

Date: 07-09-2022
Effective Date: 07-09-2022

Certificate of Calibration

Customer Name: REDCLIFFE LIFE TECH PRIVATE LTD

Model : Automated Hematology Analyzer Elite 580

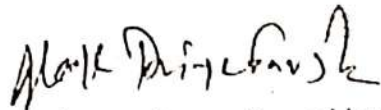
Serial No. : K11052127019

Calibration Done Date: 7.9.22

Next Calibration Due Date On or Before: 06-09-2023

Lab In-charge: . Mr. Shanshank Rai

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: Alok Priyadarshi
Designation: Area Service Manager
Transasia Bio-Medicals Ltd
Location: Moradabad

Encl:

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

Date: 07-09-2022.
Effective Date: 07-09-2022.

Certificate of Inspection

1. Model: Automated Hematology Analyzer Elite 580
2. Serial No.: K11052127015
3. Calibration Date: 07-09-2022
4. Material used: H Cal (Lot No. PLUS0822, Expiry date: 10-Sep-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

5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.0	$0.3 \times 10^3/\text{UL}$ 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

Technical Service Department
Transasia Bio-Medicals Ltd

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

SMP NO	WBC	RBC	HGB	MCV	PLT
1	7.35	4.54	13.4	97.7	293
2	7.38	4.51	13.3	97.8	289
3	7.43	4.49	13.3	97.9	297
4	7.58	4.51	13.4	98.0	282
5	7.33	4.45	13.3	97.7	277
6	7.35	4.54	13.4	97.5	297
7	7.58	4.52	13.3	97.4	290
8	7.62	4.54	13.3	97.8	281
9	7.49	4.55	13.4	97.4	284
10	7.67	4.56	13.5	97.5	268
Mean	7.48	4.52	13.36	97.67	285.80
SD	0.13	0.03	0.07	0.21	9.22
CV%	1.69	0.73	0.52	0.22	3.23
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

History

Cal. Operator : admin

Cal. Method : Calibrator

Cal. Mode : Whole Blood

Cal. Time : 2022/09/07 16:24:38

Description : PLUS0822(Lot No.) 2022/09/10(Exp. Date)

Print Time : 2022/09/07 16:34:33

Details

Para.	WBC	RBC	HGB	MCV	PLT
Target	9.27	4.49	13.3	84.6	258
1	9.18	4.36	13	89.9	285
2	9.16	4.28	13	90	282
3	9.36	4.32	13	90	288
4	9.21	4.3	13	89.9	282
5	9.14	4.36	13	90.1	284
6	9.27	4.31	12.9	90	285
7	9.38	4.31	13.1	89.8	282
8	9.3	4.33	13	89.7	273
9	9.17	4.37	13	89.9	283
10	9.11	4.31	13	90.1	277
New Calibration Coefficient (%)	100.46	103.82	102.31	94.06	91.46
Original Calibration Coefficient (%)	100.00	100.00	100.00	100.00	100.00

Hematology Analysis Report

First Name:
Last Name:
Gender:
Age:

Sample Type:
Department:
Patient ID:

Sample ID: 1
Run Time: 2022/09/07 15:28
Diagnosis:

Parameter	Result	Ref. Range	Unit	Parameter	Result	Ref. Range	Unit
1 WBC	7.35	4.00-10.00	10 ³ /uL	16 *NLR	2.50		
2 Neu%	64.0	50.0-70.0	%	17 RBC	4.54	3.50-5.50	10 ⁶ /uL
3 Lym%	25.6	20.0-40.0	%	18 HGB	13.4	11.0-16.0	g/dL
4 Mon%	7.1	3.0-12.0	%	19 HCT	44.4	37.0-54.0	%
5 Eos%	3.1	0.5-5.0	%	20 MCV	97.7	80.0-100.0	fL
6 Bas%	0.2	0.0-1.0	%	21 MCH	29.5	27.0-34.0	pg
7 Neu#	4.71	2.00-7.00	10 ³ /uL	22 MCHC	30.2 ↓	32.0-36.0	g/dL
8 Lym#	1.89	0.80-4.00	10 ³ /uL	23 RDW-CV	15.4	11.0-16.0	%
9 Mon#	0.52	0.12-1.20	10 ³ /uL	24 RDW-SD	53.5	35.0-56.0	fL
10 Eos#	0.22	0.02-0.50	10 ³ /uL	25 PLT	293	100-300	10 ³ /uL
11 Bas#	0.01	0.00-0.10	10 ³ /uL	26 MPV	12.0	6.5-12.0	fL
12 *ALY#	0.00	0.00-0.20	10 ³ /uL	27 PDW-SD	15.2	9.0-17.0	fL
13 *ALY%	0.0	0.0-2.0	%	28 PDW-CV	15.1	10.0-17.9	%
14 *LIC#	0.00	0.00-0.20	10 ³ /uL	29 PCT	0.351 ↑	0.108-0.282	%
15 *LIC%	0.1	0.0-2.5	%	30 P-LCR	40.8	11.0-45.0	%
				31 P-LCC	120 ↑	30-90	10 ⁹

