

Date: 27-10-2021
Effective Date: 27-10-2021

Certificate of Calibration

Customer Name: Redcliffe Lifetech Private Ltd

Model : Automated Hematology Analyzer Elite 580

Serial No. : K11052125001

Calibration Done Date: 27-10-2021

Next Calibration Due Date On or Before: 27-10-2022

Lab In-charge: . Mr. Banttu Yadav

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: Tara Singh Mehra
Designation: ASM
Transasia Bio-Medicals Ltd
Location: Dehradun

Encl:

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

Certificate of Inspection

1. Model: Automated Hematology Analyzer Elite 580
2. Serial No.: K11052125001
3. Calibration Date: 27-10-2021
4. Material used: H Cal (Lot No. PLUS1021, Expiry date: 10-Nov-2021)

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	$0.3 \times 10^3/\text{U}l$ or Less
RBC	0.00	$0.02 \times 10^6/\text{u}L$ or Less
HGB	0.0	0.1 g/dL or Less
PLT	0	$10 \times 10^3/\text{u}L$ or Less



Technical Service Department
Transasia Bio-Medicals Ltd

Hematology Analysis Report

First Name:	Sample Type:	Sample ID: background
Last Name:	Department:	Run Time: 2021/10/27 08:14
Gender:	Patient ID:	Diagnosis:
Age:		


Parameter	Result	Ref. Range	Unit	
1 WBC	0.01	↓	10³/uL	
2 RBC	0.00	↓	10⁶/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	↓	10³/uL	
11 MPV	**		fL	
12 PDW-SD	**		fL	
13 PDW-CV	**		%	
14 PCT	***		%	
15 P-LCR	**		%	
16 P-LCC	****		10 ⁹ /L	

Submitter:	Operator: admin	Approver:
Sampling Time: 2021/10/27 08:14	Delivery Time: 2021/10/27 08:14	Validated Time:
Report Time: 2021/10/27 09:14	Remarks:	

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

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

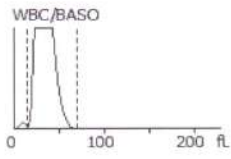
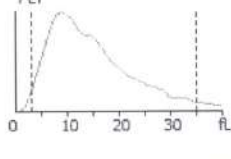



SMP NO	WBC	RBC	HGB	MCV	PLT
1	8.05	5.14	15	88.2	245
2	8.19	5.15	14.8	88.4	253
3	8.09	5.14	14.9	88.5	267
4	7.8	5.1	14.8	88.4	256
5	8.05	5.16	14.8	87.8	266
6	8.04	5.16	14.8	88.1	257
7	7.96	5.15	14.7	87.9	250
8	7.98	5.14	14.8	88.3	255
9	8	5.19	14.9	88.1	262
10	8.19	5.11	14.8	88	257
Mean	8.04	5.14	14.83	88.17	256.80
SD	0.11	0.03	0.08	0.23	6.83
CV%	1.42	0.50	0.56	0.26	2.66
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

Hematology Analysis Report

First Name:	Sample Type:	Sample ID: precision1
Last Name:	Department:	Run Time: 2021/10/27 09:26
Gender:	Patient ID:	Diagnosis:
Age:		

Parameter	Result	Ref. Range	Unit	
1 WBC	8.05	4.00-10.00	10³/uL	
2 Neu%	53.3	50.0-70.0	%	
3 Lym%	36.5	20.0-40.0	%	
4 Mon%	5.4	3.0-12.0	%	
5 Eos%	4.6	0.5-5.0	%	
6 Bas%	0.2	0.0-1.0	%	
7 Neu#	4.30	2.00-7.00	10 ³ /uL	
8 Lym#	2.93	0.80-4.00	10 ³ /uL	
9 Mon#	0.43	0.12-1.20	10 ³ /uL	
10 Eos#	0.37	0.02-0.50	10 ³ /uL	
11 Bas#	0.02	0.00-0.10	10 ³ /uL	
12 *ALY#	0.02	0.00-0.20	10 ³ /uL	
13 *ALY%	0.3	0.0-2.0	%	
14 *LIC#	0.00	0.00-0.20	10 ³ /uL	
15 *LIC%	0.0	0.0-2.5	%	
16 RBC	5.14	3.50-5.50	10⁶/uL	
17 HGB	15.0	11.0-16.0	g/dL	
18 HCT	45.3	37.0-54.0	%	
19 MCV	88.2	80.0-100.0	fL	
20 MCH	29.2	27.0-34.0	pg	
21 MCHC	33.1	32.0-36.0	g/dL	
22 RDW-CV	14.0	11.0-16.0	%	
23 RDW-SD	44.0	35.0-56.0	fL	
24 PLT	245	100-300	10³/uL	
25 MPV	11.4	6.5-12.0	fL	
26 PDW-SD	13.7	9.0-17.0	fL	
27 PDW-CV	15.5	10.0-17.9	%	
28 PCT	0.278	0.108-0.282	%	
29 P-LCR	36.3	11.0-45.0	%	
30 P-LCC	89	30-90	10 ⁹ /L	

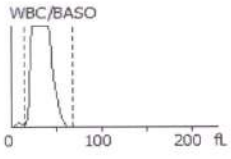
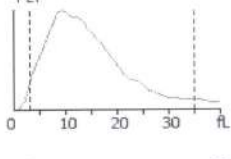



*** means "Research use only, not for diagnostic use".

Submitter:	Operator: service	Approver:
Sampling Time: 2021/10/27 09:26	Delivery Time: 2021/10/27 09:26	Validated Time:
Report Time: 2021/10/27 09:27	Remarks:	

