

DATE – 06-05-2024

INSTALLATION REPORT

Customer Name : WELL CARE PATH LAB
Place : SCO-80 Shree Balaji Evclave Dhakoli Zirkipur panjab
160104
Department : Laboratory
Contact Person : Gurnam singh
Instrument Name : Vanalyze-V30s
Serial Number : TH-3A016370T
Date of Installation : 06-05-2024
Warranty Expiry : 05-05-2025, AMC 06-05-2025 TO 05-05-2026

The Analyzer was installed along with the necessary standard accessories. All basic requirements and adjustments were checked and are found to be satisfactory. The preliminary standardization of the analyzer and the training were provided to the complete satisfaction of the customer. The analyzer is found to be working satisfactorily.

For Labsakha Diagnostics Pvt. Ltd.



Service Engineer

DATE – 06-05-2024

INSTALLATION QUALIFICATION

IQ 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.

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



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Phase-II, New Delhi-110020
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CIN : U33309DL2018PTC330012



OPERATIONAL QUALIFICATION

DATE -06-05-2024

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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3. SYSTEM BOOTING, INITIALIZATION & Check -

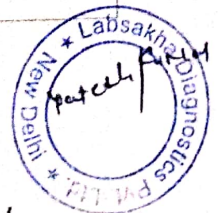
Power ON System and check instrument Initialization successfully.
Check following Parameters.

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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Date -13-05-2024

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%	



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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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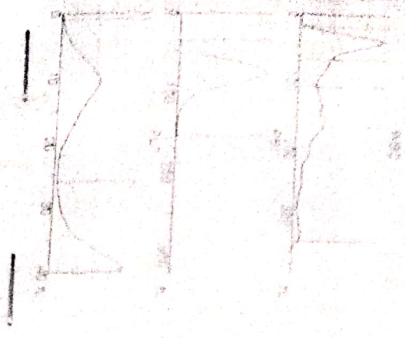
CIN : U33309DL2018PTC330012



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

LJQC

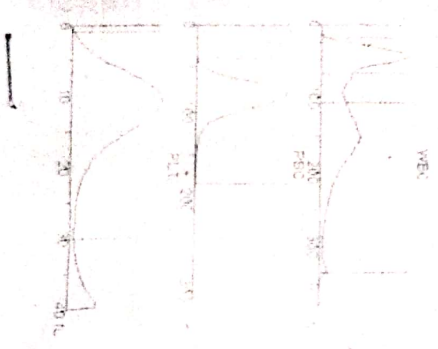
WBC	19	74-24
Lymph#	07	05-09
Mid#	03	00-06
Gran#	09	06-12
Lymph%	281	269-484
Mid%	159	41-289
Gran%	480	292-608
RBC	242	209-249
HGB	71	65-75
HCT	191	162-222
MCV	78.8	77.5-89.5
MCH	29.5	26.9-34.5
MCHC	374	319-415
RDW-CV	180	113-213
RDW-SD	433	362-522
PLT	66	43-93
MPV	127	100-160
PDW	144	110-170
PCT	0.084	0.038-0.138
P-LCC	33	22-42
P-LCR	49.5	32.1-72.1



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

LJQC

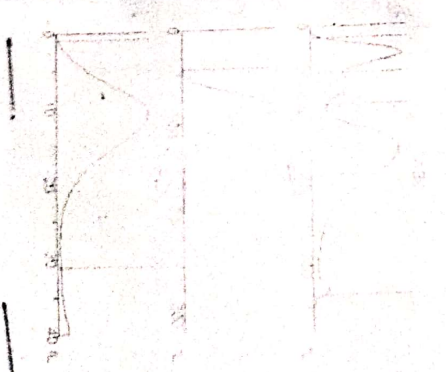
WBC	7.0	5.7-7.7
Lymph#	2.4	1.4-3.0
Mid#	1.0	0.2-1.6
Gran#	3.6	3.1-4.1
Lymph%	33.7	21.7-44.9
Mid%	13.8	2.6-24.2
Gran%	52.5	42.6-64.0
RBC	4.40	3.88-4.46
HGB	13.2	12.6-13.8
HCT	37.4	33.5-41.5
MCV	85.0	83.8-95.9
MCH	30.1	27.7-35.3
MCHC	35.4	30.3-39.9
RDW-CV	15.3	10.5-20.5
RDW-SD	44.7	36.1-54.1
PLT	239	178-268
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



