

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 fully automated 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: AUTOCHEM XPERT FULLY AUTOMATED CHEMISTRY ANALYZER

Model/Type : AUTOCHEM XPERT

Serial No: AES2KH01022YF

Installation Date: 03.08.2022

Calibration Done On: 05.08.2022

Next Calibration Due On: 04.08.2023

Laboratory/Hospital: S R Metro, Rangirkhori, Silchar

Supported By: Genworks Health Pvt Ltd, Opp Sigma Tech Park, 5th floor, White field, Bangalore

GEN/APP/QC-001/IQ-AUTOCHEM XPERT/V.1.0



CALIBRATION AND MAINTENANCE PROCEDURES MAINTENANCE:

- > Instrument was checked for cleanliness.
- > Cuvettes were manually cleaned and also performed rinsing cuvette operation in maintenance.
- ➤ Wash unit working was checked whether it is dispensing and aspirating alkaline detergent and water in the perfect sequence manually
- ➤ Cleaned sample reagent and mixing probes manually with alcohol and then with distilled water also performed sample probe rinsing in the maintenance.
- > Performed sample reagent and mixer probes horizontal and vertical checkup.
- > Auto effluent pipeline rinsing was performed using magnetic valve detergent.
- > Syringe exhaust was performed to remove any air bubbles present in the syringes.
- > Instrument mechanism operation check was done by 20 times and found instrument satisfied operation conditions.

CALIBRATION:

- ➤ Input supply and lamp voltage for the machine was found adequate using the multimeter.
- > Lamp intensity and cuvette check values are measured in the maintenance screen and reports are attached
- ➤ Incubation temperature are readings are indicated in the SW
- > Reagent compartments cooling temperature is indicated in LED display behind the machine.
- > Detectors performance were checked with and without water

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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	231V AC
LAMP INTENSITY CHECK	9000-18000 for all wavelengths	9500 to 11,500
CUVETTE CHECK	<=/-1500 for all wavelengths	within +/-150
INCUBATOR TEMP	37 degree +/- 0.3	37 degree
REAGENT COMPARTMENT	4 to 10 degrees centigrade	5.1 degree
COOLING CHECK DETECTOR PERFOMANCE Voltage b/w 3.5 to 4.5V		3.7 to 4.2V
CHECK 12V LAMP SUPPLY	12 +/- 0.3V	12.10V
5V SUPPLY	5 +/- 0.3V	5.01V
24V SUPPLY	24 +/- 0.3V	23.97V



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.

Report Sign Off:

Calibration Done By: Debilal Prajapati

Designation: Service Engineer

Date & Sign: 05.08.2022



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