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

Hematology Analysis Report

First Name:	Sample Type:	Sample ID: precision2
Last Name:	Department:	Run Time: 2021/10/27 09:28
Gender:	Patient ID:	Diagnosis:
Age:		

Parameter	Result	Ref. Range	Unit	
1 WBC	8.19	4.00-10.00	10³/uL	
2 Neu%	54.0	50.0-70.0	%	
3 Lym%	35.5	20.0-40.0	%	
4 Mon%	6.0	3.0-12.0	%	
5 Eos%	4.3	0.5-5.0	%	
6 Bas%	0.2	0.0-1.0	%	
7 Neu#	4.43	2.00-7.00	10 ³ /uL	
8 Lym#	2.90	0.80-4.00	10 ³ /uL	
9 Mon#	0.49	0.12-1.20	10 ³ /uL	
10 Eos#	0.35	0.02-0.50	10 ³ /uL	
11 Bas#	0.02	0.00-0.10	10 ³ /uL	
12 *ALY#	0.04	0.00-0.20	10 ³ /uL	
13 *ALY%	0.4	0.0-2.0	%	
14 *LIC#	0.00	0.00-0.20	10 ³ /uL	
15 *LIC%	0.0	0.0-2.5	%	
16 RBC	5.18	3.50-5.50	10⁶/uL	
17 HGB	14.8	11.0-16.0	g/dL	
18 HCT	45.7	37.0-54.0	%	
19 MCV	88.4	80.0-100.0	fL	
20 MCH	28.7	27.0-34.0	pg	
21 MCHC	32.4	32.0-36.0	g/dL	
22 RDW-CV	13.9	11.0-16.0	%	
23 RDW-SD	43.8	35.0-56.0	fL	
24 PLT	253	100-300	10³/uL	
25 MPV	11.1	6.5-12.0	fL	
26 PDW-SD	13.6	9.0-17.0	fL	
27 PDW-CV	15.2	10.0-17.9	%	
28 PCT	0.281	0.108-0.282	%	
29 P-LCR	34.5	11.0-45.0	%	
30 P-LCC	87	30-90	10 ⁹ /L	

*** means "Research use only, not for diagnostic use".

Submitter:	Operator: service	Approver:
Sampling Time: 2021/10/27 09:28	Delivery Time: 2021/10/27 09:28	Validated Time:
Report Time: 2021/10/27 09:29	Remarks:	

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

Hematology Analysis Report

First Name:
Last Name:
Gender:
Age:

Sample Type:
Department:
Patient ID:

Sample ID: precision3
Run Time: 2021/10/27 09:29
Diagnosis:

Parameter	Result	Ref. Range	Unit	
1 WBC	8.09	4.00-10.00	10³/uL	
2 Neu%	52.5	50.0-70.0	%	
3 Lym%	36.6	20.0-40.0	%	
4 Mon%	6.4	3.0-12.0	%	
5 Eos%	4.3	0.5-5.0	%	
6 Bas%	0.2	0.0-1.0	%	
7 Neu#	4.25	2.00-7.00	10 ³ /uL	
8 Lym#	2.97	0.80-4.00	10 ³ /uL	
9 Mon#	0.51	0.12-1.20	10 ³ /uL	
10 Eos#	0.34	0.02-0.50	10 ³ /uL	
11 Bas#	0.02	0.00-0.10	10 ³ /uL	
12 *ALY#	0.07	0.00-0.20	10 ³ /uL	
13 *ALY%	0.8	0.0-2.0	%	
14 *LIC#	0.00	0.00-0.20	10 ³ /uL	
15 *LIC%	0.0	0.0-2.5	%	
16 RBC	5.14	3.50-5.50	10⁶/uL	
17 HGB	14.9	11.0-16.0	g/dL	
18 HCT	45.5	37.0-54.0	%	
19 MCV	88.5	80.0-100.0	fL	
20 MCH	29.0	27.0-34.0	pg	
21 MCHC	32.8	32.0-36.0	g/dL	
22 RDW-CV	13.9	11.0-16.0	%	
23 RDW-SD	43.7	35.0-56.0	fL	
24 PLT	267	100-300	10³/uL	
25 MPV	11.1	6.5-12.0	fL	
26 PDW-SD	13.2	9.0-17.0	fL	
27 PDW-CV	15.2	10.0-17.9	%	
28 PCT	0.296	0.108-0.282	%	
29 P-LCR	34.3	11.0-45.0	%	
30 P-LCC	91	30-90	10 ⁹ /L	

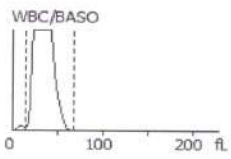
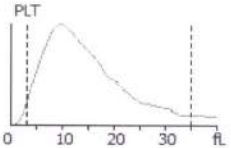



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Submitter: Operator: service Approver:
 Sampling Time: 2021/10/27 09:29 Delivery Time: 2021/10/27 09:29 Validated Time:
 Report Time: 2021/10/27 09:31 Remarks:

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Hematology Analysis Report

First Name:	Sample Type:	Sample ID: precision4
Last Name:	Department:	Run Time: 2021/10/27 09:31
Gender:	Patient ID:	Diagnosis:
Age:		

