



Certificate of Calibration

Customer Name: Redcliffe Lab , Agartala

Model : Automated Hematology Analyzer Elite 580

Serial No. : K11052203047

Calibration Done Date: 8.11.22

Next Calibration Due Date On or Before: 08-11-2023

Lab In-charge: . Mr. Sourav Paul

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
Prasenjit Das
Area Service Manager
Transasia Bio-Medicals Ltd
Agartala

Encl:

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

Date:

Effective Date:



Certificate of Inspection

1. Model: Automated Hematology Analyzer Elite 580
2. Serial No.: K11052203047
3. Calibration Date: 08-11-2022
4. Material used: H Cal (Lot No. PLUS1022, Expiry date: 10-Nov-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.



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Transasia Bio-Medicals Ltd



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



Technical Service Department
Transasia Bio-Medicals Ltd

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

Transasia Bio-Medicals Ltd., Transasia Biotech, Co. Ltd. (ORIGINALS ATTACHED)
 Tel +91 22 4030 9000 Fax +91 22 2857 3030 Email: info@transasia.co.in



SMP NO	WBC	RBC	HGB	MCV	PLT
2	10.19	4.29	11.6	82.2	327
3	10.11	4.35	11.7	82.7	323
4	10.26	4.31	11.7	82.2	315
5	10.33	4.33	11.7	82.3	316
6	9.94	4.24	11.6	82.1	305
7	10.1	4.29	11.7	82.3	312
8	10.14	4.34	11.6	82.2	318
9	10.3	4.32	11.7	82.3	324
10	10.07	4.33	11.7	82.3	312
11	10.02	4.37	11.8	82.3	300
Mean	10.15	4.32	11.68	82.29	315.20
SD	0.12	0.04	0.06	0.16	8.44
CV%	1.23	0.85	0.54	0.19	2.68
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

ELite H CAL



Hematology Calibrator / Hematologický kalibrátor / Calibrador de hematología

Assay values

Atestované hodnoty / Valores de la media

LOT

PLUS1022



2022-11-10

Name Název Nombre	Cat. No. Kat.č. No.Cat.	Package volume Objem balení Volumen
ELite H CAL	HEM00027	3 ml



Before using refer to the instruction sheet for mixing directions. Calibration errors may result if instructions are not followed exactly.
 Před použitím čtěte návod. Nepřesný postup kalibrace může způsobit chybné výsledky stanovení.
 Lea las instrucciones de mezclado antes de usar. Los errores de calibración pueden surgir si no se siguen las instrucciones exactamente.

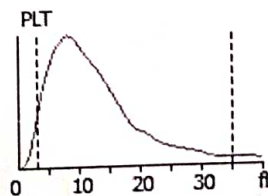
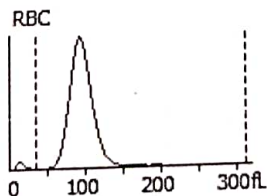
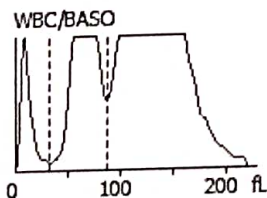
Instrument Analyzátor Instrumento	Parameter Analyt Analito	Unit Jednotka Unidad	Assigned Value Hodnota Valor	Deviation Odchyłka Desviación
ELite 580 (SW A10.4 or higher)	WBC	$\times 10^9/L$	9.51	± 0.20
	RBC	$\times 10^{12}/L$	4.54	± 0.08
	HGB	g/L	134	± 2
		g/dL	13.4	± 0.2
	MCV	fL	83.8	± 2.0
	PLT	$\times 10^9/L$	246	± 12
H560 (SW A12.2 or higher; version A only)	WBC	$\times 10^9/L$	9.30	± 0.20
	RBC	$\times 10^{12}/L$	4.62	± 0.08
	HGB	g/L	133	± 2
		g/dL	13.3	± 0.2
	MCV	fL	86.3	± 2.0
	PLT	$\times 10^9/L$	254	± 12
H560 (SW B1.0 or higher)	WBC	$\times 10^9/L$	9.37	± 0.20
	RBC	$\times 10^{12}/L$	4.52	± 0.08
	HGB	g/L	132	± 2
		g/dL	13.2	± 0.2
	MCV	fL	83.6	± 2.0
	PLT	$\times 10^9/L$	258	± 12
H360	WBC	$\times 10^9/L$	9.49	± 0.20
	RBC	$\times 10^{12}/L$	4.89	± 0.08
	HGB	g/L	137	± 2
		g/dL	13.7	± 0.2
	MCV	fL	88.4	± 2.0
	PLT	$\times 10^9/L$	247	± 12



