



Date: 29-08-2022
Effective Date: 29-08-2022

Certificate of Calibration

Customer Name: RED CLIFFE LIFETECH PVT LTD, BHUBANESWAR

Model : Automated Hematology Analyzer Erba Elite 580

Serial No. : K11052124025

Calibration Done Date: 29.08.2022

Next Calibration Due Date On or Before: 28.08.2023

Lab In-charge. : Mr. Jugajyoti Mishra

This is to certify that the above-mentioned product has been verified of calibration according to the standard procedures provided by Transasia BioMedicals LTD

The reference instruments used for value-assignment are managed by the traceability system in Sysmex Corporation and these are traceable to the International Standards, such as ICSH.



Calibration at site performed by
Mr. Soumya Ranjan Rautaray
Senior Service Engineer
Transasia Bio-Medicals Ltd
Bhubaneswar



5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.00	0.1×10^3 /uL or less
RBC	0.00	0.02×10^6 /uL or less
HGB	0.00	0.1g/dl or less
MCV	0.00	0.3f/L or less
PLT	0.00	10×10^6 /uL or less



Technical Service Department
Transasia Bio-Medicals Ltd



Date: 29/08/2022
Effective Date: 29/08/2022

Certificate of Inspection

Model: Automated Hematology analyzer Erba Elite 580

2. Serial No.: K11052124025
3. Calibration Date: 29/08/2022
4. Material Used: Elite H Cal (Lot no.: PLUS0822)

By comparing your data to the results of the standards counters in Transasia BioMedicals LTD, the Calibration Elite580 Analyzer parameters using the measurement standard material (Elite H Cal) was completed . The Calibration results of 10 run each summarise in the following table. Please refer to the attached sheets for further details.



Technical Service Department
Transasia Bio-Medicals Ltd.

History

Cal. Operator admin

Cal. Method : Calibrator

Cal. Mode : Whole Blood

Cal. Time : 2022/08/29 17:26:52

Description : PLUS822(Lot No.) 2022/09/10(Exp. Date)

Print Time : 2022/08/29 17:27:10

Details

Para.	WBC	RBC	HGB	MCV	PLT
Target	9.27	4.49	13.3	84.6	258
1	9.51	4.49	13.4	89.3	281
2	9.51	4.51	13.5	89.4	275
3	9.67	4.54	13.6	89.2	283
4	9.78	4.59	13.6	89.3	275
5	9.23	4.52	13.6	89	275
6	9.63	4.53	13.5	89.1	274
7	9.5	4.52	13.5	89.5	268
8	9.62	4.53	13.6	89.3	274
9	9.46	4.53	13.5	89.4	275
10	9.44	4.49	13.5	89.3	273
New Calibration Coefficient (%)	97.22	99.23	98.30	94.76	93.72
Original Calibration Coefficient (%)	100.00	100.00	100.00	100.00	100.00



Assay values

Atestované hodnoty / Valores de la media

LOT

PLUS0822



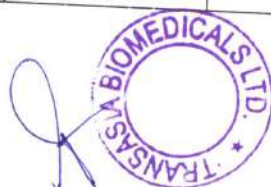
2022-09-10

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 Odchylka Desviación
ELite 580 (SW A10.4 or higher)	WBC	$\times 10^9/L$	9.27	± 0.20
	RBC	$\times 10^{12}/L$	4.49	± 0.08
	HGB	g/L	133	± 2
		g/dL	13.3	± 0.2
	MCV	fL	84.6	± 2.0
H560 (SW A12.2 or higher; version A only)	PLT	$\times 10^9/L$	258	± 12
	WBC	$\times 10^9/L$	9.10	± 0.20
	RBC	$\times 10^{12}/L$	4.57	± 0.08
	HGB	g/L	132	± 2
		g/dL	13.2	± 0.2
MCV	fL	87.5	± 2.0	
H560 (SW B1.0 or higher)	PLT	$\times 10^9/L$	264	± 12
	WBC	$\times 10^9/L$	9.24	± 0.20
	RBC	$\times 10^{12}/L$	4.47	± 0.08
	HGB	g/L	131	± 2
		g/dL	13.1	± 0.2
MCV	fL	84.4	± 2.0	
H360	PLT	$\times 10^9/L$	263	± 12
	WBC	$\times 10^9/L$	9.40	± 0.20
	RBC	$\times 10^{12}/L$	4.82	± 0.08
	HGB	g/L	136	± 2
		g/dL	13.6	± 0.2
MCV	fL	89.3	± 2.0	
PLT	$\times 10^9/L$	257	± 12	