Parameter	Result	Ref. Range	Unit	
1 WBC	7.80	4.00-10.00	10³/uL	
2 Neu%	53.0	50.0-70.0	%	
3 Lym%	35.6	20.0-40.0	%	
4 Mon%	6.0	3.0-12.0	%	
5 Eos%	5.1	0.5-5.0	%	
6 Bas%	0.3	0.0-1.0	%	
7 Neu#	4.14	2.00-7.00	10 ³ /uL	
8 Lym#	2.78	0.80-4.00	10 ³ /uL	
9 Mon#	0.47	0.12-1.20	10 ³ /uL	
10 Eos#	0.39	0.02-0.50	10 ³ /uL	
11 Bas#	0.02	0.00-0.10	10 ³ /uL	
12 *ALY#	0.03	0.00-0.20	10 ³ /uL	
13 *ALY%	0.3	0.0-2.0	%	
14 *LIC#	0.00	0.00-0.20	10 ³ /uL	
15 *LIC%	0.0	0.0-2.5	%	
16 RBC	5.10	3.50-5.50	10⁶/uL	
17 HGB	14.8	11.0-16.0	g/dL	
18 HCT	45.1	37.0-54.0	%	
19 MCV	88.4	80.0-100.0	fL	
20 MCH	28.9	27.0-34.0	pg	
21 MCHC	32.8	32.0-36.0	g/dL	
22 RDW-CV	14.2	11.0-16.0	%	
23 RDW-SD	44.8	35.0-56.0	fL	
24 PLT	256	100-300	10³/uL	
25 MPV	11.3	6.5-12.0	fL	
26 PDW-SD	13.7	9.0-17.0	fL	
27 PDW-CV	15.4	10.0-17.9	%	
28 PCT	0.288	0.108-0.282	%	
29 P-LCR	35.5	11.0-45.0	%	
30 P-LCC	91	30-90	10 ⁹ /L	

**** means "Research use only, not for diagnostic use".

Submitter:	Operator: service	Approver:
Sampling Time: 2021/10/27 09:31	Delivery Time: 2021/10/27 09:31	Validated Time:
Report Time: 2021/10/27 09:33	Remarks:	

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

Hematology Analysis Report

First Name: Sample Type: Sample ID: precision5
 Last Name: Department: Run Time: 2021/10/27 09:33
 Gender: Patient ID: Diagnosis:
 Age:

Parameter	Result	Ref. Range	Unit	
1 WBC	8.05	4.00-10.00	10³/uL	
2 Neu%	52.9	50.0-70.0	%	
3 Lym%	35.7	20.0-40.0	%	
4 Mon%	6.2	3.0-12.0	%	
5 Eos%	4.7	0.5-5.0	%	
6 Bas%	0.5	0.0-1.0	%	
7 Neu#	4.26	2.00-7.00	10 ³ /uL	
8 Lym#	2.88	0.80-4.00	10 ³ /uL	
9 Mon#	0.50	0.12-1.20	10 ³ /uL	
10 Eos#	0.37	0.02-0.50	10 ³ /uL	
11 Bas#	0.04	0.00-0.10	10 ³ /uL	
12 *ALY#	0.03	0.00-0.20	10 ³ /uL	
13 *ALY%	0.3	0.0-2.0	%	
14 *LIC#	0.00	0.00-0.20	10 ³ /uL	
15 *LIC%	0.0	0.0-2.5	%	
16 RBC	5.16	3.50-5.50	10⁶/uL	
17 HGB	14.8	11.0-16.0	g/dL	
18 HCT	45.2	37.0-54.0	%	
19 MCV	87.8	80.0-100.0	fL	
20 MCH	28.7	27.0-34.0	pg	
21 MCHC	32.7	32.0-36.0	g/dL	
22 RDW-CV	13.9	11.0-16.0	%	
23 RDW-SD	43.8	35.0-56.0	fL	
24 PLT	266	100-300	10³/uL	
25 MPV	11.4	6.5-12.0	fL	
26 PDW-SD	13.8	9.0-17.0	fL	
27 PDW-CV	15.5	10.0-17.9	%	
28 PCT	0.304	0.108-0.282	%	
29 P-LCR	36.8	11.0-45.0	%	
30 P-LCC	98	30-90	10 ⁹ /L	

**** means "Research use only, not for diagnostic use".

Submitter: Operator: service Approver:
 Sampling Time: 2021/10/27 09:33 Delivery Time: 2021/10/27 09:33 Validated Time:
 Report Time: 2021/10/27 09:34 Remarks:

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

Hematology Analysis Report

First Name: Sample Type: Sample ID: precision6
 Last Name: Department: Run Time: 2021/10/27 09:35
 Gender: Patient ID: Diagnosis:
 Age:

Parameter	Result	Ref. Range	Unit	
1 WBC	8.04	4.00-10.00	10³/uL	
2 Neu%	52.2	50.0-70.0	%	
3 Lym%	36.9	20.0-40.0	%	
4 Mon%	5.7	3.0-12.0	%	
5 Eos%	4.9	0.5-5.0	%	
6 Bas%	0.3	0.0-1.0	%	
7 Neu#	4.20	2.00-7.00	10 ³ /uL	
8 Lym#	2.97	0.80-4.00	10 ³ /uL	
9 Mon#	0.46	0.12-1.20	10 ³ /uL	
10 Eos#	0.39	0.02-0.50	10 ³ /uL	
11 Bas#	0.02	0.00-0.10	10 ³ /uL	
12 *ALY#	0.02	0.00-0.20	10 ³ /uL	
13 *ALY%	0.3	0.0-2.0	%	
14 *LIC#	0.00	0.00-0.20	10 ³ /uL	
15 *LIC%	0.0	0.0-2.5	%	
16 RBC	5.16	3.50-5.50	10⁶/uL	
17 HGB	14.8	11.0-16.0	g/dL	
18 HCT	45.5	37.0-54.0	%	
19 MCV	88.1	80.0-100.0	fL	
20 MCH	28.7	27.0-34.0	pg	
21 MCHC	32.6	32.0-36.0	g/dL	
22 RDW-CV	13.9	11.0-16.0	%	
23 RDW-SD	43.6	35.0-56.0	fL	
24 PLT	257	100-300	10³/uL	
25 MPV	11.2	6.5-12.0	fL	
26 PDW-SD	12.6	9.0-17.0	fL	
27 PDW-CV	14.8	10.0-17.9	%	
28 PCT	0.289 ↑	0.108-0.282	%	
29 P-LCR	34.9	11.0-45.0	%	
30 P-LCC	90	30-90	10 ⁹ /L	

