



02-02-2023

CALIBRATION CERTIFICATE

Customer Name : Redcliffe Lifetech Private Limited, Jabalpur MP

Model : Automated Hematology Analyzer Elite 580

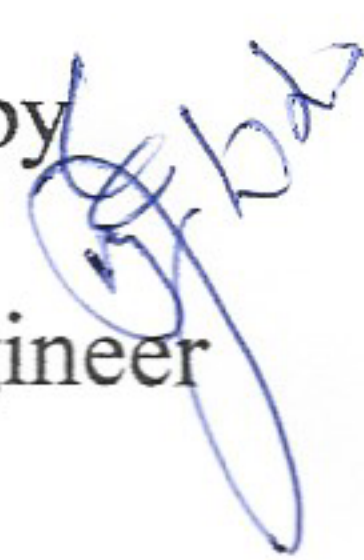
Serial No : K11052132024

Calibration Done Date : 02-02-2023

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

Lab Incharge : Mr. Arvind Maurya

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 
Name : Abhishek Choudhary
Designation : Sr. Service Engineer
Transasia Biomedicals Ltd.
Location : Jabalpur M.P.

Encl :

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

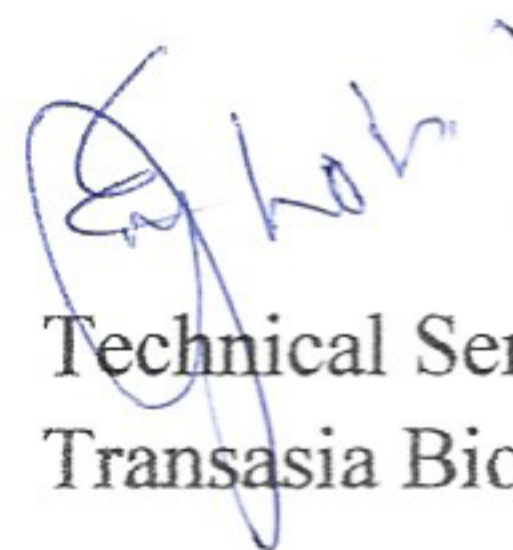


Date: 02/02/2023

Certificate of Inspection

1. Model: Automated Hematology Analyzer Elite 580
2. Serial No.: K11052132024
3. Calibration Date: 02-02-2023
4. Material used: H Cal (Lot No. PLUS0123) Exp Date-10/02/2023

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.

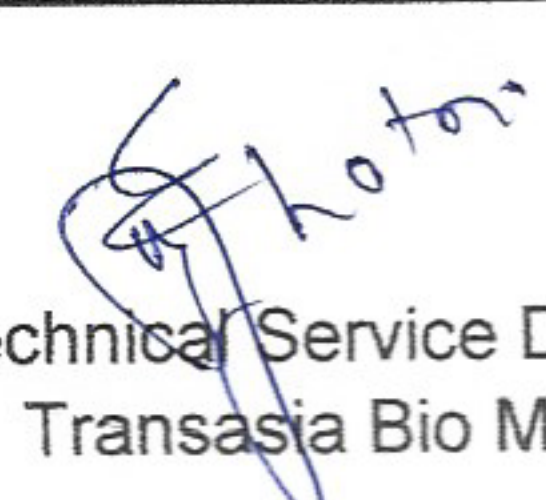


Technical Service Department
Transasia Bio-Medicals Ltd



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

SMP NO	WBC	RBC	HGB	MCV	PLT
1	9.11	4.41	13.4	88.4	251
2	9.07	4.49	13.6	88.4	256
3	9.22	4.48	13.6	88.4	255
4	9.15	4.45	13.6	88.4	258
5	9.02	4.47	13.5	88.3	260
6	9.16	4.5	13.6	88.4	262
7	9.3	4.46	13.6	88.4	257
8	9.01	4.43	13.4	88.5	249
9	9.24	4.45	13.6	88.4	258
10	9.25	4.43	13.5	88.5	262
Mean	91.53	44.57	135.40	884.10	2568.00
SD	0.10	0.03	0.08	0.06	4.29
CV%	0.11	0.06	0.06	0.20	0.17
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



5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.0	0.3 x 10 ³ /UI 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