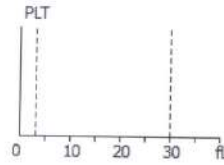
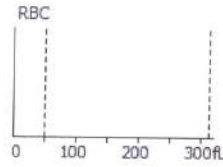
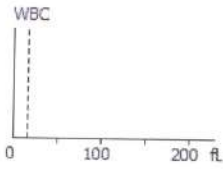
REDCLIFF LAB

First Name:
Last Name:
Gender:
Age:

Sample Type:
Department:
Patient ID:

Sample ID: background
Run Time: 2022/08/30 08:35
Diagnosis:

Parameter	Result	Ref. Range	Unit	Parameter	Result	Ref. Range	Unit
1 WBC	0.00 ↓		10 ³ /uL	16 P-LCC	****		
2 RBC	0.00 ↓		10 ⁶ /uL				10 ⁹ /L
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	***		%				



Submitter:

Operator: admin

Approver:

Sampling Time: 2022/08/30 08:35

Delivery Time: 2022/08/30 08:35

Validated Time:

Report Time: 2022/08/30 10:14

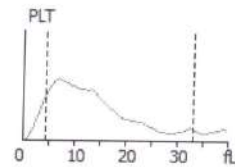
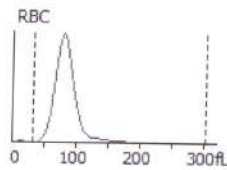
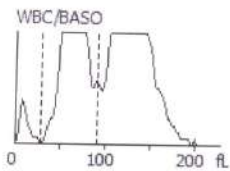
Remarks:

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

L-J QC Analysis

File No.: 16 Lot No.: EH2207L Level: Low
 Operator: admin Exp. Date: 2022/09/10 Run Time: 2022/08/30 10:37
 Print Time: 2022/08/30 10:46 QC Mode: Whole Blood-CBC+DIFF QC Sample ID:

Parameter	Result	Ref. Range	Unit
1 WBC	3.42	2.72-3.72	10³/uL
2 Neu%	57.0	41.7-59.7	%
3 Lym%	34.1	27.9-45.9	%
4 Mon%	7.2	3.4-11.4	%
5 Eos%	1.7	0.0-10.0	%
6 Bas%	60.1	54.1-70.1	%
7 Neu#	1.95	1.23-2.03	10 ³ /uL
8 Lym#	1.17	0.79-1.59	10 ³ /uL
9 Mon#	0.25	0.10-0.38	10 ³ /uL
10 Eos#	0.05	0.01-0.31	10 ³ /uL
11 Bas#	2.05	1.70-2.30	10 ³ /uL
12 RBC	2.31	2.08-2.44	10⁶/uL
13 HGB	5.8	5.2-6.0	g/dL
14 HCT	18.0	15.5-19.5	%
15 MCV	78.2	72.4-82.4	fL
16 MCH	25.1	22.0-27.0	pg
17 MCHC	32.1	28.5-34.5	g/dL
18 RDW-CV	18.7	15.4-21.4	%
19 RDW-SD	53.3	41.6-61.6	fL
20 PLT	69	41-81	10³/uL
21 MPV	10.7	7.5-13.5	fL
22 PDW-SD	11.8	9.6-15.6	fL
23 PDW-CV	14.6	11.7-17.7	%
24 PCT	0.074	0.015-0.115	%
25 P-LCR	29.8	20.9-36.9	%
26 P-LCC	21	3-33	10 ⁹ /L

