



Aspen Diagnostics Pvt. Ltd.

(Rapid Diagnostic Group Of Companies)



Certificate No.: 30903/A/0001/UK/En
ISO 9001:2015
CERTIFIED COMPANY

(Cornley- Acculyte-3P)

(Automated Electrolyte Analyzer)

**INSTALLATION QUALIFICATION
OPERATIONAL QUALIFICATION
PERFORMANCE QUALIFICATION**

(IQ/OQ/PQ)

KRSNAA DIAGNOSTIC PVT.LTD.

Civil Hospital

Batala Punjab-143505

(By Aspen Diagnostic Pvt. Ltd.)





CERTIFICATE OF INSTALLATION

Instrument Name : Acculyte-3p
Serial Number : DJ05D21110016
Customer Name : KRSNAA Diagnostic Pvt.Ltd.
Address : Civil Hospital , Batala

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

Engineer :
Signature :
Name : Ravinder Kumar
Designation : Service Engineer
Company : Aspen Diagnostics Pvt. Ltd.

Quality Manager:
Signature :
Name : Kirandeep kaur
Designation : Lab Incharge
Company : KRSNAA Diagnostic pvt. Ltd.





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INSTALLATION REPORT

Customer Name : KRSNAA DIAGNOSTIC PVT.LTD.
Place : Civil Hospital . Batala
Department : Laboratory
Contact Person : Kirandeep Kaur
Instrument Name. : Acculyte-3P
Serial Number : DJ05D21110016
Date of Installation : 10/03/2023
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

System Unpacking

System Checking: For any Damages All accessories as per check List verification

Space Requirement

Power Requirement

Reagents, Control, Calibrators verification.

1. SYSTEM UNPACKING & 2. SYSTEM CHECKING

Un packed Acculyte-3P instrument carefully and checked for any physical Damages.

3. ACCESSORIES CHECK-

Checked all accessories as per check List & found it alright.

4. SPACE REQUIREMENT –

Checked site for proper space allocation. At least 100 CM on each side and enough room for the below mentioned dimensions:

<u>DIMENSIONS</u>	
<u>Parameter</u>	<u>Analyzer OV</u>
Width(mm)	30
Depth (mm)	26
Height (mm)	36
Weight (Kg)	7.5



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5. POWER REQUIREMENT -

Requirement	Acceptable Range	Observed Ranged
Input Voltage	220 + / - 10 V	225 V
Line Frequency	50 HZ	50 HZ
Ambient Temperature	15 C - 30 C	23

6. REAGENTS, CALIBRATORS, CONTROL CHECK

Name	Check	Remark
Reagent Pack	Yes	Ok
Control	Yes	Ok
De-Proteinizer	Yes	Ok
Refill Solution for Electrodes	Yes	Ok
Refill Solution for Reference Electrode	Yes	Ok
Conditioner	Yes	Ok
Standard Solution	Yes	Ok

PRE-INSTALLATION VERIFICATION REPORT :-

PRE-INSTALLATION VERIFICATION REPORT		
S/N	Parameter	Remark
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

System Connections
Reagent & Waste Connections
Customizing the Analyzer Software
System Booting , Initialization & Check
Maintenance procedures.
Customer Training – Operation & Maintenance.

1. SYSTEM CONNECTION –

SYSTEM CONNECTIONS			
S/N	Name	Check	Remark
1	Reagent Pack	Operating Manual	Fitting in the Instrument slot
2	Input Power supply Cord	Connect	
4	Printer Paper	Operating Manual	

2. Reagent & Waste Management-

Please refer to the User Manual and the Kit Literature supplied with the instrument.





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3. CUSTOMIZING ANALYZER SOFTWARE –

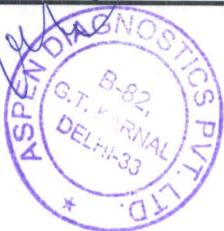
CUSTOMIZING ANALYZER SOFTWARE			
S/N	Parameters	Check	Remark
1	Date & Time	Operating Manual	Ok
2	Reagents	Operating Manual	Ok
3	Reference Ranges	Operating Manual	Ok
4	Reference Units	Operating Manual	Ok
5	Printing format	Operating Manual	Ok
6	Creating New User	Operating Manual	Ok

4. SYSTEM BOOTING , INITIALIZATION & CHECK -

Power ON System and check for successful initialization of the instrument and performed Background count for success.

5.MAINTENANCE PROCEDURES:-

MAINTENANCE			
S/N	Parameters	Check	Remark
1	Using Maintenance Menu	Operator Manual	





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PERFORMANCE QUALIFICATION-

QC Name:: Normal (Lot No:IQ211202C Exp.13-06-2023)

Parameter	Units	Range			Result
		Low	Target	High	
Sodium (Na ⁺)	mmol/L	125.50	129.50	133.50	128.37
Potassium (K ⁺)	mmol/L	3.61	3.80	3.99	3.82
Chloride (Cl ⁻)	Mmol/L	98.00	102.00	106.00	102.45

QC Name:: Low(Lot No:IQ211203C Exp.13-06-2023)

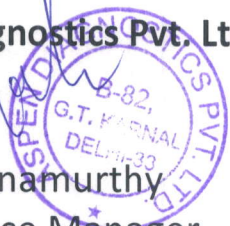
Parameter	Units	Range			Result
		Low	Target	High	
Sodium (Na ⁺)	mmol/L	99.80	107	114.20	106.50
Potassium (K ⁺)	mmol/L	1.63	1.95	2.27	1.85
Chloride (Cl ⁻)	Mmol/L	82.20	87.0	91.80	89.77

QC Name:: High(Lot No:IQ211201C Exp.13-06-2023)

Parameter	Units	Range			Result
		Low	Target	High	
Sodium (Na ⁺)	mmol/L	148.0	152.50	156.0	151.45
Potassium (K ⁺)	mmol/L	5.51	5.70	5.89	5.68
Chloride (Cl ⁻)	Mmol/L	117.0	121.0	125.0	120.76

For Aspen Diagnostics Pvt. Ltd

Rajaram Krishnamurthy
National Service Manager





Calibration Certificate

Customer Name	KRSNNA Diagnostic
Address	Civil Hospital , Batala
Contact Person	Kirandeep Kaur
Instrument	Electrolyte Analyzer
Model	Acculyte 3p
Serial No.	DJ05D21120016
Instrument Status	Under Warranty
Calibration Done On	10/03/2023
Next Calibration Due On	09/03/2024

For Aspen Diagnostic Pvt. Ltd.

Ravinder Kumar
Service Engineer




Rajaram Krishnamurthy
National Service Manager