L-J QC Analysis

File No.: 12	Lot No.: EH2301H	Level: High
Operator: admin	Exp. Date: 2023/03/10	Run Time: 2023/02/28 09:49
Print Time: 2023/02/28 17:16	QC Mode: Whole Blood-CBC+DIFF	QC Sample ID: HEM00026

Parameter	Result	Ref. Range	Unit
1 WBC	17.99	15.22-20.22	10 ³ /uL
2 Neu%	67.4	58.6-72.6	%
3 Lym%	20.5	14.5-26.5	%
4 Mon%	6.9	0.5-12.5	%
5 Eos%	5.2	0.4-14.4	%
6 Bas%	60.9	72.0-88.0	%
7 Neu#	12.13	10.22-13.02	10 ³ /uL
8 Lym#	3.69	2.53-4.73	10 ³ /uL
9 Mon#	1.24	0.05-2.25	10 ³ /uL
10 Eos#	0.93	0.01-2.61	10 ³ /uL
11 Bas#	14.55	12.78-15.78	10 ³ /uL
12 RBC	5.26	4.78-5.78	10 ⁶ /uL
13 HGB	16.7	15.9-17.5	g/dL
14 HCT	49.5	45.0-53.0	%
15 MCV	94.2	86.8-98.8	fL
16 MCH	31.7	29.2-34.2	pg
17 MCHC	33.7	31.8-37.8	g/dL
18 RDW-CV	15.4	13.2-19.2	%
19 RDW-SD	52.7	40.6-64.6	fL
20 PLT	480	427-547	10 ³ /uL
21 MPV	9.8	7.0-13.0	fL
22 PDW-SD	11.3	9.1-15.1	fL
23 PDW-CV	15.5	12.8-18.8	%
24 PCT	0.471	0.287-0.687	%
25 P-LCR	24.9	17.5-33.5	%
26 P-LCC	120	89-159	10 ⁹ /L

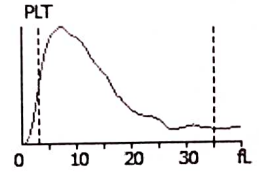
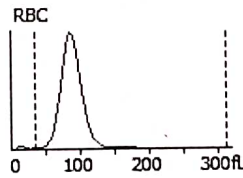
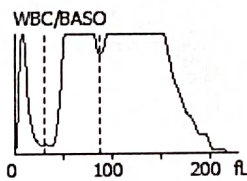


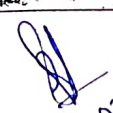
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L-J QC Analysis

Sample No.: 11 Lot No.: EH2301N Level: Normal
 Operator: admin Exp. Date: 2023/03/10 Run Time: 2023/02/28 09:48
 Print Time: 2023/02/28 18:29 QC Mode: Whole Blood-CBC+DIFF QC Sample ID: HEM00025

