

2) Environment Condition

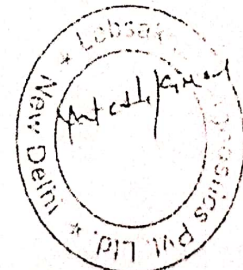
Has the Instrument been adequately acclimatized since transport or storage?

YES:

NO:

Operating Parameters	Specified Range	Conditions Met
Ambient Temperature	10 to 30 degrees	Yes
Relative Humidity	<=85%	Yes
Supply Voltage & Frequency	100 to 240V, 50/60 Hz AC	

Comments:

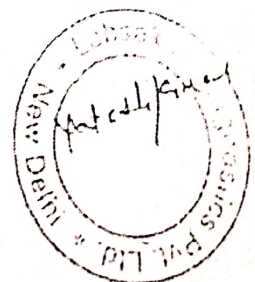


1) Instrument Identification

Auto hematology analyzer (Councell penta 2.o)

Sr. No.	Specification	As per design qualification	Specification received	Match (Yes/No)
1	General Feature	The measurement methods used in this analyzer are: the electrical Impedance method for determining the RBC and PLT data; the colorimetric method for determining the HGB; laser-based flow cytometry for determining the WBC data.		Yes
2	Sample aspiration volume.	Whole Blood mode_20µL.pri-diluted mode_20µL of whole blood/capillary blood sample and 480µL of diluent		Yes
3	LED lamp	530nm LED		Yes
4	Communication port	LAN Port		Yes
5	Printer	External ink tank and leaser printer		Yes
6	Power requirement	AC100V~240V, Input Power ≤200VA, 50/60HZ.		Yes
7	Grounding	Good grounding <5V		Yes

Comments:

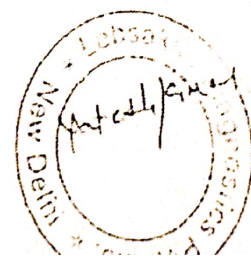


4) Instrument Safety

Manufacturer Safety Recommendations:

- | | | |
|--|--|-----|
| Allow enough space for the Instrument | YES: <input checked="" type="checkbox"/> | NO: |
| Position on level, non-combustible surface Indoors | YES: <input checked="" type="checkbox"/> | NO: |
| Area free from aggressive/ explosive chemical mixtures | YES: <input checked="" type="checkbox"/> | NO: |
| Ensure correct power supply and all power switches Easily accessible | YES: <input checked="" type="checkbox"/> | NO: |
| Keep the analyzer away from electromagnetic waves | YES: <input checked="" type="checkbox"/> | NO: |
| Read Operator Manual before use | YES: <input checked="" type="checkbox"/> | NO: |

Comments:



5) Assembly and Installation

Assembled and installed By:

User:

Specialized Engineer:

Installation Procedure:

OK

N/A

OK

Unpack and retain Packaging

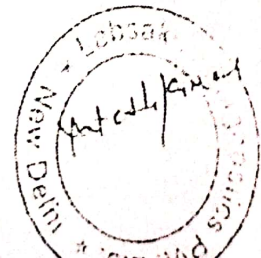
OK

Verifying the site before connecting to UPS power supply

OK

Checking the instrument before performing the Test

Comments:



3) Instrument Delivery and Documentation

Unpack the Instrument carefully. Are any items missing against the Packing List?

YES:

NO:

If yes, state the missing Items: _____

Is there any damage to the Instrument or Accessories?

YES:

NO:

If yes: Description of Damage: _____

Corrective Action: _____

Manufacturing informed: YES:

NO:

Is all Standard Documentation Included?

Operating Manual:

Present:

Missing:

Warranty Card:

Present:

Missing:

Is all additional documentation Included:

Present:

Missing:

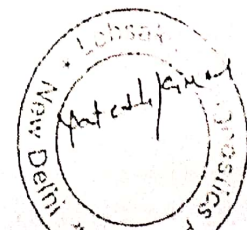
Installation Qualification: *Yes*

Operational Qualification: *Yes*

Performance Qualification: *Yes*

Comments:

Installation qualification earned out successfully.