PLUS0123 [10/2/2023

History

Cal. Operator : admin

Cal. Method : Calibrator

Cal. Mode : Whole Blood

Cal. Time : 2023/02/02 17:47:37

Description : PLUS0123(Lot No.) 2023/02/10(Exp. Date)

Print Time : 2023/05/11 18:31:07

Details

Para.	WBC	RBC	HGB	MCV	PLT
Target	9.2	4.52	13.6	86	255
1	9.11	4.41	13.4	88.4	251
2	9.07	4.49	13.6	88.4	256
3	9.22	4.48	13.6	88.4	255
4	9.15	4.45	13.6	88.4	258
5	9.02	4.47	13.5	88.3	260
6	9.16	4.5	13.6	88.4	262
7	9.3	4.46	13.6	88.4	257
8	9.01	4.43	13.4	88.5	249
9	9.24	4.45	13.6	88.4	258
10	9.25	4.43	13.5	88.5	264
New Calibration Coefficient (%)	100.51	101.41	100.44	97.27	99.22
Original Calibration Coefficient (%)	100.00	101.48	99.81	98.20	100.00

Redcliff Labs Pvt Ltd jabalpur

First Name:
Last Name:
Gender:
Age:

Sample Type:
Department:
Patient ID:

Sample ID: background
Run Time: 2023/02/02 16:14
Diagnosis:

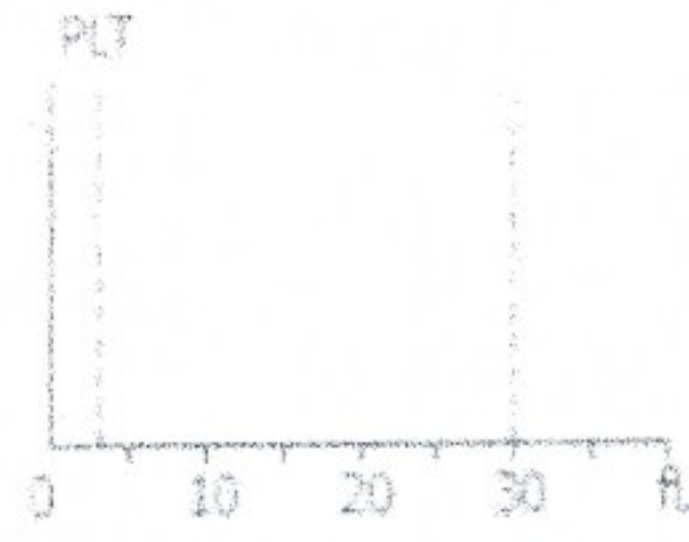
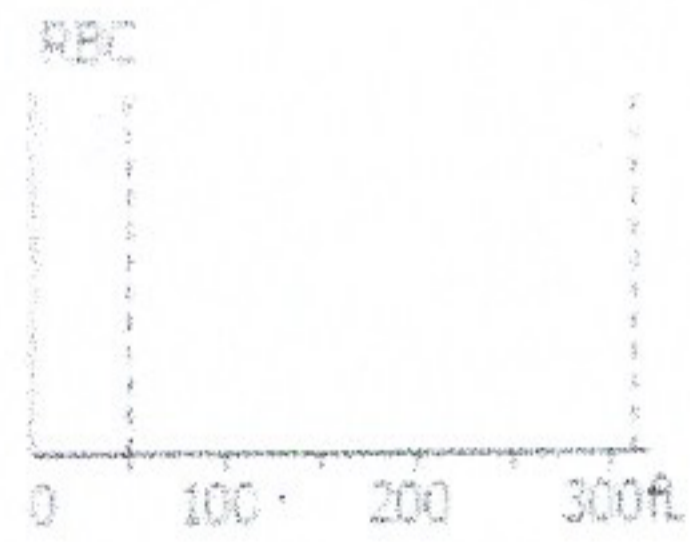
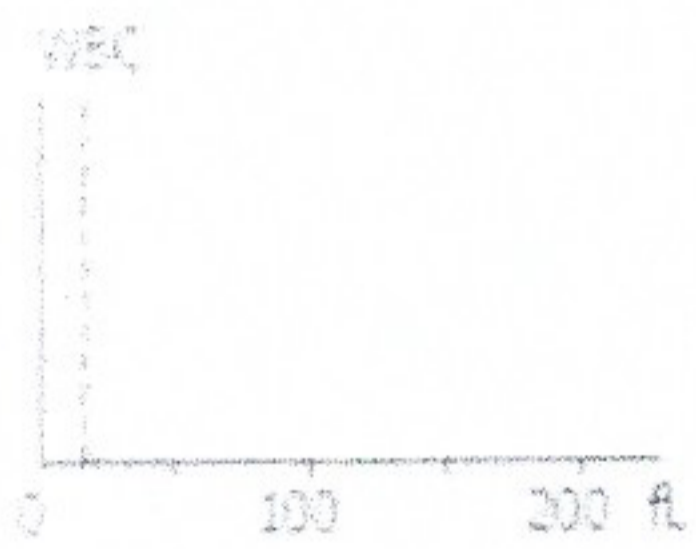
Parameter	Result	Ref. Range	Unit
1 WBC	0.00		10 ³ /uL
2 RBC	0.00		10 ⁶ /uL
3 HGB	0.0		g/dL
4 HCT	0.0		%
5 MCV	****		fL
6 MCH	****		pg
7 MCHC	****		g/dL
8 RDW-CV	***		%
9 RDW-SD	****		fL
10 PLT	0		10 ³ /uL
11 MPV	***		fL
12 PDW-SD	***		fL
13 PDW-CV	***		%
14 PCT	***		%
15 P-LCR	***		%
16 P-LCC	****		10 ⁹ /L