*** means "Research use only, not for diagnostic use".

Sample Type:
Description:

Microscopic exam. Time:

Hematology Analysis Report

First Name:
Last Name:
Gender:
Age:

Sample Type:
Department:
Patient ID:

Sample ID: background
Run Time: 2022/09/07 11:26
Diagnosis:

Parameter	Result	Ref. Range	Unit	Parameter	Result	Ref. Range	Unit
1 WBC	0.00 ↓		10 ³ /uL	16 P-LCC	****		10 ⁹ /L
2 RBC	0.00 ↓		10 ⁶ /uL				
3 HGB	0.0 ↓		g/dL				
4 HCT	0.0 ↓		%				
5 MCV	****		fL				
6 MCH	****		pg				
7 MCHC	****		g/dL				
8 RDW-CV	***		%				
9 RDW-SD	****		fL				
10 PLT	0 ↓		10 ³ /uL				
11 MPV	***		fL				
12 PDW-SD	***		fL				
13 PDW-CV	***		%				
14 PCT	***		%				
15 P-LCR	***		%				

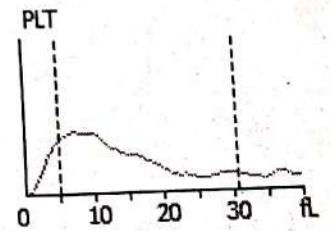
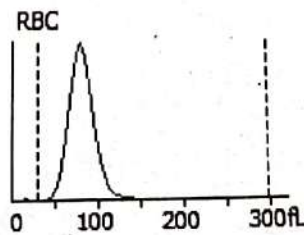
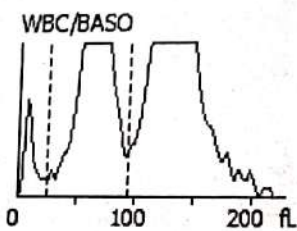
Sample Type:
Description:

Microscopic exam. Time:

L-J QC Analysis

No.: 4	Lot No.: EH2211	Level: Low
Operator: admin	Exp. Date: 2023/01/10	Run Time: 2022/12/20 07:38
Print Time: 2022/12/20 07:39	QC Mode: Whole Blood-CBC+DIFF	QC Sample ID:

Parameter	Result	Ref. Range	Unit
1 WBC	3.10	2.66-3.66	10 ³ /uL
2 Neu%	52.5	41.7-59.7	%
3 Lym%	39.2	30.0-48.0	%
4 Mon%	5.2	1.7-9.7	%
5 Eos%	3.1	0.0-9.2	%
6 Bas%	58.1	51.6-67.6	%
7 Neu#	1.63	1.20-2.00	10 ³ /uL
8 Lym#	1.22	0.83-1.63	10 ³ /uL
9 Mon#	0.16	0.04-0.32	10 ³ /uL
10 Eos#	0.09	0.00-0.30	10 ³ /uL
11 Bas#	1.80	1.60-2.20	10 ³ /uL
12 RBC	2.22	2.20-2.56	10 ⁶ /uL
13 HGB	5.6	5.5-6.3	g/dL
14 HCT	17.6	16.5-20.5	%
15 MCV	79.3	72.7-82.7	fL
16 MCH	25.3	22.2-27.2	pg
17 MCHC	31.9	28.7-34.7	g/dL
18 RDW-CV	17.3	15.4-21.4	%
19 RDW-SD	50.8	38.6-58.6	fL
20 PLT	48	23-63	10 ³ /uL
21 MPV	10.9	7.4-13.4	fL
22 PDW-SD	12.4	9.5-15.5	fL
23 PDW-CV	14.5	11.3-17.3	%
24 PCT	0.053	0.000-0.090	%
25 P-LCR	30.3	19.4-35.4	%
26 P-LCC	15	0-30	10 ⁹ /L



PLS

DIFF

PLS

DIFF

HS

DIFF

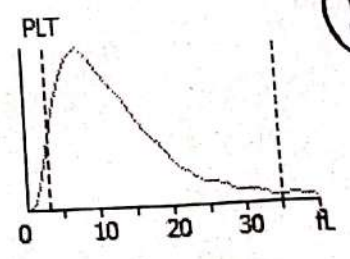
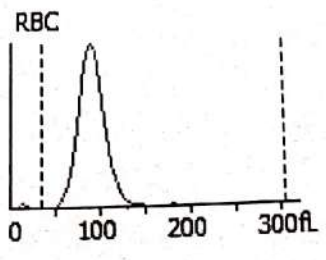
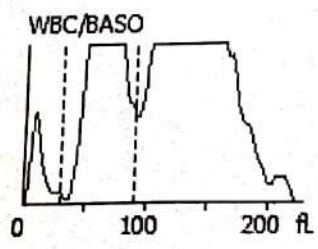
L-J QC Analysis