OPERATIONAL QUALIFICATION

The Operational Qualification procedure specifies the methodology for installation of specified system after successful installation qualification. Successful completion of procedure identifies that system is ready for operation and subsequent performance analysis.

OO PROTOCOL

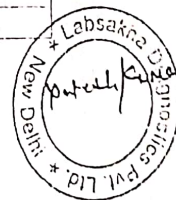
1. System Connections
2. Reagent & Waste Connections
3. System Booting , Initialization & Check
4. Maintenance procedures.
5. Customer Training – Operation & Maintenance.

1. SYSTEM CONNECTION –

SYSTEM CONNECTIONS			
S/N	NAME	Check	Remark
1	Input Power supply	Connect	OK
2	Printer Connection(Optional)	Operating manual 2 4 6	OK

2. REAGENT AND WASTE CONNECTION

REAGENT CONNECTION CHECK		
NAME	CHECK	Remark
DILUENT CONNECTION	Operating Manual Figure 4 3	OK
LYSE CONNECTION	Operating Manual Figure 4 4	OK
Waste Connection	To Waste Container 4.3	OK



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CIN : U33309DL2018PTC330012

INSTALLATION QUALIFICATION

IO PROTOCOL

1. System Unpacking
2. System Checking For any Damages
3. All accessories as per check List verification
4. Space Requirement
5. Power Requirement
6. Reagents, Control, Calibrators verification.

1. SYSTEM UNPACKING & 2. SYSTEM CHECKING

Vanalyze-V30s is unpacked and checked for physical Damages and found to be in good condition.

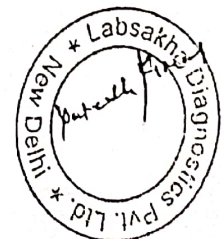
3. ACCESSORIES CHECK-

Check all accessories as per check List

4. SPACE REQUIREMENT -

- Checked site for proper space allocation. At least 100 CM on each side and enough room on below the countertop to accommodate the reagents and waste containers.

DIMENSIONS	
PARAMETER	Analyzer OV
Width mm	<300
Depth mm	<410
Height mm	<400
Weight Kg	<20



3. SYSTEM BOOTING, INITIALIZATION & Check -

Power ON System and check instrument Initialization successfully.
Check following Parameters.

Temperature & Negative Pressure				
S/N	Parameters	Actual	Range	Remark
1	ENVIRONMENT TEMP(°c)	24	15-30	Ok
2	HGB ZERO (V)	0.00	0.00-0.20	Ok
3	HGB BLANK (V)	4.2	3.80-4.60	Ok
4	DC-DC 12V (V)	11.71	10.8-12.96	Ok
5	DC-DC -12V (V)	11.84	10.8-12.96	Ok
6	5 V (V)	4.92	4.50-5.25	Ok
7	VACCUM	186	175-205	Ok

NORMAL BACKGROUND CHECK				
S/N	PARAMETER	Actual	Remark	Remark
1	WBC	0.0	<0.2	OK
2	RBC	0.0	<0.02	OK
3	HGB	0.0	<0.1	OK
4	HCT	0.0	<0.5%	OK
4	PLT	0.0	<5	OK

4. MAINTENANCE PROCEDURES:-

MAINTENANCE			
S/N	Parameters	Check	Remark
1	Using Maintenance Menu	Operator Manual 10.2	OK
2	Replacing Priming Reagents	Operator Manual 9.2.6	OK
3	Cleaning	Operator Manual 10.2	OK
4	Maintenance	Operator Manual 10.2.2	OK
5	Overall Maintenance	Operator Manual 10.2.3	OK

5. Customer Training – Operation & Maintenance: Provided



5. POWER REQUIREMENT

Requirement	Acceptable Range	Observed Ranged
Input Voltage	220 + / - 10 V	221 V
Line Frequency	50 HZ	50 HZ
Ambient Temperature	15 C - 30 C	24
Grounding Voltage	0 to 5 V	1 V

6. Reagents, Control, Calibrators Check-

NAME	Status	Remark
Diluent - Vanlyze	YES	OK
Lyse - Vanalyze	YES	OK
Probe Cleaner	YES	OK
Controls	YES	OK



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CIN : U33309DL2018PTC330012

PERFORMANCE QUALIFICATION:

The Performance of system is to be verified by the accuracy and precision analysis of the parameters by running 3 Levels of controls.