WBC Message

Background/Aspiration Abn.

RBC Message

PLT Message



Submitter: Operator: admin Approver: service
 Sampling Time: 2023/02/02 09:56 Delivery Time: 2023/02/02 09:56 Validated Time: 2023/05/11 18:34
 Report Time: 2023/05/11 18:34 Remarks:

*The Report is responsible for this sample only. If you have any questions, please contact us in 24 hours.

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.



Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, Czech Republic
Identification number: 269 18 846. Tax identification number: CZ26918846
Incorporated in the Commercial Register maintained by the Regional Court in Brno, Section C, insert 45458
Tel.: +420 517 077 111, e-mail: diagnostics@erbamannheim.com, www.erbalachema.com

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	9.23	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

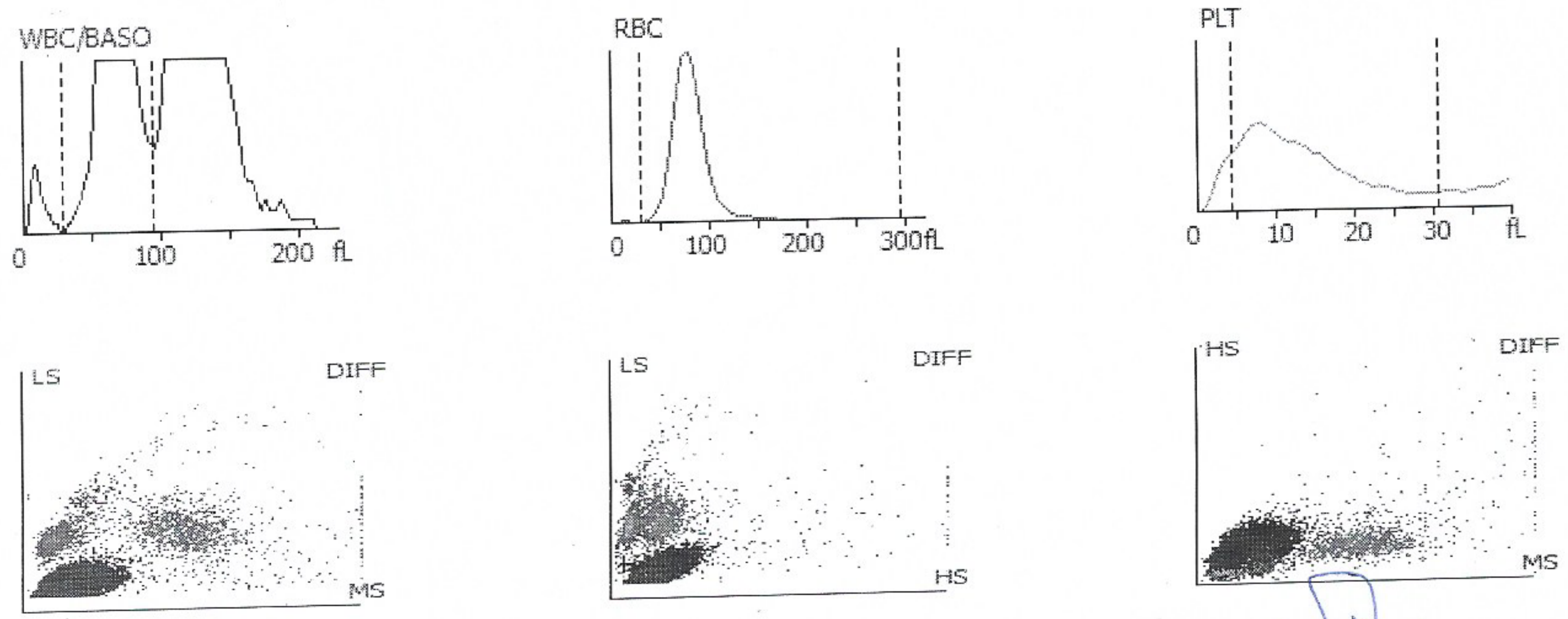


Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, Czech Republic
 Identification number: 269 18 846. Tax identification number: CZ26918846
 Incorporated in the Commercial Register maintained by the Regional Court in Brno, Section C, insert 45458
 Tel.: +420 517 077 111, e-mail: diagnostics@erbamannheim.com, www.erbalachema.com

L-J QC Analysis

File No.: 16 Lot No.: EH230524LOW Level: Low
 Operator: admin Exp. Date: 2023/07/10 Run Time: 2023/06/20 09:39
 Print Time: 2023/06/20 10:06 QC Mode: Whole Blood-CBC+DIFF QC Sample ID: 16

Parameter	Result	Ref. Range	Unit
1 WBC	3.64	3.11-4.11	10³/uL
2 Neu%	55.2	38.8-56.8	%
3 Lym%	38.3	32.0-50.0	%
4 Mon%	4.9	2.1-10.1	%
5 Eos%	1.6	0.1-10.1	%
6 Bas%	59.5	50.8-66.8	%
7 Neu#	2.01	1.32-2.12	10 ³ /uL
8 Lym#	1.40	1.08-1.88	10 ³ /uL
9 Mon#	0.18	0.08-0.36	10 ³ /uL
10 Eos#	0.05	0.03-0.33	10 ³ /uL
11 Bas#	2.16	1.82-2.42	10 ³ /uL
12 RBC	2.26	2.09-2.45	10⁶/uL
13 HGB	5.8	5.1-5.9	g/dL
14 HCT	17.6	15.6-19.6	%
15 MCV	77.9	72.5-82.5	fL
16 MCH	25.5	22.0-27.0	pg
17 MCHC	32.7	28.5-34.5	g/dL
18 RDW-CV	19.6	15.9-21.9	%
19 RDW-SD	55.4	41.9-61.9	fL
20 PLT	59	33-73	10³/uL
21 MPV	10.4	7.2-13.2	fL
22 PDW-SD	12.2	8.5-14.5	fL
23 PDW-CV	14.8	10.8-16.8	%
24 PCT	0.062	0.004-0.104	%
25 P-LCR	28.0	18.6-34.6	%
26 P-LCC	17	0-28	10 ⁹ /L

