



Date: 28-04-2023

Effective Date: 28-04-2023

## Certificate of Calibration

**Customer Name:** ACHARYA TULSI DIAGNOSTICS, MAGADI ROAD

**Model :** Automated Hematology Analyzer H560

**Serial No. :** K11042113032

**Calibration Done Date:** 28.4.23

**Next Calibration Due Date On or Before:** 27-04-2024

**Lab In-charge: .** SANTHOSH F B

*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  
Designation  
Transasia Bio-Medicals Ltd  
Location



Encl:

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



Date: 28-042023  
Effective Date: 28-04-2023

## Certificate of Inspection

1. Model: Automated Hematology Analyzer H560
2. Serial No.: K11042113032
3. Calibration Date: 28-042023
4. Material used: H Cal (Lot No. PLUS0423, Expiry date: 10-may-2023)

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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## 5. BACKGROUND CHECK

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



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Transasia Bio-Medicals Ltd



UNMATCHED SERVICE  
SINCE 1979...

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

SMP NO	WBC	RBC	HGB	MCV	PLT
PRECISION 01	6.01	4.64	12.9	88.3	236
PRECISION 02	5.99	4.59	12.9	88.1	226
PRECISION 03	5.87	4.52	12.6	88.2	221
PRECISION 04	5.88	4.66	12.6	88.4	224
PRECISION 05	5.85	4.49	12.6	88.2	217
PRECISION 06	5.77	4.48	12.5	88.2	219
PRECISION 07	5.87	4.49	12.6	88.5	223
PRECISION 08	5.71	4.65	12.6	88.1	227
PRECISION 09	5.88	4.48	12.6	88.1	214
PRECISION 10	6.04	4.66	13.0	88.1	216
Mean	5.89	4.57	12.69	88.22	222.30
SD	0.10	0.08	0.17	0.14	6.46
CV%	1.76	1.78	1.36	0.16	2.91
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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## Hematology Analysis Report

First Name:

Sample ID: background

Gender:

Run-Time: 28-04-2023 15:01

Age:

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Parameter	Result	Ref.Range	Unit
1 WBC	0.00		10 <sup>3</sup> /uL
2 RBC	0.00		10 <sup>6</sup> /uL
3 HGB	0.0		g/uL
4 HCT	0.0		%
5 PLT	0		10 <sup>3</sup> /uL

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Submitter:

Operator:

Service:

Approver

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

## Hematology Analysis Report

First Name: PRECISION 01

Sample ID: 0001

Gender:

Run-Time: 28-04-2023 15:14

Age:

Parameter	Result	Ref.Range	Unit
1 HGB	12.9	11.5-16.0	g/dL
<b>2WBC</b>	6.01	3.50-9.50	10 <sup>3</sup> /uL
3 Neu%	51.4	40.0-75.0	%
4 Lym%	30.7	20.0-50.0	%
5 Mon%	12.4	3.0-10.0	%
6 Eos%	5.3	0.4-8.0	%
7 Bas%	0.2	0.0-1.0	%
8 Neu#	3.08	1.80-6.30	10 <sup>3</sup> /uL
9 Lym#	1.85	1.10-6.30	10 <sup>3</sup> /uL
10 Mon#	0.75	0.10-0.60	10 <sup>3</sup> /uL
11 Eos#	0.32	0.02-0.52	10 <sup>3</sup> /uL
12 Bas#	0.01	0.00-0.06	10 <sup>3</sup> /UI
13 *ALY#	0.07	0.00-0.20	10 <sup>3</sup> /UI
14 *ALY%	1.1	0.0-0.2	%
15 *LIC#	0.03	0.00-0.20	10 <sup>3</sup> /uL
16 *LIC%	0.4	0.0-2.5	%
17 *NRBC#	0.000	0.000-9999.999	10 <sup>3</sup> /uL
18 *NRCB%	0.00	0.00-9999.99	%
<b>19 RBC</b>	4.64	3.80-5.80	10 <sup>6</sup> /uL
20 HCT	41.0	35.0-50.0	%
21 MCV	88.3	82.0-100.0	fL
22 MCH	27.9	27.0-34.0	pg
23 MCHC	31.6	31.6-35.4	g/dL
24 RDW-CV	12.2	11.0-16.0	%
25 RDW-SD	44.6	35.0-56.0	fL
<b>26 PLT</b>	236	125-350	10 <sup>3</sup> /uL
27 MPV	12.0	6.5-12.0	fL
28 PDW-SD	16.6	9.0-17.0	fL
29 PDW-CV	15.6	10.0-17.9	%
30 PCT	0.283	0.108-0.282	%
31 P-LCR	52.1	11.0-45.0	%
32 P-LCC	123	30-90	10 <sup>3</sup> /uL

