



Aspen Diagnostics Pvt. Ltd.

(Rapid Diagnostic Group Of Companies)



ISO 9001:2015
CERTIFIED COMPANY

**BC-5000 – Hematology Analyzer
(5part Differential Fully Automated Analyzer)**

**Installation Qualification
Operational Qualification
Performance Qualification
(IQ/OQ/PQ)**

**(ORIGYN PATH LABS)
4th Floor, HB Twin Tower, Netaji Subhash Place
Pitampura, New Delhi-110034**

By:: Aspen Diagnostic Pvt. Ltd.





Aspen Diagnostics Pvt. Ltd.

(Rapid Diagnostic Group Of Companies)




ISO 9001:2015
CERTIFIED COMPANY

CERTIFICATE OF INSTALLATION

Instrument Name : BC-5000
Serial Number : SS-22009035
Customer Name : Origyn Path Labs
Address : 4th Floor, HB Twin Tower, Netaji Subhash Place
Pitampura, New Delhi-110034

The undersigned performers certify that the Installation Qualification Protocol has been successfully completed for the instrument stated above.

Technical Executive:

Signature : 
Name : Shankar Kumar
Designation : Technical Executive

Quality Manager

Signature :
Name : Ms. Ankita Gupta
Designation : Quality Manager
Institution/Lab : Origyn Path Labs

Aspen Diagnostics Pvt. Ltd.
(Rapid Diagnostic Group Of Companies)



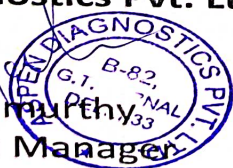
INSTALLATION REPORT

Customer Name : Origyn Path Labs
Place : Netaji Subhash Place, Pitampura, New Delhi-110034
Department : Pathology Laboratory
Contact Person : Ms. Ankita Gupta
Instrument Name : BC-5000
Serial Number : SS-22009035
Date of Installation : 26.11.2022
Instrument Status : Under Warranty

(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 Aspen Diagnostics Pvt. Ltd.

Rajaram Krishnamurthy
National Service Manager





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

Unpacked the instrument carefully and checked for any physical Damages. It was found to be perfectly OK.

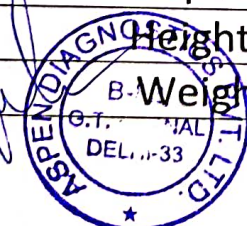
3. ACCESSORIES CHECK-

Checked 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 & pneumatic unit and waste containers.

DIMENSIONS	
Parameter	Analyzer OV
Width mm	320
Depth mm	400
Height mm	410
Weight Kg	24



Aspen Diagnostics Pvt. Ltd.

(Rapid Diagnostic Group Of Companies)



ISO 9001:2015
CERTIFIED COMPANY

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.

OQ PROTOCOL

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

1. SYSTEM CONNECTION –

SYSTEM CONNECTIONS			
S/N.	Name	Check	Remark
1	Input Power supply	Connect	Ok
2.	PC & Peripherals	Installed	Ok
3.	Printer Connection	Installed	Ok



2. REAGENT & WASTE CONNECTIONS::

Installed the reagent & waste connections as mentioned in the manual and colour coding available on instrument's rear panel.

3. CUSTOMIZING ANALYZER SOFTWARE –

Customizing Analyzer Software			
S/N	Parameters	Check	Remark
1	Date & Time	Operating Manual 5.2.1	Ok
2	Reagents	Operating Manual 5.2.1	Ok
3	Reference Ranges	Operating Manual 5.3.1	Ok
4	Reference Units	Operating Manual 5.3.1	Ok
5	Printing format	Operating Manual 5.3.1	Ok
6	Creating New User Accounts	Operating Manual 5.3.2	Ok

SYSTEM BOOTING,INITIALIZATION& Check -

Power ON System and check instrument Initialization successfully.



Checked the following Parameters.

TEMPERATURES & PRESSURES				
S/N	Parameters	Actual	Range	Remark
1	Preheat Bath	40.5	30 to 50	Ok
2	Reaction Bath	36.9	30 to 45	Ok
3	Ambience	25.4	15 to 35	Ok
4	Laser Diode	35.9	15 to 45	Ok

05.MAINTENANCE PROCEDURES:-

MAINTENANCE			
S/N	Parameters	Check	Remark
1	Using Maintenance Menu	Operator Manual 10.2	Ok
2	Replacing Priming Reagents	Operator Manual 10.2.1	Ok
3	Cleaning	Operator Manual 10.2.2	Ok
4	Maintenance	Operator Manual 10.2.3	Ok
5	Overall Maintenance	Operator Manual 10.2.4	Ok
6	Version Information	Operator Manual 10.3.1	Ok
7	Temperature & Pressure	Operator Manual 10.3.2	Ok
8	Touch Screen Calibration	Operator Manual 10.4.4	Ok



Aspen Diagnostics Pvt. Ltd.