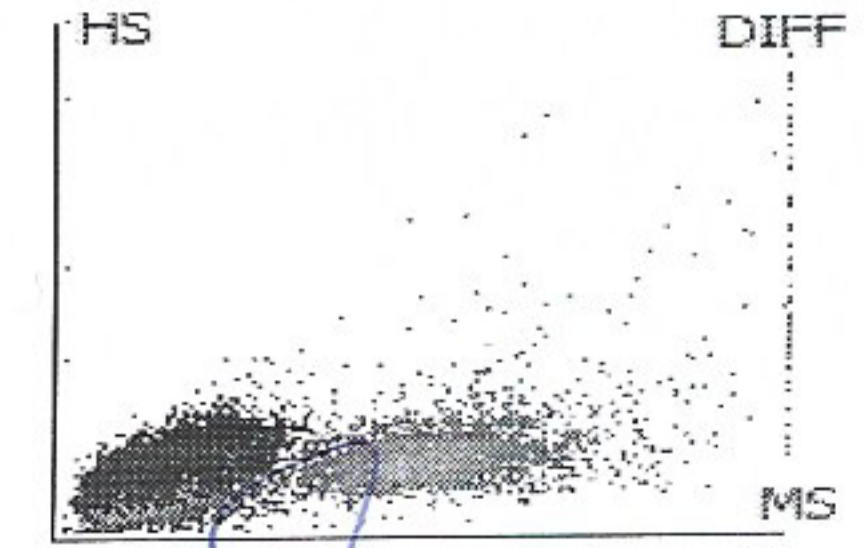
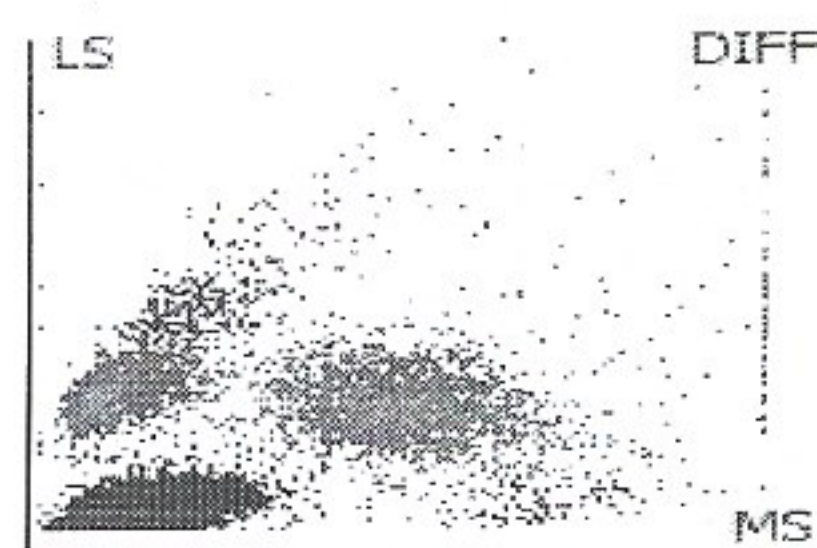
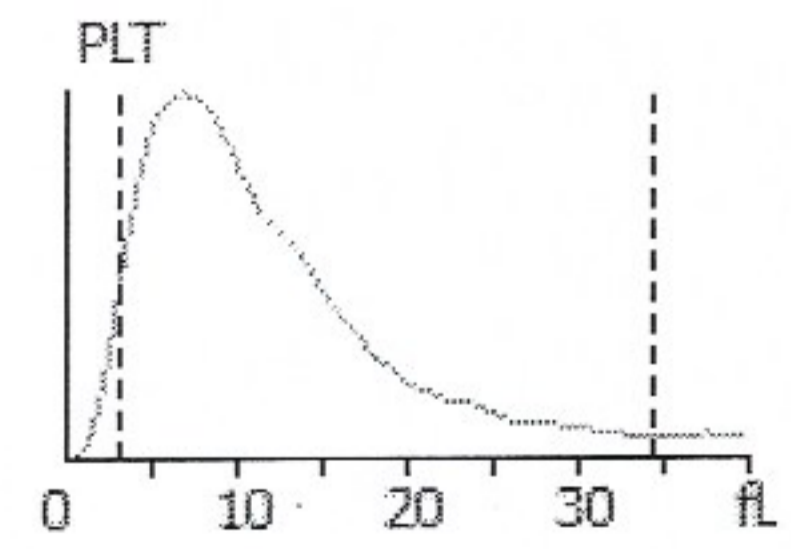
