

Date: 23/12/2021
Effective Date: 23/12/2021

Certificate of Calibration

Customer Name: Redcliffe life Tech Pvt. Ltd. Indore

Model : Automated Hematology Analyzer Elite 580

Serial No. : K11052120041

Calibration Done Date: 23.12.21

Next Calibration Due Date On or Before: 22/12/2022

Lab In-charge: . Dr. Radhika 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 Rajesh Kumar Shivhare
Designation RSM
Transasia Bio-Medicals Ltd
Location

Encl:

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

Calibrator

Lot No.: PLUS1221
Calibration Mode: Whole Blood

Exp. Date: 10-01-2022
Print Time: 23-12-2021 16:53:35

PARA.	WBC	RBC	HGB	MCV	PLT	MPV
Target	9.01	4.36	13.4	91.0	263	9.7
1	8.51	3.98	13.3	96.4	329	9.3
2	8.58	4.10	13.5	96.8	350	9.4
3	8.30	4.06	13.5	97.0	338	9.4
4	8.48	4.12	13.5	97.3	348	9.4
5	8.30	4.09	13.5	97.1	343	9.4
6	8.30	4.07	13.6	97.3	342	9.5
7	8.56	4.03	13.6	97.7	331	9.5
8	8.61	4.02	13.5	98.1	339	9.7
9	8.65	4.05	13.5	98.2	331	9.5
10	8.44	4.06	13.5	97.8	316	9.3
11	8.73	4.06	13.6	98.2	339	9.5
12	8.32	4.00	13.5	98.3	315	9.6
CBC-Mean	8.412	4.070	13.48	96.98	341.7	9.40
DIFF-Mean	8.552	4.037	13.53	98.05	328.5	9.52
CBC-CV(%)	1.5	1.2	0.7	0.4	2.2	0.7
DIFF-CV(%)	1.7	0.6	0.4	0.2	3.3	1.4
CBC Cal. Coefficient(%)	107.11	107.13	99.41	93.83	76.97	103.19
DIFF Cal. Coefficient (%)	105.36	108.00	99.04	92.81	80.06	101.89
Transfer Coefficient	1.0166	0.9919	1.0037	1.0110	0.9614	1.0128



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Certificate of Inspection

1. Model: Automated Hematology Analyzer Elite 580
2. Serial No.: K11052120041
3. Calibration Date: 23/12/2021
4. Material used: H Cal (Lot No. PLUS1221, Expiry date: 10-Jan-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	0.3×10^3 /U1 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

Shit
Technical Service Department
Transasia Bio-Medicals Ltd

Hematology Analysis Report

First Name:
Last name:
Gender:
Age:

Sample Type:
Department:
Patient ID:

Sample ID: background
Run Time: 23-12-2021 16:03
Diagnosis:

Parameter	Result	Ref. Range	Unit	Display
1 WBC	0.00 ↓		10 ³ /uL	
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	** *		%	
16 P-LCC	****		10 ⁹ /L	

Submitter:
Sampling Time: 23-12-2021 16:03
Report Time: 2021/12/23 16:05

Operator: service
Delivery Time: 23-12-2021 16:03
Remarks:

Approver:
Validated Time:

***The Report is responsible for this sample only. If you have any questions, please contact us in 24 hours.**

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	9.22	4.74	136	93.8	256
	Relative expansion Uncertainty %	2.8	0.9	0.1	0.1	4.4
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
H560	Calibrator	8.83	4.49	133	93.4	266
	Relative expansion Uncertainty %	2.6	0.8	0.1	0.1	3.8
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
ELite 580 (SW A10.4)	Calibrator	9.01	4.36	134	91.0	263
	Relative expansion Uncertainty %	2.7	0.8	0.1	0.1	4.8
	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 8. 12. 2021

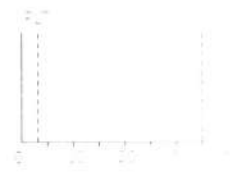
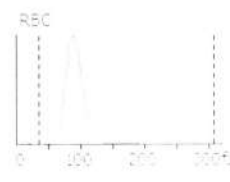
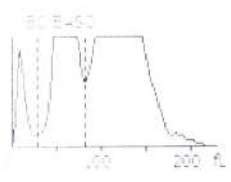


Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, Czech Republic
 Identification number: 269 18 846. Tax identification number: CZ26918846
 Incorporated in the Commercial Register maintained by the Regional Court in Brno, Section C, insert 45458
 Tel.: +420 517 077 111, e-mail: diagnostics@erbamannheim.com, www.erbalachema.com

