



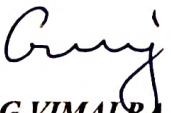
INSTALLATION QUALIFICATION

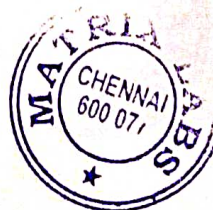
Name of Instrument	Lifotronics-H8
Serial Number	IA2D18B00160
Date of Installation	25.06.2019

Installation of the **Lifotronics-H8** (Fully Automated Hemoglobin Analyser-HPLC) at **Dialife Diabetes Lab, No-962, First floor, Vidyaranyapura, Bangalore-560091..** Involves the following checks done by the MatrixLabs Engineer as per the Installation Requirements given in the protocol.

The Installation Checklist is as given below.

#	Position	Action	Reference	Status
1	Unpacking	1.1. Unpack the Complete System	Chapter 1	OK
2	Inventory	2.1. Check Accessories As per List	Chapter 2	OK
3	Installation	3.1. Switch On: System Power Up.	Chapter 3	OK
		3.2. Check Touch screen Adjust	Chapter 3	OK
4	Service	4.1. Reagent Connection	Chapter 4	OK
		4.2. Connection of hemolytic agent and Waste Liquid	Chapter 4	OK
		4.3. Installation of Filter and Chromatography Column	Chapter 4	OK
		4.4. Loading of Recording Paper	Chapter 4	OK
		4.5. Installation of Power Adapter	Chapter 4	OK
5	User	5.1. Initial Startup	Chapter 5	OK
		5.2. Prime Liquid Line	Chapter 5	OK
		5.3. Bubble Elimination	Chapter 5	OK
		5.4. Activate Column	Chapter 5	OK
		5.6. Column Conditioning	Chapter 5	OK
		5.7. Pressure Monitoring	Chapter 5	OK
		5.8. QC Analysis	Chapter 5	OK
		5.9. Sample Preparation	Chapter 5	OK
		6.0. Sample Analysis	Chapter 5	OK

 G.VIMALRAJ Matrix Labs Engineer Signature	Authorized Customers Signature
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PERFORMANCE QUALIFICATION

Name of the Equipment	Lifotronics-H8
Date of Performance	25.06.2019
Operated By	Mr. G.VIMALRAJ

PQ is performed as needed.

According to the Assay results that are comprised in this document the Lifotronics-H8

System can be approved for the routine operation.

System Released for Routine Operation.

MatrixLabs. Representatives:

Date: 25.06.2019

A. Performed By:

Instrument has been checked thoroughly and ensured the performance of the instrument and can be released for the routine operation.

G.VIMALRAJ

(Installation Engineer Signature & Name)

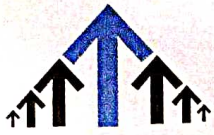
B Verified By:

Instrument has been verified & released for the routine operation.

A.RAVIKUMAR

(G.M.-Engineering Services Signature & Name)





OPERATIONAL QUALIFICATION



SYSTEM CERTIFICATION FOR LIFOTRONICS-H8 S.NO: IA2D18B00160

Study data has determined that the system described in this document either meets all Criteria outlined in this Operational Qualification Protocol.

#	Description	Status
1	Column Activation	OK
2	Assays(Parameters) Calibrator	OK
3	Assays(Parameters) Control	OK
4	Assays(Parameters) Samples(Patient)	OK

Imparted Operator's Training & Maintenance Completed

The system is ready for Usage.

 G.VIMALRAJ Matrix Labs. Service Engineer	 S.S.Raju National Manager - Scientific Support
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I confirm that the above-specified **Lifotronics-H8** HPLC analyzer is installed properly and its performance is within the specifications.

Authorized Signature of User / date with Stamp:

