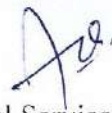


Date: 17-08-2022  
Effective  
Date: 17-08-2022

### Certificate of Inspection

1. Model: Automated Hematology Analyzer Elite 580
2. Serial No.: K11052120035
3. Calibration Date: 17-08-2022
4. Material used: H Cal (Lot No. PLUS0722, Expiry date: 08-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

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

SMP NO	WBC	RBC	HGB	MCV	PLT
1	9.73	4.66	13.9	95.1	276
2	9.77	4.61	13.8	95.3	288
3	9.69	4.55	13.7	95.1	290
4	9.55	4.56	13.8	95.2	293
5	9.72	4.58	13.8	95	293
6	9.57	4.6	13.8	95.3	287
7	9.76	4.72	13.9	95.3	268
8	9.92	4.63	13.7	94.9	290
9	9.66	4.64	13.8	95.2	278
10	9.64	4.59	13.8	95	270
Mean	9.70	4.61	13.80	95.14	283.30
SD	0.11	0.05	0.07	0.14	9.46
CV%	1.10	1.10	0.48	0.15	3.34
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

Date: 17-08-2022

Effective Date: 17-08-2022

**Certificate of Calibration****Customer Name:        REDCLIFFE LABS****Model :        Automated Hematology Analyzer Elite 580****Serial No. :        K11052120035****Calibration Done Date:        17.8.22****Next Calibration Due Date On or Before:        16-08-2023****Lab In-charge: .        AVINASH ANDRIYAS**

*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 Avinash Son  
Designation App Man  
Transasia Bio-Medicals Ltd

## Location

### Encl:

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

## 5. BACKGROUND CHECK

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

  
Technical Service Department  
Transasia Bio-Medicals Ltd

# Calibrator

Lot No.: PLUS 0722  
 Calibration Mode: Whole Blood

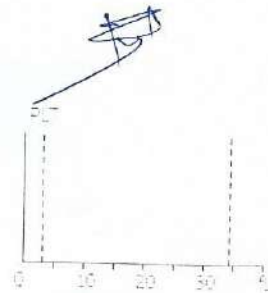
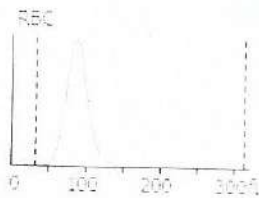
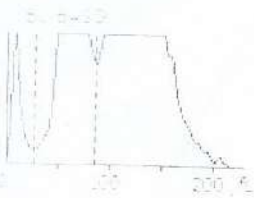
Exp. Date: 2022/10/08  
 Print Time: 2022/08/17 14:01:08

PARA.	WBC	RBC	HGB	MCV	PLT	MPV
Target	9.75	4.60	13.5	95.3	275	9.8
1	10.03	4.66	13.9	95.1	276	9.7
2	9.73	4.61	13.8	95.3	288	9.8
3	9.77	4.55	13.7	95.1	290	9.9
4	9.69	4.58	13.8	95.2	293	9.7
5	9.55	4.56	13.8	95.1	293	9.9
6	9.72	4.60	13.8	95.0	287	9.8
7	9.57	4.62	13.9	95.3	268	9.6
8	9.76	4.60	13.7	95.3	290	9.7
9	9.92	4.72	14.0	94.9	278	9.8
10	9.66	4.59	13.7	95.2	258	9.7
11	9.97	4.63	13.8	95.0	268	9.5
12	9.64	4.64	13.8	95.4	270	10.0
CBC-Mean	9.748	4.593	13.80	95.13	287.8	9.80
DIFF-Mean	9.753	4.633	13.82	95.18	272.0	9.72
CBC-CV(%)	1.6	0.9	0.5	0.1	2.2	0.9
DIFF-CV(%)	1.7	1.0	0.8	0.2	4.0	1.8
CBC Cal. Coefficient(%)	100.02	100.15	97.83	100.18	95.55	100.00
DIFF Cal. Coefficient (%)	99.97	99.29	97.68	100.13	101.10	100.82
Transfer Coefficient	1.0005	1.0087	1.0015	1.0005	0.9451	0.9919

# L-J QC Analysis

File No.: 20      Lot No.: EH2207M      Level: Normal  
 Operator: admin      Exp. Date: 2022/10/09      Run Time: 2022/08/17 10:57  
 Print Time: 2022/08/17 10:58      QC Mode: Whole Blood-CBC+DIFF      QC Sample ID:

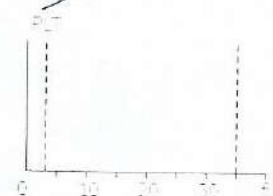
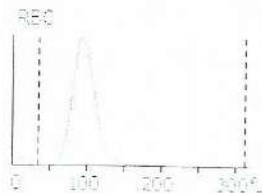
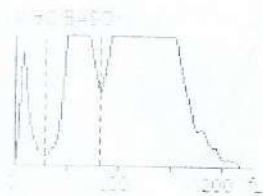
Parameter	Result	Ref. Range	Unit
1 WBC	8.47	6.73-8.73	10 <sup>3</sup> /uL
2 Neu%	56.9	47.8-63.8	%
3 Lym%	31.2	21.8-37.8	%
4 Mon%	8.8	1.9-11.9	%
5 Eos%	3.1	1.5-13.5	%
6 Bas%	70.2	63.0-79.0	%
7 Neu#	4.82	3.61-5.01	10 <sup>3</sup> /uL
8 Lym#	2.65	1.60-3.00	10 <sup>3</sup> /uL
9 Mon#	0.74	0.03-1.03	10 <sup>3</sup> /uL
10 Eos#	0.26	0.08-1.08	10 <sup>3</sup> /uL
11 Bas#	5.94	4.79-6.19	10 <sup>3</sup> /uL
12 RBC	4.57	4.25-4.73	10 <sup>6</sup> /uL
13 HGB	13.3	12.3-13.5	g/dL
14 HCT	40.9	35.3-41.3	%
15 MCV	89.7	80.4-90.4	fL
16 MCH	29.0	25.8-30.8	pg
17 MCHC	32.4	30.1-36.1	g/dL
18 RDW-CV	16.5	14.5-20.5	%
19 RDW-SD	53.6	43.3-63.3	fL
20 PLT	249	200-280	10 <sup>3</sup> /uL
21 MPV	10.2	7.1-13.1	fL
22 PDW-SD	13.0	9.5-15.5	fL
23 PDW-CV	16.9	13.0-19.0	%
24 PCT	0.253	0.144-0.344	%
25 P-LCR	28.5	19.5-35.5	%
26 P-LCC	71	42-92	10 <sup>9</sup> /L



# L-J QC Analysis

File No.: 21                      Lot No.: EH2207H                      Level: High  
 Operator: admin                      Exp. Date: 2022/10/09                      Run Time: 2022/08/17 10:58  
 Print Time: 2022/08/17 10:59                      QC Mode: Whole Blood-CBC+DIFF                      QC Sample ID:

Parameter	Result	Ref. Range	Unit
1 WBC	19.03	15.16-20.16	10 <sup>3</sup> /uL
2 Neu%	63.3	56.0-70.0	%
3 Lym%	24.7	14.5-26.5	%
4 Mon%	9.2	2.0-14.0	%
5 Eos%	2.8	1.5-15.5	%
6 Bas%	81.0	72.9-88.9	%
7 Neu#	12.05	9.73-12.53	10 <sup>3</sup> /uL
8 Lym#	4.70	2.52-4.72	10 <sup>3</sup> /uL
9 Mon#	1.75	0.31-2.51	10 <sup>3</sup> /uL
10 Eos#	0.53	0.20-2.80	10 <sup>3</sup> /uL
11 Bas#	15.41	12.79-15.79	10 <sup>3</sup> /uL
12 RBC	5.42	4.85-5.85	10 <sup>6</sup> /uL
13 HGB	17.0	15.9-17.5	g/dL
14 HCT	53.1	45.4-53.4	%
15 MCV	98.0	86.3-98.3	fL
16 MCH	31.4	28.2-33.2	pg
17 MCHC	32.0	30.1-36.1	g/dL
18 RDW-CV	15.9	14.0-20.0	%
19 RDW-SD	56.7	44.2-68.2	fL
20 PLT	520	427-547	10 <sup>3</sup> /uL
21 MPV	9.7	7.1-13.1	fL
22 PDW-SD	11.9	9.5-15.5	fL
23 PDW-CV	16.4	13.0-19.0	%
24 PCT	0.502	0.297-0.697	%
25 P-LCR	24.8	19.7-35.7	%
26 P-LCC	129	101-171	10 <sup>9</sup> /L

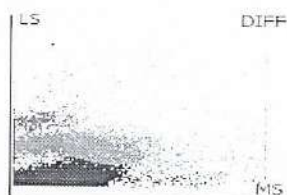
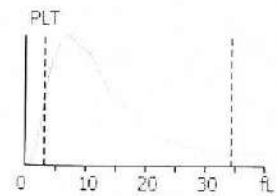
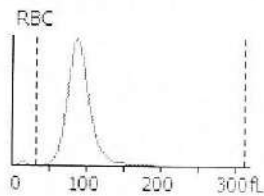
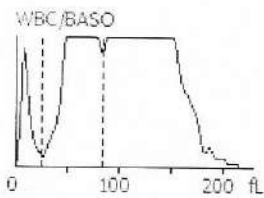




## L-J QC Analysis

File No.:	20	Lot No.:	EH2207M	Level:	Normal
Operator:	admin	Exp. Date:	2022/10/09	Run Time:	2022/09/06 10:10
Print Time:	2022/09/06 15:57	QC Mode:	Whole Blood-CBC+DIFF	QC Sample ID:	

