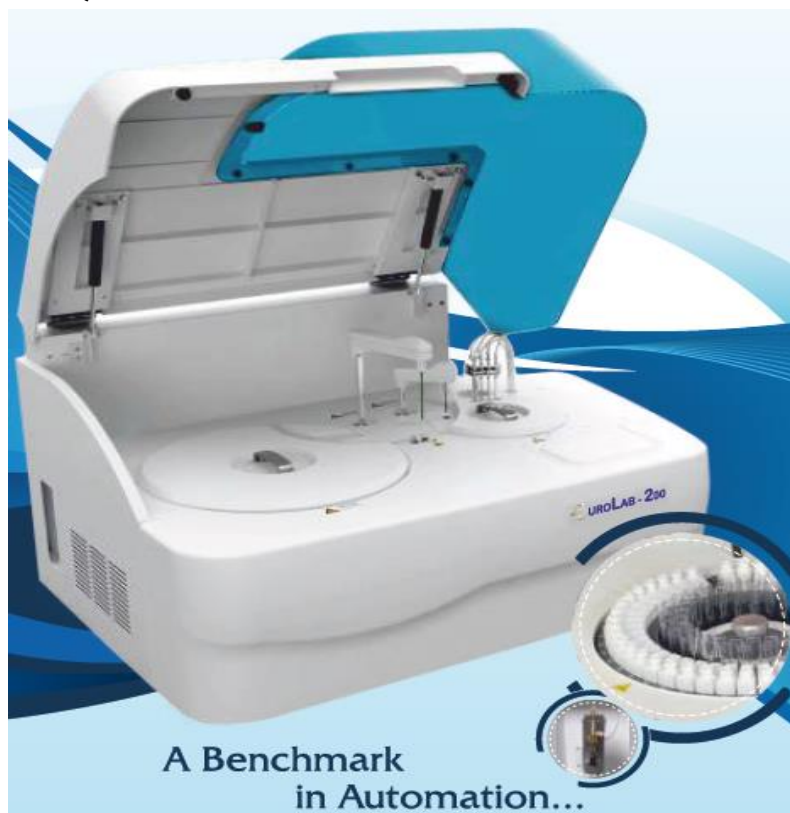




## INSTALLATION, OPERATIONAL & PERFORMANCE

### QUALIFICATION DOCUMENTS



Model : **Fully Auto Chemistry Analyser – EuroLab 200**

Marketed By : **Peerless Biotech Private Limited**

Serial No : **AES2K3KT02182A**

Installation Date : **14-08-2023**



## Installation / Validation Report

**Fully Auto Chemistry Analyser – EuroLab 200**

**IQ/ OQ / PQ Documents**

Customer Address: Bio Micro Laboratories , 67, Alagapuram Main Road, Contact Person: Mr. Shehu Ali  
Opp Suramangalam Police Station, Suramangalam, Salem - 636005 Contact Number: 9894045424  
Serial No: AES2K3KT02182A Installation date: 14-08-2023

### 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: 210 - 230V: 230V
- Earthing Voltage (0-5V): 1 V
- Room Air conditioned:  Yes  No
- Stabiliser / UPS: Online Brand: Microtek Rating : 2 KVA

#### Perform the next steps

- Install PC (Main unit, monitor, printer, keyboard and mouse)
- Install software record software version: **V4.8.3.2T4**
- Install Sample & Reagent Probe and Mixer Probe
- Install water and waste containers

Performer: Bharath Kumar  
Date: **02/11/2023**



Reviewer: *Hitesh* *Janardhan*  
**Hitesh Kumar Jain N / Janardhan M C**  
Service Manager



## Installation / Validation Report

### Fully Auto Chemistry Analyser – EuroLab 200

### IQ/ OQ / PQ Documents

Customer Address: Bio Micro Laboratories , 67, Alagapuram Main Road, Contact Person: Mr. Shehu Ali  
Opp Suramangalam Police Station, Suramangalam, Salem - 636005 Contact Number: 9894045424  
Serial No: AES2K3KT02182A Inspection date : 04-11-2023

