



## INSTALLATION, OPERATIONAL & PERFORMANCE

### QUALIFICATION DOCUMENTS



Model : **Semi Auto Chemistry Analyser – AutoLab Versa**

Marketed By : **Peerless Biotech Private Limited**

Serial No : **ES1022209PH431**

Installation Date : **14 Aug 2023**



## Installation / Validation Report

### Semi Auto Chemistry Analyser - AutoLab Versa IQ/ OQ / PQ Documents

Customer Address: Bio Micro Laboratories , 67, Alagapuram Main Road, Contact Person: Mr. Shehu Ali  
Opp Suramangalam Police Station, Suramangalam, Salem - 636005 Contact Number: 9894045424  
Serial No: ES1022209PH431 Installation date: 14-08-2023

### Installation Qualification

#### Transport damage

Package damaged:  Yes  No  
Parts damaged  Yes  No

If yes, please specify:

#### Initial check

Parts missing? (Check against packing list)	number	Part description
<input type="checkbox"/> Yes → Please specify parts	_____	_____
<input checked="" type="checkbox"/> No	_____	_____
	_____	_____
	_____	_____

\* Please return parts, including a malfunction report.

Line Voltage / Main Supply: 220 - 240V: 231V

Grounding Voltage (0-5V): 1V

Room Air conditioned:  Yes  No

Stabiliser / UPS: **Online / Microtek** Rating : **2 KVA**

#### (We recommend connecting AutoLab Versa to UPS of 1 KVA)

The system Described meets all the criteria outlined in this installation qualification Documents. All items have been checked & Installation has been completed.

The System is ready for Performing Operational Qualification.

Performer: Bharath Kumar  
Date: **02/11/2023**



Reviewer: *Hitesh*  
*M.C.J*  
**Hitesh Kumar Jain N / Janardhan M C**  
Service Manager



## Installation / Validation Report

### Semi Auto Chemistry Analyser - AutoLab Versa IQ/ OQ / PQ Documents

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Opp Suramangalam Police Station, Suramangalam, Salem - 636005 Contact Number: 9894045424  
Serial No: ES1022209PH431 Inspection date: 09-11-2023

### Operational Qualification

- Connect the instrument to the waste container.
- Switch ON the system, Check the initializing process.
- Check gain and background values for all filters.
- Check aspiration volume.
- Set system and test Parameters
- Run calibration and QC cycle
- Check normal procedure to shut down the analyser.

#### Tests/Comments (if any):

The instrument is performing in the prescribed standards; validation of the same has been performed.

**This is to certify that the instrument can be used for operational analysis.**

The system Described meets all the criteria outlined in this installation qualification Documents.

All items have been checked & Installation has been completed.

The System is ready for Performing Performance Qualification.

Performer: Bharath Kumar  
Date: 09/11/2023



Reviewer:    
Hitesh Kumar Jain N / Janardhan M C  
Service Manager



## Installation / Validation Report

### Semi Auto Chemistry Analyser - AutoLab Versa IQ/ OQ / PQ Documents

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### Performance Qualification

#### NORMAL CONTROL:

Control Manufacture : Bio-Rad LOT : 89701  
QC Name : Bio-Rad Expiry : 2024-10

Method	Parameter	Range	Values Obtain	Status
End point	Glucose	73.4-96.2	84.95	OK
Kinetic	SGOT	13.1-42.1	37.57	OK
Fixed point	Creatinine	1.16-2.83	2.32	OK

#### Precision Test

Carried out one sample and run 3 times simultaneously and found the CV is < 5%

Sl.no	Test Name	Values
1	GLU	111.05
2	GLU	111.90
3	GLU	111.53
1	SGOT	32.33
2	SGOT	33.12
3	SGOT	32.13
1	CREA	0.73
2	CREA	0.73
3	CREA	0.73

#### REMARKS:

The system meets all criteria outlined in this Performance Qualification Documents.  
All the required parameters have been checked and instrument is ready for regular use.

Performer: Bharath Kumar  
Date: 09/11/2023



Reviewer:  Hitesh Kumar Jain N /  Janardhan M C  
Service Manager



## Certificate

This is to certify that the following instrument have been validated as per the manufacturer's protocol & is found to be working satisfactorily.

**Certificate No** : 2023/VERSA/003  
**Instrument Name** : Semi Auto Chemistry Analyser  
**Model** : AutoLab Versa  
**Serial No** : ES1022209PH431  
**Marketed By** : Peerless Biotech Private Limited.

for Peerless Biotech Private Limited



*Hitesh*  
*w.c. Jan*  
**Hitesh Kumar Jain N / Janardhan M C**  
Service Manager