b>	<b>3.60</b>	<b>2.77-3.77</b>	<b>10<sup>3</sup>/uL</b>
2 Neu%	52.9	41.0-59.0	%
3 Lym%	37.8	30.1-48.1	%
4 Mon%	6.1	2.6-10.6	%
5 Eos%	3.2	0.0-8.0	%
6 Bas%	60.7	53.2-69.2	%
7 Neu#	1.91	1.24-2.04	10 <sup>3</sup> /uL
8 Lym#	1.37	0.88-1.68	10 <sup>3</sup> /uL
9 Mon#	0.21	0.08-0.36	10 <sup>3</sup> /uL
10 Eos#	0.11	0.00-0.20	10 <sup>3</sup> /uL
11 Bas#	2.18	1.70-2.30	10 <sup>3</sup> /uL
<b>12 RBC</b>	<b>2.30</b>	<b>2.09-2.45</b>	<b>10<sup>6</sup>/uL</b>
13 HGB	5.7	5.2-6.0	g/dL
14 HCT	17.3	15.3-19.3	%
15 MCV	75.5	71.3-81.3	fL
16 MCH	24.7	22.3-27.3	pg
17 MCHC	32.7	30.1-36.1	g/dL
18 RDW-CV	18.7	15.1-21.1	%
19 RDW-SD	52.3	38.6-58.6	fL
<b>20 PLT</b>	<b>68</b>	<b>32-72</b>	<b>10<sup>3</sup>/uL</b>
21 MPV	11.1	7.0-13.0	fL
22 PDW-SD	11.5	11.2-17.6	fL
23 PDW-CV	13.9	12.3-18.7	%
24 PCT	0.076	0.000-0.094	%
25 P-LCR	32.1	22.7-37.5	%
26 P-LCC	22	3-27	10 <sup>9</sup> /L



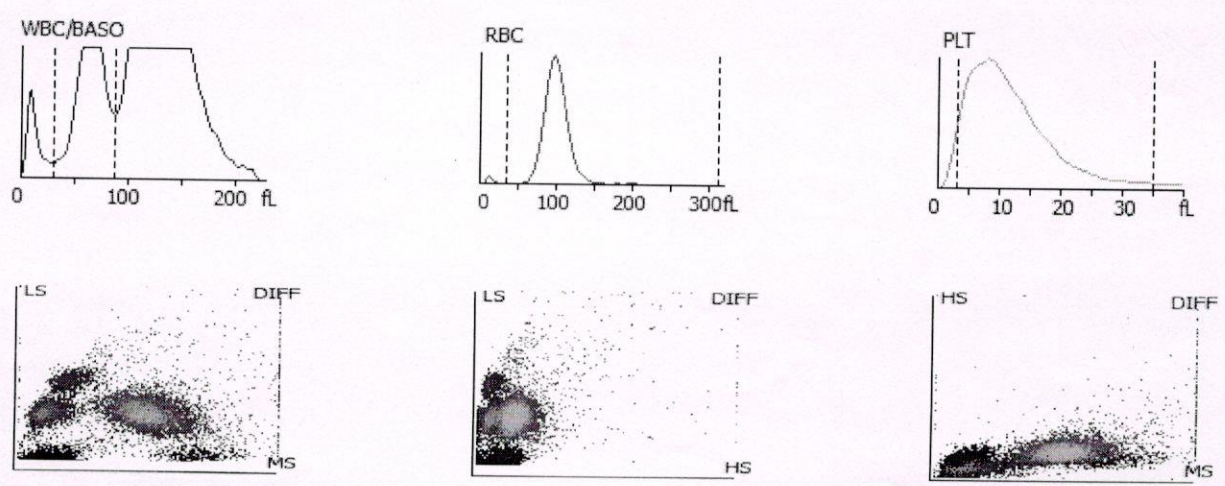
# L-J QC Analysis

File No.: 12      Lot No.: Elite H5 con H      Level: High  
 Operator: admin      Exp. Date: 2023/07/10      Run Time: 2023/06/23 08:27  
 Print Time: 2023/06/23 08:34      QC Mode: Whole Blood-CBC+DIFF      QC Sample ID: 2305

