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ANALYZER CALIBRATION CERTIFICATE

CALIBRATION PROTOCOL

The purpose of this calibration protocol is to define the qualifications and the acceptance standard in order to verify the normal operation and function of the AUTOChem Xpert auto chemistry analyzer in the laboratory. Trained knowledgeable personnel from GENWORKS Health Pvt. Ltd. along with the department personnel will perform and review analyzer calibration protocol as mentioned by the manufacturer. The satisfactorily outcome of this procedures assures that the system functions according to the parameters.

EQUIPMENT INFORMATION:-

Instrument Name	:	**AUTO CHEMISTRY ANALYZER**
Model/Type	:	AUTOChem XPert
Serial No	:	AES2K2KT10048Y
Installation Date	:	13.12.2023
Calibration Done On	:	21.05.2024
Next Calibration Due On	:	20.05.2024

Laboratory/Hospital Name : ASTRA NEST DIAGNOSTICS
Chikkasanjeevappa Building,Konanakunte Cross
Kanankapura Main Road – Bangalore -560062

Supported By : Genworks Health Pvt Ltd,
Survey No 525/1 & 538/1,
V.S Mani Nagar, Madhavaram,
Chennai-600060

CALIBRATION AND MAINTAINANCE PROCEDURES

MAINTAINANCE:

- Instrument was checked for cleanliness.
- Cuvettes were manually cleaned and performed wash cells(All) operation in maintenance.
- Wash unit working was checked whether it is dispensing and aspirating Xpert wash and water in the perfect sequence manually.
- Cleaned sample reagent and mixing probes manually with alcohol and then with distilled water also performed probe wash(Detergent) in the maintenance.
- Performed sample reagent and mixer probes horizontal and vertical movement.
- Air Purge was performed to remove any air bubbles present in the syringes.
- Instrument mechanism operation check was done and found instrument working in satisfied operation conditions.

CALIBRATION:

- Input supply and lamp voltage for the machine was found adequate using the multimeter.
- Cell blank values are measured in the maintenance screen and reports are attached.
- Cuvette temperature are readings are indicated in the Software
- Reagent compartments cooling temperature is indicated in LED display behind the machine.
- Detectors performance were checked by checking the temperature control voltage.
- All parameters Calibration and both level Quality control was done and results found satisfactory

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This is to certify that this Analyzer has been inspected and calibrated for following parameters

TEST PARAMETER	TARGET VALUE & RANGE	OBTAINED VALUE
INPUT VOLTAGE	230-240V AC	234V AC
CELL BLANK VAULE	20000- 60000 for all wavelengths	
Cuvette TEMP	37 degree +/- 0.3	37.1 degree
REAGENT COMPARTMENT COOLING CHECK	4 to 14 degrees centigrade	8.2 degree
TEMP CONTROL UNIT	24 +/- 0.2V	
6V LAMP SUPPLY	6 +/- 0.2V	
24V MAIN BOARD SUPPLY	24 +/- 0.3V	

The results are obtained as per specifications & tolerance ranges. Routine chemistry parameters precision study was carried out. The CV's obtained are in acceptable range (< 3.0% CV). Calibrations of routine tests were also done & the results of controls & samples found satisfactory.

Calibration Reports:-

The controls results are obtained as per specifications & tolerance ranges. Verified the calibration & controls results according to the specific limits and considered the satisfactory results herewith certificate that AUTOChem Xpert Analyzer operates correctly according to the instrument specifications.

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Calibration details of Standard used	: Multimeter
Make	: Fluke
Serial No	: **40640066WS**
Traceability Certificate	: HI Tech calibration Services
Certificate #	: HT\CC\201107-16\001 & CR\PCAL\51278
	Validity : 19-July-2022

Calibration details of Standard used	: Temperature Sensor
Make	: PT-100
Instrument ID	: **WI-CALT-TS02**
Traceability Certificate	: Northlab (INDIA) PVT.LTD
Certificate #	: 0261221-T04 & CC24571400002920F
	Validity : 02-DEC-2022

Report Sign Off:

Calibration Done By:

Designation:

Date & Sign:

Note: Supportive date to be attached along with this certificate.

Installation conclusion:

Upon thorough evaluation and assessment, it is concluded that the installation requirements for the AUTOChem Xpert fully automated biochemistry analyzer have been satisfactorily met. The instrument has been successfully installed and is now ready for the next stage of qualification, which is the operation and performance qualification.

