



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.

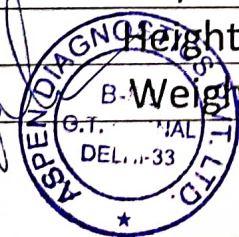
3. ACCESSORIES CHECK-

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





5. POWER REQUIREMENT –

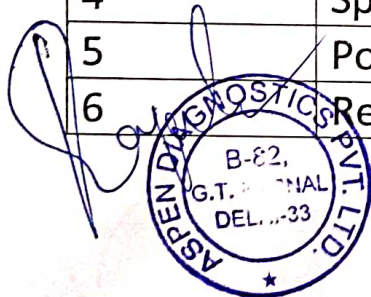
Requirement	Acceptable Range	Observed Ranged
Input Voltage	220 + / - 10 V	223 V
Line Frequency	50 HZ	50 HZ
Ambient Temperature	15 C – 30 C	23 C

6. REAGENTS , CONTROLS , CALIBRATOR CHECK-

Name	Check	Remark
Diluent BC5000	Ok	Ok
Diff. Lyse BC5000	Ok	Ok
LH Lyse BC5000	Ok	Ok
Probe Cleanser	Ok	Ok

PRE-INSTALLTION VERIFICATION REPORT :-

PRE-INSTALLATION VERIFICATION REPORT		
S/N	Parameters	Remarks
1	Unpacking Instrument	Ok
2	System Checking for damages	Ok
3	Accessories check	Ok
4	Space Check	Ok
5	Power Check	Ok
6	Reagents Check	Ok



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





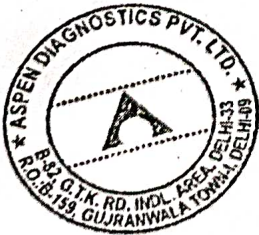
Calibration Certificate

Customer Name	ORIGYN PATH LABS,
Address	4TH FLOOR HB TWIN TOWER, NETAJI SUBHASH PLACE, PITAMPURA WAZIRPUR DISTT. CENTRE, NEW DELHI-110034,
Contact Person	Ms. ANKITA GUPTA
Contact No.	+91 9958582958
Instrument	5 Part Hematology Analyzer
Model	BC-5000
Serial No.	SS-22009035
Instrument Status	Sale
Calibration Done On	18.11.2022
Next Calibration Due On	17.10.2023

For Aspen Diagnostics Pvt. Ltd.

Raghav
Authorized Signatory

Rajaram Krishnamurthy
National Service Manager



Raghav



Aspen Diagnostics Pvt. Ltd.

(Rapid Diagnostic Group Of Companies)



Certificate No: 14348
ISO 9001:2000
CERTIFIED COMPANY

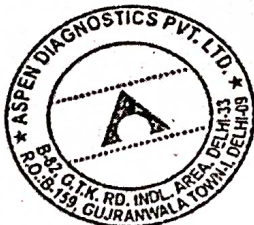
Calibrator Calibration

Instrument -5 Part Haematology Analyzer		Model-BC-5000		Serial No. SS-22009035	
Mode: OV-WB		Callibrator Lot No. PLUS01122		EXP. Date: 05.12.2022	
Parameter	WBC	RBC	HGB	MCV	PLT
Target	8.99	4.46	13.6	95.0	262
1.	7.91	4.05	12.7	89.1	261
2.	7.76	4.04	12.6	89.0	257
3.	7.82	4.04	12.7	89.5	254
4.	7.79	4.02	12.6	89.1	263
5.	7.78	4.03	12.7	89.3	253
6.	8.00	3.99	12.7	89.0	256
7.	7.94	4.03	12.7	89.1	258
8.	7.79	4.00	12.6	88.9	248
9.	7.71	3.96	12.6	88.8	264
Mean	7.833	4.018	12.66	89.08	257.1
CV(%)	1.2	0.7	0.3	0.2	2.1
New Factors (%)	114.77	110.99	107.41	106.64	101.89
Old Factors (%)	109.23	107.50	105.52	109.00	101.15

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National Service Manager



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