

# Ace Medical Solutions (India) Pvt. Ltd.

An ISO 9001-2015 Certified Company

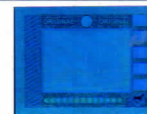
No : 3/751, 1st Cross Street, Surveyor Colony, K.Pudur, Madurai - 625 007.

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, Indian Medical Diagnostic Centre, 593/A1, KJS Complex, Near Canara Bank Main Road, New Bus Stand, Bhavani, Erode -638301	Certificate No:	AMS/LAB/2889580
		Issuing Date:	19/07/2021
		Page No:	1 of 1

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

DUC:	Bio Chemistry Analyser	Id. No:	IMDC/LAB/BCA/001
Make:	Versa Auto Lab	Department:	Laboratory
Model:	Auto Lab	Calibrated On:	17/07/2021
Sl. No:	ES1021506017	Calibration Due Suggested:	16/07/2022
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	339.0	mA	500	Normal
2	Frequency	50.1	Hz	49 -50	Normal
3	Mains Voltage Line - Neutral	231.2	Volts	220 - 240	Normal
4	Mains Voltage Line - Earth	230.4	Volts	220 - 240	Normal
5	Mains Voltage Neutral - Earth	4.5	Volts	< 7	Normal

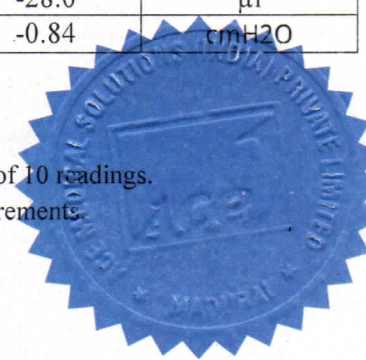
\*Electrical Safety: Please check the attached log sheet

SL.No	Parameter	Measured	Standard	Correction	Unit
1	Lamp Voltage	11.73	12.0	-0.01	Volts
2	Detector Sensitivity	-0.00	0.0	0.0	% Absorbance
3	Sipper Volume	472	500	-28.0	µl
4	Peristaltic Pump pressure	14.16	15.0	-0.84	cmH2O

Allowable Tolerance: set by Customer

Note:

1. Calibration Points were selected as per customer request.
2. Each reading is 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	0.1598	Ω	Normal	Closed	Closed	All

2	IEC60601	Leakage: Earth	Normal	AC+DC	129.71	μA	Normal	Closed	Closed	All
3		Leakage: Earth	Normal	AC+DC	121.61	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	251.44	μA	Normal	Open	Closed	All
7		Leakage: Earth	SFC	AC+DC	240.53	μA	Reversed	Open	Closed	All
8		Leakage: Enclosure	SFC	AC+DC	131.29	μA	Normal	Closed	Open	All
9		Leakage: Enclosure	SFC	AC+DC	136.46	μA	Reversed	Closed	Open	All
10		Current	Normal	AC+DC	0.339	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	231.2	V	Normal	Closed	Closed	All
13		Mains Voltage: Live to Earth	Normal	AC+DC	230.4	V	Normal	Closed	Closed	All
14		Mains Voltage: Neutral to Earth	Normal	AC+DC	4.5	V	Normal	Closed	Closed	All

15	IEC62353	Equipment Leakage	Direct Method	AC+DC	155.25	μA	Normal	Closed	Open	All
16		Equipment Leakage	Direct Method	AC+DC	154.91	μA	Reversed	Closed	Open	All

