

Date: 26-06-2023  
Effective Date: 26-06-2023

## Certificate of Calibration

**Customer Name: Redclieff Lifetech P. Ltd Ahmedabad**

**Model : Automated Hematology Analyzer Elite 580**

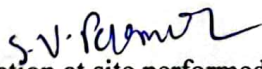
**Serial No. : 1105220304**

**Calibration Done Date: 26.6.23**

**Next Calibration Due Date On or Before: 26-06-2024**

**Lab In-charge: . Dr. Kamal Jadhav**

*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  
Shailesh Parmar  
Area Service Manager  
Transasia Bio-Medicals Ltd  
Ahmedabad

Encl:

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

Date: 26-06-2023  
Effective Date: 26-06-2023

## Certificate of Inspection

1. Model: Automated Hematology Analyzer Elite 580
2. Serial No.: K11052203046
3. Calibration Date: 26-06-2023
4. Material used: H Cal (Lot No. PLUS0623, Expiry date: 10-July-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.

*S. J. Chavhan*

Technical Service Department  
Transasia Bio-Medicals Ltd

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

SMP NO	WBC	RBC	HGB	MCV	PLT
2	6.61	4.42	12.9	92.4	257
3	6.49	4.41	12.9	92.6	260
4	6.53	4.43	13	92.5	247
5	6.44	4.41	13	92.4	256
6	6.32	4.46	13	92.4	246
7	6.4	4.43	13	92.3	253
8	6.51	4.42	13	92.1	253
9	6.6	4.44	13.3	92.2	254
10	6.31	4.43	12.9	92.2	260
11	6.49	4.39	13	92.1	245
Mean	6.47	4.42	13.00	92.32	253.10
SD	0.10	0.02	0.12	0.17	5.51
CV%	1.60	0.43	0.89	0.18	2.18
Acceptable CV%	Within 3.5%	Within 2.0%	Within 1.5%	Within 2.0%	Within 6.0%
Result	PASS	PASS	PASS	PASS	PASS

*S. V. Kumar*

Technical Service Department  
Transasia Bio Medicals Ltd

## 5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.0	$0.3 \times 10^3/\text{UI}$ or Less
RBC	0.0	$0.02 \times 10^6/\text{uL}$ or Less
HGB	0.0	0.1 g/dL or Less
PLT	0.0	$10 \times 10^3/\text{uL}$ or Less

*S. V. Patil*

Technical Service Department  
Transasia Bio-Medicals Ltd

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

## Calibrator

Lot No.: PLUS0623  
 Calibration Mode: Whole Blood

Exp. Date: 2023/07/19  
 Print Time: 2023/06/26 18:48:44

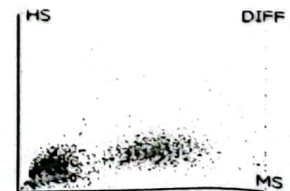
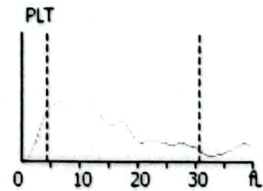
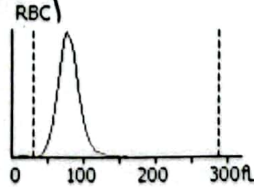
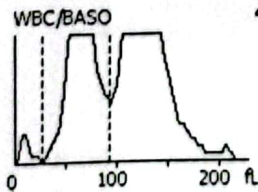
PARA.	WBC	RBC	HGB	MCV	PLT
Target	9.23	4.56	13.1	85.4	251
√1	9.05	4.44	12.9	87.8	242
√2	9.12	4.42	12.9	87.9	248
√3	9.28	4.49	12.9	87.7	264
√4	9.23	4.47	12.8	87.7	246
√5	9.06	4.41	12.9	88.0	247
√6	9.03	4.47	12.8	87.6	252
√7	9.14	4.46	12.9	87.7	251
√8	9.16	4.40	12.9	87.9	246
√9	9.23	4.45	12.8	87.7	247
√10	9.05	4.40	12.7	88.0	239
Mean	9.135	4.441	12.85	87.80	248.2
CV(%)	1.0	0.7	0.6	0.2	2.7
Calibration Coefficient (%)	101.04	102.68	101.95	97.27	101.13
Final Calibration Coefficient (%)	99.54	102.19	101.84	99.50	96.17

# L-J QC Analysis

File No.:	16	Lot No.:	EH2305L	Level:	Low
Operator:	admin	Exp. Date:	2023/07/10	Run Time:	2023/06/27 10:25
Print Time:	2023/06/27 10:28	QC Mode:	Whole Blood-CBC+DIFF	QC Sample ID:	

Parameter	Result	Ref. Range	Unit
1 WBC	3.64	3.11-4.11	10 <sup>3</sup> /uL
2 Neu%	51.3	38.8-56.8	%
3 Lym%	40.6	32.0-50.0	%
4 Mon%	4.8	2.1-10.1	%
5 Eos%	3.3	0.1-10.1	%
6 Bas%	58.7	50.8-66.8	%
7 Neu#	1.87	1.32-2.12	10 <sup>3</sup> /uL
8 Lym#	1.48	1.08-1.88	10 <sup>3</sup> /uL
9 Mon#	0.17	0.08-0.36	10 <sup>3</sup> /uL
10 Eos#	0.12	0.03-0.33	10 <sup>3</sup> /uL
11 Bas#	2.14	1.82-2.42	10 <sup>3</sup> /uL
12 RBC	2.26	2.09-2.45	10 <sup>6</sup> /uL
13 HGB	5.5	5.1-5.9	g/dL
14 HCT	17.8	15.6-19.6	%
15 MCV	78.9	72.5-82.5	fL
16 MCH	24.3	22.0-27.0	pg
17 MCHC	30.8	28.5-34.5	g/dL
18 RDW-CV	18.7	15.9-21.9	%
19 RDW-SD	53.9	41.9-61.9	fL
20 PLT	64	33-73	10 <sup>3</sup> /uL
21 MPV	10.9	7.2-13.2	fL
22 PDW-SD	12.9	8.5-14.5	fL
23 PDW-CV	15.2	10.8-16.8	%
24 PCT	0.069	0.004-0.104	%
25 P-LCR	32.2	18.6-34.6	%
26 P-LCC	21	0-28	10 <sup>9</sup> /L