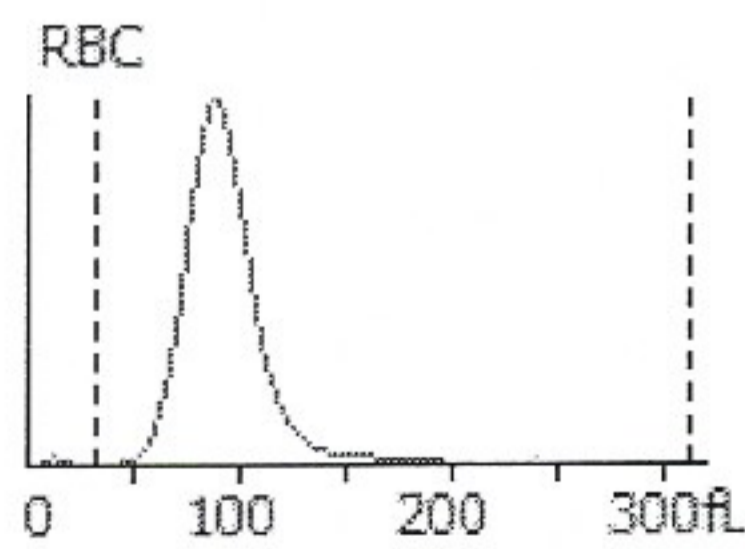
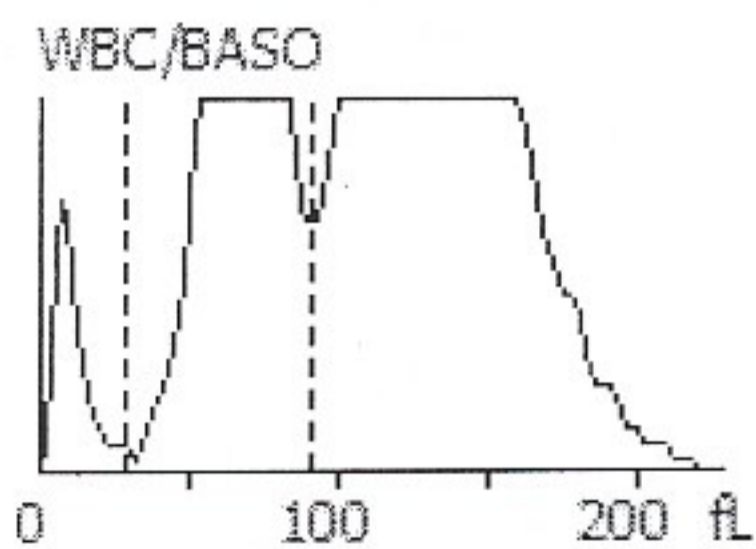


