

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 satisfactory outcome of this procedure assures that the system functions according to the parameters.

EQUIPMENT INFORMATION:-

Instrument Name	:	AUTO CHEMISTRY ANALYZER
Model/Type	:	AUTOChem XPert
Serial No	:	AES2K1KH11075YF
Installation Date	::	1 st November 2022
Calibration Done On	::	15 Jan 2023
Next Calibration Due On	::	15 July 2023

Laboratory/Hospital Name : Modern Diagnostic Centre Chadoora
Budgam-191113

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

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

TEST PARAMETER	TARGET VALUE & RANGE	OBTAINED VALUE
<i>INPUT VOLTAGE</i>	230-240V AC	234V AC
<i>CELL BLANK VAULE</i>	20000- 60000 for all wavelengths	
<i>Cuvette TEMP</i>	37 degree +/- 0.3	37.1 degree
<i>REAGENT COMPARTMENT COOLING CHECK</i>	4 to 14 degrees centigrade	8.2 degree
<i>TEMP CONTROL UNIT</i>	24 +/- 0.2V	
<i>6V LAMP SUPPLY</i>	6 +/- 0.2V	
<i>24V MAIN BOARD SUPPLY</i>	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-2024

Report Sign Off:

Calibration Done By:

Designation:

Date & Sign:

For
M. Neelakandan
(M. NEELAKANDAN)

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