



CALIBRATION CERTIFICATE

Hospital Name	:	Nirnaya Diagnostics Centre, Trivandrum
Address	:	Mainroad, Kunnathukal, Karakonam P O, Trivandrum
Instrument Name	:	Microlab 300LX
Serial No.	:	16-5585
Department	:	Laboratory
Calibration Date	:	10/11/2021
Next Calibration Due	:	10/11/2022
Appearance	:	Clean

Instrument Condition:

- Room is Air Conditioned Yes No
- Power Supply Earthing less than 5 V Yes No
- Room Working Environment is Good Yes No

Initial check : Switch On ML300

- Instrument is Initialising properly Yes No
- Display is showing all Characters Yes No
- Inlet and Outlet Valves working during aspiration Yes No
- Bellows pump is moving to Home position Yes No
- Start Up the analyser software Yes No
- Lamp is Glowing Yes No
- Key pad is working Yes No
- Aspiration Lever is working Yes No
- Temperature of Peltier is showing 37 degrees Yes No

Validation: Performing Filter Check

Select Filter	Range in Abs	Abs Value	Replacement Needed	
Filter 340nm	1.7 to 2.6	1.6	Yes	No
Filter 405nm	1.2 to 2.6	1.7	Yes	No
Filter 505nm	0.8 to 2.6	1.8	Yes	No
Filter 546nm	0.8 to 2.6	1.5	Yes	No
Filter 578nm	0.6 to 2.6	0.8	Yes	No
Filter 620nm	0.6 to 2.6	1.1	Yes	No

Must Stock Parts List**Recommended for Replacement**

- Tubing Assay Yes No
- Source Lamp Yes No
- Waste Tube Yes No

Call: 0471 - 2982488 / 9400 101 488 | Email: labxmedicalsistemas@labx.in

Performance Check:

- | | | |
|-------------------------------------|--|-----|
| <input checked="" type="checkbox"/> | Aspiration Volume during Flush mode: 1500 µl | Yes |
| <input checked="" type="checkbox"/> | Blanking is proper during test: | Yes |
| <input checked="" type="checkbox"/> | Results are Satisfactory | Yes |

Remarks:

Instrument is calibrated and working in good condition. Tested Samples and found results are satisfactory

This Calibration is valid from **10-11-2021 to 09-11-2022** .

Next Calibration is on **10-11-2022**.

Technical Acceptance



Amal V K

FSE – Elitech Instruments

LabX Medical Systems



INSTALLATION QUALIFICATION

CUSTOMER NAME	Nirnaya Diagnostics Centre - Trivandrum
CUSTOMER ADDRESS	Main Road, Kunnathukal, Karakonam P.O, Thiruvananthapuram
INSTRUMENT NAME	Microlab 300 LX
INSTRUMENT SERIAL NUMBER	16-5585
INSTALLATION DATE	09-11-2016

INSTALLATION, OPERATIONAL AND PERFORMANCE QUALIFICATION

Transport damages
 Package damaged Yes No
 Parts damaged
 If yes, please specify: Yes No

Initial check:

Parts missing?

Part Number	Part Description

(Check against packing list)


Yes → Please specify parts
 No

* Please return parts, including a malfunction report.

- Line Voltage / Main Supply: 210 – 270V:
- Earthing Voltage (0-5V):
- Room Air conditioned: Yes / No
- Stabiliser / UPS Brand: Rating:

(We recommend connecting CA620 to CVT or UPS of 0.5 KVA to 1 KVA)


-----END OF QUALIFICATION-----

The customer confirms that the conditions required to ensure the proper functioning of the device according to the supplier's recommendations have been inspected and qualified.			
<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO			
Customer's comments		Installer's comments	
		Successfully verified all installation criteria as per manufacturer recommendation.	
Customer (Name and Position)	Signature	Installer (Name and Position)	Signature
		Amal V K Field Service Engineer LabX Medical Systems	
This document is prepared and signed in duplicate. Each page must be initialled by the installer.			

OPERATIONAL QUALIFICATION

- Remove all the Transpiration accessories / Clips / Packing.
- Connect the Waste Tubing.
- Switch ON the system and check the Display
- Check the initialising process.
- Check the Key pad Keys
- Set System Parameters
- Check Valves and motor in the service Menu.
- Check Aspiration of Liquid by pressing Flush Key. (Should aspirate 1500ul)
- Check Filter wheel movement and Absorbance of each filter. (Check the data sheet)
- Check the Temperature of the Peltier element (Should be 37 degrees)

-----END OF QUALIFICATION-----

The customer confirms that the conditions required to ensure the proper functioning of the device according to the supplier's recommendations have been inspected and qualified.			
<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO			
Customer's comments		Installer's comments	
		Successfully verified all operational criteria as per manufacturer recommendation.	
Customer (Name and Position)	Signature	Installer (Name and Position)	Signature
		Amal V K Field Service Engineer LabX Medical Systems	
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PERFORMANCE QUALIFICATION

Filter Absorbance

<u>Calibrator</u>	<u>Target Value</u>	<u>Range</u>	<u>Measured Value</u>	<u>Status</u>
340	1.8	1.8 to 2.4	1.7	OK
405	1.2	1.2 to 2.4	1.6	OK
505	0.8	0.80 to 2.4	1.8	OK
546	0.7	0.70 to 2.4	1.5	OK
578	0.6	0.60 to 2.4	0.8	OK
620	0.6	0.60 to 2.4	1.1	OK
Level 1	Target Value	Tolerance	Measured Value	Status
GLU	87.5	12	85	OK
Chol	249	14	248	OK
SGOT	39.3	8	37	OK
SGPT	28.9	6.9	29	OK
CREAT	20.04	0.6	1.99	OK
Level 2	Target Value	Tolerance	Measured Value	Status
GLU	271	31	269	OK
Chol	102	13	104	OK
SGOT	196	24	193	OK
SGPT	98	13	101	OK
CREAT	5.54	0.6	5.67	OK

-----END OF QUALIFICATION-----

INSTALLATION, OPERATIONAL AND PERFORMANCE QUALIFICATION

The customer confirms that the conditions required to ensure the proper functioning of the device according to the supplier's recommendations have been inspected and qualified.			
<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO			
Customer's comments		Installer's comments	
		Successfully verified all the performance criteria as per manufacturer recommendation	
Customer (Name and Position)	Signature	Installer (Name and Position)	Signature
		Amal V K Field Service Engineer LabX Medical Systems	
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