Alex S. H.
20/06/23

L-J QC Analysis

File No.: 17	Lot No.: EH230525NORMAL	Level: Normal
Operator: admin	Exp. Date: 2023/07/10	Run Time: 2023/06/20 09:40
Print Time: 2023/06/20 10:06	QC Mode: Whole Blood-CBC+DIFF	QC Sample ID: 17

Parameter	Result	Ref. Range	Unit
1 WBC	8.35	7.20-9.20	10³/uL
2 Neu%	59.8	49.3-65.3	%
3 Lym%	32.0	22.4-38.4	%
4 Mon%	5.6	0.6-10.6	%
5 Eos%	2.6	0.7-12.7	%
6 Bas%	70.2	62.1-78.1	%
7 Neu#	5.00	4.00-5.40	10 ³ /uL
8 Lym#	2.68	1.79-3.19	10 ³ /uL
9 Mon#	0.46	0.00-0.92	10 ³ /uL
10 Eos#	0.21	0.05-1.05	10 ³ /uL
11 Bas#	5.87	5.05-6.45	10 ³ /uL
12 RBC	4.57	4.39-4.87	10⁶/uL
13 HGB	13.7	12.6-13.8	g/dL
14 HCT	40.5	37.6-43.6	%
15 MCV	88.7	82.8-92.8	fL
16 MCH	30.0	26.1-31.1	pg
17 MCHC	33.9	29.6-35.6	g/dL
18 RDW-CV	17.6	14.4-20.4	%
19 RDW-SD	57.3	43.7-63.7	fL
20 PLT	259	216-296	10³/uL
21 MPV	9.3	6.7-12.7	fL
22 PDW-SD	10.4	9.0-15.0	fL
23 PDW-CV	15.6	13.1-19.1	%
24 PCT	0.241	0.149-0.349	%
25 P-LCR	22.4	17.7-33.7	%
26 P-LCC	58	41-91	10 ⁹ /L