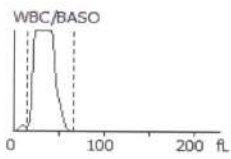
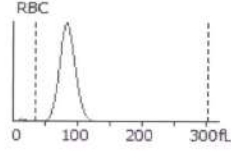
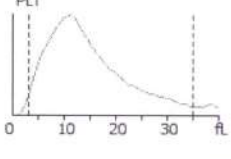



*** means "Research use only, not for diagnostic use".

Submitter: Operator: service Approver:
 Sampling Time: 2021/10/27 09:35 Delivery Time: 2021/10/27 09:35 Validated Time:
 Report Time: 2021/10/27 09:36 Remarks:

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

Hematology Analysis Report

First Name:	Sample Type:	Sample ID: precision7
Last Name:	Department:	Run Time: 2021/10/27 09:36
Gender:	Patient ID:	Diagnosis:
Age:		

Parameter	Result	Ref. Range	Unit		
1 WBC	7.96	4.00-10.00	10³/uL		
2 Neu%	54.8	50.0-70.0	%		
3 Lym%	35.0	20.0-40.0	%		
4 Mon%	5.7	3.0-12.0	%		
5 Eos%	4.2	0.5-5.0	%		
6 Bas%	0.3	0.0-1.0	%		
7 Neu#	4.37	2.00-7.00	10 ³ /uL		
8 Lym#	2.79	0.80-4.00	10 ³ /uL		
9 Mon#	0.45	0.12-1.20	10 ³ /uL		
10 Eos#	0.33	0.02-0.50	10 ³ /uL		
11 Bas#	0.02	0.00-0.10	10 ³ /uL		
12 *ALY#	0.02	0.00-0.20	10 ³ /uL		
13 *ALY%	0.2	0.0-2.0	%		
14 *LIC#	0.01	0.00-0.20	10 ³ /uL		
15 *LIC%	0.1	0.0-2.5	%		
16 RBC	5.15	3.50-5.50	10⁶/uL		
17 HGB	14.7	11.0-16.0	g/dL		
18 HCT	45.3	37.0-54.0	%		
19 MCV	87.9	80.0-100.0	fL		
20 MCH	28.6	27.0-34.0	pg		
21 MCHC	32.5	32.0-36.0	g/dL		
22 RDW-CV	13.9	11.0-16.0	%		
23 RDW-SD	43.7	35.0-56.0	fL		
24 PLT	250	100-300	10³/uL		
25 MPV	11.4	6.5-12.0	fL		
26 PDW-SD	13.0	9.0-17.0	fL		
27 PDW-CV	14.8	10.0-17.9	%		
28 PCT	0.286 ↑	0.108-0.282	%		
29 P-LCR	35.6	11.0-45.0	%		
30 P-LCC	89	30-90	10 ⁹ /L		

*** means "Research use only, not for diagnostic use".

Submitter:	Operator: service	Approver:
Sampling Time: 2021/10/27 09:36	Delivery Time: 2021/10/27 09:36	Validated Time:
Report Time: 2021/10/27 09:37	Remarks:	

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

Hematology Analysis Report

First Name:	Sample Type:	Sample ID: precision8
Last Name:	Department:	Run Time: 2021/10/27 09:37
Gender:	Patient ID:	Diagnosis:
Age:		

Parameter	Result	Ref. Range	Unit	
1 WBC	7.98	4.00-10.00	10³/uL	
2 Neu%	52.7	50.0-70.0	%	
3 Lym%	36.9	20.0-40.0	%	
4 Mon%	5.7	3.0-12.0	%	
5 Eos%	4.2	0.5-5.0	%	
6 Bas%	0.5	0.0-1.0	%	
7 Neu#	4.21	2.00-7.00	10 ³ /uL	
8 Lym#	2.95	0.80-4.00	10 ³ /uL	
9 Mon#	0.45	0.12-1.20	10 ³ /uL	
10 Eos#	0.33	0.02-0.50	10 ³ /uL	
11 Bas#	0.04	0.00-0.10	10 ³ /uL	
12 *ALY#	0.02	0.00-0.20	10 ³ /uL	
13 *ALY%	0.2	0.0-2.0	%	
14 *LIC#	0.01	0.00-0.20	10 ³ /uL	
15 *LIC%	0.1	0.0-2.5	%	
16 RBC	5.14	3.50-5.50	10⁶/uL	
17 HGB	14.8	11.0-16.0	g/dL	
18 HCT	45.4	37.0-54.0	%	
19 MCV	88.3	80.0-100.0	fL	
20 MCH	28.8	27.0-34.0	pg	
21 MCHC	32.6	32.0-36.0	g/dL	
22 RDW-CV	14.0	11.0-16.0	%	
23 RDW-SD	43.8	35.0-56.0	fL	
24 PLT	255	100-300	10³/uL	
25 MPV	11.2	6.5-12.0	fL	
26 PDW-SD	14.3	9.0-17.0	fL	
27 PDW-CV	15.7	10.0-17.9	%	
28 PCT	0.286	0.108-0.282	%	
29 P-LCR	35.9	11.0-45.0	%	
30 P-LCC	91	30-90	10 ⁹ /L	

