

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	:	AES2K2KH04116YA
Installation Date	:	13/09/2022
Calibration Done On	:	15/09/2023
Next Calibration Due On	:	14/09/2024

Laboratory/Hospital Name : MEDRAY CLINICS PVT.LTD
No.962,12th Main Road, Opp.Lakme Salon
Doopannahalli, Indiranagr, Bangalore,
Karnataka - 560008.

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
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.

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

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-2024

Report Sign Off:

Calibration Done By: Mr.Suresh G J

Designation: Circle Manager

Date & Sign: 15.09.2023



For
Mr. Suresh G. J.
(Circle Manager)

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

BIOELAB Auto chemistry analyzer inspection report

Quality Certification Report

Name	Auto chemistry analyzer	Model	GEN WORKS- AUTOChem Xpert	
No.	AES2K2KH04116YA	Testing Date	15/09/2023	
Testing Standard	YY/T 0654-2017			
Standard clause number	Name of inspection item	Standard requirements	Measured results	Comments
5.2	stray light	Abs>2.3	6.524	Qualified
5.3	Linear range of absorbance	The maximum absorbance with relative bias in the range of ($\pm 5\%$) should be great than or equal to 2.0.	340nm: 3.8812,-1.558% 505nm: 3.7276,-1.782%	Qualified
5.4	Absorbance accuracy	0.5Abs: permissible error (± 0.025)Abs 1.0Abs: permissible error(± 0.07)Abs	-0.012Abs -0.048Abs	Qualified
5.5	Absorbance stability	The change of absorbance should be not more than 0.01.	340nm: 0.0076Abs 660nm: 0.0013Abs	Qualified
5.6	Absorbance repeatability	In terms of the coefficient of variation, it should be less than or equal to 1.5%	0.31%	Qualified
5.7	Temperature accuracy and	Temperature within the set value of plus or minus	Temperature accuracy:0.1 °C	Qualified

				Temperature fluctuation:0.08 °C				
5.8	Sample needle carrying contamination rate	The contamination rate of needle is less than 0.1%.		0.00599%		Qualified		
5.9	Sampling error and repeatability	The minimum sample addition amount (2μL), maximum sample addition amount (30μL) and 5μL sample addition amount of the nominal sample of the instrument were tested, and the sampling error was no more than (±5%), and the coefficient of variation was no more than 2%. The minimum reagent addition amount (20μL) and the maximum reagent addition amount (300μL) of the standard reagent for the instrument were tested. The sampling error of adding reagent was not more than (±5%) and the coefficient of variation was not more than 2%.		S: 2ul	CV: 1.40%	Qualified		
					Error: 3.26%			
				S: 30ul	CV: 0.5%			
					Error: 2.4%			
				S: 5ul	CV: 0.63%			
					Error: 0.84%			
				R1: 20ul	CV: 0.26%			
					Error: -2.1%			
R: 300ul	CV: 0.25%							
	Error: -1.6%							
	R2: ul	CV:						
		Error:						
	R2: ul	CV:						
		Error:						
5.10	Intra-batch precision of clinical projects	ALT(Alanine aminotransferase) (30 U/L ~50 U/L)	CV:≤5%	ALT	CV:1.51%	Qualified		
		UREA (7.0 mmol/L ~11.0 mmol/L)	CV:≤2.5%	UREA	CV:1.35%			
		TP(Total Protein) (50.0 g/L ~70.0 g/L)	CV:≤2.5%	TP	CV:1.02%			

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5.11	Appearance requirement	<p>a) The appearance of biochemical analyzer is clean and smooth, with uniform color, no obvious color difference, no scars and cracks.</p> <p>b) The characters and symbols on the biochemical instrument panel are clearly marked.</p> <p>c) The fastener connection of biochemical instrument should be firm and reliable, and should not be loosened.</p> <p>d) The moving parts of the biochemical instrument should be stable, not stuck, sudden jump and significant empty return, and the key group should be flexible back jump.</p>	Accepted	Qualified
5.12	Protective grounding impedance	The impedance of the protective conductor terminal and each accessible component with a protective connection is less than 0.1Ω , excluding the impedance of the power line.	0.021Ω	Qualified
5.13	Dielectric strength(Moisture-free pretreatment)	a) According to 6.8.2 of GB4793.1 (without wet pretreatment), basic insulation 1390V/50HZ AC voltage test should be carried out. The voltage should rise to the specified value within 5S or 5S, and then keep 5S. Breakdown or repeated arc should not occur during the test, and corona discharge effect and similar phenomena should be neglected.	Accepted	Qualified

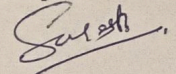
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b) According to 6.8.2 of GB4793.1 (without wet pretreatment) for double insulation or enhanced insulation 2240V/50HZ AC voltage test, the voltage should rise to the specified value within 5S or 5S, and then keep 5S. Breakdown or repeated arc should not occur during the test, and corona discharge effect and similar phenomena should be neglected.
The results should meet the requirements of 5.16.5.

Inspection conclusion

Qualified

NOTE: All the major values listed above are unable to print from equipment and recorded manually service engineer updated in this report.



QC: Zhang Qiangli

Re-check: Huang Xiaofei

Approve: Liu Yiming

Date: Sep. 15, 2023