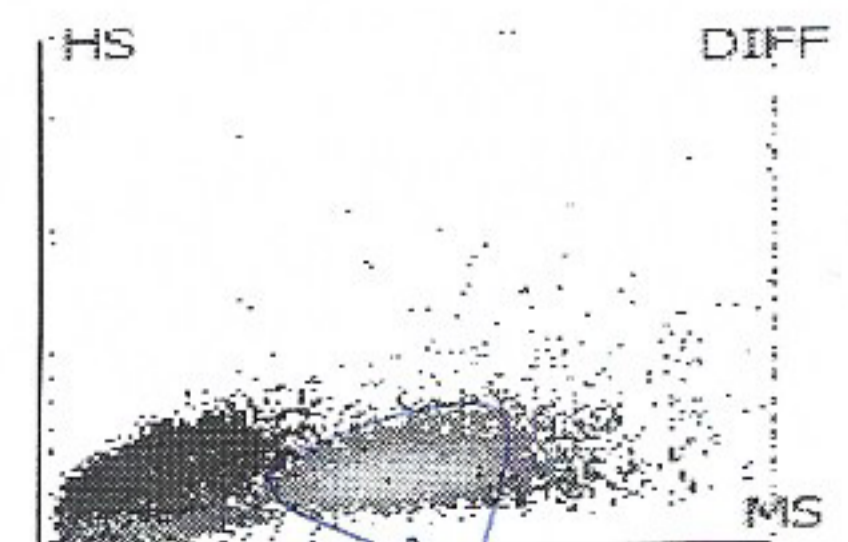
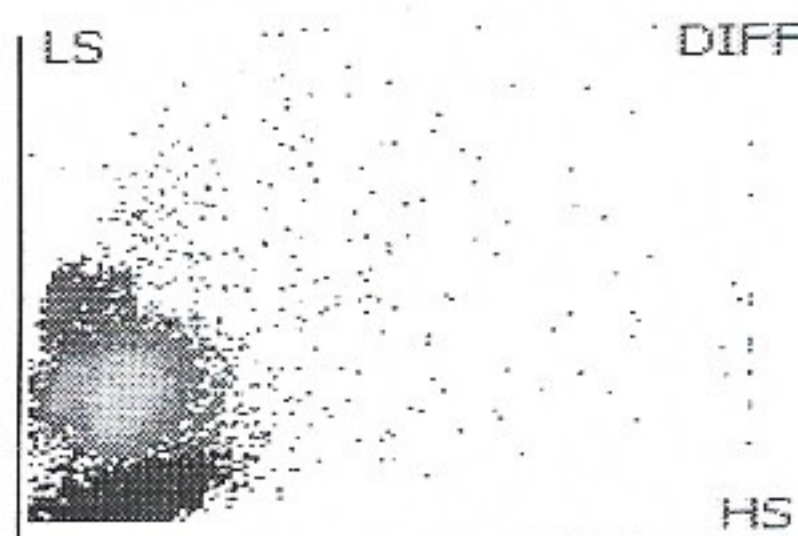
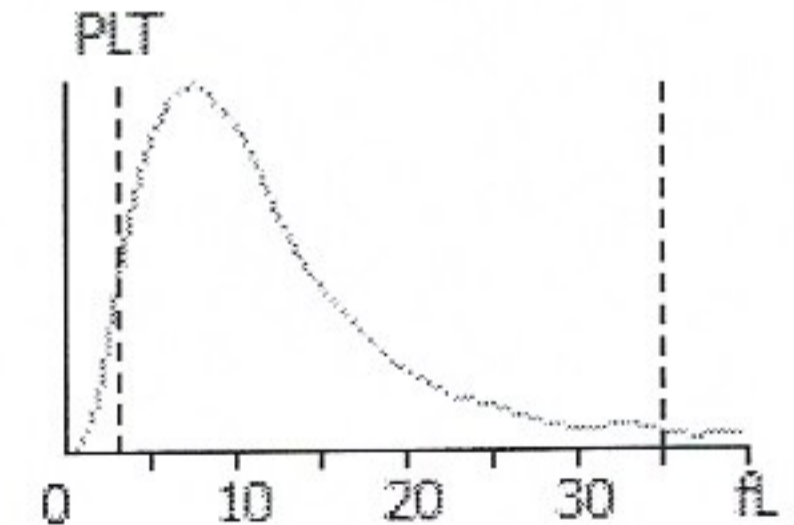
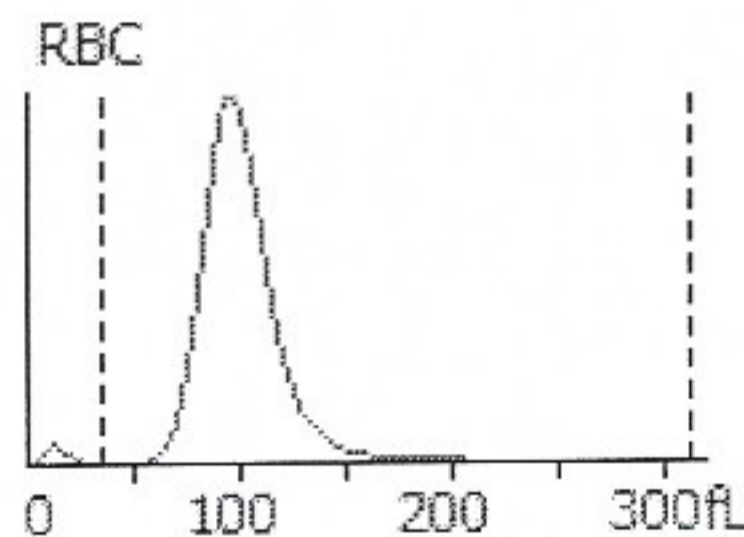
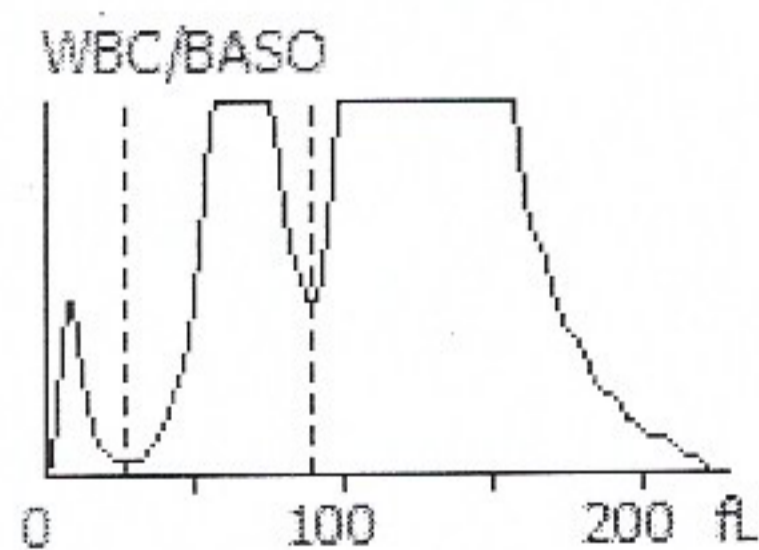