All necessary steps and criteria outlined in the installation qualification protocol have been followed and fulfilled. The instrument's location, power and utility connections, calibration and verification processes, safety measures, and documentation have been reviewed and found to be in compliance with the specified requirements.

With the completion of the installation qualification, the instrument is now being handed over for the subsequent operation and performance qualification, where its functionality, accuracy, precision, and overall performance will be thoroughly assessed.

It is important to continue following the established protocols and guidelines during the operation and performance qualification to ensure that the AUTOChem Xpert fully automated biochemistry analyzer continues to operate optimally and delivers accurate results in the biochemistry department.

Installation Certificate : Enclosed

Engineer (S) Sign :

Date :

Installation Protocol Remarks:

Action to be taken (if any) :

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AUTOCHEM XPERT

FULLY AUTOMATED BIOCHEMISTRY ANALYZER

INSTALLATION QUALIFICATION PROTOCOL DOCUMENT

The purpose of this installation qualification protocol is to establish the qualifications and acceptance standards necessary to verify the proper installation, normal operation, and functionality of the AUTOChem Xpert fully automated biochemistry analyzer in the laboratory. The successful completion of this protocol ensures that the system operates according to the defined parameters.

The results obtained from these installation activities serve as the foundation for the subsequent Operational & Performance Qualification Protocol, which further evaluates the operational and performance aspects of the analyzer.

As part of the process, it is important for the customer to verify that all results/data are correct. This includes reviewing and confirming that the controls meet the required specifications and standards. Additionally, the customer is responsible for subscribing to the validity of the results obtained and indicating the acceptance date, signifying their agreement that the system meets the necessary requirements.

By conducting the installation qualification protocol and obtaining satisfactory results, the AUTOChem Xpert fully automated biochemistry analyzer can be deemed as installed correctly and capable of functioning within the specified parameters in the laboratory.

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Protocol Prepared By

Designated Company Person Name	:	Mr. Allu Manikanta Reddy
Designation	:	Application Specialist
Date	:	16/12/2023

Protocol Prepared For

Customer / Contact Person Name	:	Dr. Mubeen Ahmed
Hospital / Institution	:	ASTRA NEST DIAGNOSTICS
Address	:	No. 21/8, Chikkasanjeevappa Buliding, Kanakapura Road, Konanakunte, Bengaluru, Karnataka 560062.

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Designated Person Name: Allu Manikanta Reddy Laboratory Personal Name: DR. Mubeen Ahmed

Designation: Application Specialist Designation: Head of Department

Signature: _____ Signature: _____

Date: _____ Date: _____

Attachments:

1. Instrument Installation certificate
2. Instrument User manual

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S. No	Installation Requirement Item	Description	Requirement Qualification	Remark
1.	Ground requirement	The ground of the installation site should be flat and bear at equipment weight.	Satisfactory	Nil
2.	Sun Light	Direct sunlight may cause heating of the reaction plate, refrigeration of the reagent storehouse and abnormal working of some sensors	Satisfactory	Nil
3.	Power	AC220V ± 10%	Satisfactory	Nil
4.	Ground	N-G ≤ 5V, L-G ~ 220V	Satisfactory	Nil
6.	Indoor temperature/ humidity	Temperature 15-30°C Humidity 35-85%RH	Satisfactory	Nil
7.	Air conditioner available	Air conditioner	Satisfactory	
8.	Drainage method	Tank or outfall	Satisfactory	Tank
13.	Computer	CPU2.2 GHZ above; Memory 4GB or above; More than 500GB hard disk; Cable inlet	Satisfactory	Nil
14.	Computer System	Windows 7, Windows 8, Windows10 professional or flagship	Satisfactory	Nil

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FULLY AUTOMATED BIOCHEMISTRY ANALYZER

PERFORMANCE QUALIFICATION PROTOCOL DOCUMENT

The purpose of this performance qualification protocol is to establish the criteria and standards necessary to verify the normal operation and functionality of the AUTOChem Xpert fully automated biochemistry analyzer in the laboratory. The successful completion of this procedure ensures that the system operates within the specified parameters and meets the required standards.

The results of the installation qualification protocol and operation qualification protocol serve as the bases for the subsequent performance qualification protocol.