Submitter: \_\_\_\_\_ Operator: \_\_\_\_\_ Service: \_\_\_\_\_ Approver \_\_\_\_\_

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## Hematology Analysis Report

First Name: PRECISION 02

Sample ID: 0002

Gender:

Run-Time: 28-04-2023 15:16

Age:

Parameter	Result	Ref.Range	Unit
1 HGB	12.9	11.5-16.0	g/dL
2 WBC	5.99	3.50-9.50	10 <sup>3</sup> /uL
3 Neu%	51.7	40.0-75.0	%
4 Lym%	30.5	20.0-50.0	%
5 Mon%	12.1	3.0-10.0	%
6 Eos%	5.4	0.4-8.0	%
7 Bas%	0.3	0.0-1.0	%
8 Neu#	3.10	1.80-6.30	10 <sup>3</sup> /uL
9 Lym#	1.83	1.10-6.30	10 <sup>3</sup> /uL
10 Mon#	0.72	0.10-0.60	10 <sup>3</sup> /uL
11 Eos#	0.32	0.02-0.52	10 <sup>3</sup> /uL
12 Bas#	0.02	0.00-0.06	10 <sup>3</sup> /UI
13 *ALY#	0.03	0.00-0.20	10 <sup>3</sup> /UI
14 *ALY%	0.6	0.0-0.2	%
15 *LIC#	0.04	0.00-0.20	10 <sup>3</sup> /uL
16 *LIC%	0.6	0.0-2.5	%
17 *NRBC#	0.000	0.000-9999.999	10 <sup>3</sup> /uL
18 *NRCB%	0.00	0.00-9999.99	%
19 RBC	4.59	3.80-5.80	10 <sup>6</sup> /uL
20 HCT	40.5	35.0-50.0	%
21 MCV	88.1	82.0-100.0	fL
22 MCH	28.0	27.0-34.0	pg
23 MCHC	31.8	31.6-35.4	g/dL
24 RDW-CV	12.1	11.0-16.0	%
25 RDW-SD	44.5	35.0-56.0	fL
26 PLT	226	125-350	10 <sup>3</sup> /uL
27 MPV	11.8	6.5-12.0	fL
28 PDW-SD	16.3	9.0-17.0	fL
29 PDW-CV	15.0	10.0-17.9	%
30 PCT	0.268	0.108-0.282	%
31 P-LCR	51.9	11.0-45.0	%
32 P-LCC	118	30-90	10 <sup>3</sup> /uL

Submitter: \_\_\_\_\_ Operator: \_\_\_\_\_ Service: \_\_\_\_\_ Approver \_\_\_\_\_

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## Hematology Analysis Report

First Name: PRECISION 03

Sample ID: 0003

Gender:

Run-Time: 28-04-2023 15:18

Age:

Parameter	Result	Ref.Range	Unit
1 HGB	12.6	11.5-16.0	g/dL
<b>2WBC</b>	5.87	3.50-9.50	10 <sup>3</sup> /uL
3 Neu%	50.8	40.0-75.0	%
4 Lym%	31.3	20.0-50.0	%
5 Mon%	13.0	3.0-10.0	%
6 Eos%	4.6	0.4-8.0	%
7 Bas%	0.3	0.0-1.0	%
8 Neu#	2.98	1.80-6.30	10 <sup>3</sup> /uL
9 Lym#	1.84	1.10-6.30	10 <sup>3</sup> /uL
10 Mon#	0.76	0.10-0.60	10 <sup>3</sup> /uL
11 Eos#	0.27	0.02-0.52	10 <sup>3</sup> /uL
12 Bas#	0.02	0.00-0.06	10 <sup>3</sup> /UI
13 *ALY#	0.06	0.00-0.20	10 <sup>3</sup> /UI
14 *ALY%	1.0	0.0-0.2	%
15 *LIC#	0.03	0.00-0.20	10 <sup>3</sup> /uL
16 *LIC%	0.5	0.0-2.5	%
17 *NRBC#	0.000	0.000-9999.999	10 <sup>3</sup> /uL
18 *NRCB%	0.00	0.00-9999.99	%
<b>19 RBC</b>	4.52	3.80-5.80	10 <sup>6</sup> /uL
20 HCT	38.8	35.0-50.0	%
21 MCV	88.2	82.0-100.0	fL
22 MCH	28.0	27.0-34.0	pg
23 MCHC	31.7	31.6-35.4	g/dL
24 RDW-CV	12.1	11.0-16.0	%
25 RDW-SD	44.4	35.0-56.0	fL
<b>26 PLT</b>	221	125-350	10 <sup>3</sup> /uL
27 MPV	11.8	6.5-12.0	fL
28 PDW-SD	16.1	9.0-17.0	fL
29 PDW-CV	15.3	10.0-17.9	%
30 PCT	0.261	0.108-0.282	%
31 P-LCR	51.4	11.0-45.0	%
32 P-LCC	114	30-90	10 <sup>3</sup> /uL

Submitter:

Operator:

Service:

Approver

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## Hematology Analysis Report

First Name: PRECISION 04

Sample ID: 0004

Gender:

Run-Time: 28-04-2023 15:22

Age:

Parameter	Result	Ref.Range	Unit
1 HGB	13.0	11.5-16.0	g/dL
2 WBC	5.88	3.50-9.50	10 <sup>3</sup> /uL
3 Neu%	50.1	40.0-75.0	%
4 Lym%	31.1	20.0-50.0	%
5 Mon%	12.9	3.0-10.0	%
6 Eos%	5.5	0.4-8.0	%
7 Bas%	0.4	0.0-1.0	%
8 Neu#	2.95	1.80-6.30	10 <sup>3</sup> /uL
9 Lym#	1.83	1.10-6.30	10 <sup>3</sup> /uL
10 Mon#	0.76	0.10-0.60	10 <sup>3</sup> /uL
11 Eos#	0.32	0.02-0.52	10 <sup>3</sup> /uL
12 Bas#	0.02	0.00-0.06	10 <sup>3</sup> /UI
13 *ALY#	0.06	0.00-0.20	10 <sup>3</sup> /UI
14 *ALY%	1.0	0.0-0.2	%
15 *LIC#	0.02	0.00-0.20	10 <sup>3</sup> /uL
16 *LIC%	0.3	0.0-2.5	%
17 *NRBC#	0.000	0.000-9999.999	10 <sup>3</sup> /uL
18 *NRCB%	0.00	0.00-9999.99	%
19 RBC	4.66	3.80-5.80	10 <sup>6</sup> /uL
20 HCT	41.2	35.0-50.0	%
21 MCV	88.4	82.0-100.0	fL
22 MCH	27.9	27.0-34.0	pg
23 MCHC	31.6	31.6-35.4	g/dL
24 RDW-CV	12.1	11.0-16.0	%
25 RDW-SD	44.4	35.0-56.0	fL
26 PLT	224	125-350	10 <sup>3</sup> /uL
27 MPV	11.8	6.5-12.0	fL
28 PDW-SD	16.6	9.0-17.0	fL
29 PDW-CV	15.5	10.0-17.9	%
30 PCT	0.265	0.108-0.282	%
31 P-LCR	51.6	11.0-45.0	%
32 P-LCC	116	30-90	10 <sup>3</sup> /uL

Submitter:

Operator:

Service:

Approver

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## Hematology Analysis Report

First Name: PRECISION 05

Sample ID: 0005

Gender:

Run-Time: 28-04-2023 15:24

Age:

Parameter	Result	Ref.Range	Unit
1 HGB	12.6	11.5-16.0	g/dL
2WBC	5.85	3.50-9.50	10 <sup>3</sup> /uL
3 Neu%	51.0	40.0-75.0	%
4 Lym%	31.1	20.0-50.0	%
5 Mon%	12.2	3.0-10.0	%
6 Eos%	5.5	0.4-8.0	%
7 Bas%	0.3	0.0-1.0	%
8 Neu#	2.97	1.80-6.30	10 <sup>3</sup> /uL
9 Lym#	1.83	1.10-6.30	10 <sup>3</sup> /uL
10 Mon#	0.71	0.10-0.60	10 <sup>3</sup> /uL
11 Eos#	0.28	0.02-0.52	10 <sup>3</sup> /uL
12 Bas#	0.02	0.00-0.06	10 <sup>3</sup> /UI
13 *ALY#	0.05	0.00-0.20	10 <sup>3</sup> /UI
14 *ALY%	0.9	0.0-0.2	%
15 *LIC#	0.02	0.00-0.20	10 <sup>3</sup> /uL
16 *LIC%	0.4	0.0-2.5	%
17 *NRBC#	0.000	0.000-9999.999	10 <sup>3</sup> /uL
18 *NRCB%	0.00	0.00-9999.99	%
19 RBC	4.49	3.80-5.80	10 <sup>6</sup> /uL
20 HCT	39.2	35.0-50.0	%
21 MCV	88.2	82.0-100.0	fL
22 MCH	28.9	27.0-34.0	pg
23 MCHC	31.7	31.6-35.4	g/dL
24 RDW-CV	12.1	11.0-16.0	%
25 RDW-SD	44.4	35.0-56.0	fL
26 PLT	217	125-350	10 <sup>3</sup> /uL
27 MPV	11.7	6.5-12.0	fL
28 PDW-SD	16.2	9.0-17.0	fL
29 PDW-CV	15.0	10.0-17.9	%
30 PCT	0.255	0.108-0.282	%
31 P-LCR	50.2	11.0-45.0	%
32 P-LCC	109	30-90	10 <sup>3</sup> /uL

Submitter:

Operator:

Service:

Approver

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## Hematology Analysis Report

First Name: PRECISION 06

Sample ID: 0006

Gender:

Run-Time: 28-04-2023 15:26

Age:

Parameter	Result	Ref.Range	Unit
1 HGB	12.5	11.5-16.0	g/dL
<b>2WBC</b>	5.77	3.50-9.50	10 <sup>3</sup> /uL
3 Neu%	51.6	40.0-75.0	%
4 Lym%	29.8	20.0-50.0	%
5 Mon%	13.5	3.0-10.0	%
6 Eos%	4.8	0.4-8.0	%
7 Bas%	0.3	0.0-1.0	%
8 Neu#	2.97	1.80-6.30	10 <sup>3</sup> /uL
9 Lym#	1.72	1.10-6.30	10 <sup>3</sup> /uL
10 Mon#	0.78	0.10-0.60	10 <sup>3</sup> /uL
11 Eos#	0.28	0.02-0.52	10 <sup>3</sup> /uL
12 Bas#	0.02	0.00-0.06	10 <sup>3</sup> /uL
13 *ALY#	0.03	0.00-0.20	10 <sup>3</sup> /uL
14 *ALY%	0.5	0.0-0.2	%
15 *LIC#	0.03	0.00-0.20	10 <sup>3</sup> /uL
16 *LIC%	0.5	0.0-2.5	%
17 *NRBC#	0.000	0.000-9999.999	10 <sup>3</sup> /uL
18 *NRBC%	0.00	0.00-9999.99	%
<b>19 RBC</b>	4.48	3.80-5.80	10 <sup>6</sup> /uL
20 HCT	39.5	35.0-50.0	%
21 MCV	88.2	82.0-100.0	fL
22 MCH	28.0	27.0-34.0	pg
23 MCHC	31.7	31.6-35.4	g/dL
24 RDW-CV	12.0	11.0-16.0	%
25 RDW-SD	44.1	35.0-56.0	fL
<b>26 PLT</b>	219	125-350	10 <sup>3</sup> /uL
27 MPV	11.8	6.5-12.0	fL
28 PDW-SD	16.7	9.0-17.0	fL
29 PDW-CV	15.6	10.0-17.9	%
30 PCT	0.258	0.108-0.282	%
31 P-LCR	51.6	11.0-45.0	%
32 P-LCC	113	30-90	10 <sup>3</sup> /uL