Alkash
20/06/23

L-J QC Analysis

File No.: 18	Lot No.: EH230526HIGH	Level: High
Operator: admin	Exp. Date: 2023/07/10	Run Time: 2023/06/20 09:41
Print Time: 2023/06/20 10:06	QC Mode: Whole Blood-CBC+DIFF	QC Sample ID: 18

Parameter	Result	Ref. Range	Unit
1 WBC	18.81	16.02-21.02	10³/uL
2 Neu%	68.3	56.3-70.3	%
3 Lym%	21.5	15.6-27.6	%
4 Mon%	7.1	0.1-12.1	%
5 Eos%	3.1	2.0-16.0	%
6 Bas%	80.1	71.0-87.0	%
7 Neu#	12.85	10.32-13.12	10 ³ /uL
8 Lym#	4.05	2.90-5.10	10 ³ /uL
9 Mon#	1.33	0.03-2.23	10 ³ /uL
10 Eos#	0.58	0.37-2.97	10 ³ /uL
11 Bas#	15.07	13.13-16.13	10 ³ /uL
12 RBC	5.27	4.76-5.76	10⁶/uL
13 HGB	17.0	15.7-17.3	g/dL
14 HCT	50.8	46.0-54.0	%
15 MCV	96.5	89.2-101.2	fL
16 MCH	32.2	28.9-33.9	pg
17 MCHC	33.4	30.1-36.1	g/dL
18 RDW-CV	16.3	13.4-19.4	%
19 RDW-SD	57.5	42.6-66.6	fL
20 PLT	504	419-539	10³/uL
21 MPV	9.3	7.0-13.0	fL
22 PDW-SD	10.3	9.6-15.6	fL
23 PDW-CV	15.2	13.4-19.4	%
24 PCT	0.469	0.279-0.679	%
25 P-LCR	21.9	18.1-34.1	%
26 P-LCC	110	90-160	10 ⁹ /L



OK
20/06/23