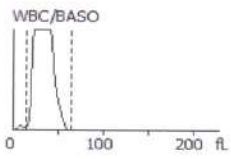
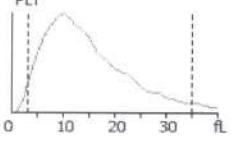

*** means "Research use only, not for diagnostic use".

Submitter:	Operator: service	Approver:
Sampling Time: 2021/10/27 09:37	Delivery Time: 2021/10/27 09:37	Validated Time:
Report Time: 2021/10/27 09:38	Remarks:	

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

Hematology Analysis Report

First Name:	Sample Type:	Sample ID: precision9
Last Name:	Department:	Run Time: 2021/10/27 09:39
Gender:	Patient ID:	Diagnosis:
Age:		

Parameter	Result	Ref. Range	Unit	
1 WBC	8.00	4.00-10.00	10³/uL	
2 Neu%	53.0	50.0-70.0	%	
3 Lym%	36.0	20.0-40.0	%	
4 Mon%	5.6	3.0-12.0	%	
5 Eos%	5.0	0.5-5.0	%	
6 Bas%	0.4	0.0-1.0	%	
7 Neu#	4.25	2.00-7.00	10 ³ /uL	
8 Lym#	2.88	0.80-4.00	10 ³ /uL	
9 Mon#	0.44	0.12-1.20	10 ³ /uL	
10 Eos#	0.40	0.02-0.50	10 ³ /uL	
11 Bas#	0.03	0.00-0.10	10 ³ /uL	
12 *ALY#	0.01	0.00-0.20	10 ³ /uL	
13 *ALY%	0.2	0.0-2.0	%	
14 *LIC#	0.00	0.00-0.20	10 ³ /uL	
15 *LIC%	0.0	0.0-2.5	%	
16 RBC	5.19	3.50-5.50	10⁶/uL	
17 HGB	14.9	11.0-16.0	g/dL	
18 HCT	45.7	37.0-54.0	%	
19 MCV	88.1	80.0-100.0	fL	
20 MCH	28.7	27.0-34.0	pg	
21 MCHC	32.6	32.0-36.0	g/dL	
22 RDW-CV	14.0	11.0-16.0	%	
23 RDW-SD	43.9	35.0-56.0	fL	
24 PLT	262	100-300	10³/uL	
25 MPV	11.3	6.5-12.0	fL	
26 PDW-SD	15.0	9.0-17.0	fL	
27 PDW-CV	16.7	10.0-17.9	%	
28 PCT	0.295 ↑	0.108-0.282	%	
29 P-LCR	35.4	11.0-45.0	%	
30 P-LCC	93 ↑	30-90	10 ⁹ /L	

*** means "Research use only, not for diagnostic use".

Submitter:	Operator: service	Approver:
Sampling Time: 2021/10/27 09:39	Delivery Time: 2021/10/27 09:39	Validated Time:
Report Time: 2021/10/27 09:40	Remarks:	

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

Hematology Analysis Report

First Name:	Sample Type:	Sample ID: precisio10
Last Name:	Department:	Run Time: 2021/10/27 09:41
Gender:	Patient ID:	Diagnosis:
Age:		

Parameter	Result	Ref. Range	Unit	
1 WBC	8.19	4.00-10.00	10³/uL	
2 Neu%	53.2	50.0-70.0	%	<p style="font-size: small;">WBC/BASO 0 100 200 fL</p>
3 Lym%	36.1	20.0-40.0	%	
4 Mon%	6.0	3.0-12.0	%	
5 Eos%	4.4	0.5-5.0	%	
6 Bas%	0.3	0.0-1.0	%	
7 Neu#	4.36	2.00-7.00	10 ³ /uL	
8 Lym#	2.96	0.80-4.00	10 ³ /uL	
9 Mon#	0.49	0.12-1.20	10 ³ /uL	
10 Eos#	0.36	0.02-0.50	10 ³ /uL	
11 Bas#	0.02	0.00-0.10	10 ³ /uL	
12 *ALY#	0.02	0.00-0.20	10 ³ /uL	<p style="font-size: small;">PLT 0 10 20 30 fL</p>
13 *ALY%	0.3	0.0-2.0	%	
14 *LIC#	0.00	0.00-0.20	10 ³ /uL	
15 *LIC%	0.0	0.0-2.5	%	
16 RBC	5.11	3.50-5.50	10⁶/uL	
17 HGB	14.8	11.0-16.0	g/dL	<p style="font-size: x-small;">LS DIFF MS</p>
18 HCT	44.9	37.0-54.0	%	
19 MCV	88.0	80.0-100.0	fL	
20 MCH	28.9	27.0-34.0	pg	
21 MCHC	32.8	32.0-36.0	g/dL	
22 RDW-CV	13.9	11.0-16.0	%	<p style="font-size: x-small;">LS DIFF HS</p>
23 RDW-SD	43.8	35.0-56.0	fL	
24 PLT	257	100-300	10³/uL	
25 MPV	11.3	6.5-12.0	fL	
26 PDW-SD	13.7	9.0-17.0	fL	
27 PDW-CV	15.4	10.0-17.9	%	<p style="font-size: x-small;">HS DIFF MS</p>
28 PCT	0.290 ↑	0.108-0.282	%	
29 P-LCR	35.5	11.0-45.0	%	
30 P-LCC	91 ↑	30-90	10 ⁹ /L	