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

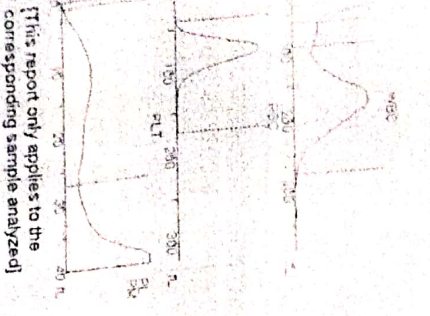
LJQC

WBC	17.3	13.0-25.3
Lymph#	3.8	1.4-5.8
Mid#	1.9	0.5-2.9
Gran#	11.6	3.3-18.7
Lymph%	22.0	12.9-26.7
Mid%	10.8	2.1-18.7
Gran%	67.2	59.3-80.3
RBC	5.44	2.62-7.62
HGB	16.9	15.9-17.9
HCT	48.8	43.9-52.8
MCV	89.3	88.3-92.7
MCH	31.0	28.2-36.2
MCHC	34.6	29.8-35.4
RDW-CV	15.0	10.1-20.1
RDW-SD	46.1	36.2-56.2
PLT	511	418-548
MPV	13.0	9.6-15.6
PDW	14.5	11.7-17.7
PCT	0.666	0.409-0.909
P-LCC	285	162-292
P-LCR	51.6	28.8-68.8



Last Name: [blacked out]
Patient ID: 24050210
Sample ID: WB
Mode: WB
Time of Analysis: 12-05-2024 13:45

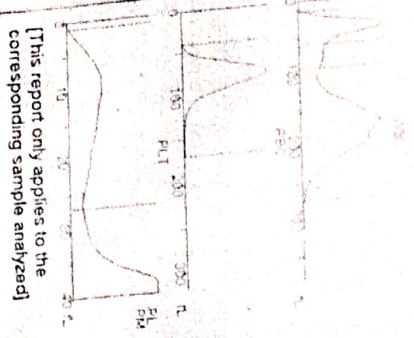
Modules	Result	Unit
WBC	5.5	10 ³ /uL
Lymph#	1.2	10 ³ /uL
Mid#	0.5	10 ³ /uL
Gran#	3.8	10 ³ /uL
Lymph%	21.4	%
Mid%	8.3	%
Gran%	70.3	%
RBC	4.42	10 ⁶ /uL
HGB	11.2	g/dL
HCT	35.8	%
MCV	81.0	fL
MCH	25.3	pg
MCHC	31.2	g/dL
RDW-CV	13.5	%
RDW-SD	37.6	fL
PLT	55	10 ³ /uL
MPV	14.6	fL
PDW	16.0	fL
PCT	0.080	%
P-LCC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



[This report only applies to the corresponding sample analyzed]

Last Name: [blacked out]
Patient ID: 24050210
Sample ID: WB
Mode: WB
Time of Analysis: 12-05-2024 13:51

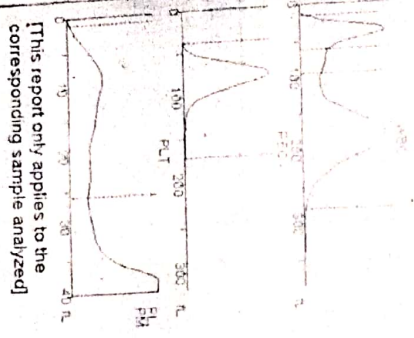
Modules	Result	Unit
WBC	5.5	10 ³ /uL
Lymph#	1.2	10 ³ /uL
Mid#	0.5	10 ³ /uL
Gran#	3.8	10 ³ /uL
Lymph%	22.0	%
Mid%	5.2	%
Gran%	69.8	%
RBC	4.45	10 ⁶ /uL
HGB	11.1	g/dL
HCT	36.0	%
MCV	80.8	fL
MCH	25.0	pg
MCHC	31.0	g/dL
RDW-CV	13.7	%
RDW-SD	38.0	fL
PLT	64	10 ³ /uL
MPV	14.0	fL
PDW	16.1	fL
PCT	0.090	%
P-LCC	37	10 ⁹ /L
P-LCR	RH 57.3	%