Parameter	Result	Ref. Range	Unit
<b>1 WBC</b>	<b>8.19</b>	<b>6.73-8.73</b>	<b>10<sup>3</sup>/uL</b>
2 Neu%	58.8	47.8-63.8	%
3 Lym%	29.6	21.8-37.8	%
4 Mon%	8.6	1.9-11.9	%
5 Eos%	3.0	1.5-13.5	%
6 Bas%	70.9	63.0-79.0	%
7 Neu#	4.82	3.61-5.01	10 <sup>3</sup> /uL
8 Lym#	2.43	1.60-3.00	10 <sup>3</sup> /uL
9 Mon#	0.70	0.03-1.03	10 <sup>3</sup> /uL
10 Eos#	0.24	0.08-1.08	10 <sup>3</sup> /uL
11 Bas#	5.81	4.79-6.19	10 <sup>3</sup> /uL
<b>12 RBC</b>	<b>4.53</b>	<b>4.25-4.73</b>	<b>10<sup>6</sup>/uL</b>
13 HGB	13.2	12.3-13.5	g/dL
14 HCT	41.3	36.6-42.6	%
15 MCV	91.3	85.2-95.2	fL
16 MCH	29.1	25.8-30.8	pg
17 MCHC	31.9	30.1-36.1	g/dL
18 RDW-CV	16.8	14.5-20.5	%
19 RDW-SD	56.1	43.3-63.3	fL
<b>20 PLT</b>	<b>258</b>	<b>200-280</b>	<b>10<sup>3</sup>/uL</b>
21 MPV	9.9	7.1-13.1	fL
22 PDW-SD	12.0	9.5-15.5	fL
23 PDW-CV	16.4	13.0-19.0	%
24 PCT	0.256	0.144-0.344	%
25 P-LCR	27.0	19.5-35.5	%
26 P-LCC	70	42-92	10 <sup>9</sup> /L

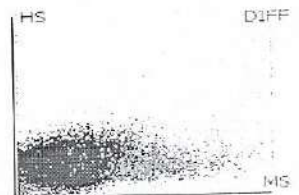
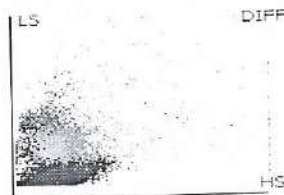
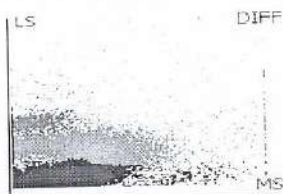
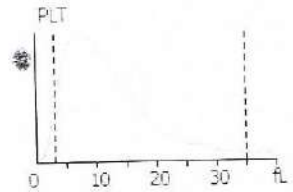
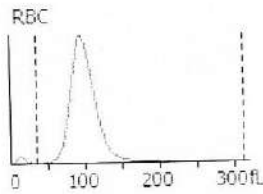
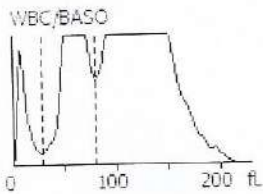


  
 06/09/2022

# L-J QC Analysis

File No.:	21	Lot No.:	EH2207H	Level:	High
Operator:	admin	Exp. Date:	2022/10/09	Run Time:	2022/09/06 10:22
Print Time:	2022/09/06 15:57	QC Mode:	Whole Blood-CBC+DIFF	QC Sample ID:	

Parameter	Result	Ref. Range	Unit
1 <b>WBC</b>	<b>19.27</b>	<b>15.16-20.16</b>	<b>10<sup>3</sup>/uL</b>
2 Neu%	64.0	56.0-70.0	%
3 Lym%	23.8	14.5-26.5	%
4 Mon%	8.8	2.0-14.0	%
5 Eos%	3.4	1.5-15.5	%
6 Bas%	80.8	72.9-88.9	%
7 Neu#	12.34	10.81-13.61	10 <sup>3</sup> /uL
8 Lym#	4.59	2.52-4.72	10 <sup>3</sup> /uL
9 Mon#	1.69	0.31-2.51	10 <sup>3</sup> /uL
10 Eos#	0.65	0.20-2.80	10 <sup>3</sup> /uL
11 Bas#	15.57	12.79-15.79	10 <sup>3</sup> /uL
12 <b>RBC</b>	<b>5.51</b>	<b>4.85-5.85</b>	<b>10<sup>6</sup>/uL</b>
13 HGB	17.4	15.9-17.5	g/dL
14 HCT	55.0	47.5-55.5	%
15 MCV	99.7	91.8-103.8	fL
16 MCH	31.6	28.2-33.2	pg
17 MCHC	31.7	30.1-36.1	g/dL
18 RDW-CV	16.7	14.0-20.0	%
19 RDW-SD	61.1	44.2-68.2	fL
20 <b>PLT</b>	<b>539</b>	<b>427-547</b>	<b>10<sup>3</sup>/uL</b>
21 MPV	9.7	7.1-13.1	fL
22 PDW-SD	11.9	9.5-15.5	fL
23 PDW-CV	16.3	13.0-19.0	%
24 PCT	0.521	0.297-0.697	%
25 P-LCR	24.8	19.7-35.7	%
26 P-LCC	134	101-171	10 <sup>9</sup> /L



*[Signature]*  
06/09/2022