The results should be with in control range as per the assay sheet.

PQ Protocol:-

1. Carry over check
2. Precision Check
3. Control Check (Three Levels)

1. Carry Over Check.

CARRYOVER				
S/N	PARAMETER	Actual	Range	Remark
1	WBC	0.0	0.50%	OK
2	RBC	0.0	0.50%	OK
3	HGB	0.0	0.50%	OK
4	PLT	0.0	1%	OK

2. Precision Check.

REPRODUCIABILTY CHECK				
S/N	PARAMETER	Actual	Range CV%	Remark
1	WBC (7.0 – 15.0)	1.27	2.0%	1.75
	(4.0 – 6.9)	2.30	3.5 %	
2	RBC	0.50	1.5%	0.9
3	HGB	0.30	1.5%	0.46
4	MCV	0.30	0.5%	0.40
5	PLT (150 – 500)	1.74	4.0 %	3.86
	(100 – 149)	3.8	5.0%	



3. Reagents & Control

Name	Lot no	Expiry
DILUENT	240402	31-03-2026
Lyse	240201	31-01-2026
Probe Cleanser	240302	31-08-2025
Diagon Control	1X0301	05.09.2024

4. Control Data :

Parameter	Data Range	Value Normal Control
WBC	5.7 - 7.7	7.0
RBC	3.38 - 4.48	4.4
HGB	12.6 - 13.8	13.2
MCV	83.8 - 95.8	85.0
PLT	178 - 268	239



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MIN/MED/2023-2024/205535
12th may 2024

CALIBRATION CERTIFICATE

This is to certify that the Hematology Analyzer Vanalyze-v30s bearing serial number: TH3A016370T installed at Dr. Anita Ranjan Multispecialty Hospital as calibrated on 12th may 2023.

Calibrator : ABX MINOCAL
Lot No. : CX23
Expiry Date : 25th june 2024

The reports of Blank Cycle, Repeatability and Calibration Values were all found in acceptable range.

Next calibration cycle is due on 13th may 2025.

Sheetal Dixit
(Head- Products & Marketing)
For



CALIBRATION DATA

SMP NO/TIME	WBC	RBC	HGB	HCT	PLT
SCS1	6.74	3.77	10.9	33.3	230
SCS2	6.72	3.99	10.9	33.3	225
SCS3	6.73	3.78	10.9	33.4	206
SCS4	6.69	3.79	10.8	33.5	206
SCS5	6.79	3.88	10.9	34.3	228
MEAN	6.73	3.84	10.88	33.56	219
Acceptable Limits	6.61 - 6.82	3.690 - 4.0	10.21 - 11.36	33.06 - 35.55	190 - 256
Result	PASS	PASS	PASS	PASS	PASS

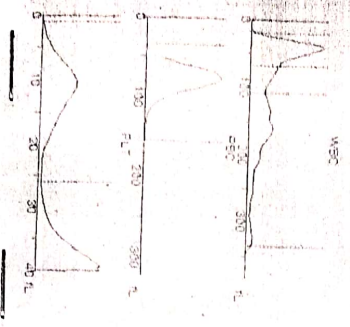
(Traceability System) :
The traceability system of VANALYZE V30S Hematology analyzers are shown in attached sheet.



LJ QC

File No: 1
 Lot No: 1X0301
 Level: Low
 Time of Analysis: 12-05-2024 13:40

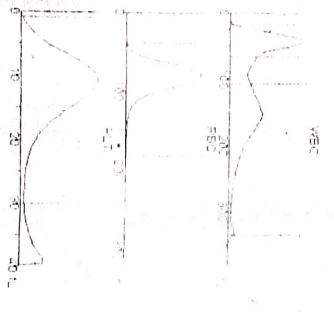
WBC	19	14-24
Lymph#	0.7	0.5-0.9
Mid#	0.3	0.0-0.6
Gran#	0.9	0.6-1.2
Lymph%	38.1	28.9-48.1
Mid%	15.9	4.1-23.9
Gran%	46.0	29.2-60.8
RBC	2.42	2.09-2.49
HGB	7.1	6.5-7.5
HCT	19.1	16.2-22.2
MCV	78.8	77.5-86.5
MCH	29.5	26.9-34.5
MCHC	37.4	31.9-41.5
RDW-CV	18.0	11.3-21.3
RDW-SD	43.3	36.2-52.2
PLT	66	43-93
MPV	12.7	10.0-16.0
PDW	14.4	11.0-17.0
PCT	0.084	0.036-0.138
P-LCC	33	22-42
P-LCR	49.5	32.1-72.1



