

Date:

Effective Date:



Certificate of Calibration

Customer Name: REDCLIFFE LIFETECH PRIVATE LTD

Model : Automated Hematology Analyzer Elite 580

Serial No. : K11052133032

Calibration Done Date: 29-11-22

Next Calibration Due Date On or Before: 28-11-23

Lab In-charge: . Dr.ANNU JHANJHI

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.

Singh

Calibration at site performed by
Engineer Name DINESH SINGH
Designation Sr.SERVICE ENGINEER
Transasia Bio-Medicals Ltd
Location BAREILLY

Encl:


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

Date: 00/01/1900
Effective Date: 00/01/1900

Certificate of Inspection

1. Model: Automated Hematology Analyzer Elite 580
2. Serial No.: K11052133032
3. Calibration Date: 29-11-22
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

5. BACKGROUND CHECK

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

Diya
Technical Service Department
Transasia Bio-Medicals Ltd

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

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

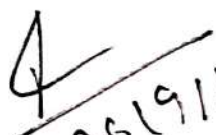
SMP NO	WBC	RBC	HGB	MCV	PLT
1	7.71	4.37	13.1	90.2	231
2	8.06	4.44	13.3	90	210
3	8.02	4.42	13.2	90.3	227
4	8.08	4.42	13.1	90.2	228
5	7.9	4.39	13.3	90.1	224
6	7.83	4.37	13.2	90.4	230
7	8.13	4.41	13.3	90.3	223
8	7.93	4.41	13.3	90.2	225
9	7.86	4.37	13.2	90.2	219
10	7.75	4.38	13.2	90	214
Mean	7.93	4.40	13.22	90.19	223.10
SD	0.14	0.03	0.08	0.13	6.87
CV%	1.80	0.58	0.60	0.14	3.08
Acceptable CV%	Within 3.5%	Within 2.0%	Within 1.5%	Within 2.0%	Within 6.0%
Result	PASS	PASS	PASS	PASS	PASS

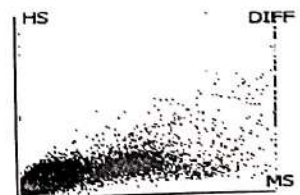
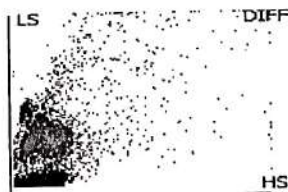
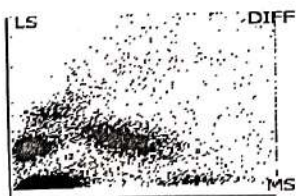
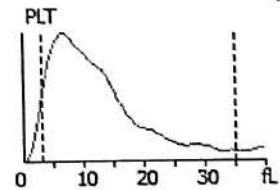
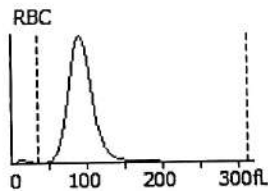
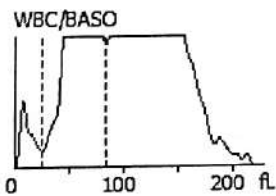
Omik
Technical Service Department
Transasia Bio Medicals Ltd

L-J QC Analysis

File No.: 13 Lot No.: EH2307 Level: Normal
 Operator: admin Exp. Date: 2023/09/10 Run Time: 2023/09/26 09:11
 Print Time: 2023/09/26 11:19 QC Mode: Whole Blood-CBC+DIFF QC Sample ID:

Parameter	Result	Ref. Range	Unit
1 WBC	8.81	6.97-8.97	10 ³ /uL
2 Neu%	55.1	48.4-64.4	%
3 Lym%	32.7	24.5-40.5	%
4 Mon%	6.6	1.0-11.0	%
5 Eos%	5.6	0.0-10.2	%
6 Bas%	66.4	60.4-76.4	%
7 Neu#	4.69	3.79-5.19	10 ³ /uL
8 Lym#	2.79	1.89-3.29	10 ³ /uL
9 Mon#	0.56	0.00-0.96	10 ³ /uL
10 Eos#	0.47	0.00-0.82	10 ³ /uL
11 Bas#	5.65	4.75-6.15	10 ³ /uL
12 RBC	4.55	4.45-4.93	10 ⁶ /uL
13 HGB	13.4	12.8-14.0	g/dL
14 HCT	39.9	38.0-44.0	%
15 MCV	87.8	82.5-92.5	fL
16 MCH	29.5	25.7-30.7	pg
17 MCHC	33.6	29.8-35.8	g/dL
18 RDW-CV	17.0	13.7-19.7	%
19 RDW-SD	56.0	42.3-62.3	fL
20 PLT	254	218-298	10 ³ /uL
21 MPV	9.7	6.9-12.9	fL
22 PDW-SD	11.1	9.3-15.3	fL
23 PDW-CV	15.9	13.3-19.3	%
24 PCT	0.248	0.155-0.355	%
25 P-LCR	24.5	18.2-34.2	%
26 P-LCC	62	43-93	10 ⁹ /L

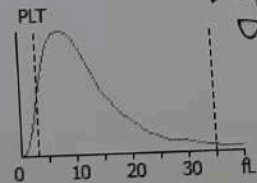
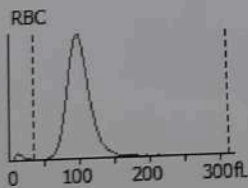
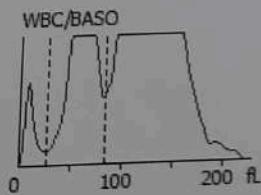

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L-J QC Analysis

File No.: 15 Lot No.: EH2307 Level: High
 Operator: admin Exp. Date: 2023/09/10 Run Time: 2023/09/26 09:16
 Print Time: 2023/09/26 11:19 QC Mode: Whole Blood-CBC+DIFF QC Sample ID:

Parameter	Result	Ref. Range	Unit
1 WBC	19.80	16.04-21.04	10³/uL
2 Neu%	63.3	57.1-71.1	%
3 Lym%	22.6	16.6-28.6	%
4 Mon%	7.0	0.4-12.4	%
5 Eos%	7.1	0.0-13.8	%
6 Bas%	77.7	70.9-86.9	%
7 Neu#	12.54	10.49-13.29	10 ³ /uL
8 Lym#	4.48	3.09-5.29	10 ³ /uL
9 Mon#	1.38	0.09-2.29	10 ³ /uL
● Eos#	1.40	0.00-2.56	10 ³ /uL
11 Bas#	15.38	13.13-16.13	10 ³ /uL
12 RBC	5.31	4.90-5.90	10⁶/uL
13 HGB	17.5	16.4-18.0	g/dL
14 HCT	51.4	48.3-56.3	%
15 MCV	96.7	90.8-102.8	fL
16 MCH	33.0	29.0-34.0	pg
17 MCHC	34.1	30.1-36.1	g/dL
18 RDW-CV	16.0	12.1-18.1	%
19 RDW-SD	57.1	39.9-63.9	fL
20 PLT	498	444-564	10³/uL
21 MPV	9.5	7.0-13.0	fL
22 PDW-SD	10.8	0.0-42.4	fL
23 PDW-CV	15.5	13.1-19.1	%
● PCT	0.473	0.304-0.704	%
25 P-LCR	23.5	19.0-35.0	%
26 P-LCC	117	101-171	10 ⁹ /L



[Signature]
26/9/23

