

Date: 16/11/2022

Effective Date:

## Certificate of Calibration

**Customer Name: Redcliffe Lifetech Private Ltd Gwalior**

**Model : Automated Hematology Analyzer Elite 580**

**Serial No. :** [REDACTED] K11052203048

**Calibration Done Date: 16.11.22**

**Next Calibration Due Date On or Before:** [REDACTED]

**Lab In-charge: .** [REDACTED]

*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 Gaurav Chand Gupta

Designation Sr.service engineer

Transasia Bio-Medicals Ltd

Location Gwalior

Encl:

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

Date: 16/11/2022

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## Certificate of Inspection

1. Model: Automated Hematology Analyzer Elite 580

2. Serial No.:            0            K11052203048

3. Calibration Date: 16/11/2022

4. Material used: H Cal (Lot No. PLUS1122, Expiry date: 10-Dec-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.



Technical Service Department  
Transasia Bio-Medicals Ltd

**Erba**

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

SMP NO	WBC	RBC	HGB	MCV	PLT
1	9.19	4.52	13.2	86.2	261
2	9.23	4.47	13.1	86.4	257
3	9.09	4.49	13.2	86.7	250
4	9.31	4.55	13.2	86.5	268
5	9.10	4.46	13.0	86.5	252
6	8.88	4.49	13.1	86.4	256
7	9.19	4.45	13.1	86.7	249
8	9.01	4.51	13.2	86.5	261
9	9.29	4.54	13.0	86.3	254
10	8.86	4.44	13.1	86.6	249
Mean	9.14	4.49	13.12	86.48	255.70
SD	0.14	0.04	0.08	0.16	6.22
CV%	1.51	0.84	0.60	0.19	2.43
Acceptable CV%	Within 3.5%	Within 2.0%	Within 1.5%	Within 2.0%	Within 6.0%
Result	PASS	PASS	PASS	PASS	PASS

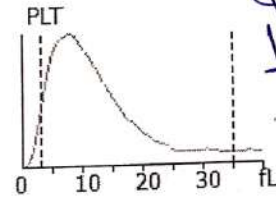
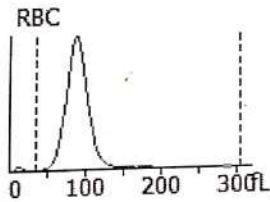
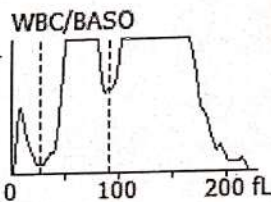


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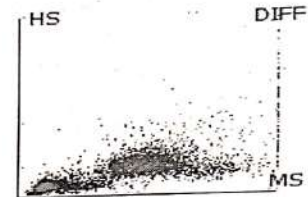
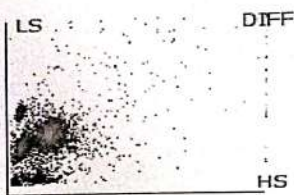
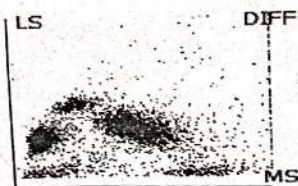
# L-J QC Analysis

File No.: 14                      Lot No.: EH2211NORMAL                      Level: Normal  
 Operator: admin                      Exp. Date: 2023/01/10                      Run Time: 2022/12/13 09:48  
 Print Time: 2022/12/13 12:35                      QC Mode: Whole Blood-CBC+DIFF                      QC Sample ID:

