Transasia Bio-Medicals Ltd., B-Wing, 1st Floor ,C 107, Build High, Naraina Industrial Area, Phase-I,
New Delhi-110028 Tel.: 011 - 25732223 Fax: 011-25785451 Email: nz1@transasia.co.in
CIN: U33110MH1985PLC036198

Date: 07.2023
Effective Date: 07.2023

Certificate of Calibration

Customer Name: THE HEALTH COUNTY LAB

Model : Automated Hematology Analyzer Elite 580

Serial No. : K11052315035

Calibration Done Date: 3.7.23

Next Calibration Due Date On or Before: 02-07-2024

Lab In-charge: . Dr.RAHUL GOYAL

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 Dileep Kumar yadav
Designation Sr.Service Engineer
Transasia Bio-Medicals Ltd.
Location Delhi

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

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CIN: U33110MH1985PLC036198

TRANSASIA®

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Date: 03-07-2023
Effective Date: 03-07-2023

Certificate of Inspection

1. Model: Automated Hematology Analyzer Elite 580

2. Serial No.: K11052315035

3. Calibration Date: 03-07-2023

4. Material used: H Cal (Lot No. PLUS0623, Expiry date: 10-07-2023)

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.

Transasia Bio Medicals Ltd. NEW DELHI

Technical Service Department
Transasia Bio-Medicals Ltd

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

Technical Service Department
Transasia Bio-Medicals Ltd

History

Cal. Operator :admin
Cal. Method :Calibrator
Cal. Mode : Whole Blood
Cal. Time : 2023-07-03 18:45:57
Description : PLUS0623(Lot No.) 2023/07/10(Exp. Date)
Print Time : 2024-04-30 14:25:06

Details

Para.	WBC	RBC	HGB	MCV	PLT
Target	9.23	4.56	13.1	85.4	251
1	9.32	4.52	12.9	91.6	280
2	9.45	4.58	13	91.9	275
3	9.36	4.62	12.9	91.6	282
4	9.46	4.59	13.2	91.7	280
5	9.58	4.56	13.2	91.8	264
6	9.59	4.59	13.1	91.7	285
7	9.5	4.61	13.1	91.9	283
8	9.5	4.58	13	92.1	282
9	9.73	4.64	13.1	91.7	286
10	9.58	4.62	13.1	91.5	283
New Calibration Coefficient (%)	97.09	99.32	100.31	93.08	89.64
Original Calibration Coefficient (%)	93.63	103.00	102.00	93.00	91.11

ELite H CAL

Hematology Calibrator / Hematologický kalibrátor / Calibrador de hematología

Assay values
Atestované hodnoty / Valores de la media

Name Název Nombre	Cat. No. Kat.č. No.Cat.	Package volume Objem balení Volumen
ELite H CAL	HEM00027	3 ml

LOT PLUS0623

2023-07-10

CE IVD

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	$x10^9/L$	9.23	± 0.20
	RBC	$x10^{12}/L$	4.56	± 0.08
	HGB	g/L	131	± 2
		g/dL	13.1	± 0.2
	MCV	fL	85.4	± 2.0
	PLT	$x10^9/L$	251	± 12
H560 (SW A12.2 or higher; version A only)	WBC	$x10^9/L$	9.10	± 0.20
	RBC	$x10^{12}/L$	4.61	± 0.08
	HGB	g/L	130	± 2
		g/dL	13.0	± 0.2
	MCV	fL	88.0	± 2.0
	PLT	$x10^9/L$	260	± 12
H560 (SW B1.0 or higher)	WBC	$x10^9/L$	9.14	± 0.20
	RBC	$x10^{12}/L$	4.63	± 0.08
	HGB	g/L	130	± 2
		g/dL	13.0	± 0.2
	MCV	fL	84.3	± 2.0
	PLT	$x10^9/L$	265	± 12
H360	WBC	$x10^9/L$	9.16	± 0.20
	RBC	$x10^{12}/L$	4.75	± 0.08
	HGB	g/L	130	± 2
		g/dL	13.0	± 0.2
	MCV	fL	89.4	± 2.0
	PLT	$x10^9/L$	257	± 12

Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, CZ

Date of Issue / Datum vydání / Fecha de emisión: 29. 5. 2023
HEMA/PI/31-A/23/A

Erba Lachema s.r.o.

Erba Mannheim

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	9.08	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