LJ QC

File No: 2
 Lot No: 1X0301
 Level: Normal
 Time of Analysis: 12-05-2024 13:41

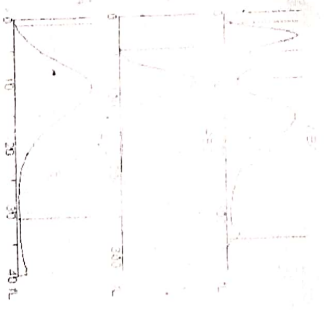
WBC	7.0	5.7-7.7
Lymph#	2.4	1.4-3.0
Mid#	1.0	0.2-1.6
Gran#	3.6	3.1-4.1
Lymph%	33.7	21.7-44.9
Mid%	13.8	2.6-24.2
Gran%	52.5	42.6-64.0
RBC	4.40	3.66-4.48
HGB	13.2	12.6-13.8
HCT	37.4	33.5-41.5
MCV	85.0	83.8-95.8
MCH	30.1	27.7-35.2
MCHC	35.4	30.3-39.9
RDW-CV	15.3	10.5-20.5
RDW-SD	44.7	36.1-54.1
PLT	239	178-288
MPV	12.9	9.6-15.6
PDW	14.5	11.3-17.3
PCT	0.309	0.182-0.382
P-LCC	120	75-135
P-LCR	50.4	28.3-68.3



LJ QC

File No: 3
 Lot No: 1X0301
 Level: High
 Time of Analysis: 12-05-2024 13:45

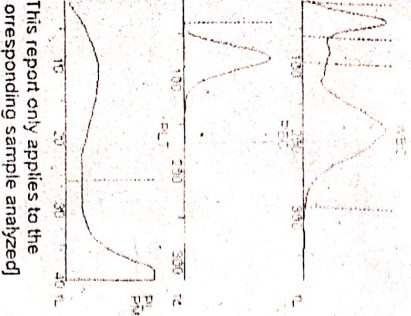
WBC	17.3	13.0-19.3
Lymph#	3.8	1.4-4.8
Mid#	1.9	0.5-2.9
Gran#	11.6	3.3-18.7
Lymph%	22.0	12.9-28.7
Mid%	10.8	2.1-18.7
Gran%	57.2	59.3-80.3
RBC	5.44	2.52-7.62
HGB	16.9	15.9-17.2
HCT	48.6	43.2-52.8
MCV	89.5	68.3-100.3
MCH	31.0	28.2-36.4
MCHC	34.5	29.8-39.4
RDW-CV	15.0	10.1-20.1
RDW-SD	45.1	36.2-56.2
PLT	511	418-548
MPV	13.0	9.6-15.6
PDW	14.5	11.7-17.7
PCT	0.856	0.409-0.809
P-LCC	265	182-282
P-LCR	51.5	28.8-68.8



351 PARTIAL

Last Name: Patient ID: 24050210
Sample ID: WB
Mode: WB
Time of Analysis: 12-05-2024 13:56