Parameter	Result	Ref. Range	Unit
<b>1 WBC</b>	<b>19.02</b>	<b>16.02-21.02</b>	<b>10<sup>3</sup>/uL</b>
2 Neu%	68.6	56.3-70.3	%
3 Lym%	20.7	15.6-27.6	%
4 Mon%	6.2	0.1-12.1	%
5 Eos%	4.5	2.0-16.0	%
6 Bas%	80.8	71.0-87.0	%
7 Neu#	13.05	10.32-13.12	10 <sup>3</sup> /uL
8 Lym#	3.94	2.90-5.10	10 <sup>3</sup> /uL
9 Mon#	1.18	0.03-2.23	10 <sup>3</sup> /uL
10 Eos#	0.85	0.37-2.97	10 <sup>3</sup> /uL
11 Bas#	15.36	13.13-16.13	10 <sup>3</sup> /uL
<b>12 RBC</b>	<b>5.31</b>	<b>4.76-5.76</b>	<b>10<sup>6</sup>/uL</b>
13 HGB	16.9	15.7-17.3	g/dL
14 HCT	50.0	46.0-54.0	%
15 MCV	94.1	89.2-101.2	fL
16 MCH	31.8	28.9-33.9	pg
17 MCHC	33.8	30.1-36.1	g/dL
18 RDW-CV	14.6	13.4-19.4	%
19 RDW-SD	51.0	42.6-66.6	fL
<b>20 PLT</b>	<b>448</b>	<b>419-539</b>	<b>10<sup>3</sup>/uL</b>
21 MPV	9.4	7.0-13.0	fL
22 PDW-SD	11.4	9.6-15.6	fL
23 PDW-CV	15.9	13.4-19.4	%
24 PCT	0.420	0.279-0.679	%
25 P-LCR	22.6	18.1-34.1	%
26 P-LCC	101	90-160	10 <sup>9</sup> /L

*(Handwritten signature/initials)*

*Aakash*



# L-J QC Analysis

File No.: 11      Lot No.: Elite H5 con N      Level: Normal  
 Operator: admin      Exp. Date: 2023/07/10      Run Time: 2023/06/23 08:25  
 Print Time: 2023/06/23 08:34      QC Mode: Whole Blood-CBC+DIFF      QC Sample ID: 2305

Parameter	Result	Ref. Range	Unit
<b>1 WBC</b>	<b>8.31</b>	<b>7.20-9.20</b>	<b>10<sup>3</sup>/uL</b>
2 Neu%	60.7	49.3-65.3	%
3 Lym%	29.1	22.4-38.4	%
4 Mon%	6.2	0.6-10.6	%
5 Eos%	4.0	0.7-12.7	%
6 Bas%	70.6	62.1-78.1	%
7 Neu#	5.05	4.00-5.40	10 <sup>3</sup> /uL
8 Lym#	2.42	1.79-3.19	10 <sup>3</sup> /uL
9 Mon#	0.51	0.00-0.92	10 <sup>3</sup> /uL
10 Eos#	0.33	0.05-1.05	10 <sup>3</sup> /uL
11 Bas#	5.87	5.05-6.45	10 <sup>3</sup> /uL
<b>12 RBC</b>	<b>4.58</b>	<b>4.39-4.87</b>	<b>10<sup>6</sup>/uL</b>
13 HGB	13.3	12.6-13.8	g/dL
14 HCT	39.4	37.6-43.6	%
15 MCV	86.2	82.8-92.8	fL
16 MCH	29.0	26.1-31.1	pg
17 MCHC	33.7	29.6-35.6	g/dL
18 RDW-CV	15.9	14.4-20.4	%
19 RDW-SD	51.0	43.7-63.7	fL
<b>20 PLT</b>	<b>248</b>	<b>216-296</b>	<b>10<sup>3</sup>/uL</b>
21 MPV	9.5	6.7-12.7	fL
22 PDW-SD	10.8	9.0-15.0	fL
23 PDW-CV	15.5	13.1-19.1	%
24 PCT	0.235	0.149-0.349	%
25 P-LCR	22.8	17.7-33.7	%
26 P-LCC	56	11-121	10 <sup>9</sup> /L



Dikash