Submitter: \_\_\_\_\_ Operator: \_\_\_\_\_ Service: \_\_\_\_\_ Approver: \_\_\_\_\_

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## Hematology Analysis Report

First Name: PRECISION 08  
 Gender:

Sample ID: 0008  
 Run-Time: 28-04-2023 15:32  
 Age:

Parameter	Result	Ref.Range	Unit
1 HGB	12.6	11.5-16.0	g/dL
2 WBC	5.87	3.50-9.50	10 <sup>3</sup> /uL
3 Neu%	52.1	40.0-75.0	%
4 Lym%	29.8	20.0-50.0	%
5 Mon%	12.1	3.0-10.0	%
6 Eos%	5.7	0.4-8.0	%
7 Bas%	0.3	0.0-1.0	%
8 Neu#	3.06	1.80-6.30	10 <sup>3</sup> /uL
9 Lym#	1.75	1.10-6.30	10 <sup>3</sup> /uL
10 Mon#	0.71	0.10-0.60	10 <sup>3</sup> /uL
11 Eos#	0.33	0.02-0.52	10 <sup>3</sup> /uL
12 Bas#	0.02	0.00-0.06	10 <sup>3</sup> /UI
13 *ALY#	0.04	0.00-0.20	10 <sup>3</sup> /UI
14 *ALY%	0.6	0.0-0.2	%
15 *LIC#	0.02	0.00-0.20	10 <sup>3</sup> /uL
16 *LIC%	0.4	0.0-2.5	%
17 *NRBC#	0.000	0.000-9999.999	10 <sup>3</sup> /uL
18 *NRCB%	0.00	0.00-9999.99	%
19 RBC	4.49	3.80-5.80	10 <sup>6</sup> /uL
20 HCT	39.7	35.0-50.0	%
21 MCV	88.5	82.0-100.0	fL
22 MCH	28.0	27.0-34.0	pg
23 MCHC	31.6	31.6-35.4	g/dL
24 RDW-CV	12.1	11.0-16.0	%
25 RDW-SD	44.2	35.0-56.0	fL
26 PLT	223	125-350	10 <sup>3</sup> /uL
27 MPV	12.0	6.5-12.0	fL
28 PDW-SD	17.0	9.0-17.0	fL
29 PDW-CV	15.6	10.0-17.9	%
30 PCT	0.268	0.108-0.282	%
31 P-LCR	52.9	11.0-45.0	%
32 P-LCC	118	30-90	10 <sup>3</sup> /uL

Submitter: \_\_\_\_\_ Operator: \_\_\_\_\_ Service: \_\_\_\_\_ Approver \_\_\_\_\_

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## Hematology Analysis Report

First Name: PRECISION 09

Sample ID: 0009

Gender:

Run-Time: 28-04-2023 15:35

Age:

Parameter	Result	Ref.Range	Unit
1 HGB	12.6	11.5-16.0	g/dL
<b>2WBC</b>	5.87	3.50-9.50	10 <sup>3</sup> /uL
3 Neu%	51.0	40.0-75.0	%
4 Lym%	30.3	20.0-50.0	%
5 Mon%	12.7	3.0-10.0	%
6 Eos%	5.7	0.4-8.0	%
7 Bas%	0.3	0.0-1.0	%
8 Neu#	2.99	1.80-6.30	10 <sup>3</sup> /uL
9 Lym#	1.78	1.10-6.30	10 <sup>3</sup> /uL
10 Mon#	0.75	0.10-0.60	10 <sup>3</sup> /uL
11 Eos#	0.33	0.02-0.52	10 <sup>3</sup> /uL
12 Bas#	0.02	0.00-0.06	10 <sup>3</sup> /UI
13 *ALY#	0.05	0.00-0.20	10 <sup>3</sup> /UI
14 *ALY%	0.8	0.0-0.2	%
15 *LIC#	0.03	0.00-0.20	10 <sup>3</sup> /uL
16 *LIC%	0.5	0.0-2.5	%
17 *NRBC#	0.000	0.000-9999.999	10 <sup>3</sup> /uL
18 *NRBC%	0.00	0.00-9999.99	%
<b>19 RBC</b>	4.48	3.80-5.80	10 <sup>6</sup> /uL
20 HCT	39.5	35.0-50.0	%
21 MCV	88.1	82.0-100.0	fL
22 MCH	28.1	27.0-34.0	pg
23 MCHC	31.9	31.6-35.4	g/dL
24 RDW-CV	12.1	11.0-16.0	%
25 RDW-SD	44.5	35.0-56.0	fL
<b>26 PLT</b>	214	125-350	10 <sup>3</sup> /uL
27 MPV	11.9	6.5-12.0	fL
28 PDW-SD	15.9	9.0-17.0	fL
29 PDW-CV	14.7	10.0-17.9	%
30 PCT	0.256	0.108-0.282	%
31 P-LCR	52.6	11.0-45.0	%
32 P-LCC	113	30-90	10 <sup>3</sup> /uL

Submitter:

Operator:

Service:

Approver

**\*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 <sup>9</sup> /L)	RBC (10 <sup>12</sup> /L)	HGB (g/L)	MCV (fL)	PLT (10 <sup>9</sup> /L)
H360	Calibrator	9.08	4.61	127	89.3	249
	Relative expansion Uncertainty %	2.3	0.5	0.4	0.2	4.1
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
H560 (SW A12.2 or higher; version A only)	Calibrator	9.00	4.51	128	88.7	259
	Relative expansion Uncertainty %	2.6	0.3	0.1	0.4	4.2
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
H560 (SW B1.0 or higher)	Calibrator	8.99	4.44	126	85.0	262
	Relative expansion Uncertainty %	2.5	0.4	0.2	0.3	4.6
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
ELite 580 (SW A10.4 or higher)	Calibrator	9.31	4.39	129	85.1	245
	Relative expansion Uncertainty %	2.4	0.2	0.3	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 06.04.2023



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  
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## 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<sup>(1)</sup>. Readings are made at 540 nm in a colorimeter/spectrophotometer calibrated according to CLSI H15-A3 and ICSH recommendations<sup>(1)</sup>.

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<sup>(2)</sup>. 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.





# ELite H CAL



Hematology Calibrator / Hematologický kalibrátor / Calibrador de hematología

## Assay values

Atestované hodnoty / Valores de la media

**LOT**

PLUS0423



2023-05-05

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
<b>ELite 580</b> (SW A10.4 or higher)	WBC	$\times 10^9/L$	9.31	$\pm 0.20$
	RBC	$\times 10^{12}/L$	4.39	$\pm 0.08$
	HGB	g/L	129	$\pm 2$
		g/dL	12.9	$\pm 0.2$
	PLT	$\times 10^9/L$	245	$\pm 12$
<b>H560</b> (SW A12.2 or higher; version A only)	WBC	$\times 10^9/L$	9.00	$\pm 0.20$
	RBC	$\times 10^{12}/L$	4.51	$\pm 0.08$
	HGB	g/L	128	$\pm 2$
		g/dL	12.8	$\pm 0.2$
	PLT	$\times 10^9/L$	259	$\pm 12$
<b>H560</b> (SW B1.0 or higher)	WBC	$\times 10^9/L$	8.99	$\pm 0.20$
	RBC	$\times 10^{12}/L$	4.44	$\pm 0.08$
	HGB	g/L	126	$\pm 2$
		g/dL	12.6	$\pm 0.2$
	PLT	$\times 10^9/L$	262	$\pm 12$
<b>H360</b>	WBC	$\times 10^9/L$	9.08	$\pm 0.20$
	RBC	$\times 10^{12}/L$	4.61	$\pm 0.08$
	HGB	g/L	127	$\pm 2$
		g/dL	12.7	$\pm 0.2$
	PLT	$\times 10^9/L$	249	$\pm 12$

