Calibration & Validation Certificate : 23082

Customer Name   : **Meditrust Diagnostic Centre**
     33, Anukul Chandra Naskar Road
     Garia
     Kolkata - 700084

Instrument Model   : **Innolab 200**

Serial No.   : **ESI032305PT121P**

Date of Calibration   : **06/12/2023**

Validity   : **05/06/2024**

This is to certify that the above mentioned product has been verified of calibration electronically and the instrument is working satisfactory.

Next Calibration   : **06/06/2024**
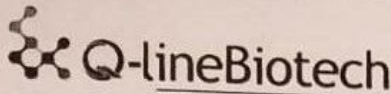
For SCIENCE & SERVICE

Gurudas Kusari
Engineer

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Installation Qualification (IQ)

InnoLab200

Company (Name & Add) :
Q-Line Biotech Pvt Ltd
New Delhi - 110028

Contact Person : Mr. Dipankar Ghush

Telephone No. : 9339521840

Customer (Name & Add) Meditrust diagnostic
Centre
33, Anukul chandra Road, Garia-84,

Contact Person Rahul De

Telephone No. 9830411196

Name of instrument: Innolab 200 (Semi Automatic Biochemistry Analyzer)

Serial No. : ESI03230SPTI2IP   **Installation Date :** 06.12.2023
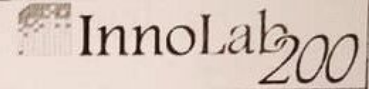
Installation

Perform the next steps

- ☑ Place the analyser on a Dry and Vibration free surface.
- ☑ Check Power Supply AC 100-240 V (±10V), 50/60Hz
- ☑ Check ground voltage ..1v.......V (<5.0 V).
- ☑ The instrument should not be placed near brush-type motors and electrical contacts that are frequently turned on and off.
- ☑ Room Temperature ..25°c...... (15 °C to 35 °C)
- ☐ Humidity .... (35- 80% RH)
- ☑ AC power plug must be grounded at the main socket.
- ☑ Check and install the flow cell properly by connecting inlet & outlet tubes if required
- ☑ Connect the waste pipe to the wate bottle supplied
- ☑ Plug in the power cable to power source and connect to the power socket of instrument in back side
- ☑ Start up the Innolab 200 by switching on the power switch.

Q-LINE BIOTECH PRIVATE LIMITED (Formerly known as "POCT Services Pvt. Ltd.")

Corp. Office: 20A (Basement), Main Shivaji Marg, Najafgarh Road, Near Moti Nagar Police Station, New Delhi-110015, INDIA. Tel.: 011-45577407
Regd. Office: 298-281, Transport Nagar, Kanpur Road, Adjacent Transport Nagar Metro Station, Lucknow-226023 (U.P.), INDIA. Tel.: 0522-2433023
E-mail: info@qlinebiotech.com I Website: www.qlinebiotech.com

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Operational Qualification (OQ)

InnoLab200

☑ Switch on the instrument on using power switch and wait 10 seconds, you will see the product name & Software version followed by main screen with eight different function dialogue boxes on display

☑ After self check, system displays main menu

☑ Check the functioning of touch screen by touching/operating it with hand and stylus provided.

☑ Test icon has sample, QC test, reagent blank and standard test functions

☑ View Result - View test results after analysis, or history samples information. Query QC results, Standard results. Clear and backup the data.

☑ Reagent Setup - Setup the assay parameters for analysis.

☑ QC Setup - Setup the QC parameters that for analysis.

☑ System Setup - Setup printer, data and language, Combo box configuration. Define sleep time and do touch screen calibration.

☑ Maintenance - Do flow cell washing, pump calibration, optical calibration.

☑ About - Display the version information about instrument and software.

☑ Power management - Shut down the program or run sleep mode of instrument.

☑ Set the System Parameters from System Setup box (Date & Time, Printer settings etc)

☑ Check the functioning of printer

☑ Connect USB mouse or USB keypad cable to instrument USB port, check its working

☑ Go to maintenance and wash the flow cell two-three times with Microwash followed by distilled water.

☑ Go to reagent set up and create some analysis programmes like Glucose, Albumin, ALT, Creat etc.

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Performance Qualification (PQ)

InnoLab 200

☑ Go to Test Menu and select any programme parameter to be tested

☑ Run some (few enzymes, few substrate) tests using customer's reagent and fill the data in the table below

Test	QC Range (Level 1) Bio-Rad	Test Result	QC Range (Level 2)	Test Result
GLUCOSE	84·1 (74·8-93·3)	89	271 (241-301)	255
CHOL	269 (229-309)	258	106 (90-122)	98·5
ALT/GPT	28·0 (19·0-37·0)	26·7	104 (81·0-127)	95·5
AST/GOT	44 (33·0-55·0)	41·8	193 (143-243)	189
CREAT	2·64 (2·24-3·03)	2·42	5·86 (4·98-6·74)	5·15
UREA	16·0 (13·6-18·4)	18	46·0 (39·1-52·9)	41·8

☑ Remarks:

We hereby certify that Instrument performance check has been carried out . Verified the instrument linearity, precision & accuracy by evaluating controls. Obtained results are satisfactory. Instrument is ready for regular use.

Technical acceptance

Date (dd-mm-yyyy) : ....

Service Engineer / Application Person Name

Sanjib Chattopadhyay

Customer Name

Rahul Deb

Signature : ....

Signature & Stamp : ....

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