Parameter	Result	Ref. Range	Unit
<b>1 WBC</b>	<b>7.71</b>	<b>6.74-8.74</b>	<b>10<sup>3</sup>/uL</b>
2 Neu%	58.1	50.7-66.7	%
3 Lym%	29.2	21.7-37.7	%
4 Mon%	6.4	1.4-11.4	%
5 Eos%	6.3	0.0-10.4	%
6 Bas%	71.3	63.2-79.2	%
7 Neu#	4.48	3.84-5.24	10 <sup>3</sup> /uL
8 Lym#	2.26	1.60-3.00	10 <sup>3</sup> /uL
9 Mon#	0.49	0.00-1.00	10 <sup>3</sup> /uL
10 Eos#	0.48	0.00-0.80	10 <sup>3</sup> /uL
11 Bas#	5.49	4.81-6.21	10 <sup>3</sup> /uL
<b>12 RBC</b>	<b>4.32</b>	<b>4.32-4.80</b>	<b>10<sup>6</sup>/uL</b>
13 HGB	12.9	12.5-13.7	g/dL
14 HCT	38.3	36.0-42.0	%
15 MCV	88.6	80.5-90.5	fL
16 MCH	29.9	26.2-31.2	pg
17 MCHC	33.7	30.5-36.5	g/dL
18 RDW-CV	15.9	14.5-20.5	%
19 RDW-SD	52.4	42.3-62.3	fL
<b>20 PLT</b>	<b>241</b>	<b>195-275</b>	<b>10<sup>3</sup>/uL</b>
21 MPV	9.7	7.0-13.0	fL
22 PDW-SD	10.9	9.9-15.9	fL
23 PDW-CV	15.5	13.6-19.6	%
24 PCT	0.234	0.135-0.335	%
25 P-LCR	24.0	19.8-35.8	%
26 P-LCC	58	42-92	10 <sup>9</sup> /L



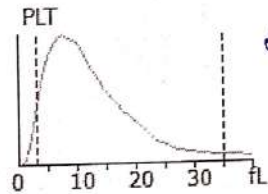
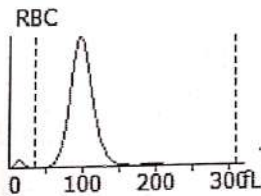
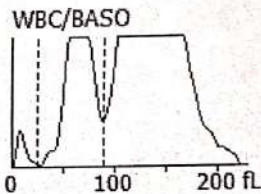
*Shinas*  
12/12/22



# L-J QC Analysis

File No.: 15                      Lot No.: EH2211HIGH                      Level: High  
 Operator: admin                      Exp. Date: 2023/01/10                      Run Time: 2022/12/13 09:51  
 Print Time: 2022/12/13 12:36                      QC Mode: Whole Blood-CBC+DIFF                      QC Sample ID:

Parameter	Result	Ref. Range	Unit
1 WBC	18.00	15.07-20.07	10 <sup>3</sup> /uL
2 Neu%	64.8	58.7-72.7	%
3 Lym%	19.7	14.3-26.3	%
4 Mon%	6.9	0.8-12.8	%
5 Eos%	8.6	0.2-14.2	%
6 Bas%	80.9	72.3-88.3	%
7 Neu#	11.67	10.14-12.94	10 <sup>3</sup> /uL
8 Lym#	3.55	2.47-4.67	10 <sup>3</sup> /uL
9 Mon#	1.24	0.09-2.29	10 <sup>3</sup> /uL
10 Eos#	1.54	0.00-2.54	10 <sup>3</sup> /uL
11 Bas#	14.57	12.61-15.61	10 <sup>3</sup> /uL
12 RBC	4.97	4.68-5.68	10 <sup>6</sup> /uL
13 HGB	16.7	15.9-17.5	g/dL
14 HCT	49.0	45.7-53.7	%
15 MCV	98.5	89.9-101.9	fL
16 MCH	33.6	29.8-34.8	pg
17 MCHC	34.1	30.7-36.7	g/dL
18 RDW-CV	15.6	13.8-19.8	%
19 RDW-SD	57.0	44.1-68.1	fL
20 PLT	503	417-537	10 <sup>3</sup> /uL
21 MPV	9.7	7.1-13.1	fL
22 PDW-SD	11.9	9.7-15.7	fL
23 PDW-CV	16.1	13.3-19.3	%
24 PCT	0.490	0.282-0.682	%
25 P-LCR	25.6	18.8-34.8	%
26 P-LCC	129	93-163	10 <sup>9</sup> /L



*Blp  
12/12/22*

