



UNMATCHED SERVICE  
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Date: 02-02-2023

Effective Date: 02-02-2023

## Certificate of Calibration

**Customer Name:** Chinmayi Hospital

**Model :** Automated Hematology Analyzer H560

**Serial No.** K11041936058

**Calibration Done Date:** 2.2.23

**Next Calibration Due Date On or Before:** 01-02-2024

**Lab In-charge :** Pradeep Kumar

*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:- SANJAY UNNIKRIISHNAN P K  
Designation:- SERVICE ENGINEER  
Transasia Bio-Medicals Ltd  
Location:- UDUPI

*P. Cooley*  
**LABORATORY**  
**CHINMAYI HOSPITAL**  
**KUNDAPURA**

Encl:

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

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

SMP NO	WBC	RBC	HGB	MCV	PLT
S1	9.41	5.1	15.7	84.6	320
S2	9.52	5.06	15.6	84.8	317
S3	9.6	5.06	15.5	84.7	320
S4	9.53	5.08	15.6	84.8	323
S5	9.73	5.07	15.6	84.7	323
S6	9.59	5.06	15.6	84.5	319
S7	9.69	5.06	15.5	84.6	314
S8	9.65	5.07	15.5	84.7	315
S9	9.52	5.1	15.7	84.7	316
S10	9.67	5.11	15.6	84.6	317
Mean	9.59	5.08	15.59	84.67	318.40
SD	0.10	0.02	0.07	0.09	3.13
CV%	1.02	0.38	0.47	0.11	0.98
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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## 5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.2	$0.3 \times 10^3$ /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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## Certificate of Inspection

1. Model: Automated Hematology Analyzer H560
2. Serial No.: K11041936058
3. Calibration Date: 02-02-2023
4. Material used: H Cal (Lot No. PLUS1223, Expiry date: 10-feb-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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## 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.



Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, Czech Republic  
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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	9.23	4.90	137	88.5	249
	Relative expansion Uncertainty %	2.2	0.1	0.3	0.5	4.4
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
H560 (SW A12.2 or higher; version A only)	Calibrator	8.96	4.62	134	88.4	256
	Relative expansion Uncertainty %	2.4	0.2	0.6	0.3	4.1
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
H560 (SW B1.0 or higher)	Calibrator	9.18	4.56	133	85.4	262
	Relative expansion Uncertainty %	2.3	0.6	0.5	0.4	4.2
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
ELite 580 (SW A10.4 or higher)	Calibrator	9.20	4.52	135	85.3	250
	Relative expansion Uncertainty %	2.1	0.5	0.4	0.2	4.3
	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 03.01.2023



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