



Date: 18.09.2023
Effective Date: 8.09.2023

Certificate of Calibration

Customer Name: M.S. REGIONAL AYURVEDA RESEARCH INSTITUTE

Model : Automated Hematology Analyzer H560

Serial No. : K1104B2141071

Calibration Done Date: 18.09.2023

Next Calibration Due Date On or Before: 17.09.2024

Lab In-charge: . Mr. B.K. MEENA

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 Suchin Kumar Patanwala
Designation Sr. Area Service Manager
Transasia Bio-Medicals Ltd.
Location Jaipur



Encl:

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



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Certificate of Inspection

1. Model: Automated Hematology Analyzer H560
2. Serial No.: K1104B2141071
3. Calibration Date: 18.09.2023
4. Material used: H Cal (Lot No. PLUS0923, Expiry date: 10-Oct-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	0.3×10^3 /U1 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



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Transasia Bio-Medicals Ltd



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

SMP NO	WBC	RBC	HGB	MCV	PLT
1	4.16	4.26	11.3	80.9	226
2	4.15	4.33	11.6	80.6	236
3	4.18	4.37	11.6	80.6	243
4	4.28	4.3	11.5	80.5	228
5	4.23	4.31	11.6	80.5	241
6	4.22	4.36	11.6	80.4	234
7	4.34	4.32	11.6	80.7	232
8	4.27	4.31	11.5	80.6	242
9	4.3	4.37	11.7	80.7	231
10	4.25	4.34	11.7	80.6	236
Mean	4.24	4.33	11.57	80.61	234.90
SD	0.06	0.03	0.12	0.14	5.84
CV%	1.47	0.80	1.00	0.17	2.49
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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ELite H CAL



Hematology Calibrator / Hematologický kalibrátor / Calibrador de hematología

Assay values

Atestované hodnoty / Valores de la media

LOT

PLUS0923



2023-10-10

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	$\times 10^9/L$	9.36	± 0.20
	RBC	$\times 10^{12}/L$	4.57	± 0.08
	HGB	g/L	134	± 2
		g/dL	13.4	± 0.2
	MCV	fL	85.3	± 2.0
	PLT	$\times 10^9/L$	254	± 12
H560 (SW A12.2 or higher; version A only)	WBC	$\times 10^9/L$	9.21	± 0.20
	RBC	$\times 10^{12}/L$	4.61	± 0.08
	HGB	g/L	132	± 2
		g/dL	13.2	± 0.2
	MCV	fL	89.1	± 2.0
	PLT	$\times 10^9/L$	255	± 12
H560 (SW B1.0 or higher)	WBC	$\times 10^9/L$	9.21	± 0.20
	RBC	$\times 10^{12}/L$	4.67	± 0.08
	HGB	g/L	133	± 2
		g/dL	13.3	± 0.2
	MCV	fL	86.6	± 2.0
	PLT	$\times 10^9/L$	262	± 12
H360	WBC	$\times 10^9/L$	9.40	± 0.20
	RBC	$\times 10^{12}/L$	4.83	± 0.08
	HGB	g/L	134	± 2
		g/dL	13.4	± 0.2
	MCV	fL	89.3	± 2.0
	PLT	$\times 10^9/L$	257	± 12

