

INSTALLATION, OPERATIONAL & PERFORMANCE QUALIFICATION DOCUMENTS



Model : Semi Auto Chemistry Analyser – AutoLab Versa

Marketed By : Peerless Biotech Private Limited

Serial No : ES1021705272

Installation Date : 31 Aug 2017

Installation / Validation Report

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

Customer Address: **Anu sakthi Micro Lab**
No.5/118N KMS TVS Opp, Salem S2 Bus
Stop Near, Laxmi Nagar – 638316.

Contact Person: **Mr. N Ramkumar**
Telephone No: 8973188990
6381708766

Serial No: **ES1021705272**

Installation date: **31/08/2017**

Installation Qualification

Transport damage

Package damaged: Yes No
Parts damaged Yes No

If yes, please specify:

Initial check

	number	Part description
Parts missing? (Check against packing list)	_____	_____
<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: **Offline UPS** Rating : > 1 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: **Gowthaman**

Reviewer: **Karthikeyan K**

Date: 11/01/2022

Installation / Validation Report

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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: **Gowthaman**

Date: 11/01/2022

Reviewer: **Karthikeyan K**

Semi Auto Chemistry Analyser - AutoLab Versa IQ/ OQ / PQ DocumentsCustomer Address: **Anu sakthi Micro Lab**No.5/118N KMS TVS Opp, Salem S2 Bus
Stop Near, Laxmi Nagar – 638316.Contact Person: **Mr. N Ramkumar**Telephone No: 8973188990
6381708766Serial No: **ES1021705272**Installation date: **31/08/2017****Performance Qualification****NORMAL CONTROL:****Control Manufacture : SPINREACT**
QC Name : Spintrol "H" Normal Human Serum
LOT : 34589
Expiry : 2022-11

Method	Parameter	Range	Values Obtain	Status
End point	Total Cholesterol	82.6 - 111	97	OK
End point	GLUCOSE	88.4 - 120	103	OK
Fixed time	Creatinine	0.82 – 1.18	0.9	OK
Fixed time	UREA(BERTHELOT)	35.9 – 48.5	43	OK
Kinetic	SGOT	41.4 – 59.6	50	OK
Kinetic	SGPT	39.5 – 56.9	51	OK

ABNORMAL CONTROL:**Control Manufacture : SPINREACT**
QC Name : Spintrol "H" Pathological Human Serum
LOT : 16575
Expiry : 2022-11

Method	Parameter	Range	Values Obtain	Status
End point	Total Cholesterol	156 - 210	186	OK
End point	GLUCOSE	200 - 270	242	OK
Fixed time	Creatinine	3.27 – 4.71	3.79	OK
Fixed time	UREA(BERTHELOT)	106 – 144	120	OK
Kinetic	SGOT	118 – 170	139	OK
Kinetic	SGPT	91 – 131	118	OK

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: **Gowthaman**Reviewer: **Karthikeyan K**

Date: 11/01/2022

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 : 202202IOP004
Instrument Name : Semi Auto Chemistry Analyser
Model : AutoLab Versa
Serial No : ES1021705272
Marketed By : Peerless Biotech Private Limited.

The validation is valid from **11/01/2022** to **10/01/2023**

for **Peerless Biotech Private Limited**



Mr. Karthikeyan K
Service Manager - Technical Support

Ace Medical Solutions (India) Pvt. Ltd.

An ISO 9001-2015 Certified Company

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GSTIN. 33AAHCA8053H1ZR • DL No. MDU/4205/20B,MDU/3971/21B • CIN : U33110TN2009PTC072140

CALIBRATION CERTIFICATE



Customer Name & Address:	M/S. Anusakthi Micro Lab,	Certificate No:	AMS/LAB/2889696
	5/118 N, KMS Complex, Salem Service Road,	Issuing Date:	14/08/2021
	Bus Stop, Lakshmi Nagar, Erode - 638 316.	Page No:	1 of 1

Details of Device under Calibration (DUC):

DUC:	Bio Chemistry Analyser	Id. No:	ASM/LAB /BCA/001
Make:	VERSA	Department:	Laboratory
Model:	Auto Lab	Calibrated On:	13/08/2021
Sl. No:	ES1021705272	Calibration Due Suggested:	12/08/2022
Type:	Semi Auto	DUC Condition on Receipt:	OK
Range & Least Count:	---		

Traceability Details:

Sl.No.	Test Equipment	Make	Certificate Number	Valid Up to
1	Electrical Safety Analyser	RigelSafeTest60	PSG/CIRD/BMCC/5507/2021	18/01/2022
2	Thermo Hygrometer	Beetech/088	PC/01/21/ATL/0194-01	22/01/2022

Room Temperature: 25°C±2 Room Humidity: 30-60%

(At the time of Calibration)

ESA Test Results:

SL.No	Parameter	ESA Reading	Unit	Normal Range	Condition
1	Current	0.368	mA	500	Normal
2	Frequency	50.0	Hz	49 -50	Normal
3	Mains Voltage Line - Neutral	232.2	Volts	220 - 240	Normal
4	Mains Voltage Line - Earth	233.3	Volts	220 - 240	Normal
5	Mains Voltage Neutral - Earth	4.2	Volts	< 7	Normal

*Electrical Safety: Please check the attached log sheet

SL.No	Parameter	Measured	Standard	Correction	Unit
1	Lamp Voltage	11.68	12.00	-0.32	Volts
2	Detector Sensitivity	-0.00	0.0	0.0	% Absorbance
3	Sipper Volume	404.0	450	-46.0	µl
4	Peristaltic Pump pressure	-13.47	-15	+1.53	cmH ₂ O

Note:

1. Calibration Points were selected as per customer request.
2. Each reading were taken by Repeatability Test (i.e.) each reading in a row is a mean of 10 readings.
3. Results Reported are valid at the time of and under the stated conditions of measurements.

Calibrated By:

(Calibration Engineer)

B. S. S.



Approved by:

(Technical Manager)

B. S. S.