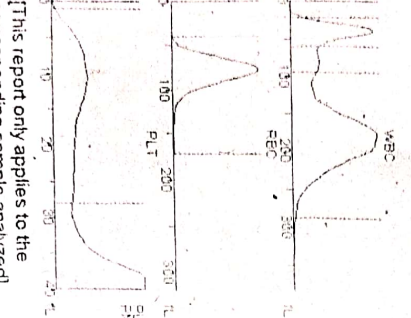
Modules	Result	Unit
WBC	5.8	10 ⁹ /uL
Lymph#	1.3	10 ³ /uL
Mid#	0.5	10 ³ /uL
Gran#	4.0	10 ³ /uL
Lymph%	22.0	%
Mid%	8.5	%
Gran%	69.5	%
RBC	4.37	10 ⁶ /uL
HGB	11.2	g/dL
HCT	35.4	%
MCV	81.1	fL
MCH	25.5	pg
MCHC	31.5	g/dL
RDW-CV	13.5	%
RDW-SD	37.6	fL
PLT	59	10 ³ /uL
MPV	13.8	fL
PDW	16.1	fL
PCT	0.081	%
P-LCC	34	10 ⁹ /L
P-LCR	58.6	%



This report only applies to the corresponding sample analyzed

Last Name: Patient ID: 24050210
Sample ID: WB
Mode: WB
Time of Analysis: 12-05-2024 13:57

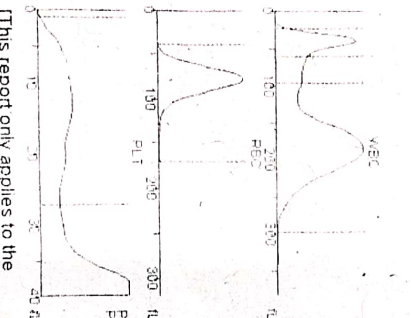
Modules	Result	Unit
WBC	5.5	10 ⁹ /uL
Lymph#	1.1	10 ³ /uL
Mid#	0.5	10 ³ /uL
Gran#	3.9	10 ³ /uL
Lymph%	19.2	%
Mid%	9.0	%
Gran%	71.8	%
RBC	4.38	10 ⁶ /uL
HGB	11.1	g/dL
HCT	35.6	%
MCV	81.1	fL
MCH	25.4	pg
MCHC	31.3	g/dL
RDW-CV	13.4	%
RDW-SD	37.4	fL
PLT	62	10 ³ /uL
MPV	14.6	fL
PDW	16.4	fL
PCT	0.090	%
P-LCC	36	10 ⁹ /L
P-LCR	58.7	%



This report only applies to the corresponding sample analyzed

Last Name: Patient ID: 24050210
Sample ID: WB
Mode: WB
Time of Analysis: 12-05-2024 13:58

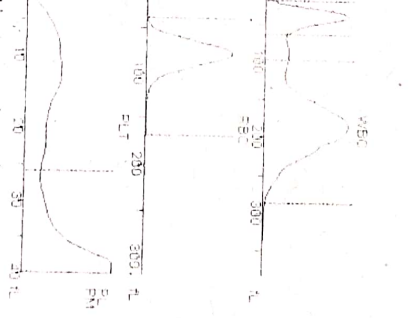
Modules	Result	Unit
WBC	5.5	10 ⁹ /uL
Lymph#	1.0	10 ³ /uL
Mid#	0.5	10 ³ /uL
Gran#	4.0	10 ³ /uL
Lymph%	18.0	%
Mid%	9.4	%
Gran%	72.6	%
RBC	4.43	10 ⁶ /uL
HGB	11.1	g/dL
HCT	35.8	%
MCV	81.0	fL
MCH	25.1	pg
MCHC	31.0	g/dL
RDW-CV	13.6	%
RDW-SD	37.7	fL
PLT	59	10 ³ /uL
MPV	14.6	fL
PDW	16.3	fL
PCT	0.086	%
P-LCC	37	10 ⁹ /L
P-LCR	63.0	%



This report only applies to the corresponding sample analyzed

Last Name: Patient ID: 24050210
Sample ID: WB
Mode: WB
Time of Analysis: 12-05-2024 13:59