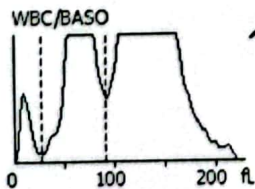
Pan  
27/6/23



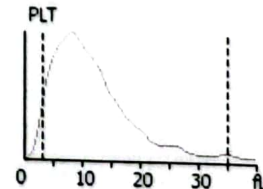
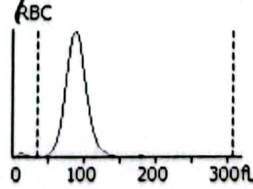
# L-J QC Analysis

File No.: 17      Lot No.: EH2305N      Level: Normal  
 Operator: admin      Exp. Date: 2023/07/10      Run Time: 2023/06/27 10:15  
 Print Time: 2023/06/27 10:20      QC Mode: Whole Blood-CBC+DIFF      QC Sample ID:

Parameter	Result	Ref. Range	Unit
1 WBC	8.52	7.20-9.20	10 <sup>3</sup> /uL
2 Neu%	58.4	49.3-65.3	%
3 Lym%	32.3	22.4-38.4	%
4 Mon%	5.5	0.6-10.6	%
5 Eos%	3.8	0.7-12.7	%
6 Bas%	71.1	62.1-78.1	%
7 Neu#	4.98	4.00-5.40	10 <sup>3</sup> /uL
8 Lym#	2.76	1.79-3.19	10 <sup>3</sup> /uL
9 Mon#	0.46	0.00-0.92	10 <sup>3</sup> /uL
10 Eos#	0.32	0.05-1.05	10 <sup>3</sup> /uL
11 Bas#	6.06	5.05-6.45	10 <sup>3</sup> /uL
12 RBC	4.55	4.39-4.87	10 <sup>6</sup> /uL
13 HGB	13.3	12.6-13.8	g/dL
14 HCT	40.1	37.6-43.6	%
15 MCV	88.2	82.8-92.8	fL
16 MCH	29.3	26.1-31.1	pg
17 MCHC	33.2	29.6-35.6	g/dL
18 RDW-CV	16.1	14.4-20.4	%
19 RDW-SD	52.2	43.7-63.7	fL
20 PLT	274	216-296	10 <sup>3</sup> /uL
21 MPV	9.5	6.7-12.7	fL
22 PDW-SD	11.3	9.0-15.0	fL
23 PDW-CV	15.6	13.1-19.1	%
24 PCT	0.260	0.149-0.349	%
25 P-LCR	22.8	17.7-33.7	%
26 P-LCC	62	41-91	10 <sup>9</sup> /L



*Handwritten:* Run 27/6/2023



# L-J QC Analysis

File No.: 18                      Lot No.: EH2305H                      Level: High  
 Operator: admin                      Exp. Date: 2023/07/10                      Run Time: 2023/06/27 10:12  
 Print Time: 2023/06/27 10:14                      QC Mode: Whole Blood-CBC+DIFF                      QC Sample ID:

Parameter	Result	Ref. Range	Unit
1 WBC	18.36	16.02-21.02	10 <sup>3</sup> /uL
2 Neu%	65.7	56.3-70.3	%
3 Lym%	22.4	15.6-27.6	%
4 Mon%	7.1	0.1-12.1	%
5 Eos%	4.8	2.0-16.0	%
6 Bas%	80.8	71.0-87.0	%
7 Neu#	12.07	10.32-13.12	10 <sup>3</sup> /uL
8 Lym#	4.11	2.90-5.10	10 <sup>3</sup> /uL
9 Mon#	1.30	0.03-2.23	10 <sup>3</sup> /uL
10 Eos#	0.88	0.37-2.97	10 <sup>3</sup> /uL
11 Bas#	14.83	13.13-16.13	10 <sup>3</sup> /uL
12 RBC	5.19	4.76-5.76	10 <sup>6</sup> /uL
13 HGB	16.6	15.7-17.3	g/dL
14 HCT	49.8	46.0-54.0	%
15 MCV	95.9	89.2-101.2	fL
16 MCH	31.9	28.9-33.9	pg
17 MCHC	33.3	30.1-36.1	g/dL
18 RDW-CV	14.7	13.4-19.4	%
19 RDW-SD	51.8	42.6-66.6	fL
20 PLT	501	419-539	10 <sup>3</sup> /uL
21 MPV	9.7	7.0-13.0	fL
22 PDW-SD	12.4	9.6-15.6	fL
23 PDW-CV	16.6	13.4-19.4	%
24 PCT	0.488	0.279-0.679	%
25 P-LCR	25.9	18.1-34.1	%
26 P-LCC	130	90-160	10 <sup>9</sup> /L

