



Date: 15-07-2022
Effective Date: 15-07-2022

Certificate of Calibration

Customer Name: Redcliffe Lifetech Private Ltd

Model : Automated Hematology Analyzer Elite 580

Serial No. : K11052123030

Calibration Done Date: 15.7.22

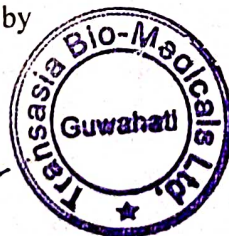
Next Calibration Due Date On or Before: 14-07-2023

Lab In-charge: . Mr. Bhargab Kalita

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
Bipul Baishya
Senior Service Engineer
Transasia Bio-Medicals Ltd
Guwahati

B. Baishya



Encl:

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

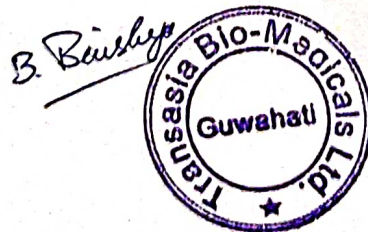


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Certificate of Inspection

1. Model: Automated Hematology Analyzer Elite 580
2. Serial No.: K11052123030
3. Calibration Date: 15-07-2022
4. Material used: H Cal (Lot No. PLUS0722, Expiry date: 10-Aug-2022)

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.



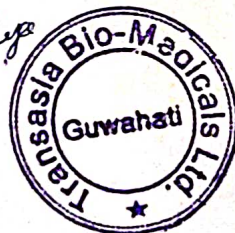
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5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.0	0.3×10^3 /UI or Less
RBC	0.00	0.02×10^6 /uL or Less
HGB	0.0	0.1 g/dL or Less
PLT	0	10×10^3 /uL or Less

B. Basheer



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

SMP NO	WBC	RBC	HGB	MCV	PLT
PRE01	6.47	4.77	11.2	82.2	205
PRE02	6.47	4.85	11.3	82.2	207
PRE03	6.73	4.79	11.3	82.1	197
PRE04	6.56	4.9	11.4	81.9	208
PRE05	6.7	4.84	11.3	81.7	203
PRE06	6.5	4.86	11.4	81.9	203
PRE07	6.61	4.84	11.3	81.9	198
PRE08	6.55	4.83	11.3	82	207
PRE09	6.65	4.81	11.2	81.8	202
PRE10	6.66	4.83	11.3	81.8	193
Mean	6.59	4.83	11.30	81.95	202.30
SD	0.09	0.04	0.07	0.17	4.92
CV%	1.43	0.75	0.59	0.21	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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Table 1: Assignment results and uncertainty of reference method

	Reference	WBC (10 ⁹ /L)	RBC (10 ¹² /L)	HGB (g/L)	MCV (fL)	PLT (10 ⁹ /L)
H360	Calibrator	9.48	4.86	138	91.0	251
	Relative expansion Uncertainty %	2.0	0.6	0.3	0.2	4.3
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
H560 (SW A12.2 or higher; version A only)	Calibrator	8.98	4.61	135	90.3	256
	Relative expansion Uncertainty %	2.3	0.5	0.1	0.3	4.1
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
H560 (SW B1.0 or higher)	Calibrator	9.04	4.53	134	88.4	260
	Relative expansion Uncertainty %	2.2	0.6	0.3	0.2	4.2
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
ELite 580 (SW A10.4 or higher)	Calibrator	9.15	4.51	135	87.1	246
	Relative expansion Uncertainty %	2.4	0.5	0.2	0.4	4.0
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified

The reported expanded uncertainty in Table 1 is based on a standard uncertainty multiplied by a coverage factor of k=2 providing a level of confidence of approximately 95%.

Technical Product Management

Erba Lachema s.r.o.

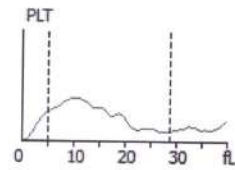
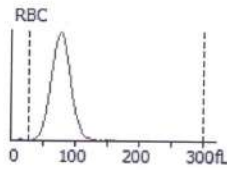
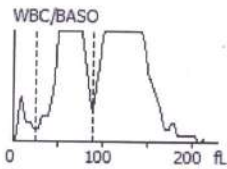
Brno 28.07.2022



L-J QC Analysis

File No.: 13	Lot No.: EH2209 L	Level: Low
Operator: admin	Exp. Date: 2022/11/10	Run Time: 2022/09/17 10:01
Print Time: 2022/09/17 13:02	QC Mode: Whole Blood-CBC+DIFF	QC Sample ID: HEM00024

Parameter	Result	Ref. Range	Unit
1 WBC	3.48	2.88-3.88	10³/uL
2 Neu%	50.6	38.3-56.3	%
3 Lym%	38.9	32.1-50.1	%
4 Mon%	6.2	2.6-10.6	%
5 Eos%	4.3	0.0-10.0	%
6 Bas%	60.1	50.6-66.6	%
7 Neu#	1.77	1.20-2.00	10 ³ /uL
8 Lym#	1.36	0.99-1.79	10 ³ /uL
9 Mon#	0.21	0.08-0.36	10 ³ /uL
10 Eos#	0.14	0.02-0.32	10 ³ /uL
11 Bas#	2.09	1.68-2.28	10 ³ /uL
12 RBC	2.46	2.15-2.51	10⁶/uL
13 HGB	6.0	5.4-6.2	g/dL
14 HCT	18.6	15.7-19.7	%
15 MCV	75.5	70.8-80.8	fL
16 MCH	24.3	22.1-27.1	pg
17 MCHC	32.2	29.1-35.1	g/dL
18 RDW-CV	18.9	16.5-22.5	%
19 RDW-SD	52.0	44.2-64.2	fL
20 PLT	47	26-66	10³/uL
21 MPV	10.9	7.4-13.4	fL
22 PDW-SD	13.3	9.3-15.3	fL
23 PDW-CV	14.3	11.0-17.0	%
24 PCT	0.051	0.000-0.098	%
25 P-LCR	31.3	20.4-36.4	%
26 P-LCC	15	0-30	10 ⁹ /L



