



SPECTRUM
MEDICAL INDUSTRIES PVT. LTD.

Corporate Off: 105, Balaji Plaza, L5.C-3, Sector-8, Rohini,
Delhi-110085 (INDIA) | Tel: 011-41064962, 27050502, 27050503
website : www.spectralab.net | Email: info@spectralab.net
Toll Free No: 1800 103 0502



Ref. No: Cust/Smi/2023-24/9187
Date: 18/06/2023

CALIBRATION REPORT

This is to certify that the machine Model: Spectralab Genie Sr. no ATCD017-422SMI has been successfully calibrated at Photon Hospital Moradabad – 244001 Uttar Pradesh.

This calibration certificate is valid for one year next calibration due date on 16/06/2024

Issued by: Pinnu Kumar
(Service Engineer)

Date of Calibration: 17/06/2023



EQUIPMENT CALIBRATION

The Following calibrations were performed on the instrument during the installation procedure.

- **Automatic Reagent Calibration by using of Clinical Chemistry Serum Calibrator .**

Calibration performed by

Sign:

Name: Pinnu Kumar

Designation Service Engineer

Date: 17-06-2023



PREQUALIFICATION

Equipment Name	Semi - Automatic Biochemistry Analyzer
Model No.	Spectralab Genie
Serial No.	ATCD017-422SMI
Design	Standard
Manufacturer	Spectrum Medical Industries Pvt. Ltd. 105 LSC Balaji Plaza Sector -8 Rohini Delhi-110085

PRE QUALIFICATION CERTIFICATE

(Equipment was checked as per specifications given in purchase order)

Installed by
Service Engineer : Pinnu Kumar

Sign:

Date: 17-06-2023





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DESIGN QUALIFICATION

INTENDED USE:

The Spectralab Genie system is a multi-parameter Semi Automatic Biochemistry Analyzer designed for in-vitro diagnostics use in clinical/ research labs.

OPERATION :

The Spectralab Genie is Semi Automatic Biochemistry Analyzer capable to perform tests on whole blood, serum, plasma, cerebrospinal fluid and urine samples.

SUPPORT /MAINTENANCE:

Spectrum Medical Industries Pvt. Ltd – Delhi provides Service Support

TRAINING FOR USERS:

Training to be provided to all the users during the installation process.

Service Engineer : Pinnu Kumar

Sign:

Date: 17-06-2023





INSTALLATION QUALIFICATION

BASIC CONDITIONS:

(The location for installation and the equipment were checked as per specification and the equipment was installed)

	Description	Remark
1	Installation Table/Platform	OK
2	Table/ Platform	OK
3	Distance between wall and instrument	OK
4	Place of Table/Platform should have proper ventilation	OK
5	Two Holes on Table/Platform on Rear Side	OK
6	Environmental conditions:-	OK
	A: Dust Proof Area	OK
	B: Room Temperature	OK
	C: Relative Humidity	OK
7	Power Requirement:	OK
	ON-LINE UPS 1KVA With Back-Up	OK
	Electrical Insulation	OK
	(220Vac +/-10%), 43/65Hz	OK
	Power Plugs	OK
8	De-ionized water with neutral pH	OK

Installed by
Service Engineer : Pinnu Kumar

Sign:

Date: 17-06-2023





PERFORMANCE QUALIFICATION

The performance of the equipment was checked for the following.

- Reagent volume** **Sufficient**
- Water verification** **Neutral pH (Lab Grade Water)**
- Kinetic with linearity check** **Automatic**

The results were well within the acceptable range

Operation status	Working
Calibration date	16-06-2023
Calibration Frequency	One Year

PERFORMANCE QUALIFICATION CERTIFICATE

Equipment has been calibrated by the Manufacturer M/s Spectrum Medical Industries Pvt Ltd detailed evaluation performance data are being enclosed & Reagent are supplied along with instrument & test were performed by Engineers of Spectrum Medical Industries Pvt Ltd)

Performance for parameters verified with commercial calibrators. Run calibrator and result are within acceptable range.

Installed by

Service Engineer : **Pinnu Kumar**

Sign:

Date: **17-06-2023**



OPERATION QUALIFICATION

1. Purchase Order #	NIL Dated 11-06-2022
2. Equipment Received as per order	YES
3. Equipment Accessories	OK
4. Equipment utilities	OK
5. Equipment safety and control provisions	OK
6. Certificate , Drawings	N.A

Other Remarks (if any)

OPERATION QUALIFICATION CERTIFICATE

(Equipment was checked for operation and checked. Equipment found to be operating satisfactorily as per the specification (Refer Operation manual))

Sign:

Head of Dept.

Date: 17-06-2023