### Operational Qualification

- Power up the Computer and Analyser
- Run software from start menu.
- Run "Fluidic Prime".
- Reaction tray and Reagent pre-heat temperature status : Normal
- Main control unit, Reaction unit, Reagent unit, sample unit status : Normal
- Loading and mixing unit status : Normal
- Temperature control unit : Normal
- Set system and test Parameters
- Run "Cuvette Check".
- Run "Lamp Check"

#### 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: Bharath Kumar  
Date: 04/11/2023



Reviewer:  Hitesh Kumar Jain N /  Janardhan M C  
Service Manager



## Installation / Validation Report

### Fully Auto Chemistry Analyser – EuroLab 200

### IQ/ OQ / PQ Documents

Customer Address: Bio Micro Laboratories , 67, Alagapuram Main Road, Contact Person: Mr. Shehu Ali  
Opp Suramangalam Police Station, Suramangalam, Salem - 636005 Contact Number: 9894045424  
Serial No: AES2K3KT02182A Inspection date : 04-11-2023

### Performance Qualification

#### CALIBRATION

Calibrator : Spinreact  
LOT No : 2492

Calibrator Name : Spintrol H CAL  
Expiry Date : 2024-12

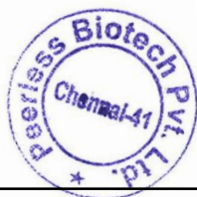
#### QUALITY CONTROL CHECK

QC Name : Bio-Rad  
LOT No : 89701  
Expiry : 2024-10

QC Name : Bio-Rad  
LOT NO : 89702  
Expiry : 2024-108

Parameter	QC range	Test result	QC range	Test result
	Level: 1		Level : 2	
Glucose	73.4-96.2	74.5	238-298	246.9
Creatinine	1.16-2.83	2.37	4.31-5.83	4.81
ALT/SGPT	13.1-42.1	22.1	74.5-113	80.4
Total Cholesterol	218-315	249.1	75-113	94.5
TGL	129-216	214.5	64.3-96.3	90.4

Performer: Bharath Kumar  
Date: 04/11/2023



Reviewer: *Hitesh* *M.C.J*  
Hitesh Kumar Jain N / Janardhan M C  
Service Manager



## Precision Test

Carried out one sample and run 5 times simultaneously and found the CV is < 5%

Sl.no	Test Name	Values
1	SGOT	20.9
2	SGOT	22.2
3	SGOT	20.9
4	SGOT	20.4
5	SGOT	21.1
1	GLU	215.5
2	GLU	223.9
3	GLU	222.1
4	GLU	222.1
5	GLU	219.6
1	CREAT	0.82
2	CREAT	0.83
3	CREAT	0.84
4	CREAT	0.82
5	CREAT	0.82

## Summary of the results

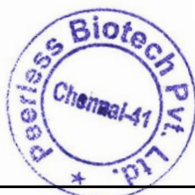
Sl.no	Test Name	Unit	Calibration Factor	QC Results	Mean	SD	CV % (n=5)
1	SGOT	U/L	In Range	In range	21.10	0.59	2.8022%
2	CREAT	mg/dl	In Range	In range	0.82	0.01	0.7600%
3	GLU	mg/dl	In Range	In range	220.64	2.90	1.3129%

The CV in % for each test was found to be in the specific range.

## REMARKS

The system is installed with all required software and it meets all criteria outlined in this Performance Qualification Documents. All the required parameters have been checked and instrument is ready for regular use.

Performer: Bharath Kumar  
Date: 04/11/2023



Reviewer: *Hitesh* *Janardhan*  
Hitesh Kumar Jain N / Janardhan M C  
Service Manager



## 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** : 2023/EL200/008  
**Instrument Name** : Fully Auto Chemistry Analyser  
**Model** : EuroLab 200  
**Serial No** : AES2K3KT02182A  
**Marketed By** : Peerless Biotech Private Limited.

For **Peerless Biotech Private Limited**

**Hitesh Kumar Jain N / Janardhan M C**  
Service Manager

