

### History

Cal. Operator	Service engineer	Cal. Method	Calibrator
Cal Mode	Whole Blood-Factory	Cal Date	2021/05/08
Description	PLUS0421(Lot No.) 2021/05/08 (Exp Date) 2021/05/10		

Details

Para.	WBC	RBC	HGB	MCV	PLT	MPV
Target	9.13	4.47	13.7	89.6	254	
1	9.14	4.49	13.7	91.9	247	
2	9.07	4.45	13.5	91.8	258	
3	9.39	4.46	13.7	91.9	256	
4	9.15	4.48	13.6	91.9	256	
5	9.14	4.51	13.7	91.5	261	
6	9.43	4.55	13.6	91.8	266	
7	9.06	4.53	13.6	92.1	244	
8	9.2	4.52	13.7	91.7	239	
9	9.49	4.5	13.6	91.4	236	
10	9.28	4.51	13.8	91.7	244	
11	9.13	4.51	13.7	91.6	242	
12	9.28	4.42	13.7	91.8	249	
New CBC+ DIFF Cal Coefficient (%)	98.81	99.38	100.15	97.69	104.83	
Original CBC+DIFF Cal. Coefficient (%)	106.45	97.75	102.86	102.3	100.08	100.00
New Transfer Coefficient	1.0021	1.0017	1.0036	0.9991	0.9417	
Original Transfer Coefficient	1.0195	1.0143	1.0086	0.9977	0.9450	1.0000



## PRECISION HISTORY

SMP NO	WBC	RBC	HGB	MCV	PLT
T-1	5.9	4.51	12.2	84	308
T-2	5.89	4.52	12.3	84.1	310
T-3	5.88	4.51	12.2	84.2	312
T-4	5.9	4.49	12.2	84.1	314
T-5	5.8	4.4	12.2	84.1	312
T-6	5.85	4.49	12.3	84.1	310
T-7	5.95	4.45	12.2	83.7	315
T-8	5.9	4.46	12.3	83.9	310
T-9	5.95	0.43	12.2	84.3	309
T-10	5.98	4.5	12.3	83.8	310
Mean	5.9	4.48	12.24	84.03	311
SD	0.05	0.04	0.05	0.18	2.21
CV%	0.88	0.88	0.42	0.22	0.71
Acceptable CV%	Within 3.5%	Within 2.0%	Within 1.5%	Within 2.0%	Within 6.0%
Result	PASS	PASS	PASS	PASS	PASS



## 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.

