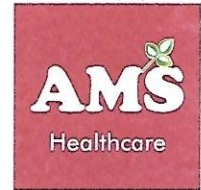


# Ace Medical Solutions (India) Pvt. Ltd.

An ISO 9001-2015 Certified Company

No : 3/751, 1st Cross Street, Surveyor Colony, K.Pudur, Madurai - 625 007.

Phone : 0452 - 2561691 Mobile : +91 94434 74610



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

## CALIBRATION CERTIFICATE



Customer Name & Address:	M/S. Gowtham Diagnostic Centre, 744-B, Uthukuli Main Road, OPP. GH, Kunnathur, Tirupur Dt. - 638 103.	Certificate No:	AMS/LAB/2889721
		Issuing Date:	14/08/2021
		Page No:	1 of 1

### Details of Device under Calibration (DUC):

DUC:	Bio Chemistry Analyser	Id. No:	GDC/LAB /BCA/001
Make:	VERSA	Department:	Laboratory
Model:	Auto Lab	Calibrated On:	13/08/2021
Sl. No:	ES1021709066	Calibration	
Type:	Semi Auto	Due Suggested:	12/08/2022
Range & Least Count:	---	DUC Condition on Receipt:	OK

### 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	0.268	mA	500	Normal
2	Frequency	50.1	Hz	49 -50	Normal
3	Mains Voltage Line - Neutral	253.9	Volts	220 - 240	Abnormal
4	Mains Voltage Line - Earth	256.3	Volts	220 - 240	Abnormal
5	Mains Voltage Neutral - Earth	5.7	Volts	< 7	Normal

\*Electrical Safety: Please check the attached log sheet

SL.No	Parameter	Measured	Standard	Correction	Unit
1	Lamp Voltage	12.14	12.00	+0.14	Volts
2	Detector Sensitivity	-0.00	0.0	0.0	% Absorbance
3	Sipper Volume	392	450	-58.0	ml
4	Peristaltic Pump pressure	-13.07	-15	+0.93	cmH <sub>2</sub> 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)

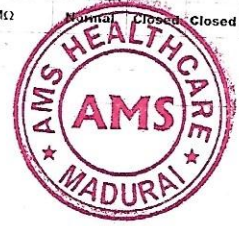
*B. S. S.*

ESA Results:

Test Number	Test Standard	Test	Condition	Filter Selection	Reading Value	Reading Unit	Polarity	Neutral	Earth	Applied Parts
1	Earth Bonding	Earth Bond Voltage	Normal	AC+DC	0.2024	Ω	Normal	Closed	Closed	All
2	IEC60601	Leakage: Earth	Normal	AC+DC	164.30	μA	Normal	Closed	Closed	All
3		Leakage: Earth	Normal	AC+DC	154.04	μA	Reversed	Closed	Closed	All
4		Leakage: Enclosure	Normal	AC+DC	0.00	μA	Normal	Closed	Open	All
5		Leakage: Enclosure	Normal	AC+DC	0.00	μA	Reversed	Closed	Closed	All
6		Leakage: Earth	SFC	AC+DC	316.49	μA	Normal	Open	Closed	All
7		Leakage: Earth	SFC	AC+DC	304.68	μA	Reversed	Open	Closed	All
8		Leakage: Enclosure	SFC	AC+DC	166.30	μA	Normal	Closed	Open	All
9		Leakage: Enclosure	SFC	AC+DC	172.85	μA	Reversed	Closed	Open	All
10		Current	Normal	AC+DC	0.268	Amps	Normal	Closed	Closed	All
11		Frequency	Normal	AC+DC	50.1	Hz	Normal	Closed	Closed	All
12		Mains Voltage: Live to Neutral	Normal	AC+DC	253.9	V	Normal	Closed	Closed	All
13		Mains Voltage: Live to Earth	Normal	AC+DC	256.3	V	Normal	Closed	Closed	All
14		Mains Voltage: Neutral to Earth	Normal	AC+DC	5.7	V	Normal	Closed	Closed	All
15		IEC62353	Equipment Leakage	Direct Method	AC+DC	196.65	μA	Normal	Closed	Open
16	Equipment Leakage		Direct Method	AC+DC	196.22	μA	Reversed	Closed	Open	All
17	NFPA-99	Ground Leakage	Normal	AC+DC	167.15	μA	Normal	Closed	Closed	All
18		Ground Leakage	Normal	AC+DC	162.74	μA	Reversed	Closed	Closed	All
19		Ground Leakage	SFC	AC+DC	321.34	μA	Normal	Open	Closed	All
20		Ground Leakage	SFC	AC+DC	321.62	μA	Reversed	Open	Closed	All
21		Chassis Leakage	Normal	AC+DC	0.00	μA	Normal	Closed	Closed	All
22		Chassis Leakage	Normal	AC+DC	0.00	μA	Reversed	Closed	Closed	All
23		Chassis Leakage	SFC	AC+DC	170.00	μA	Normal	Closed	Open	All
24		Chassis Leakage	SFC	AC+DC	163.73	μA	Reversed	Closed	Open	All
25	IEC61010	Touch Leakage	Normal	AC+DC	0.00	μA	Normal	Closed	Closed	All
26		Touch Leakage	Normal	AC+DC	0.00	μA	Reversed	Closed	Closed	All
27		Touch Voltage	Normal	AC+DC	3.26	V	Normal	Closed	Closed	All
28		Touch Voltage	Normal	AC+DC	3.26	V	Reversed	Closed	Closed	All
29		Touch Leakage	SFC	AC+DC	158.26	μA	Normal	Closed	Open	All
30		Touch Leakage	SFC	AC+DC	157.18	μA	Reversed	Closed	Open	All
31		Touch Voltage	SFC	AC+DC	3.26	V	Normal	Closed	Open	All
32		Touch Voltage	SFC	AC+DC	3.26	V	Reversed	Closed	Open	All
33	Insulation Testing	Insulation Resistance	Normal	AC+DC	>20	MΩ	Normal	Closed	Closed	All
34	Point to Point Testing	Point to Point Earth Bond Test	Normal	AC+DC	>19.9	Ω	Normal	Closed	Closed	All
35		Point to Point Leakage Test	Normal	AC+DC	0	mA	Normal	Closed	Closed	All
36		Standard Insulation Test	Normal	AC+DC	>20	MΩ	Normal	Closed	Closed	All