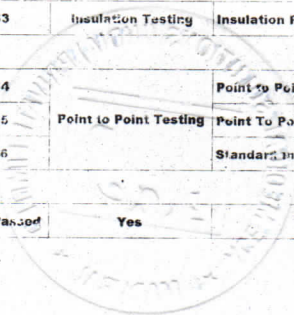
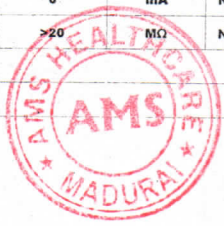
17	NFPA-99	Ground Leakage	Normal	AC+DC	131.96	μA	Normal	Closed	Closed	All
18		Ground Leakage	Normal	AC+DC	128.48	μA	Reversed	Closed	Closed	All
19		Ground Leakage	SFC	AC+DC	253.69	μA	Normal	Open	Closed	All
20		Ground Leakage	SFC	AC+DC	253.91	μA	Reversed	Open	Closed	All
21		Chassis Leakage	Normal	AC+DC	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	134.21	μA	Normal	Closed	Open	All
24		Chassis Leakage	SFC	AC+DC	129.26	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	2.57	V	Normal	Closed	Closed	All
28		Touch Voltage	Normal	AC+DC	2.57	V	Reversed	Closed	Closed	All
29		Touch Leakage	SFC	AC+DC	124.94	μA	Normal	Closed	Open	All
30		Touch Leakage	SFC	AC+DC	124.09	μA	Reversed	Closed	Open	All
31		Touch Voltage	SFC	AC+DC	2.57	V	Normal	Closed	Open	All
32		Touch Voltage	SFC	AC+DC	2.57	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	17/07/2021	Tested By	B. S. S.					
-------------	-----	-----------	------------	-----------	----------	--	--	--	--	--



# 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, Indian Medical Diagnostic Centre, 593/A1, KJS Complex, Near Canara Bank Main Road, New Bus Stand, Bhavani, Erode -638301	Certificate No:	AMS/LAB/289/0112
		Issuing Date:	19/11/2021
		Page No:	1 of 1

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

DUC:	Digital Thermometer	Id. No:	IMDC/LAB/DT/001
Make:	R tek	Department:	Laboratory
Model:	RT - 116	Calibrated On:	18/11/2021
Sl. No:	---	Calibration Due Suggested:	17/11/2022
Type:	PT 100	DUC Condition on Receipt:	OK
Range & Least Count:	0 - 6°C / LC 1°C		

### Traceability Details:

Sl.No.	Test Equipment	Make	Certificate Number	Valid Up to
1	RTD Thermometer	Center / RTD 375	PC/01/21/ATL/0107-01	22/01/2022
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)

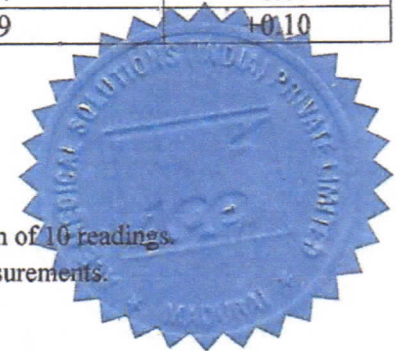
### Test Results:

SL.No.	Refrigerator Place	DUC Reading (°C)	Standard Reading (°C)	Correction (°C)
1	Freezer	-1.56	-1.49	+0.07
2		-1.42	-1.33	+0.09
3	Chiller	1.39	1.46	+0.07
4		1.51	1.58	+0.07
5	Chamber I	2.55	2.61	+0.06
6		2.38	2.48	+0.10
7	Chamber II	3.18	3.26	+0.08
8		3.32	3.38	+0.06
9	Chamber III	4.27	4.34	+0.07
10		4.39	4.49	+0.10

Allowable Tolerance: User Defined.

Note:

1. Calibration Points were selected as per customer request.
2. Each reading is 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. Dhya



Approved by:  
(Technical Manager)

