Transasia Bio-Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (East), Mumbai - 400 072
**Tel:** +91 22 4030 9000 **Fax:** +91 22 2857 3030 **Email :** transasia@transasia.co.in **CIN :** U33110MH1985PLC036198

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Date: 01-05-2024

Effective Date: 01-05-2024

# Certificate of Calibration

**Customer Name: Ankur Pathology**

**Model : Automated Hematology Analyzer H560**

**Serial No. : K1104B2317116**

**Calibration Done Date: 1.5.24**

**Next Calibration Due Date On or Before: 1.5.25**

**Lab In-charge: . DR RAJESH MOHANTI**

*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 TANMOY NATH
Designation SENIOR SERVICE ENGINEER
Transasia Bio-Medicals Ltd
Location

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

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Date: 01-05-2024
Effective Date: 01-05-2024

# Certificate of Inspection

1. Model: Automated Hematology Analyzer H560

2. Serial No.: K1104B2317116

3. Calibration Date: 01.05.2024

4. Material used: H Cal (Lot No. PLUS0424, Expiry date: 10-May-2024)

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 x $10^3$/Ul or Less |
| RBC | 0.00 | 0.02 x $10^6$/uL or Less |
| HGB | 0.0 | 0.1 g/dL or Less |
| PLT | 0 | 10 x $10^3$/uL or Less |

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

| SMP NO | WBC | RBC | HGB | MCV | PLT |
|---|---|---|---|---|---|
| 1 | 9.16 | 4.65 | 10.1 | 69.5 | 128 |
| 2 | 9.18 | 4.59 | 10 | 69.3 | 127 |
| 3 | 9.37 | 4.62 | 10 | 69.5 | 122 |
| 4 | 9.21 | 4.59 | 10.1 | 69.5 | 132 |
| 5 | 9.35 | 4.61 | 10 | 69.4 | 128 |
| 6 | 9.28 | 4.58 | 10 | 69.4 | 126 |
| 7 | 9.24 | 4.61 | 10.2 | 69.2 | 130 |
| 8 | 9.17 | 4.58 | 10 | 69.4 | 121 |
| 9 | 9.18 | 4.61 | 10 | 69.4 | 124 |
| 10 | 9.08 | 4.65 | 10.1 | 69.5 | 118 |
| Mean | 9.22 | 4.61 | 10.05 | 69.41 | 125.60 |
| SD | 0.09 | 0.03 | 0.07 | 0.10 | 4.33 |
| **CV%** | **0.97** | **0.56** | **0.70** | **0.14** | **3.44** |
| | | | | | |
| 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

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Erba Lachema s.r.o.

# TRACEABILITY

**ELite H CAL**
**HEM00027**

**LOT: PLUS0424**
**EXP.: 2024-05-10**

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**

**Haematology Calibrator** values are traceable to standard reference methods.

Haematology analysers 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 analysed within six hours of collection.

The **White Blood Cell (WBC)** and **Red Blood Cell (RBC)** are analysed 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 haemocytometer 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 analyser 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), Haemocytometer by phase-contrast (PLT), spectrophotometer (HGB), and ruler (HCT).
- Uncertainty of the haematology analyser 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 | 9.25 | 4.69 | 139 | 91.9 | 243 |
| | Relative expansion Uncertainty % | 3.4 | 2.3 | 2.5 | 3.8 | 6.7 |
| H560 (SW A12.2 or higher; version A only) | Calibrator | 9.03 | 4.48 | 134 | 93.9 | 244 |
| | Relative expansion Uncertainty % | 3.2 | 2.6 | 2.7 | 3.9 | 6.1 |
| H560 (SW B1.0 or higher) | Calibrator | 9.29 | 4.58 | 136 | 90.0 | 252 |
| | Relative expansion Uncertainty % | 3.0 | 2.7 | 2.4 | 3.8 | 5.9 |
| ELite 580 (SW A10.4 or higher) | Calibrator | 9.46 | 4.51 | 137 | 89.6 | 250 |
| | Relative expansion Uncertainty % | 2.9 | 2.5 | 2.8 | 3.7 | 6.4 |

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 02.04.2024