




**SEMI AUTO - CHEMISTRY ANALYZER
ADX-CHEM-220**

**Installation, Performance and Operation
Qualification**

Document Number: IQ/OQ/PQ/ INS/ADX-CHEM-220

Instrument Serial Number: Adx - F2K1KH08219



	Installation, Performance and Operational Qualification Protocol	Model Number	ADX-CHEM-220
		Doc. No.	IQ/OQ/PQ/INS/ ADXCHEM-220
		Revision	A
		Effective Date	02.02.2021

1. OBJECTIVE

The objective of this protocol is to provide an outline for the inspection of **SEMI AUTO Chemistry Analyzer (ADX-CHEM-220)** to verify that:

- Each installed instrument complies with the engineering designs and equipment specification & manufacturer recommendations.
- To ensure that appropriate interconnections are made for utilities / equipment and that the safety features are defined before the startup of Operational Qualification exercise.

2. SCOPE

The scope of this protocol is procedures for Installation of the subjected equipment within the following boundaries:

- Identification & verification of the subjected instruments & its major components.
- identification, Verification & Classification of all the process control instruments (stepper motors, optical sensors, indicators, controllers etc.)
- Identification & verification of all safety features, if any.
- Identification & Verification of all supporting utilities for proper connections.
- Identification & verification of all supporting documents.
- No unauthorized or unrecorded modifications have taken place.
- ***Athenese Dx. Pvt. Ltd. will not be responsible for any possible consequence caused by either not read or violate the instructions mentioned herein.***





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3. VERIFICATION OF ACCESSORIES

Sr.No.	Particulars	Quantity	Present (Yes/No)	Checked by Sign & date	Remark
1	Main Unit	1	Yes		OK
2	Power Cord	1	Yes		OK
4	Lamp House	1	Yes		OK
5	Power Adaptor	1	Yes		OK
6	Waste Tube	1	Yes		OK
7	Aspiration Tube	1	Yes		OK
8	Printer Paper Roll	2	Yes		OK
9	Touch Pen	1	Yes		OK
10	Clotting Cuvette	100	Yes		OK
11	Clotting Cuvette Adaptor	1	Yes		OK
12	User Manual	1	Yes		OK


I. INSTALLATION QUALIFICATION: IQ/INS/ADX-CHEM-220


- To ensure that the machine is installed as per the Manufacturer Specifications.



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Sr. No.	Particulars	Checked by Sign & date	Remark
1	Avoid installation of instrument next to water fixtures, baths, sinks etc. exposed to excess heat, to direct sunshine or dusty area.		OK
2	Do not place near centrifuges, dishwashers or heavy inductive loads.		OK
3	Proper Earthing to be checked. L-E (approx. 230V) L-N (approx. 230V) N- E (approx. 0-5V)	<i>[Signature]</i> 28.10.2021	OK
4	Temperature limitation: 10°C~30°C, with fluctuation less than $\pm 2^{\circ}\text{C}/\text{H}$. Humidity limitation: 30%RH - 80%RH, without condensation.		OK
6	For 7 Filter Cells AD check Status range must be in [35,000- 59000] And Offset [0-4000]		OK
7	Flow Cell and Incubator Temperature Maintain Must be in 37°		OK

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II. OPERATIONAL QUALIFICATION: OQ/INS/ADX-CHEM-220

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.

- To ensure that the machine is operated as per the Manufacturer's recommendation

1. Equipment/ System Start up:

To check the standard sequence of initializing the instrument.

2. Functional checks:

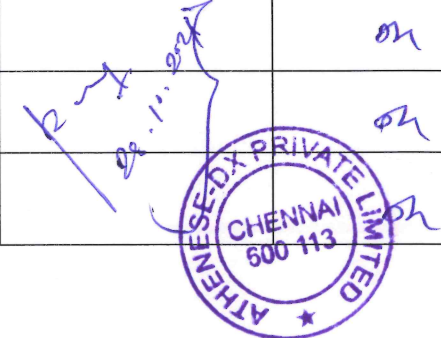
To check and ensure the different functions such as switching devices, feedback system, indicators, machine interface, cell status etc. are operating as expected.