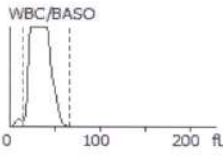
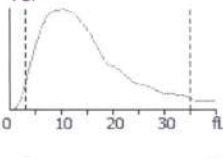

*** means "Research use only, not for diagnostic use".

Submitter:	Operator: service	Approver:
Sampling Time: 2021/10/27 09:41	Delivery Time: 2021/10/27 09:41	Validated Time:
Report Time: 2021/10/27 09:48	Remarks:	

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

Hematology Analysis Report

First Name:	Sample Type:	Sample ID: precisio11
Last Name:	Department:	Run Time: 2021/10/27 09:46
Gender:	Patient ID:	Diagnosis:
Age:		

Parameter	Result	Ref. Range	Unit	
1 WBC	8.10	4.00-10.00	10³/uL	
2 Neu%	52.3	50.0-70.0	%	
3 Lym%	36.6	20.0-40.0	%	
4 Mon%	6.0	3.0-12.0	%	
5 Eos%	4.8	0.5-5.0	%	
6 Bas%	0.3	0.0-1.0	%	
7 Neu#	4.24	2.00-7.00	10 ³ /uL	
8 Lym#	2.97	0.80-4.00	10 ³ /uL	
9 Mon#	0.49	0.12-1.20	10 ³ /uL	
10 Eos#	0.38	0.02-0.50	10 ³ /uL	
11 Bas#	0.02	0.00-0.10	10 ³ /uL	
12 *ALY#	0.02	0.00-0.20	10 ³ /uL	
13 *ALY%	0.2	0.0-2.0	%	
14 *LIC#	0.00	0.00-0.20	10 ³ /uL	
15 *LIC%	0.0	0.0-2.5	%	
16 RBC	5.17	3.50-5.50	10⁶/uL	
17 HGB	14.9	11.0-16.0	g/dL	
18 HCT	45.5	37.0-54.0	%	
19 MCV	88.2	80.0-100.0	fL	
20 MCH	28.8	27.0-34.0	pg	
21 MCHC	32.7	32.0-36.0	g/dL	
22 RDW-CV	13.9	11.0-16.0	%	
23 RDW-SD	43.6	35.0-56.0	fL	
24 PLT	262	100-300	10³/uL	
25 MPV	11.2	6.5-12.0	fL	
26 PDW-SD	14.1	9.0-17.0	fL	
27 PDW-CV	15.8	10.0-17.9	%	
28 PCT	0.294 ↑	0.108-0.282	%	
29 P-LCR	34.4	11.0-45.0	%	
30 P-LCC	90	30-90	10 ⁹ /L	

*** means "Research use only, not for diagnostic use".

Submitter:	Operator: service	Approver:
Sampling Time: 2021/10/27 09:46	Delivery Time: 2021/10/27 09:46	Validated Time:
Report Time: 2021/10/27 09:48	Remarks:	

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

ELite H CAL



Hematology Calibrator / Hematologický kalibrátor / Calibrador de hematología

Assay values

Atestované hodnoty / Valores de la media

LOT

PLUS1021



2021-11-10

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 Analýzator Instrumento	Parameter Analyt Analito	Unit Jednotka Unidad	Assigned Value Hodnota Valor	Deviation Odchylka Desviación
ELite 580 (SW A10.4 or higher)	WBC	$\times 10^9/L$	9.26	± 0.20
	RBC	$\times 10^{12}/L$	4.43	± 0.08
	HGB	g/L	133	± 2
		g/dL	13.3	± 0.2
	MCV	fL	89.2	± 2.0
PLT	$\times 10^9/L$	262	± 12	
H560	WBC	$\times 10^9/L$	8.97	± 0.20
	RBC	$\times 10^{12}/L$	4.49	± 0.08
	HGB	g/L	132	± 2
		g/dL	13.2	± 0.2
	MCV	fL	91.9	± 2.0
PLT	$\times 10^9/L$	264	± 12	
H360	WBC	$\times 10^9/L$	9.10	± 0.20
	RBC	$\times 10^{12}/L$	4.75	± 0.08
	HGB	g/L	136	± 2
		g/dL	13.6	± 0.2
	MCV	fL	91.8	± 2.0
PLT	$\times 10^9/L$	250	± 12	



Calibrator

Lot No.: PLUS1021
 Calibration Mode: Whole Blood

Exp. Date: 2021/11/10
 Print Time: 2021/10/27 10:43:58

PARA.	WBC	RBC	HGB	MCV	PLT	MPV
Target	9.26	4.43	13.3	89.2	262	
1	9.32	4.33	13.2	90.4	260	
2	9.18	4.28	13.0	90.6	271	
3	9.34	4.28	13.1	90.5	279	
4	9.19	4.34	13.2	90.5	279	
5	9.22	4.32	13.1	90.3	280	
6	9.01	4.27	13.1	90.7	269	
7	9.02	4.29	13.2	90.4	266	
8	9.30	4.33	13.1	90.5	263	
9	9.36	4.33	13.3	90.4	259	
10	9.46	4.34	13.3	90.3	257	
11	9.41	4.34	13.2	90.4	263	
12	9.28	4.37	13.1	90.6	253	
CBC-Mean	9.210	4.303	13.12	90.50	273.0	
DIFF-Mean	9.305	4.333	13.20	90.43	260.2	
CBC-CV(%)	1.3	0.7	0.6	0.2	2.9	
DIFF-CV(%)	1.7	0.6	0.7	0.1	1.8	
CBC Cal. Coefficient(%)	100.54	102.95	101.37	98.56	95.97	
DIFF Cal. Coefficient (%)	99.52	102.24	100.76	98.64	100.69	
Transfer Coefficient	1.0102	1.0069	1.0061	0.9992	0.9531	

TRACEABILITY

Erba Lachema s.r.o., Karásek 1d, 621 00 Brno hereby certifies the traceability of the assigned values of the product listed below to a reference material.