File No.: 5
 Operator: admin
 Print Time: 2022/12/20 07:42

Lot No.: EH2211
 Exp. Date: 2023/01/10
 QC Mode: Whole Blood-CBC+DIFF

Level: Normal
 Run Time: 2022/12/20 07:40
 QC Sample ID:

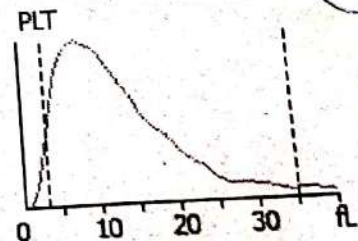
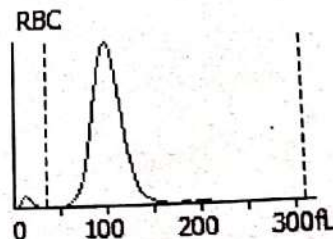
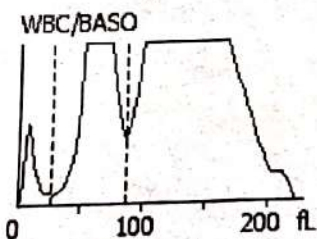
Parameter	Result	Ref. Range	Unit
1 WBC	7.72	6.74-8.74	10 ³ /uL
2 Neu%	57.6	50.7-66.7	%
3 Lym%	30.8	21.7-37.7	%
4 Mon%	6.9	1.4-11.4	%
5 Eos%	4.7	0.0-10.4	%
6 Bas%	71.0	63.2-79.2	%
7 Neu#	4.45	3.84-5.24	10 ³ /uL
8 Lym#	2.38	1.60-3.00	10 ³ /uL
9 Mon#	0.53	0.00-1.00	10 ³ /uL
10 Eos#	0.36	0.00-0.80	10 ³ /uL
11 Bas#	5.49	4.81-6.21	10 ³ /uL
12 RBC	4.34	4.32-4.80	10 ⁶ /uL
13 HGB	12.7	12.5-13.7	g/dL
14 HCT	38.9	36.0-42.0	%
15 MCV	89.6	80.5-90.5	fL
16 MCH	29.3	26.2-31.2	pg
17 MCHC	32.7	30.5-36.5	g/dL
18 RDW-CV	15.6	14.5-20.5	%
19 RDW-SD	51.8	42.3-62.3	fL
20 PLT	234	195-275	10 ³ /uL
21 MPV	9.8	7.0-13.0	fL
22 PDW-SD	12.4	9.9-15.9	fL
23 PDW-CV	16.5	13.6-19.6	%
24 PCT	0.229	0.135-0.335	%
25 P-LCR	25.8	19.8-35.8	%
26 P-LCC	60	42-92	10 ⁹ /L



L-J QC Analysis

No.: 6
 Operator: admin
 Print Time: 2022/12/20 07:43
 Lot No.: EH2211
 Exp. Date: 2023/01/10
 QC Mode: Whole Blood-CBC+DIFF
 Level: High
 Run Time: 2022/12/20 07:42
 QC Sample ID:

Parameter	Result	Ref. Range	Unit
1 WBC	17.39	15.07-20.07	10 ³ /uL
2 Neu%	64.8	58.7-72.7	%
3 Lym%	19.6	14.3-26.3	%
4 Mon%	6.5	0.8-12.8	%
5 Eos%	9.1	0.2-14.2	%
6 Bas%	81.1	72.3-88.3	%
7 Neu#	11.27	10.14-12.94	10 ³ /uL
8 Lym#	3.41	2.47-4.67	10 ³ /uL
9 Mon#	1.13	0.09-2.29	10 ³ /uL
10 Eos#	1.58	0.00-2.54	10 ³ /uL
11 Bas#	14.11	12.61-15.61	10 ³ /uL
12 RBC	5.03	4.68-5.68	10 ⁶ /uL
13 HGB	16.5	15.9-17.5	g/dL
14 HCT	50.2	45.7-53.7	%
15 MCV	99.7	89.9-101.9	fL
16 MCH	32.7	29.8-34.8	pg
17 MCHC	32.8	30.7-36.7	g/dL
18 RDW-CV	15.3	13.8-19.8	%
19 RDW-SD	56.6	44.1-68.1	fL
20 PLT	476	417-537	10 ³ /uL
21 MPV	9.8	7.1-13.1	fL
22 PDW-SD	12.9	9.7-15.7	fL
23 PDW-CV	16.8	13.3-19.3	%
24 PCT	0.466	0.282-0.682	%
25 P-LCR	25.9	18.8-34.8	%
26 P-LCC	123	93-163	10 ⁹ /L



(H)