Parameter	Result	Ref. Range	Unit
1 WBC	8.33	6.99-8.99	10³/uL
2 Neu%	60.8	48.2-64.2	%
3 Lym%	28.4	23.3-39.3	%
4 Mon%	7.1	1.4-11.4	%
5 Eos%	3.7	0.1-12.1	%
6 Bas%	69.0	61.8-77.8	%
7 Neu#	5.07	3.77-5.17	10 ³ /uL
8 Lym#	2.37	1.79-3.19	10 ³ /uL
9 Mon#	0.59	0.01-1.01	10 ³ /uL
10 Eos#	0.30	0.00-0.98	10 ³ /uL
11 Bas#	5.75	4.85-6.25	10 ³ /uL
12 RBC	4.55	4.31-4.79	10⁶/uL
13 HGB	13.3	12.6-13.8	g/dL
14 HCT	39.5	36.0-42.0	%
15 MCV	86.7	80.6-90.6	fL
16 MCH	29.1	26.5-31.5	pg
17 MCHC	33.6	31.6-37.6	g/dL
18 RDW-CV	16.8	14.0-20.0	%
19 RDW-SD	53.1	41.3-61.3	fL
20 PLT	274	222-302	10³/uL
21 MPV	10.2	6.6-12.6	fL
22 PDW-SD	12.0	8.4-14.4	fL
23 PDW-CV	16.3	12.7-18.7	%
24 PCT	0.279	0.151-0.351	%
25 P-LCR	27.6	15.7-31.7	%
26 P-LCC	76	37-87	10 ⁹ /L




 28-02-23

Calibratic

zer Elite 580

Before:

Paul

ove-mentioned
RBC, HGB, MC
Erba Lachema s

at site performed

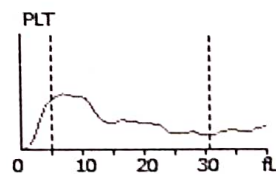
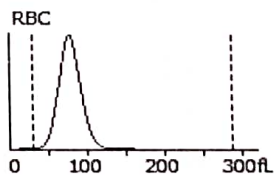
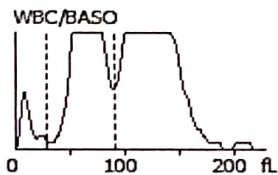
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2. Assay Sheet c
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L-J QC Analysis

Specimen No.: 10	Lot No.: EH2301L	Level: Low	
Operator: admin	Exp. Date: 2023/03/10	Run Time: 2023/02/28 09:47	
Print Time: 2023/02/28 18:29	QC Mode: Whole Blood-CBC+DIFF	QC Sample ID: HEM00024	

Parameter	Result	Ref. Range	Unit
1 WBC	3.51	2.77-3.77	
2 Neu%	54.9	41.0-59.0	10 ³ /uL
3 Lym%	34.6	30.1-48.1	%
4 Mon%	6.9	2.6-10.6	%
5 Eos%	3.6	0.0-8.6	%
6 Bas%	61.3	53.2-69.2	%
7 Neu#	1.93	1.24-2.04	10 ³ /uL
8 Lym#	1.22	0.88-1.68	10 ³ /uL
9 Mon#	0.24	0.08-0.36	10 ³ /uL
10 Eos#	0.12	0.00-0.28	10 ³ /uL
11 Bas#	2.15	1.70-2.30	10 ³ /uL
12 RBC	2.28	2.09-2.45	10⁶/uL
13 HGB	5.8	5.2-6.0	g/dL
14 HCT	17.5	15.3-19.3	%
15 MCV	76.9	71.3-81.3	fL
16 MCH	25.6	22.3-27.3	pg
17 MCHC	33.3	30.1-36.1	g/dL
18 RDW-CV	18.1	15.1-21.1	%
19 RDW-SD	51.1	38.6-58.6	fL
20 PLT	56	27-67	10³/uL
21 MPV	11.3	7.0-13.0	fL
22 PDW-SD	15.7	7.4-13.4	fL
23 PDW-CV	16.8	10.2-16.2	%
24 PCT	0.064	0.000-0.094	%
25 P-LCR	34.9	16.0-32.0	%
26 P-LCC	20	0-28	10 ⁹ /L



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28-02-23