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

TRANSASIA®

TRANSASIA Proud to be Indian UNMATCHED SERVICE SINCE 1979...

Date: 12.07.2022
Effective Date: 12.07.2022

Certificate of Calibration

Customer Name: Health Plus Wellness Diagnosics, Rohini,Delhi.

Model : Automated Hematology Analyzer H360

Serial No. : K10012102151

Calibration Done Date: 12.07.2022

Next Calibration Due Date On or Before: 11.07.2023

Lab In-charge: . Dr. Anju Kacker (H.O.D)

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
Sunil Gautam
Service Engineer
Transasia Bio-Medicals Ltd
Delhi

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

Erba® Mannheim

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TRANSASIA®

UNMATCHED SERVICE SINCE 1979...

Date: 12.07.2022
Effective Date: 12.07.2022

Certificate of Inspection

1. Model: Automated Hematology Analyzer H360

2. Serial No.: K10012102151

3. Calibration Date: 12.07.2022

4. Material use H Cal (Lot No. PLUS0722, Expiry date: 10-Aug-2022)

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.

Technical Service Department
Transasia Bio-Medicals Ltd

Erba® Mannheim

5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.0	0.3 x 103/UI or Less
RBC	0.00	0.02 x 106/uL or Less
HGB	0.0	0.1 g/dL or Less
PLT	0	10 x 103/uL or Less

Technical Service Department
Transasia Bio-Medicals Ltd

BackGround Data

Hematology Analysis Report

First Name: BACKGROUND
Last Name:
Sample ID:27
Run Time:
2022/07/12 17:42
Diagnosis:

Parameter	Result	Unit
WBC	0.00	10^3/uL
Lym%	***.*	%
Gran%	***.*	%
Mid%	***.*	%
Lym#	****.**	10^3/uL
Gran#	****.**	10^3/uL
Mid#	****.**	10^3/uL
RBC	0.00	10^6/uL
HGB	0.0	g/dL
HCT	0.0	%
MCV	****.*	fL
MCH	****.*	pg
MCHC	****.*	g/dL
RDW-CV	***.*	%
RDW-SD	****.*	fL
PLT	0	10^3/uL
MPV	***.*	fL
PDW-SD	***.*	fL
PDW-CV	***.*	%
PCT	.***	%
P-LCR	***.*	%
P-LCC	****	10^3/uL

ansasia Bio-Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (East), Mumbai - 400 072
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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	7	4.7	13.1	88.9	298
2	7.04	4.78	13.3	88.9	297
3	7.06	4.66	13.1	88.9	288
4	6.79	4.58	13.2	88.9	286
5	7.02	4.74	13.2	88.9	299
6	6.95	4.66	13	88.8	296
7	7.07	4.68	13	88.7	284
8	7.03	4.66	13	88.7	291
9	6.94	4.69	13	88.5	287
10	6.8	4.62	12.9	88.4	280
Mean	6.97	4.68	13.08	88.76	290.60
SD	0.10	0.06	0.12	0.18	6.60
CV%	**1.46**	**1.21**	**0.94**	**0.21**	**2.27**
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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Precision Data

Hematology Analysis Report

First Name:
Last Name:
Sample ID:1
Run Time:
2022/07/12 17:47
Diagnosis:

Parameter	Result	Unit
WBC	7.00	10^3/uL
Lym%	30.9	%
Gran%	60.4	%
Mid%	8.7	%
Lym#	2.16	10^3/uL
Gran#	4.23	10^3/uL
Mid#	0.61	10^3/uL
RBC	4.70	10^6/uL
HGB	13.1	g/dL
HCT	41.8	%
MCV	88.9	fL
MCH	27.8	pg
MCHC	31.3	g/dL
RDW-CV	14.3	%
RDW-SD	51.8	fL
PLT	298	10^3/uL
MPV	9.9	fL
PDW-SD	13.4	fL
PDW-CV	16.4	%
PCT	0.296	%
P-LCR	28.1	%
P-LCC	84	10^3/uL

Hematology Analysis Report

First Name:
Last Name:
Sample ID:2
Run Time:
2022/07/12 17:48
Diagnosis:

Parameter	Result	Unit
WBC	7.04	10^3/uL
Lym%	29.8	%
Gran%	61.3	%
Mid%	8.9	%
Lym#	2.10	10^3/uL
Gran#	4.31	10^3/uL
Mid#	0.63	10^3/uL
RBC	4.78	10^6/uL
HGB	13.3	g/dL
HCT	42.5	%
MCV	88.9	fL
MCH	27.8	pg
MCHC	31.3	g/dL
RDW-CV	14.5	%
RDW-SD	52.5	fL
PLT	297	10^3/uL
MPV	9.8	fL
PDW-SD	13.3	fL
PDW-CV	16.2	%
PCT	0.291	%
P-LCR	26.8	%
P-LCC	80	10^3/uL

Hematology Analysis Report

First Name:
Last Name:
Sample ID:3
Run Time:
2022/07/12 17:50
Diagnosis:

Parameter	Result	Unit
WBC	7.06	10^3/uL
Lym%	29.5	%
Gran%	62.4	%
Mid%	8.1	%
Lym#	2.08	10^3/uL
Gran#	4.41	10^3/uL
Mid#	0.57	10^3/uL
RBC	4.66	10^6/uL
HGB	13.1	g/dL
HCT	41.4	%
MCV	88.9	fL
MCH	28.1	pg
MCHC	31.7	g/dL
RDW-CV	14.3	%
RDW-SD	51.9	fL
PLT	288	10^3/uL
MPV	9.9	fL
PDW-SD	12.7	fL
PDW-CV	15.7	%
PCT	0.285	%
P-LCR	26.7	%
P-LCC	77	10^3/uL

Hematology Analysis Report

First Name:
Last Name:
Sample ID:4
Run Time:
2022/07/12 17:51
Diagnosis:

Parameter	Result	Unit
WBC	6.79	10^3/uL
Lym%	30.0	%
Gran%	61.3	%
Mid%	8.7	%
Lym#	2.04	10^3/uL
Gran#	4.16	10^3/uL
Mid#	0.59	10^3/uL
RBC	4.58	10^6/uL
HGB	13.2	g/dL
HCT	40.7	%
MCV	88.9	fL
MCH	28.9	pg
MCHC	32.5	g/dL
RDW-CV	14.3	%
RDW-SD	52.0	fL
PLT	286	10^3/uL
MPV	9.9	fL
PDW-SD	14.3	fL
PDW-CV	16.9	%
PCT	0.283	%
P-LCR	28.0	%
P-LCC	80	10^3/uL

Hematology Analysis Report

First Name:
Last Name:
Sample ID:5
Run Time:
2022/07/12 17:52
Diagnosis:

Parameter	Result	Unit
WBC	7.02	10^3/uL
Lym%	31.0	%
Gran%	60.3	%
Mid%	8.7	%
Lym#	2.18	10^3/uL
Gran#	4.23	10^3/uL
Mid#	0.61	10^3/uL
RBC	4.74	10^6/uL
HGB	13.2	g/dL
HCT	42.1	%
MCV	88.9	fL
MCH	27.9	pg
MCHC	31.4	g/dL
RDW-CV	14.4	%
RDW-SD	52.3	fL
PLT	299	10^3/uL
MPV	9.9	fL
PDW-SD	12.8	fL
PDW-CV	16.0	%
PCT	0.296	%
P-LCR	27.5	%
P-LCC	82	10^3/uL

Hematology Analysis Report

First Name:
Last Name:
Sample ID:6
Run Time:
2022/07/12 17:53
Diagnosis:

Parameter	Result	Unit
WBC	6.95	10^3/uL
Lym%	31.0	%
Gran%	61.2	%
Mid%	7.8	%
Lym#	2.15	10^3/uL
Gran#	4.26	10^3/uL
Mid#	0.54	10^3/uL
RBC	4.66	10^6/uL
HGB	13.0	g/dL
HCT	41.4	%
MCV	88.8	fL
MCH	27.9	pg
MCHC	31.4	g/dL
RDW-CV	14.2	%
RDW-SD	51.4	fL
PLT	296	10^3/uL
MPV	9.8	fL
PDW-SD	13.2	fL
PDW-CV	16.4	%
PCT	0.289	%
P-LCR	26.4	%
P-LCC	78	10^3/uL

Precision Data, H-360

Hematology Analysis Report

First Name:
Last Name:
Sample ID:7
Run Time:
2022/07/12 17:54
Diagnosis:

Parameter	Result	Unit
WBC	7.07	10^3/uL
Lym%	31.1	%
Gran%	61.4	%
Mid%	7.5	%
Lym#	2.20	10^3/uL
Gran#	4.34	10^3/uL
Mid#	0.53	10^3/uL
RBC	4.68	10^6/uL
HGB	13.0	g/dL
HCT	41.5	%
MCV	88.7	fL
MCH	27.7	pg
MCHC	31.3	g/dL
RDW-CV	14.2	%
RDW-SD	51.3	fL
PLT	284	10^3/uL
MPV	9.9	fL
PDW-SD	13.1	fL
PDW-CV	15.7	%
PCT	0.283	%
P-LCR	26.6	%
P-LCC	76	10^3/uL

Hematology Analysis Report

First Name:
Last Name:
Sample ID:8
Run Time:
2022/07/12 17:55
Diagnosis:

Parameter	Result	Unit
WBC	7.03	10^3/uL
Lym%	29.0	%
Gran%	61.6	%
Mid%	9.4	%
Lym#	2.04	10^3/uL
Gran#	4.33	10^3/uL
Mid#	0.66	10^3/uL
RBC	4.66	10^6/uL
HGB	13.0	g/dL
HCT	41.4	%
MCV	88.7	fL
MCH	27.8	pg
MCHC	31.4	g/dL
RDW-CV	14.2	%
RDW-SD	51.6	fL
PLT	291	10^3/uL
MPV	9.9	fL
PDW-SD	12.8	fL
PDW-CV	16.0	%
PCT	0.288	%
P-LCR	27.2	%
P-LCC	79	10^3/uL

Hematology Analysis Report

First Name:
Last Name:
Sample ID:9
Run Time:
2022/07/12 17:57
Diagnosis:

Parameter	Result	Unit
WBC	6.94	10^3/uL
Lym%	31.6	%
Gran%	60.5	%
Mid%	7.9	%
Lym#	2.19	10^3/uL
Gran#	4.20	10^3/uL
Mid#	0.55	10^3/uL
RBC	4.69	10^6/uL
HGB	13.0	g/dL
HCT	41.5	%
MCV	88.5	fL
MCH	27.8	pg
MCHC	31.5	g/dL
RDW-CV	14.4	%
RDW-SD	52.3	fL
PLT	287	10^3/uL
MPV	9.8	fL
PDW-SD	13.7	fL
PDW-CV	16.5	%
PCT	0.282	%
P-LCR	26.5	%
P-LCC	76	10^3/uL

Precision Data, H-360

Hematology Analysis Report

First Name:
Last Name:
Sample ID:10
Run Time:
2022/07/12 17:58
Diagnosis:

Parameter	Result	Unit
WBC	6.80	10^3/uL
Lym%	30.4	%
Gran%	60.9	%
Mid%	8.7	%
Lym#	2.07	10^3/uL
Gran#	4.14	10^3/uL
Mid#	0.59	10^3/uL
RBC	4.62	10^6/uL
HGB	12.9	g/dL
HCT	40.8	%
MCV	88.4	fL
MCH	28.0	pg
MCHC	31.7	g/dL
RDW-CV	14.3	%
RDW-SD	51.8	fL
PLT	280	10^3/uL
MPV	9.7	fL
PDW-SD	12.7	fL
PDW-CV	15.8	%
PCT	0.271	%
P-LCR	25.2	%
P-LCC	71	10^3/uL

ELite H CAL

Hematology Calibrator / Hematologický kalibrátor / Calibrador de hematología

LOT PLUS0722

2022-08-10

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

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	$x10^9/L$	9.15	± 0.20
	RBC	$x10^{12}/L$	4.51	± 0.08
	HGB	g/L	135	± 2
		g/dL	13.5	± 0.2
	MCV	fL	87.1	± 2.0
	PLT	$x10^9/L$	246	± 12
H560 (SW A12.2 or higher; version A only)	WBC	$x10^9/L$	8.98	± 0.20
	RBC	$x10^{12}/L$	4.61	± 0.08
	HGB	g/L	135	± 2
		g/dL	13.5	± 0.2
	MCV	fL	90.3	± 2.0
	PLT	$x10^9/L$	256	± 12
H560 (SW B1.0 or higher)	WBC	$x10^9/L$	9.04	± 0.20
	RBC	$x10^{12}/L$	4.53	± 0.08
	HGB	g/L	134	± 2
		g/dL	13.4	± 0.2
	MCV	fL	88.4	± 2.0
	PLT	$x10^9/L$	260	± 12
H360	WBC	$x10^9/L$	9.48	± 0.20
	RBC	$x10^{12}/L$	4.86	± 0.08
	HGB	g/L	138	± 2
		g/dL	13.8	± 0.2
	MCV	fL	91.0	± 2.0
	PLT	$x10^9/L$	251	± 12

10020492

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

Date of Issue / Datum vydání / Fecha de emisión 29 6 2022
HEMA/PI/28-A/22/F/INT

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.