Assignment of Reference Values to Fresh Whole Blood

Hematology Calibrator values are traceable to standard reference methods.

Hematology analyzers in the Quality Assurance Laboratory of the Supplier are whole blood calibrated to values obtained using the following standard reference methods. Whole blood samples drawn from normal, healthy donors are collected in EDTA anticoagulant and analyzed within six hours of collection.

The **White Blood Cell (WBC)** and **Red Blood Cell (RBC)** are analyzed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.

Hemoglobin is measured using the Clinical Laboratory Standards Institute (CLSI) recommended reagent for the hemoglobincyanide (cyanmethemoglobin) method⁽¹⁾. Readings are made at 540 nm in a colorimeter/spectrophotometer calibrated according to CLSI H15-A3 and ICSH recommendations⁽¹⁾.

The **hematocrit** (packed cell volume) is measured using plain glass microhematocrit tubes (not coated with anticoagulant) centrifuged for 5 minutes in a microhematocrit centrifuge according to the CLSI H7-A3 document⁽²⁾. No correction is made for trapped plasma.

Platelets are assayed using a hemocytometer and phase contrast optics.

Determination of uncertainty

Uncertainty is an estimate of the range in which the true value of a reported result may occur.

The uncertainty associated with the calibration of the H360, H560 and ELite 580 analyzer using the ELite H CAL calibrator has been estimated by adding the following sources of uncertainty:

- Uncertainty of the equipment used to determine the reference values: flask, pipette, single aperture impedance counter (WBC, RBC), Hemocytometer by phase-contrast (PLT), spectrophotometer (HGB), and ruler (HCT).
- Uncertainty of the hematology analyzer when calibrating with the ELite H CAL.



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	9.10	4.75	136	91.8	250
	Relative expansion Uncertainty %	1.8	1.0	0.2	0.1	5.0
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
H560	Calibrator	8.97	4.49	132	91.9	264
	Relative expansion Uncertainty %	2.0	1.0	0.2	0.1	4.9
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
ELite 580 (SW A10.4)	Calibrator	9.26	4.43	133	89.2	262
	Relative expansion Uncertainty %	2.1	1.0	0.2	0.1	4.5
	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.

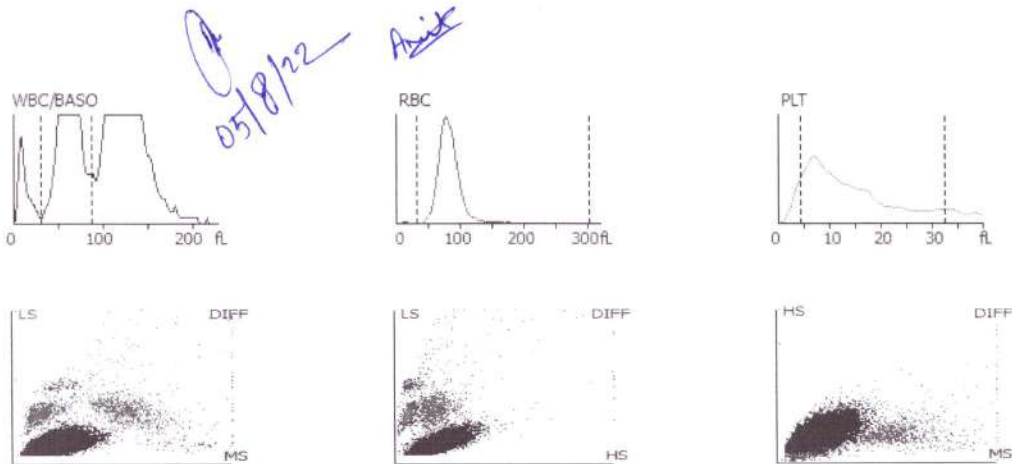
Brno 11. 10. 2021



L-J QC Analysis

File No.: 16 Lot No.: EH2207L Level: Low
 Operator: admin Exp. Date: 2022/09/10 Run Time: 2022/08/05 12:06
 Print Time: 2022/08/05 12:07 QC Mode: Whole Blood-CBC+DIFF QC Sample ID:

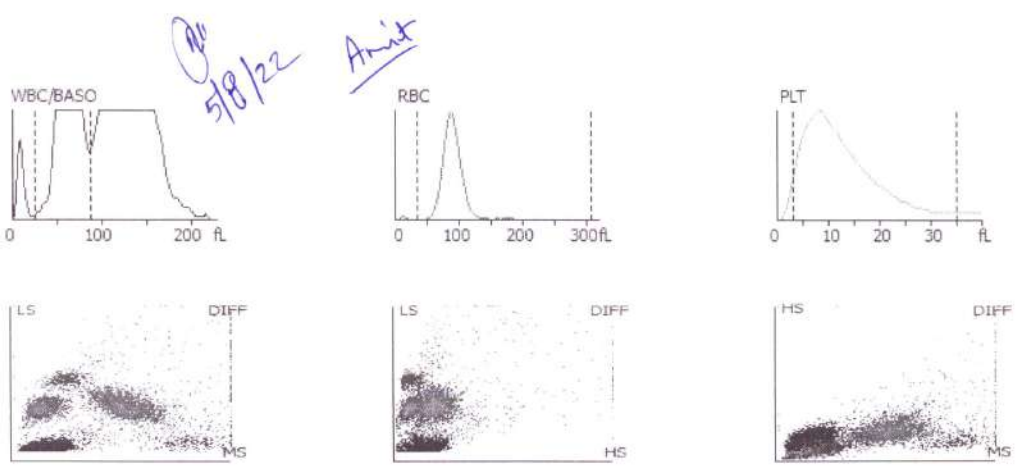
Parameter	Result	Ref. Range	Unit
1 WBC	3.26	2.72-3.72	10³/uL
2 Neu%	54.3	41.7-59.7	%
3 Lym%	35.9	27.9-45.9	%
4 Mon%	7.0	3.4-11.4	%
5 Eos%	2.8	0.0-10.0	%
6 Bas%	62.3	54.1-70.1	%
7 Neu#	1.78	1.23-2.03	10 ³ /uL
8 Lym#	1.17	0.79-1.59	10 ³ /uL
9 Mon#	0.22	0.10-0.38	10 ³ /uL
10 Eos#	0.09	0.01-0.31	10 ³ /uL
11 Bas#	2.03	1.70-2.30	10 ³ /uL
12 RBC	2.27	2.08-2.44	10⁶/uL
13 HGB	5.6	5.2-6.0	g/dL
14 HCT	18.2	15.5-19.5	%
15 MCV	80.1	72.4-82.4	fL
16 MCH	24.8	22.0-27.0	pg
17 MCHC	30.9	28.5-34.5	g/dL
18 RDW-CV	18.2	15.4-21.4	%
19 RDW-SD	53.4	41.6-61.6	fL
20 PLT	72	41-81	10³/uL
21 MPV	10.8	7.5-13.5	fL
22 PDW-SD	12.1	9.6-15.6	fL
23 PDW-CV	15.2	11.7-17.7	%
24 PCT	0.077	0.015-0.115	%
25 P-LCR	31.0	20.9-36.9	%
26 P-LCC	22	3-33	10 ⁹ /L



L-J QC Analysis

File No.: 17 Lot No.: EH220N Level: Normal
 Operator: admin Exp. Date: 2022/09/10 Run Time: 2022/08/05 11:43
 Print Time: 2022/08/05 11:45 QC Mode: Whole Blood-CBC+DIFF QC Sample ID:

Parameter	Result	Ref. Range	Unit
1 WBC	7.86	6.73-8.73	10³/uL
2 Neu%	57.3	47.8-63.8	%
3 Lym%	29.3	21.8-37.8	%
4 Mon%	7.3	1.9-11.9	%
5 Eos%	6.1	1.5-13.5	%
6 Bas%	70.4	63.0-79.0	%
7 Neu#	4.51	3.61-5.01	10 ³ /uL
8 Lym#	2.31	1.60-3.00	10 ³ /uL
9 Mon#	0.57	0.03-1.03	10 ³ /uL
10 Eos#	0.47	0.08-1.08	10 ³ /uL
11 Bas#	5.54	4.79-6.19	10 ³ /uL
12 RBC	4.54	4.25-4.73	10⁶/uL
13 HGB	12.8	12.3-13.5	g/dL
14 HCT	39.5	35.3-41.3	%
15 MCV	87.0	80.4-90.4	fL
16 MCH	28.3	25.8-30.8	pg
17 MCHC	32.5	30.1-36.1	g/dL
18 RDW-CV	15.1	14.5-20.5	%
19 RDW-SD	48.4	43.3-63.3	fL
20 PLT	231	200-280	10³/uL
21 MPV	10.0	7.1-13.1	fL
22 PDW-SD	11.8	9.5-15.5	fL
23 PDW-CV	15.8	13.0-19.0	%
24 PCT	0.231	0.144-0.344	%
25 P-LCR	27.0	19.5-35.5	%
26 P-LCC	62	42-92	10 ⁹ /L



L-J QC Analysis

File No.: 18 Lot No.: EH220H Level: High
 Operator: admin Exp. Date: 2022/09/10 Run Time: 2022/08/05 11:44
 Print Time: 2022/08/05 11:45 QC Mode: Whole Blood-CBC+DIFF QC Sample ID:

Parameter	Result	Ref. Range	Unit
1 WBC	17.41	15.16-20.16	10³/uL
2 Neu%	68.1	56.0-70.0	%
3 Lym%	18.7	14.5-26.5	%
4 Mon%	8.3	2.0-14.0	%
5 Eos%	4.9	1.5-15.5	%
6 Bas%	81.1	72.9-88.9	%
7 Neu#	11.86	9.73-12.53	10 ³ /uL
8 Lym#	3.26	2.52-4.72	10 ³ /uL
9 Mon#	1.44	0.31-2.51	10 ³ /uL
10 Eos#	0.85	0.20-2.80	10 ³ /uL
11 Bas#	14.11	12.79-15.79	10 ³ /uL
12 RBC	5.37	4.85-5.85	10⁶/uL
13 HGB	16.6	15.9-17.5	g/dL
14 HCT	51.3	45.4-53.4	%
15 MCV	95.4	86.3-98.3	fL
16 MCH	30.9	28.2-33.2	pg
17 MCHC	32.4	30.1-36.1	g/dL
18 RDW-CV	15.0	14.0-20.0	%
19 RDW-SD	51.9	44.2-68.2	fL
20 PLT	480	427-547	10³/uL
21 MPV	9.6	7.1-13.1	fL
22 PDW-SD	11.4	9.5-15.5	fL
23 PDW-CV	15.7	13.0-19.0	%
24 PCT	0.462	0.297-0.697	%
25 P-LCR	24.4	19.7-35.7	%
26 P-LCC	117	101-171	10 ⁹ /L

P
5/8/22
Anit

