



Date: 21-03-2023
Effective Date: 21-03-2023

Certificate of Calibration

Customer Name: CENTRAL AYURVEDA RESEARCH INSTITUTE

Model : Automated Hematology Analyzer H560

Serial No. : K1104B2145264

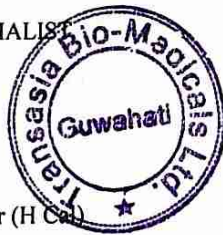
Calibration Done Date: 21.03.2023

Next Calibration Due Date On or Before: 21.03.2024

Lab In-charge: . Dr G K BORA

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: SUDHAM DAS
Designation: SR APPLICATION SPECIALIST
Transasia Bio-Medicals Ltd
Location



Encl:

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

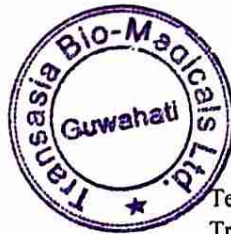


Date: 21-03-2023
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Certificate of Inspection

1. Model: Automated Hematology Analyzer H560
2. Serial No.: K1104B2145264
3. Calibration Date: 21.03.2023
4. Material used: H Cal (Lot No. PLUS0323, Expiry date: 10-APRIL-2023)

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 /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

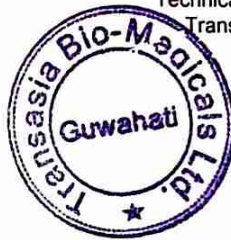


UNMATCHED SERVICE
SINCE 1979...

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

SMP NO	WBC	RBC	HGB	MCV	PLT
1	8.57	5.47	13.6	74.5	188
2	8.92	5.51	13.7	74.5	197
3	8.44	5.54	13.6	74.2	181
4	8.65	5.48	13.5	74.7	189
5	8.56	5.55	13.7	74.7	200
6	8.42	5.48	13.6	74.5	195
7	8.67	5.55	13.6	74.7	205
8	8.83	5.5	13.7	74.4	205
9	8.45	5.55	13.7	74.3	193
10	8.51	5.53	13.6	74.6	200
Mean	8.60	5.52	13.63	74.51	195.30
SD	0.17	0.03	0.07	0.17	7.73
CV%	1.95	0.58	0.50	0.23	3.96
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



History

Cal. Operator : admin

Cal. Method : Calibrator

Cal. Mode : Whole Blood

Cal. Time : 2023/03/21 15:46:57

Description : PLUS0323(Lot No.), 2023/04/10(Exp. Date)

Print Time : 2023/03/21 15:48:06

Details

Para.	WBC	RBC	HGB	MCV	PLT
Target	8.92	4.59	13.2	85.3	262
√ 1	8.82	4.74	13.3	92.7	269
√ 2	9.01	4.73	13.3	93.0	255
√ 3	8.93	4.74	13.3	93.0	261
√ 4	8.89	4.71	13.3	92.8	255
√ 5	9.00	4.68	13.4	92.9	257
√ 6	9.07	4.71	13.4	92.9	262
√ 7	8.83	4.72	13.3	93.1	260
√ 8	8.98	4.70	13.3	92.9	267
√ 9	9.02	4.71	13.3	93.0	265
√ 10	8.95	4.74	13.3	93.0	249
New Cal. Coefficient (%)	99.66	97.29	99.10	91.79	100.77
Original Cal. Coefficient (%)	100.00	100.00	100.00	95.00	100.00



Calibrator

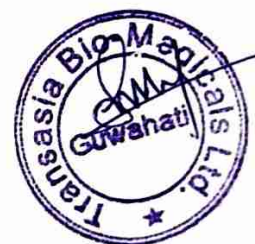
Lot No.: PLUS0323

Exp. Date: 2023/04/10

Cal. Mode: Whole Blood

Print Time: 2023/03/21 15:47:06

Para.	WBC	RBC	HGB	MCV	PLT
Target	8.92	4.59	13.2	85.3	262
√ 1	8.82	4.74	13.3	92.7	269
√ 2	9.01	4.73	13.3	93.0	255
√ 3	8.93	4.74	13.3	93.0	261
√ 4	8.89	4.71	13.3	92.8	255
√ 5	9.00	4.68	13.4	92.9	257
√ 6	9.07	4.71	13.4	92.9	262
√ 7	8.83	4.72	13.3	93.1	260
√ 8	8.98	4.70	13.3	92.9	267
√ 9	9.02	4.71	13.3	93.0	265
√ 10	8.95	4.74	13.3	93.0	249
Mean	8.950	4.718	13.32	92.93	260.0
CV(%)	0.9	0.4	0.3	0.1	2.4
New Cal. Coefficient (%)	99.66	97.29	99.10	91.79	100.77
Original Cal. Coefficient (%)	100.00	100.00	100.00	95.00	100.00



ELite H CAL



Hematology Calibrator / Hematologický kalibrátor / Calibrador de hematología

Assay values

Atestované hodnoty / Valores de la media

LOT

PLUS0323



2023-04-10

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	x10 ⁹ /L	9.09	± 0.20
	RBC	x10 ¹² /L	4.54	± 0.08
	HGB	g/L	135	± 2
		g/dL	13.5	± 0.2
	MCV	fL	85.7	± 2.0
	PLT	x10 ⁹ /L	248	± 12
H560 (SW A12.2 or higher; version A only)	WBC	x10 ⁹ /L	8.89	± 0.20
	RBC	x10 ¹² /L	4.68	± 0.08
	HGB	g/L	135	± 2
		g/dL	13.5	± 0.2
	MCV	fL	89.1	± 2.0
	PLT	x10 ⁹ /L	255	± 12
H560 (SW B1.0 or higher)	WBC	x10 ⁹ /L	8.92	± 0.20
	RBC	x10 ¹² /L	4.59	± 0.08
	HGB	g/L	132	± 2
		g/dL	13.2	± 0.2
	MCV	fL	85.3	± 2.0
	PLT	x10 ⁹ /L	262	± 12
H360	WBC	x10 ⁹ /L	9.04	± 0.20
	RBC	x10 ¹² /L	4.82	± 0.08
	HGB	g/L	136	± 2
		g/dL	13.6	± 0.2
	MCV	fL	90.3	± 2.0
	PLT	x10 ⁹ /L	256	± 12



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.

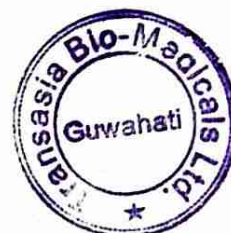


Table 1: Assignment results and uncertainty of reference method

	Reference	WBC (10 ⁹ /L)	RBC (10 ¹² /L)	HGB (g/L)	MCV (fL)	PLT (10 ⁹ /L)
H360	Calibrator	9.04	4.82	136	90.3	256
	Relative expansion Uncertainty %	2.5	0.4	0.2	0.1	4.3
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
H560 (SW A12.2 or higher; version A only)	Calibrator	8.89	4.68	135	89.1	255
	Relative expansion Uncertainty %	2.3	0.1	0.4	0.2	4.6
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
H560 (SW B1.0 or higher)	Calibrator	8.92	4.59	132	85.3	262
	Relative expansion Uncertainty %	2.4	0.2	0.3	0.6	4.5
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
ELite 580 (SW A10.4 or higher)	Calibrator	9.09	4.54	135	85.7	248
	Relative expansion Uncertainty %	2.2	0.3	0.1	0.5	4.4
	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 02.03.2023