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	9.48	4.86	138	91.0	251
	Relative expansion Uncertainty %	2.0	0.6	0.3	0.2	4.3
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
H560 (SW A12.2 or higher; version A only)	Calibrator	8.98	4.61	135	90.3	256
	Relative expansion Uncertainty %	2.3	0.5	0.1	0.3	4.1
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
H560 (SW B1.0 or higher)	Calibrator	9.04	4.53	134	88.4	260
	Relative expansion Uncertainty %	2.2	0.6	0.3	0.2	4.2
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
ELite 580 (SW A10.4 or higher)	Calibrator	9.15	4.51	135	87.1	246
	Relative expansion Uncertainty %	2.4	0.5	0.2	0.4	4.0
	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 28.07.2022

Erba Mannheim

Sample Analysis | Review | Reagent Manageme

QC Type: L-J | Edit Result | Print

QC Settings | QC Graph | QC Tabl

File No.: 3

Existing / Total: 1/500

QC Mode: Whole Blood Lot No E0522L

Exp. Date: 2022/08/10 Level Normal

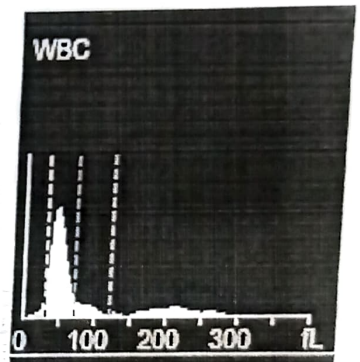
Editor: admin

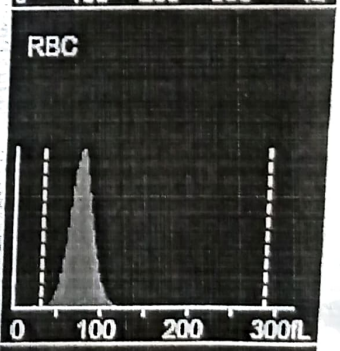
Operator: admin

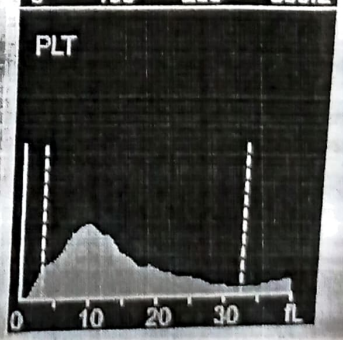
QC Sample ID

Run Time: 2022/07/12 19:18:20

Para.	Result	Unit
WBC	1.67	10^3/uL
Lym%	65.0	%
Gran%	23.1	%
Mid%	11.9	%
Lym#	1.09	10^3/uL
Gran#	0.38	10^3/uL
Mid#	0.20	10^3/uL
RBC	2.37	10^6/uL
HGB	5.7	g/dL
HCT	18.8	%
MCV	79.3	fL
MCH	23.8	pg
MCHC	30.0	g/dL
RDW-CV	14.5	%
RDW-SD	46.9	fL
PLT	64	10^3/uL
MPV	9.9	fL
PDW-SD	10.9	fL
PDW-CV	14.4	%
PCT	0.063	%
P-LCR	27.2	%
P-LCC	17	10^3/uL