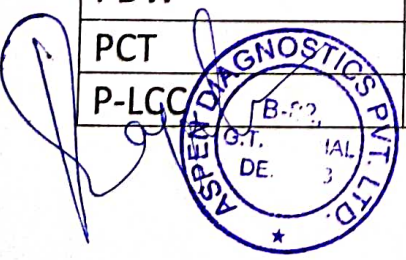
(Rapid Diagnostic Group Of Companies)



ISO 9001:2015
CERTIFIED COMPANY

1. High Level Control

High Control	Lot No. BC2211BH	Exp. 01.10.2023	Mode- WB
Test Item	Result	Unit	Ref. Range
WBC	17.87	10 ⁹ /L	14.32-19.32
Neu#	11.33	10 ⁹ /L	9.00-13.04
Lym#	2.85	10 ⁹ /L	1.68-4.04
Mon#	1.72	10 ⁹ /L	0.00-1.98
Eos#	1.71	10 ⁹ /L	0.00-3.30
Bas#	0.26	10 ⁹ /L	0.00-0.60
Neu%	63.4	%	53.5-77.5
Lym%	16.0	%	10.0-24.0
Mon%	9.6	%	0.0-11.8
Eos%	9.5	%	0.0-19.6
Bas%	1.5	%	0.0-3.6
RBC	5.22	10 ¹² /L	4.63-5.23
HGB	16.4	g/dL	15.4-17.0
HCT	51.7	%	48.2-53.0
MCV	99.0	fL	97.6-107.6
MCH	31.5	pg	30.4-35.4
MCHC	31.8	g/dL	29.0-35.0
RDW-CV	15.8	%	12.9-18.9
RDW-SD	58.5	fL	51.6-67.6
PLT	538	10 ⁹ /L	443-563
MPV	11.0	fL	8.1-14.1
PDW	16.5		13.3-19.3
PCT	5.91	mL/L	3.58-7.58
P-LCC	174	10 ⁹ /L	127-197



Aspen Diagnostics Pvt. Ltd.

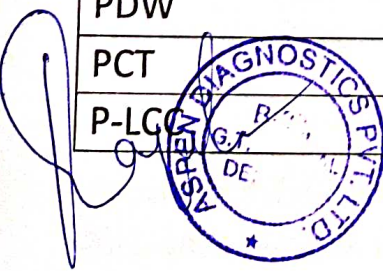
(Rapid Diagnostic Group Of Companies)



ISO 9001:2015
CERTIFIED COMPANY

2. Normal Level Control

Normal Control	Lot No. BC2211BN	Exp. 01.10.2023	Mode- WB
Test Item	Result	Unit	Ref. Range
WBC	8.52	10 ⁹ /L	6.92-8.92
Neu#	5.03	10 ⁹ /L	3.86-5.76
Lym#	2.14	10 ⁹ /L	1.39-2.67
Mon#	0.67	10 ⁹ /L	0.00-0.86
Eos#	0.60	10 ⁹ /L	0.00-1.10
Bas#	0.08	10 ⁹ /L	0.00-0.20
Neu%	59.0	%	48.8-72.8
Lym%	25.2	%	17.6-33.6
Mon%	7.9	%	0.0-10.8
Eos%	7.0	%	0.0-14.0
Bas%	0.9	%	0.0-2.4
RBC	4.38	10 ¹² /L	3.97-4.45
HGB	12.4	g/dL	11.8-13.0
HCT	38.7	%	36.9-40.9
MCV	88.3	fL	87.3-97.3
MCH	28.4	pg	27.0-32.0
MCHC	32.1	g/dL	28.9-34.9
RDW-CV	17.8	%	14.4-20.4
RDW-SD	58.5	fL	50.4-66.4
PLT	256	10 ⁹ /L	209-289
MPV	10.8	fL	8.3-14.3
PDW	16.8		13.5-19.5
PCT	2.77	mL/L	1.81-3.81
P-LCC	82	10 ⁹ /L	62-112



Aspen Diagnostics Pvt. Ltd.

(Rapid Diagnostic Group Of Companies)



ISO 9001:2015
CERTIFIED COMPANY

3.Low Level Control

Low Control	Lot No.BC2211BL	Exp.01/10/2023	Mode-WB
Test Item	Result	Unit	Ref. Range
WBC	3.55	10 ⁹ /L	2.77-3.77
Neu#	1.77	10 ⁹ /L	1.33-2.13
Lym#	1.21	10 ⁹ /L	0.81-1.41
Mon#	0.32	10 ⁹ /L	0.00-0.48
Eos#	0.24	10 ⁹ /L	0.00-0.32
Bas#	0.01	10 ⁹ /L	0.00-0.06
Neu%	49.8	%	40.9-64.9
Lym%	34.1	%	24.8-42.8
Mon%	9.0	%	0.0-14.8
Eos%	6.6	%	0.0-9.8
Bas%	0.5	%	0.0-2.0
RBC	2.08	10 ¹² /L	1.80-2.16
HGB	5.4	g/dL	4.9-5.7
HCT	16.7	%	15.0-18.0
MCV	80.2	fL	78.3-88.3
MCH	26.0	pg	24.3-29.3
MCHC	32.4	g/dL	29.1-35.1
RDW-CV	18.9	%	15.7-21.7
RDW-SD	56.5	fL	48.0-64.0
PLT	55	10 ⁹ /L	28-68
MPV	10.0	fL	7.4-13.4
PDW	16.1		12.5-18.5
PCT	0.55	mL/L	0.00-1.00
P-LCC	82	10 ⁹ /L	0-28

For Aspen Diagnostics Pvt. Ltd.


Rajaram Krishnamurthy
National Service Manager