L-J QC Analysis

File No.: 35 Lot No.: EH2207HEM0025 Level: Normal
 Operator: admin Exp. Date: 2022/09/10 Run Time: 31-08-2022 12:47
 Print Time: 2022/08/31 12:51 QC Mode: Whole Blood-CBC+DIFF QC Sample ID:

Parameter	Result	Ref. Range	Unit
1 WBC	8.59	6.73-8.73	10 ³ /uL
2 Neu%	58.2	47.8-63.8	%
3 Lym%	29.2	21.8-37.8	%
4 Mon%	7.4	1.9-11.9	%
5 Eos%	5.2	1.5-13.5	%
6 Bas%	70.7	63.0-79.0	%
7 Neu#	5.00	3.65-5.05	10 ³ /uL
8 Lym#	2.51	1.60-3.00	10 ³ /uL
9 Mon#	0.64	0.03-1.03	10 ³ /uL
10 Eos#	0.44	0.08-1.08	10 ³ /uL
11 Bas#	6.07	4.79-6.19	10 ³ /uL
12 RBC	4.69	4.25-4.73	10 ⁶ /uL
13 HGB	12.8	12.3-13.5	g/dL
14 HCT	40.6	35.3-41.3	%
15 MCV	86.4	80.4-90.4	fL
16 MCH	27.3	25.8-30.8	pg
17 MCHC	31.6	30.1-36.1	g/dL
18 RDW-CV	15.6	14.5-20.5	%
19 RDW-SD	49.7	43.3-63.3	fL
20 PLT	223	200-280	10 ³ /uL
21 MPV	10.3	7.1-13.1	fL
22 PDW-SD	11.9	9.5-15.5	fL
23 PDW-CV	16.1	13.0-19.0	%
24 PCT	0.231	0.144-0.344	%
25 P-LCR	27.9	19.5-35.5	%
26 P-LCC	62	42-92	10 ⁹ /L

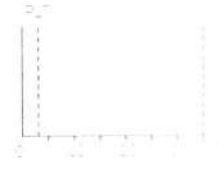
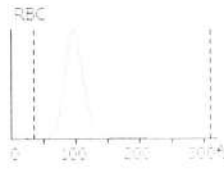
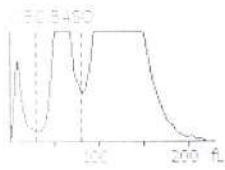


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L-J QC Analysis

File No.: 36 Lot No.: EH2207HEM0025 Level: High
 Operator: admin Exp. Date: 2022/09/10 Run Time: 31-08-2022 12:49
 Print Time: 2022/08/31 12:51 QC Mode: Whole Blood-CBC+DIFF QC Sample ID:

Parameter	Result	Ref. Range	Unit
1 WBC	19.03	15.16-20.16	10 ³ /uL
2 Neu%	67.6	56.0-70.0	%
3 Lym%	19.6	14.5-26.5	%
4 Mon%	8.7	2.0-14.0	%
5 Eos%	4.1	1.5-15.5	%
6 Bas%	81.2	72.9-88.9	%
7 Neu#	12.87	11.10-13.90	10 ³ /uL
8 Lym#	3.73	2.52-4.72	10 ³ /uL
9 Mon#	1.65	0.31-2.51	10 ³ /uL
10 Eos#	0.78	0.20-2.80	10 ³ /uL
11 Bas#	15.44	12.79-15.79	10 ³ /uL
12 RBC	5.60	4.85-5.85	10 ⁶ /uL
13 HGB	16.7	15.9-17.5	g/dL
14 HCT	53.3	45.4-53.4	%
15 MCV	95.1	86.3-98.3	fL
16 MCH	29.7	28.2-33.2	pg
17 MCHC	31.3	30.1-36.1	g/dL
18 RDW-CV	15.3	14.0-20.0	%
19 RDW-SD	53.4	44.2-68.2	fL
20 PLT	452	427-547	10 ³ /uL
21 MPV	9.8	7.1-13.1	fL
22 PDW-SD	10.8	9.5-15.5	fL
23 PDW-CV	15.4	13.0-19.0	%
24 PCT	0.443	0.297-0.697	%
25 P-LCR	23.9	19.7-35.7	%
26 P-LCC	108	101-171	10 ⁹ /L



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