3. Equipment /system stop:

To check and establish the standard sequence to be followed to shut down the subject equipment to avoid any damage to the product, equipment & personnel.

4. Verification of User:

After checking all possible test/functions and minimum verification of SOPs as per User manual shall be carried out to demonstrate that the equipment /system as an integral system is capable of achieving the desired results when operated as per the manufacturer instructions.

Sr. No.	Particulars	Instructed by Sign & date	Remark
1	Instruct the user about how to use the application software as per the user manual		OK
2	Instruct the user about how to operate the machine as per the user manual		OK
3	Monitor the user to ensure that he/she is operating the machine in proper way		

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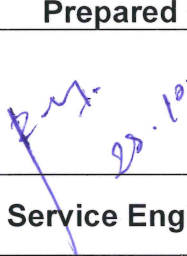
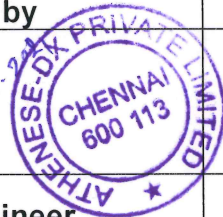
III. PERFORMANCE QUALIFICATION: PQ/INS/ADX-CHEM-220

Table 1: Material used for Performance Qualification

S.No	Name of the Material	Lot Number	Expiry

Table 2: Performance Testing

Parameters	Expected Range of Result	Actual Result	Remarks

Responsibility	Prepared by	Reviewed & Approved by
Signature & Date	 	
Designation	Service Engineer	Customer

CALIBRATION CERTIFICATE

Certificate No.	: FULLY AUTO CHEMISTRY ANALYZER –ADX-AUTO-CHEM-200-301/2021-22
Date of Calibration	: 02/09/2021
Calibration Due on	: 01/09/2022
Page No.	: 01/01

DETAILS OF UNIT UNDER CALIBRATION

Model Name: FULLY AUTO CHEMISTRY ANALYZER(ADX-CHEM-200)	Sr. No.: ADX-F2K1KH08219
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BIOCHEMISTRY CONTROL NORMAL (LEVEL-1)

S.No	Component	Wave Length(nm)	Units	Value	Range	Result
1	AST	340	U/L	36	(29 - 43)	31
3	Bilirubin Total	546	mg/dL	1.61	(1.28 - 1.94)	1.62
4	Glucose	505	mg/dL	114	(96.6 - 131)	101
5	Urea Kinetic	578	mg/dL	43.8	(37.3 - 50.3)	48.2
6	Albumin	630	g/dl	4.16	(3.53 - 4.79)	3.62

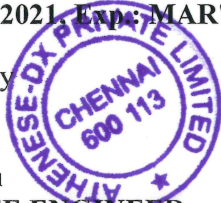
BIOCHEMISTRY CONTROL ABNORMAL (LEVEL-2)

S.No	Component	Wave Length(nm)	Units	Value	Range	Result
1	AST	340	U/L	148	(119 - 177)	142
3	Bilirubin Total	546	mg/dL	5.12	(4.04 - 6.20)	5.8
4	Glucose	505	mg/dL	279	(238 - 320)	283
5	Urea Kinetic	578	mg/dL	126	(107 - 145)	120
6	Albumin	630	g/dl	3.13	(2.66 - 3.60)	2.91

ALTA -Semi-Auto Chemistry Analyzer **ADX-CHEM-200**, Sr. No. **ADX-F2K1KH08219** has been calibrated by Randox, QC Control which is having a **Lot No.: BCL22062L1** and **BCL22062L2**, (Mfg.: JUN'2021, Exp: MAR'2023) the results are found to be within its acceptance criteria.

Calibrated By

Prabu Ragu
Sr. SERVICE ENGINEER



Regd. Office:

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