

Date:  
Effective Date:



## Certificate of Calibration

**Customer Name: Redcliffe Labs**

**Model : Automated Hematology Analyzer Elite 580**

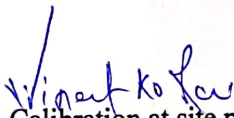
**Serial No. : K11052128083**

**Calibration Done Date: 23.9.22**

**Next Calibration Due Date On or Before: 23-09-2023**

**Lab In-charge: . Dr.Param Prakash**

*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  
Vineet Kumar Rai  
Sr.Service Engineer  
Transasia Bio-Medicals Ltd  
Delhi

Encl:

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



Date: ~~23-09-2022~~  
Effective Date: ~~23-09-2022~~  
UNMATCHED SINCE 1979

## Certificate of Inspection

1. Model: Automated Hematology Analyzer Elite 580
2. Serial No.: K11052128083
3. Calibration Date: 23-09-2022
4. Material used: H Cal (Lot No. PLUS0922, Expiry date: 10-Oct-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



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SINCE 1979...

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

SMP NO	WBC	RBC	HGB	MCV	PLT
1	7.01	4.62	15.4	96.6	203
2	6.93	4.66	15.5	97.1	197
3	6.9	4.67	15.6	96.4	196
4	7.12	4.62	15.5	96.7	200
5	7.03	4.59	15.5	96.8	197
6	7.15	4.58	15.5	4.58	197
7	7	4.64	15.5	96.8	191
8	7.07	4.63	15.4	96.8	192
9	7.19	4.73	15.5	97	193
10	7.18	4.69	15.5	96.8	191
Mean	7.06	4.64	15.49	87.51	195.70
SD	0.10	0.05	0.06	29.14	3.97
CV%	<b>1.44</b>	<b>0.98</b>	<b>0.37</b>	<b>33.30</b>	<b>2.03</b>
Acceptable CV%	Within 3.5%	Within 2.0%	Within 1.5%	Within 2.0%	Within 6.0%
Result	<b>PASS</b>	<b>PASS</b>	<b>PASS</b>	<b>FAIL</b>	<b>PASS</b>

*Amol Rehtani*  
Technical Service Department  
Transasia Bio Medicals Ltd



Cal. Operator : admin

Cal. Method : Calibrator

Cal. Mode : Whole Blood

Cal. Time : 2022/09/23 11:59:26

Description : PLUS0922(Lot No.) 2022/10/10(Exp. Date)

Print Time : 2023/05/18 17:47:49

Details

Para.	WBC	RBC	HGB	MCV	PLT
Target	9.27	4.49	13.3	84.6	258
1	9.5	4.4	13.6	88.4	265
2	9.74	4.36	13.5	88.3	254
3	9.67	4.38	13.5	88.5	248
4	9.53	4.4	13.7	88.4	260
5	9.61	4.45	13.6	88.4	247
6	9.31	4.37	13.5	88.4	255
7	9.52	4.42	13.6	88.6	256
8	9.74	4.45	13.6	88.4	258
9	9.48	4.37	13.6	88.4	253
10	9.44	4.41	13.7	88.6	270
New Calibration Coefficient (%)	97.03	102.02	97.87	95.66	100.55
Original Calibration Coefficient (%)	100.00	100.00	100.00	100.00	100.00

*Amal Rehman*



## 5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.0	0.3 x 10 <sup>3</sup> /U1 or Less
RBC	0.00	0.02 x 10 <sup>6</sup> /uL or Less
HGB	0.0	0.1 g/dL or Less
PLT	0	10 x 10 <sup>3</sup> /uL or Less

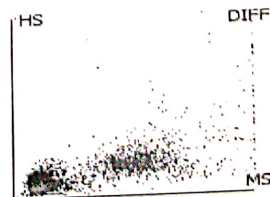
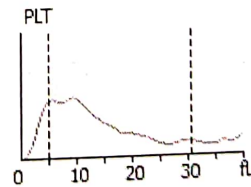
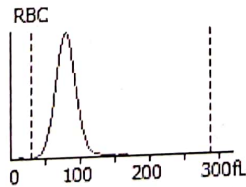
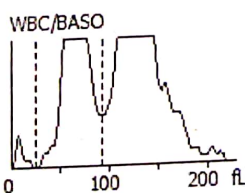
*Amal Khatkar*

Technical Service Department  
Transasia Bio-Medicals Ltd

# L-J QC Analysis

File No.: 13                                      Lot No.: EH2305L                                      Level: Low  
 Operator: admin                                      Exp. Date: 2023/07/10                                      Run Time: 2023/05/29 05:58  
 Print Time: 2023/05/29 06:00                                      QC Mode: Whole Blood-CBC+DIFF                                      QC Sample ID:

Parameter	Result	Ref. Range	Unit
1 <b>WBC</b>	<b>3.58</b>	<b>3.11-4.11</b>	<b>10<sup>3</sup>/uL</b>
2 Neu%	50.7	38.8-56.8	%
3 Lym%	40.1	32.0-50.0	%
4 Mon%	5.0	2.1-10.1	%
5 Eos%	4.2	0.1-10.1	%
6 Bas%	59.5	50.8-66.8	%
7 Neu#	1.82	1.32-2.12	10 <sup>3</sup> /uL
8 Lym#	1.44	1.08-1.88	10 <sup>3</sup> /uL
9 Mon#	0.17	0.08-0.36	10 <sup>3</sup> /uL
10 Eos#	0.15	0.03-0.33	10 <sup>3</sup> /uL
11 Bas#	2.13	1.82-2.42	10 <sup>3</sup> /uL
12 <b>RBC</b>	<b>2.20</b>	<b>2.09-2.45</b>	<b>10<sup>6</sup>/uL</b>
13 HGB	5.4	5.1-5.9	g/dL
14 HCT	16.6	15.6-19.6	%
15 MCV	75.5	72.5-82.5	fL
16 MCH	24.7	22.0-27.0	pg
17 MCHC	32.7	28.5-34.5	g/dL
18 RDW-CV	18.4	15.9-21.9	%
19 RDW-SD	51.1	41.9-61.9	fL
20 <b>PLT</b>	<b>57</b>	<b>33-73</b>	<b>10<sup>3</sup>/uL</b>
21 MPV	10.6	7.2-13.2	fL
22 PDW-SD	10.6	8.5-14.5	fL
23 PDW-CV	13.3	10.8-16.8	%
24 PCT	0.061	0.004-0.104	%
25 P-LCR	28.2	18.6-34.6	%
26 P-LCC	16	0-28	10 <sup>9</sup> /L

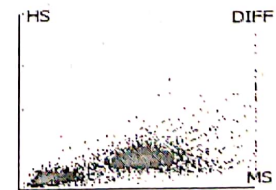
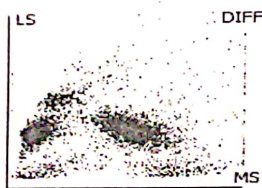
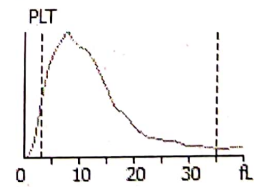
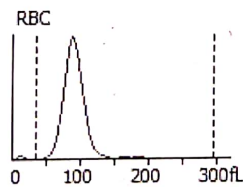
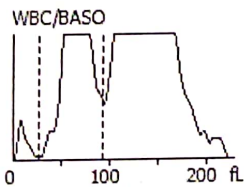


*Plausibel*  
 29/05/23

# L-J QC Analysis

File No.: 14 Lot No.: EH2305N Level: Normal  
 Operator: admin Exp. Date: 2023/07/10 Run Time: 2023/05/29 06:00  
 Print Time: 2023/05/29 06:02 QC Mode: Whole Blood-CBC+DIFF QC Sample ID:

Parameter	Result	Ref. Range	Unit
1 <b>WBC</b>	<b>8.28</b>	<b>7.20-9.20</b>	<b>10<sup>3</sup>/uL</b>
2 Neu%	57.7	49.3-65.3	%
3 Lym%	31.9	22.4-38.4	%
4 Mon%	5.7	0.6-10.6	%
5 Eos%	4.7	0.7-12.7	%
6 Bas%	70.5	62.1-78.1	%
7 Neu#	4.78	4.00-5.40	10 <sup>3</sup> /uL
8 Lym#	2.65	1.79-3.19	10 <sup>3</sup> /uL
9 Mon#	0.47	0.00-0.92	10 <sup>3</sup> /uL
10 Eos#	0.38	0.05-1.05	10 <sup>3</sup> /uL
11 Bas#	5.84	5.05-6.45	10 <sup>3</sup> /uL
12 <b>RBC</b>	<b>4.58</b>	<b>4.39-4.87</b>	<b>10<sup>6</sup>/uL</b>
13 HGB	13.0	12.6-13.8	g/dL
14 HCT	38.9	37.6-43.6	%
15 MCV	84.9	82.8-92.8	fL
16 MCH	28.4	26.1-31.1	pg
17 MCHC	33.4	29.6-35.6	g/dL
18 RDW-CV	15.7	14.4-20.4	%
19 RDW-SD	49.4	43.7-63.7	fL
20 <b>PLT</b>	<b>253</b>	<b>216-296</b>	<b>10<sup>3</sup>/uL</b>
21 MPV	9.7	6.7-12.7	fL
22 PDW-SD	10.9	9.0-15.0	fL
23 PDW-CV	15.3	13.1-19.1	%
24 PCT	0.246	0.149-0.349	%
25 P-LCR	23.8	17.7-33.7	%
26 P-LCC	60	41-91	10 <sup>9</sup> /L

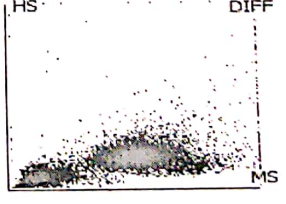
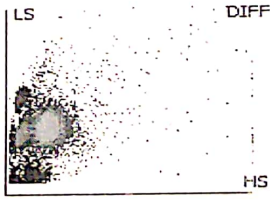
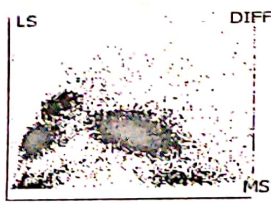
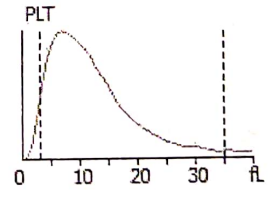
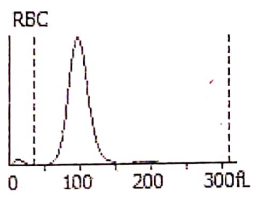
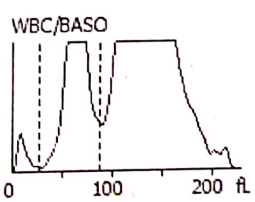


*Mansoor*  
29/05/23

# L-J QC Analysis

File No.: 15                      Lot No.: EH2305H                      Level: High  
 Operator: admin                      Exp. Date: 2023/07/10                      Run Time: 2023/05/29 06:02  
 Print Time: 2023/05/29 06:03                      QC Mode: Whole Blood-CBC+DIFF                      QC Sample ID:

Parameter	Result	Ref. Range	Unit
<b>1 WBC</b>	<b>18.36</b>	<b>16.02-21.02</b>	<b>10<sup>3</sup>/uL</b>
2 Neu%	66.3	56.3-70.3	%
3 Lym%	21.7	15.6-27.6	%
4 Mon%	6.2	0.1-12.1	%
5 Eos%	5.8	2.0-16.0	%
6 Bas%	80.6	71.0-87.0	%
7 Neu#	12.18	10.32-13.12	10 <sup>3</sup> /uL
8 Lym#	3.99	2.90-5.10	10 <sup>3</sup> /uL
9 Mon#	1.13	0.03-2.23	10 <sup>3</sup> /uL
10 Eos#	1.06	0.37-2.97	10 <sup>3</sup> /uL
11 Bas#	14.80	13.13-16.13	10 <sup>3</sup> /uL
<b>12 RBC</b>	<b>5.20</b>	<b>4.76-5.76</b>	<b>10<sup>6</sup>/uL</b>
13 HGB	16.2	15.7-17.3	g/dL
14 HCT	48.2	46.0-54.0	%
15 MCV	92.7	89.2-101.2	fL
16 MCH	31.1	28.9-33.9	pg
17 MCHC	33.6	30.1-36.1	g/dL
18 RDW-CV	14.4	13.4-19.4	%
19 RDW-SD	49.4	42.6-66.6	fL
<b>20 PLT</b>	<b>483</b>	<b>419-539</b>	<b>10<sup>3</sup>/uL</b>
21 MPV	9.5	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	0.461	0.279-0.679	%
25 P-LCR	23.6	18.1-34.1	%
26 P-LCC	114	90-160	10 <sup>9</sup> /L



*Manual*  
 29/05/23