B. Dhya

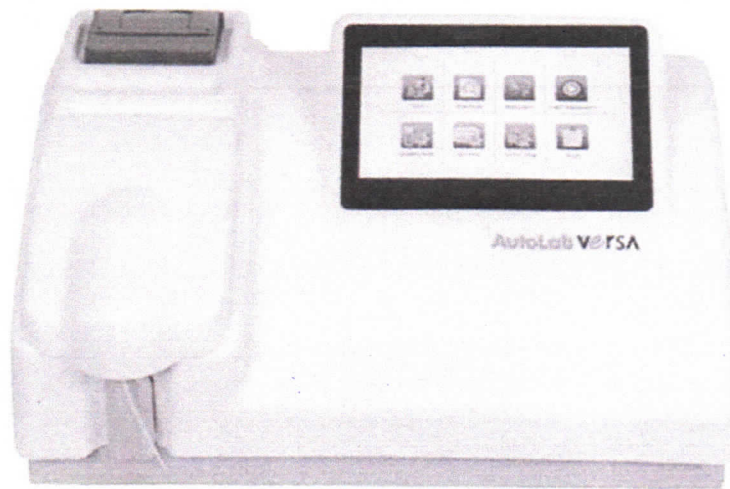


**Peerless Biotech Pvt. Ltd.**

#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

## **INSTALLATION, OPERATIONAL & PERFORMANCE**

### **QUALIFICATION DOCUMENTS**



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

**Marketed By : Peerless Biotech Private Limited**

**Serial No : ES1021506017**

**Installation Date : 12 Mar 2016**



Installation / Validation Report

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

Customer Address: Indian Medical Diagnostics Centre Contact Person: Madhu
593/A1, KJS Complex, Near Canara Bank, Telephone No: 9442725591
Main Road,New Bustand, Bhavani 638 301.

Serial No: ES1021506017 Installation date: 12/03/2016

Installation Qualification

Transport damage

Package damaged: [ ] Yes [x] No
Parts damaged [ ] Yes [x] No

If yes, please specify:

Initial check

Table with 2 columns: number, Part description. Includes 'Parts missing?' section with checkboxes for Yes and No.

\* Please return parts, including a malfunction report.

- Line Voltage / Main Supply: 220 - 240V: 231V
Grounding Voltage (0-5V): 1V
Room Air conditioned: [x] Yes [ ] No
Stabiliser / UPS: Offline UPS Rating : > 1 KVA

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

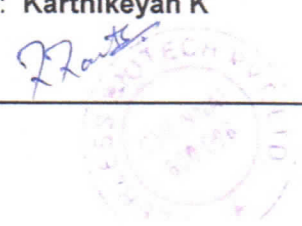
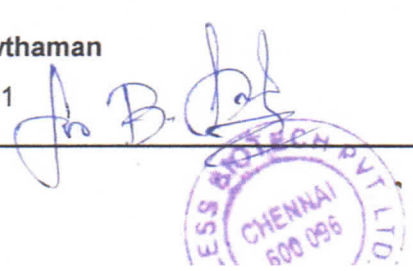
The system Described meets all the criteria outlined in this installation qualification Documents. All items have been checked & Installation has been completed.

The System is ready for Performing Operational Qualification.

Performer: Gowthaman

Reviewer: Karthikeyan K

Date: 08/06/2021





## Installation / Validation Report

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

Customer Address: **Indian Medical Diagnostics Centre**  
593/A1, KJS Complex, Near Canara Bank,  
Main Road, New Bustand, Bhavani 638 301.

Contact Person: **Madhu**  
Telephone No: 9442725591

Serial No: **ES1021506017**

Installation date: **12/03/2016**

### 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: 08/06/2021

Reviewer: **Karthikeyan K**





## Installation / Validation Report

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

Customer Address: **Indian Medical Diagnostics Centre** Contact Person: **Madhu**  
593/A1, KJS Complex, Near Canara Bank, Telephone No: 9442725591  
Main Road, New Bustand, Bhavani 638 301.

Serial No: **ES1021506017**

Installation date: **12/03/2016**

### 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	98	OK
End point	GLUCOSE	88.4 - 120	102	OK
Fixed time	Creatinine	0.82 - 1.18	1.1	OK
Fixed time	UREA(BERTHELOT)	35.9 - 48.5	41	OK
Kinetic	SGOT	41.4 - 59.6	51	OK
Kinetic	SGPT	39.5 - 56.9	49	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	187	OK
End point	GLUCOSE	200 - 270	234	OK
Fixed time	Creatinine	3.27 - 4.71	3.90	OK
Fixed time	UREA(BERTHELOT)	106 - 144	123	OK
Kinetic	SGOT	118 - 170	141	OK
Kinetic	SGPT	91 - 131	113	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**

Date: 08/06/2021

Reviewer: **Karthikeyan K**



# 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** : 202112IOP002  
**Instrument Name** : Semi Auto Chemistry Analyser  
**Model** : AutoLab Versa  
**Serial No** : ES1021506017  
**Marketed By** : Peerless Biotech Private Limited.

The validation is valid from 08/06/2021 to 07/06/2022

for Peerless Biotech Private Limited

77  
  
Mr. Karthikeyan K  
Service Manager - Technical Support