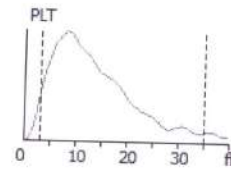
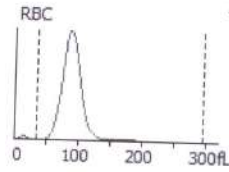
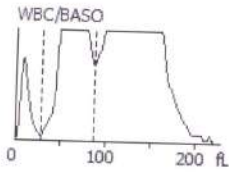


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L-J QC Analysis

File No.: 17 Lot No.: EH2207N Level: Normal
 Operator: admin Exp. Date: 2022/09/10 Run Time: 2022/08/30 10:09
 Print Time: 2022/08/30 10:11 QC Mode: Whole Blood-CBC+DIFF QC Sample ID:

Parameter	Result	Ref. Range	Unit
1 WBC	7.92	6.73-8.73	
2 Neu%	57.9	47.8-63.8	10 ³ /uL
3 Lym%	30.0	21.8-37.8	%
4 Mon%	7.6	1.9-11.9	%
5 Eos%	4.5	1.5-13.5	%
6 Bas%	71.1	63.0-79.0	%
7 Neu#	4.59	3.61-5.01	10 ³ /uL
8 Lym#	2.38	1.60-3.00	10 ³ /uL
9 Mon#	0.60	0.03-1.03	10 ³ /uL
10 Eos#	0.35	0.08-1.08	10 ³ /uL
11 Bas#	5.62	4.79-6.19	10 ³ /uL
12 RBC	4.51	4.25-4.73	10⁶/uL
13 HGB	13.2	12.3-13.5	g/dL
14 HCT	37.9	35.3-41.3	%
15 MCV	84.2	80.4-90.4	fL
16 MCH	29.3	25.8-30.8	pg
17 MCHC	34.7	30.1-36.1	g/dL
18 RDW-CV	15.7	14.5-20.5	%
19 RDW-SD	48.6	43.3-63.3	fL
20 PLT	230	200-280	10³/uL
21 MPV	10.6	7.1-13.1	fL
22 PDW-SD	14.1	9.5-15.5	fL
23 PDW-CV	17.1	13.0-19.0	%
24 PCT	0.244	0.144-0.344	%
25 P-LCR	32.0	19.5-35.5	%
26 P-LCC	74	42-92	10 ⁹ /L



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L-J QC Analysis

File No.: 18	Lot No.: EH2207H	Level: High
Operator: admin	Exp. Date: 2022/09/10	Run Time: 2022/08/30 10:12
Print Time: 2022/08/30 10:13	QC Mode: Whole Blood-CBC+DIFF	QC Sample ID:

Parameter	Result	Ref. Range	Unit
1 WBC	18.12	15.16-20.16	10³/uL
2 Neu%	67.2	56.0-70.0	%
3 Lym%	20.0	14.5-26.5	%
4 Mon%	8.7	2.0-14.0	%
5 Eos%	4.1	1.5-15.5	%
6 Bas%	80.5	72.9-88.9	%
7 Neu#	12.18	9.73-12.53	10 ³ /uL
8 Lym#	3.63	2.52-4.72	10 ³ /uL
9 Mon#	1.57	0.31-2.51	10 ³ /uL
10 Eos#	0.74	0.20-2.80	10 ³ /uL
11 Bas#	14.59	12.79-15.79	10 ³ /uL
12 RBC	5.25	4.85-5.85	10⁶/uL
13 HGB	17.0	15.9-17.5	g/dL
14 HCT	48.6	45.4-53.4	%
15 MCV	92.5	86.3-98.3	fL
16 MCH	32.3	28.2-33.2	pg
17 MCHC	34.9	30.1-36.1	g/dL
18 RDW-CV	15.4	14.0-20.0	%
19 RDW-SD	52.0	44.2-68.2	fL
20 PLT	454	427-547	10³/uL
21 MPV	10.0	7.1-13.1	fL
22 PDW-SD	12.3	9.5-15.5	fL
23 PDW-CV	16.1	13.0-19.0	%
24 PCT	0.456	0.297-0.697	%
25 P-LCR	27.0	19.7-35.7	%
26 P-LCC	123	101-171	10 ⁹ /L