[This report only applies to the corresponding sample analyzed]

Last Name: [blacked out]
Patient ID: 24050210
Sample ID: WB
Mode: WB
Time of Analysis: 12-05-2024 13:52

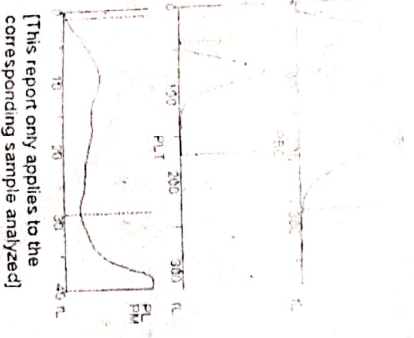
Modules	Result	Unit
WBC	5.5	10 ³ /uL
Lymph#	1.3	10 ³ /uL
Mid#	0.4	10 ³ /uL
Gran#	3.8	10 ³ /uL
Lymph%	22.8	%
Mid%	8.1	%
Gran%	69.1	%
RBC	4.36	10 ⁶ /uL
HGB	11.1	g/dL
HCT	34.9	%
MCV	80.2	fL
MCH	25.6	pg
MCHC	31.9	g/dL
RDW-CV	13.9	%
RDW-SD	38.2	fL
PLT	63	10 ³ /uL
MPV	13.9	fL
PDW	16.4	fL
PCT	0.088	%
P-LCC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



[This report only applies to the corresponding sample analyzed]

Last Name: [blacked out]
Patient ID: 24050210
Sample ID: WB
Mode: WB
Time of Analysis: 12-05-2024 13:53

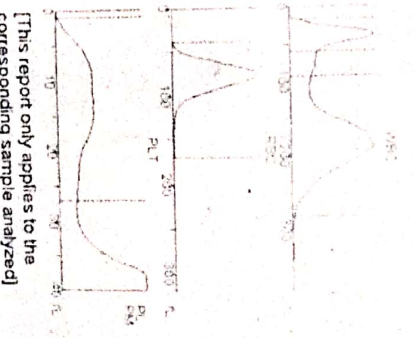
Modules	Result	Unit
WBC	5.6	10 ³ /uL
Lymph#	1.2	10 ³ /uL
Mid#	0.5	10 ³ /uL
Gran#	3.9	10 ³ /uL
Lymph%	22.0	%
Mid%	8.6	%
Gran%	69.4	%
RBC	4.40	10 ⁶ /uL
HGB	11.2	g/dL
HCT	35.6	%
MCV	81.0	fL
MCH	25.4	pg
MCHC	31.4	g/dL
RDW-CV	13.5	%
RDW-SD	37.6	fL
PLT	70	10 ³ /uL
MPV	15.2	fL
PDW	16.5	fL
PCT	0.106	%
P-LCC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



[This report only applies to the corresponding sample analyzed]

Last Name: [blacked out]
Patient ID: 24050210
Sample ID: WB
Mode: WB
Time of Analysis: 12-05-2024 13:54

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	RH 61.6	%




[This report only applies to the corresponding sample analyzed]

To whomsoever it may concern

This is to inform that the following points are being confirmed by M/S Vanguard Diagnostics (P) Limited, C-123, Okhla Industrial Area, Phase-1, New Delhi-110020 regarding the 3 part hamatology analyser Model Vanalyse-V30s serial number TH-3A016370T

1. The model Vanalyse-V30s with the serial number TH-3A016370T is an OEM model of BC-30s
2. The calibration of the instrument has been done and the testing report of the same is attached herewith.

For M/s Vanguard diagnostics (P) Limited


Authorized Signatory

20.06.2024