Test Passed Yes Tested On 13/08/2021 Tested By

B. B. B.





## **INSTALLATION, OPERATIONAL & PERFORMANCE**

### **QUALIFICATION DOCUMENTS**



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

**Marketed By : Peerless Biotech Private Limited**

**Serial No : ES1021709066**

**Installation Date : 20 Nov 2017**



## Installation / Validation Report

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

Customer Address: **Gowtham Diagnostic Centre**  
744-B, Uthukuli Mainroad, Opp. GH,  
Kunnathur-638103, Tirupur-Dt

Contact Person: **Bathragiri. E**  
Telephone No: 9842018734

Serial No: **ES1021709066**

Installation date: **20/11/2017**

### 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**

Date: 07/06/2021

*J. B. A.*

Reviewer: **Karthikeyan K**

*K. Karthikeyan*



## Installation / Validation Report

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

Customer Address: **Gowtham Diagnostic Centre**  
744-B, Uthukuli Mainroad, Opp. GH,  
Kunnathur-638103, Tirupur-Dt

Contact Person: **Bathragiri. E**  
Telephone No: 9842018734

Serial No: **ES1021709066**

Installation date: **20/11/2017**

### 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: 07/06/2021



Reviewer: **Karthikeyan K**





## Installation / Validation Report

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

Customer Address: **Gowtham Diagnostic Centre**  
744-B, Uthukuli Mainroad, Opp. GH,  
Kunnathur-638103, Tirupur-Dt

Contact Person: **Bathragiri. E**  
Telephone No: 9842018734

Serial No: **ES1021709066**

Installation date: **20/11/2017**

### 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: 07/06/2021





# Peerless Biotech Pvt. Ltd.

#99 & 100, Nehru Nagar Industrial Estate, 2nd Link Street, Kottivakkam,  
Chennai-600 041, Tamil Nadu, India. Phone: 044 - 24541688  
eMail:access.peerless@gmail.com; Website:www.peerlessbio.com

## 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** : 202112IOP001  
**Instrument Name** : Semi Auto Chemistry Analyser  
**Model** : AutoLab Versa  
**Serial No** : ES1021709066  
**Marketed By** : Peerless Biotech Private Limited.

The validation is valid from 07/06/2021 to 06/06/2022

for Peerless Biotech Private Limited



**Mr. Karthikeyan K**  
**Service Manager - Technical Support**