JHO

L-J QC Analysis

File No.: 14

Lot No.: EH2209 N

Level: Normal

Operator: admin

Exp. Date: 2022/11/10

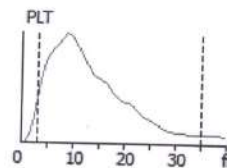
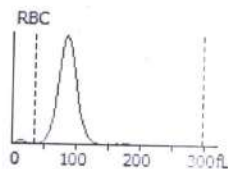
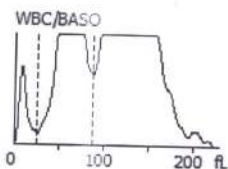
Run Time: 2022/09/17 10:03

Print Time: 2022/09/17 17:34

QC Mode: Whole Blood-CBC+DIFF

QC Sample ID: HEM00025

Parameter	Result	Ref. Range	Unit
1 WBC	8.04	6.74-8.74	10 ³ /uL
2 Neu%	57.6	48.7-64.7	%
3 Lym%	29.5	22.0-38.0	%
4 Mon%	7.5	2.2-12.2	%
5 Eos%	5.4	0.1-12.1	%
6 Bas%	69.6	62.3-78.3	%
7 Neu#	4.64	3.69-5.09	10 ³ /uL
8 Lym#	2.37	1.62-3.02	10 ³ /uL
9 Mon#	0.60	0.06-1.06	10 ³ /uL
10 Eos#	0.43	0.00-0.94	10 ³ /uL
11 Bas#	5.60	4.74-6.14	10 ³ /uL
12 RBC	4.75	4.37-4.85	10 ⁶ /uL
13 HGB	13.3	12.5-13.7	g/dL
14 HCT	40.0	36.0-42.0	%
15 MCV	84.3	79.5-89.5	fL
16 MCH	28.0	25.8-30.8	pg
17 MCHC	33.2	30.8-36.8	g/dL
18 RDW-CV	16.3	14.7-20.7	%
19 RDW-SD	49.7	44.1-64.1	fL
20 PLT	251	216-296	10 ³ /uL
21 MPV	13.5	6.9-12.9	fL
22 PDW-SD	12.9	8.9-14.9	fL
23 PDW-CV	16.5	13.0-19.0	%
24 PCT	0.276	0.152-0.352	%
25 P-LCR	31.0	18.2-34.2	%
26 P-LCC	82	42-92	10 ⁹ /L

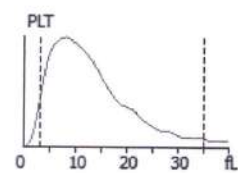
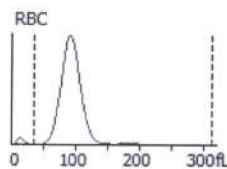
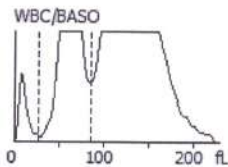


L-J QC Analysis

File No.: 15	Lot No.: EH2209 H	Level: High
Operator: admin	Exp. Date: 2022/11/10	Run Time: 2022/09/17 10:04
Print Time: 2022/09/17 13:14	QC Mode: Whole Blood-CBC+DIFF	QC Sample ID: HEM0026

Parameter	Result	Ref. Range	Unit
1 WBC	18.56	15.33-20.33	10³/uL
2 Neu%	63.5	56.8-70.8	%
3 Lym%	21.0	14.6-26.6	%
4 Mon%	6.9	1.2-13.2	%
5 Eos%	8.6	1.4-15.4	%
6 Bas%	79.8	72.0-88.0	%
7 Neu#	11.79	9.98-12.78	10 ³ /uL
8 Lym#	3.90	2.57-4.77	10 ³ /uL
9 Mon#	1.28	0.18-2.38	10 ³ /uL
10 Eos#	1.59	0.20-2.80	10 ³ /uL
11 Bas#	14.82	12.77-15.77	10 ³ /uL
12 RBC	5.60	4.99-5.99	10⁶/uL
13 HGB	17.3	9.1-25.1	g/dL
14 HCT	50.9	45.9-53.9	%
15 MCV	90.9	84.7-96.7	fL
16 MCH	30.8	28.5-33.5	pg
17 MCHC	33.9	31.3-37.3	g/dL
18 RDW-CV	15.8	13.4-19.4	%
19 RDW-SD	51.7	43.0-67.0	fL
20 PLT	506	415-535	10³/uL
21 MPV	10.2	6.7-12.7	fL
22 PDW-SD	12.4	8.7-14.7	fL
23 PDW-CV	16.2	12.9-18.9	%
24 PCT	0.516	0.271-0.671	%
25 P-LCR	28.3	17.0-33.0	%
26 P-LCC	143	79-149	10 ⁹ /L

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J. J. J.