The performance qualification protocol aims to validate the accuracy and precision of the instrument's test results by assessing the calibration and control results against predefined acceptance criteria.

The customer is responsible for verifying the accuracy of all results/data and must endorse the validity of the results along with the acceptance date.

Protocol Prepared By

Designated Company Person Name	:	Mr. Allu Manikanta Reddy
Designation	:	Application Specialist
Date	:	16/12/2023

Protocol Prepared For

Customer / Contact Person Name	:	Dr. Mubeen Ahmed
Hospital / Institution	:	ASTRA NEST DIAGNOSTICS
Address	:	No,21/8, Chikkasanjeevappa Buliding, Kanakapuraroad, Konanakunte, Bengaluru, Karnataka 560062.

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Equipment Information: -

Equipment Name	:	**AUTOChem Xpert Fully Automated Biochemistry Analyzer**
Model/Type	:	**AUTOChem Xpert**
Serial No	:	**AES2K2KT10048Y**
Equipment Installed Location	:	**Department of Biochemistry**
Installation date	:	**16/12/2023**

INSTRUMENT PERFORMANCE QUALIFICATION PROTOCOL

1. Performance Qualification Procedures

1. Assay Calibration & Calibration Verification:

Test Purpose:

To calibrate testing parameters and assess the performance of quality control material on the equipment, the following procedure was followed:

Procedure:

a. Assay calibration was conducted according to the manufacturer's protocol.

b. Following a successful calibration, duplicate testing of appropriate controls was performed. The calibration success was confirmed as the obtained control values fell well within the expected limits.

c. Overall, the procedure involved calibration of testing parameters and subsequent verification of calibration success through the analysis of control samples.

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2. **Precision Verification:**

Test Purpose:

In order to evaluate the precision performance of a piece of equipment, this will help ensure a standardized and reliable assessment of precision performance.

Procedures:

a. By conducting the experiment with 3 days of testing and 7 replicates each day, a total of 20 replicates were obtained. This dataset allows for the assessment of precision by analyzing the variability and consistency of the results.

b. Calculate the Mean, SD and CV%, and compare obtained values with manufacturer data, If the calculated values fall within the manufacturer's specified ranges, it indicates acceptable precision performance.

3. **Accuracy:**

To ensure that the data or information we are using accurate and reliable.

4. **Carryover study:**

Test Purpose:

a. The purpose of a carryover study on laboratory equipment is indeed to evaluate whether there is any contamination or residue left from a previous sample that could impact the accuracy and reliability of subsequent samples. It helps identify and quantify any carryover effects that may be present.

b. this will help ensure a standardized and reliable assessment of carryover performance.

c. In this specific carryover study, three identical specimens with high and low concentrations were used. The samples were run in The day. This design allows for a comprehensive assessment of potential carryover effects across different concentration levels and multiple testing days.

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Conclusion:

Based on the results obtained from the controls and their adherence to the specified specifications and tolerance ranges, the calibration and control results were verified. Based on this verification, it is confirmed that the AUTOChem Xpert fully automated biochemistry analyzer operates correctly in accordance with the instrument specifications.

In reference to the installation, operation, and performance procedures, as well as the studies conducted in the laboratory, the AUTOChem Xpert fully automated biochemistry analyzer fulfills all the criteria outlined in the respective protocols. This indicates that the analyzer meets the required standards and performance expectations.

Furthermore, user operation and maintenance hands-on training were provided to the designated technical personnel in the laboratory, following the protocol. This training ensures that the personnel are equipped with the necessary knowledge and skills to operate and maintain the AUTOChem Xpert analyzer effectively.

Based on the satisfactory results obtained from the controls, verification of calibration and control results, adherence to protocol criteria, and the provision of appropriate training, it can be concluded that the AUTOChem Xpert fully automated biochemistry analyzer is functioning correctly and meets the necessary requirements for accurate and reliable operation in the laboratory.

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Performance Protocol Remarks :

Action to be taken (if any) :

Designated Person Name: Allu Manikanta Reddy

Designation: Application Specialist

Signature: _____

Date: _____

Laboratory Personal Name: Dr. Mubeen Ahmed

Designation: Head of the Department

Signature: _____

Date: _____

Attachments:

1. Calibration & Control result in raw data
2. User Operation Training Certificate

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