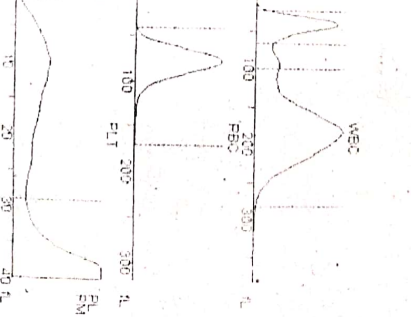
Modules	Result	Unit
WBC	5.6	10 ⁹ /uL
Lymph#	1.2	10 ³ /uL
Mid#	0.4	10 ³ /uL
Gran#	4.0	10 ³ /uL
Lymph%	21.2	%
Mid%	7.5	%
Gran%	71.3	%
RBC	4.36	10 ⁶ /uL
HGB	11.1	g/dL
HCT	35.3	%
MCV	81.0	fL
MCH	25.5	pg
MCHC	31.5	g/dL
RDW-CV	13.6	%
RDW-SD	37.7	fL
PLT	62	10 ³ /uL
MPV	13.9	fL
PDW	16.3	fL
PCT	0.086	%
P-LCC	36	10 ⁹ /L
P-LCR	58.1	%



This report only applies to the corresponding sample analyzed

First Name: Last Name: Patient ID: 24050210
Sample ID: WB
Mode: WB
Time of Analysis: 12-05-2024 14:01

Modules	Result	Unit
WBC	5.5	10 ⁹ /uL
Lymph#	1.1	10 ³ /uL
Mid#	0.4	10 ³ /uL
Gran#	4.0	10 ³ /uL
Lymph%	20.1	%
Mid%	6.4	%
Gran%	73.5	%
RBC	4.37	10 ⁶ /uL
HGB	11.1	g/dL
HCT	35.5	%
MCV	81.2	fL
MCH	25.5	pg
MCHC	31.4	g/dL
RDW-CV	13.5	%
RDW-SD	37.6	fL
PLT	63	10 ³ /uL
MPV	14.7	fL
PDW	16.5	fL
PCT	0.093	%
P-LCC	37	10 ⁹ /L
P-LCR	59.1	%

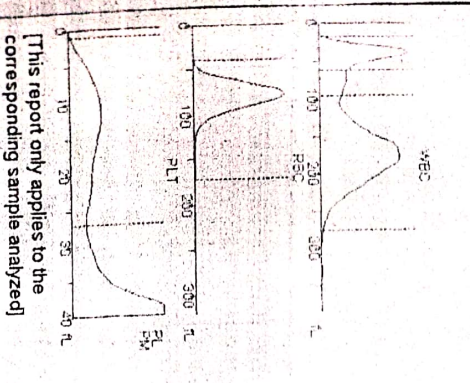


This report only applies to the corresponding sample analyzed

New Delhi

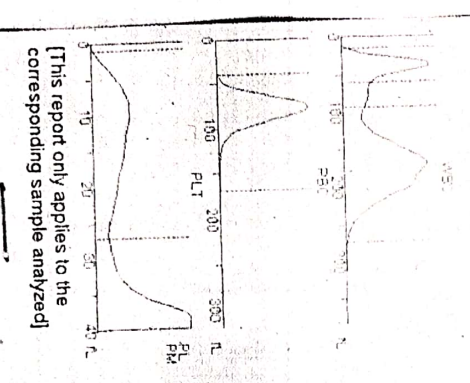
First Name: Last Name: Patient ID: Sample ID: Mode: Time of Analysis:

Modules	Result	Unit
WBC	5.5	10 ³ /uL
Lymph#	1.2	10 ³ /uL
Mid#	0.5	10 ³ /uL
Gran#	3.8	10 ³ /uL
Lymph%	21.4	%
Mid%	8.3	%
Gran%	70.3	%
RBC	4.42	10 ⁶ /uL
HGB	11.2	g/dL
HCT	35.8	%
MCV	81.0	fL
MCH	25.3	pg
MCHC	31.2	g/dL
RDW-CV	13.5	%
RDW-SD	37.6	fL
PLT	55	10 ³ /uL
MPV	14.6	fL
PDW	16.0	fL
PCT	0.080	%
P-LCC	34	10 ⁹ /L
P-LCR	61.9	%



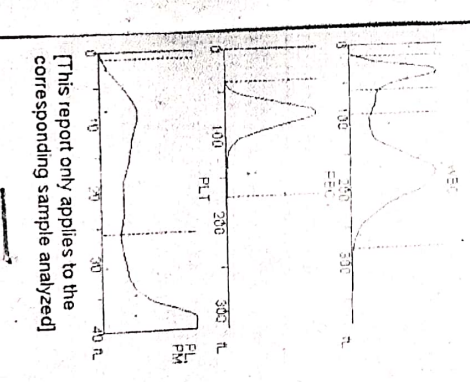
First Name: Last Name: Patient ID: Sample ID: Mode: Time of Analysis:

Modules	Result	Unit
WBC	5.5	10 ³ /uL
Lymph#	1.2	10 ³ /uL
Mid#	0.5	10 ³ /uL
Gran#	3.8	10 ³ /uL
Lymph%	22.0	%
Mid%	8.2	%
Gran%	69.8	%
RBC	4.45	10 ⁶ /uL
HGB	11.1	g/dL
HCT	36.0	%
MCV	80.8	fL
MCH	25.0	pg
MCHC	31.0	g/dL
RDW-CV	13.7	%
RDW-SD	38.0	fL
PLT	64	10 ³ /uL
MPV	14.0	fL
PDW	16.1	fL
PCT	0.090	%
P-LCC	37	10 ⁹ /L
P-LCR	57.3	%



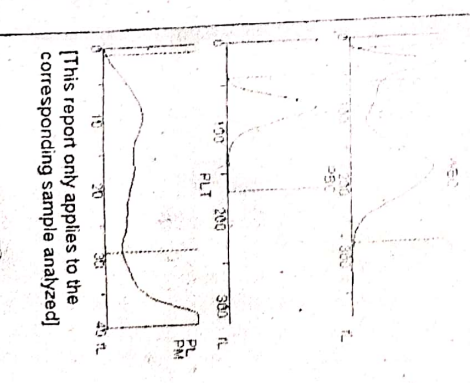
First Name: Last Name: Patient ID: Sample ID: Mode: Time of Analysis:

Modules	Result	Unit
WBC	5.5	10 ³ /uL
Lymph#	1.3	10 ³ /uL
Mid#	0.4	10 ³ /uL
Gran#	3.8	10 ³ /uL
Lymph%	22.8	%
Mid%	8.1	%
Gran%	69.1	%
RBC	4.36	10 ⁶ /uL
HGB	11.1	g/dL
HCT	34.9	%
MCV	80.2	fL
MCH	25.6	pg
MCHC	31.9	g/dL
RDW-CV	13.9	%
RDW-SD	38.2	fL
PLT	63	10 ³ /uL
MPV	13.9	fL
PDW	16.4	fL
PCT	0.088	%
P-LCC	36	10 ⁹ /L
P-LCR	57.0	%



First Name: Last Name: Patient ID: Sample ID: Mode: Time of Analysis:

Modules	Result	Unit
WBC	5.6	10 ³ /uL
Lymph#	1.2	10 ³ /uL
Mid#	0.5	10 ³ /uL
Gran#	3.9	10 ³ /uL
Lymph%	22.0	%
Mid%	8.6	%
Gran%	69.4	%
RBC	4.40	10 ⁶ /uL
HGB	11.2	g/dL
HCT	35.6	%
MCV	81.0	fL
MCH	25.4	pg
MCHC	31.4	g/dL
RDW-CV	13.5	%
RDW-SD	37.6	fL
PLT	70	10 ³ /uL
MPV	15.2	fL
PDW	16.5	fL
PCT	0.106	%
P-LCC	43	10 ⁹ /L
P-LCR	61.7	%



First Name: Last Name: Patient ID: Sample ID: Mode: Time of Analysis:

Modules	Result	Unit
WBC	5.5	10 ³ /uL
Lymph#	1.2	10 ³ /uL
Mid#	0.4	10 ³ /uL
Gran#	3.9	10 ³ /uL
Lymph%	21.5	%
Mid%	8.1	%
Gran%	70.4	%
RBC	4.47	10 ⁶ /uL
HGB	11.2	g/dL
HCT	35.9	%
MCV	80.4	fL
MCH	25.1	pg
MCHC	31.2	g/dL
RDW-CV	13.8	%
RDW-SD	38.0	fL
PLT	66	10 ³ /uL
MPV	14.4	fL
PDW	16.0	fL
PCT	0.095	%
P-LCC	41	10 ⁹ /L
P-LCR	61.6	%