Next Sample | Mode:WB

QC | User.admin | 2022/07/12 19:20:10

Erba Mannheim

Sample Analysis | Review

QC Type: L-J | Edit Result | Previous | Next | Print

QC Settings | QC Graph | QC Table

File No.: 4

Existing / Total: 2/500

QC Mode: Whole Blood Lot No. E0522N

Exp. Date: 2022/08/10 Level: Normal

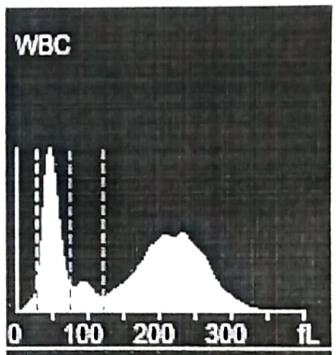
Editor: admin

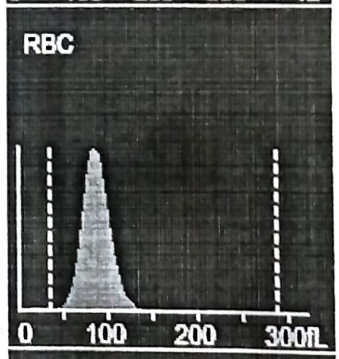
Operator: admin

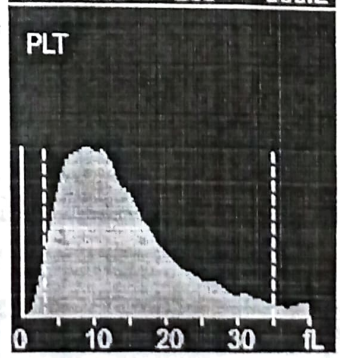
QC Sample ID.

Run Time: 2022/07/12 19:16:48

Para.	Result	Unit
WBC	8.10	10^3/uL
Lym%	30.3	%
Gran%	61.8	%
Mid%	7.9	%
Lym#	2.45	10^3/uL
Gran#	5.01	10^3/uL
Mid#	0.64	10^3/uL
RBC	5.01	10^6/uL
HGB	13.9	g/dL
HCT	45.2	%
MCV	90.2	fL
MCH	27.8	pg
MCHC	30.8	g/dL
RDW-CV	14.5	%
RDW-SD	53.6	fL
PLT	283	10^3/uL
MPV	10.0	fL
PDW-SD	13.2	fL
PDW-CV	16.2	%
PCT	0.282	%
P-LCR	27.6	%
P-LCC	78	10^3/uL







Analyzing | Mode:WB

QC | User:admin

2022/07/12 19:17:51

Erba Mannheim

Sample Analysis | Review | Record Management

QC Type: L-J | Edit Result | Previous

QC Settings | QC Graph | QC Table

File No.: 5

Existing / Total: 1/500

QC Mode: Whole Blood Lot No.:

Exp. Date: 2022/08/10 Level: Normal

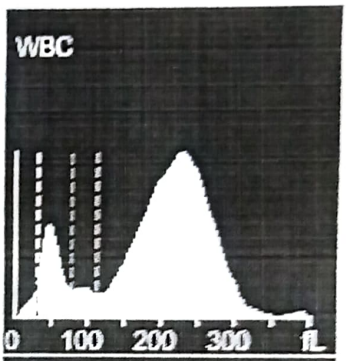
Editor: admin

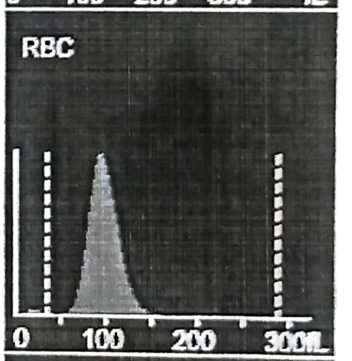
Operator: admin

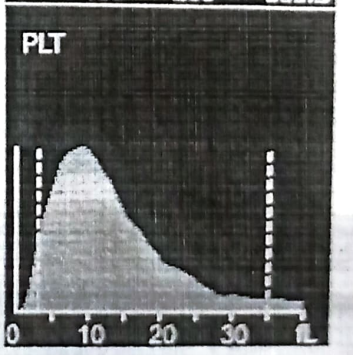
QC Sample ID

Run Time: 2022/07/12 19:20:31

Para.	Result	
WBC	21.17	10^3/uL
Lym%	13.0	%
Gran%	82.5	%
Mid%	4.5	%
Lym#	2.75	10^3/uL
Gran#	17.47	10^3/uL
Mid#	0.95	10^3/uL
RBC	6.12	10^6/uL
HGB	19.3	g/dL
HCT	62.3	%
MCV	101.8	fL
MCH	31.5	pg
MCHC	31.0	g/dL
RDW-CV	13.8	%
RDW-SD	57.4	fL
PLT	552	10^3/uL
MPV	9.6	fL
PDW-SD	12.2	fL
PDW-CV	15.9	%
PCT	0.529	%
P-LCR	25.3	%
P-LCC	140	10^3/uL







Next Sample | Mode:WB

QC | User:admin

2022/07/12 19:21