

CALIBRATION CERTIFICATE

Calibration of the **LIFOTRONICS-H9** (HbA1cAnalyzer) has been carried out as per the recommendations of the principle company **SHENZHEN LIFOTRONIC TECHNOLOGY CO.,LTD, China.**

Customer Name& Address: REDCLIFF LABS GROUND FLOOR E 7/137 HIG ARERA COLONY 10-1/2 NO SQR BHOPAL (MP) 462016	InstallationDate:06.01.2023 CalibrationDate:06.01.2023 CalibrationDueDate:06.01.2024
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Serial No:	IA2B00003335
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Software Version Information:

System Version:	01.00.22-S
MCU1Version:	01.00.02-H
MCU2Version:	01.00.01-G

Monitoring Information:

Test Mode	96s
HP Pressure pump stepping Value	103
Column Temp	39
H9Temp	28
N.P.	60
ADC415	25747
ADC500	17651
ADC	7640

INSTRUMENT CALIBRATION DATAS:

Global Data:

System Parameters:

2D Arm Parameters:

X-axis	Value
Rack Routine(50-200mm)	116
ST Routine(50-200mm)	149

Z-axis	Value
Blood Tube Routine(10-250mm)	117
Diluted Tube Routine(10-250mm)	47
Diluting Cup Routine(10-250mm)	200
Press Cap Routine(10-100mm)	50

Hardware Parameter Settings:

High Pressure Pump Stepping value	103
Distance from Rack Detector to 1 st Tube(0-50mm)	3
Distance Between 2 Consecutive Tubes(150-250mm)	196

Operation Parameters:

Test Mode	96s
Reagent Version	A1
E/D/S/C Peak ABS Limit	50
Variant Ratio Limit	10

Elution Parameters:

Peaks	Start Time	End Time
HbA1a	7	14
HbA1b	14	18
HbF	18	23
LA1C	23	28
HbA1C	32	50
HbA0	50	90

Variant Parameters:

Peaks	Start Time	End Time
HbA2	200	239
HbD	240	259
HbS	260	289
HbC	290	310

Pressure Settings:

Parameters	Value
N.P(%)	63
N.P.(s)	60
Pressure (Mpa)>	3
Pressure (Mpa)<	12
HP Pump(PPS)	103

Flowcell Adjustment:

Parameters	Value
DAC_LED	1860
Gain415	25747
Gain500	17651

Reagent Setup:

Parameters	Value
Reagent Version	A1
Test Mode	96s

MatrixLabs.

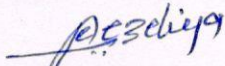
Representatives:

Date:06.01.2023

A. Performed By:

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

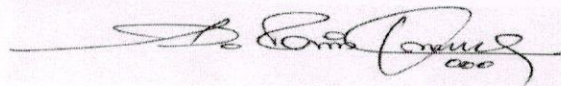
KRISHNKANT BELIYA



(Engineer-Customer Support Signature Name)

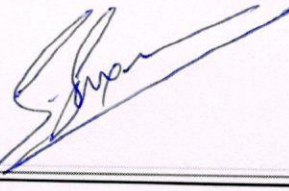
B. Verified By:

Instrument has been verified & released for the routine operation.



A.RAVIKUMAR

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





MATRIX LABS

HEALTHCARE SOLUTIONS

INSTALLATION QUALIFICATION

Customer Name : **REDCLIFFE LABS**
Address : GROUND FLOOR E 7/137 HIG ARERA COLONY 10-1/2 NO SQR
BHOPAL (MP) 462016

Contact Person : **DR. SAKAR SAXENA**
Instrument Model : **LIFOTRONIC H9 HBA1c**
Serial No. : **IA2B00003335**
Date Of installation : 06/01/2023

The instrument was installed And was found to be working satisfactory. Preliminary Customer Training was provided And standardization of the parameters Were done. The results were found to be within the expected range and system found to be working satisfactorily.

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CUSTOMER

Technical Services Department

: **REDCLIFFE LABS**

Name : **G.Sathish Kumar**

Contact Person : **DR. SAKAR SAXENA**

Designation : Service Engineer

Designation : Incharge and consultant pathologist

Signature :

G. Sathish Kumar

Signature :

Dr. Sakar Saxena



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HEALTHCARE SOLUTIONS

INSTALLATION CERTIFICATE

This is to certify that the instrument **LIFOTRONIC H 9 HBA1C**
S.No: IA2B00003335 is successfully installed at **REDCLIFFE LABS GROUND FLOOR E 7/137 HIG**
ARERA COLONY 10-1/2 NO SQR BHOPAL (MP) 462016 and the Installation Protocol/ checklist has
been Successfully completed for the above Instrument.

Date of Installation:- 06/01/2023

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Technical Services Department

G. Sathish Kumar

Name : **G.Sathish Kumar**

Designation : Service Engineer



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HEALTHCARE SOLUTIONS

INSTALLATION QUALIFICATION

Customer Name : **REDCLIFFE LABS**
Address : **GROUND FLOOR E 7/137 HIG ARERA COLONY 10-1/2 NO SQR
BHOPAL (MP) 462016**

Instrument Name : **LIFOTRONIC H9 HBA1c**
Serial No : **IA2B00003335**

Initial Inspection of the unit carried out and the details are as follows:

System Condition Report

Found the system to have been delivered in satisfactory condition and no external physical damaged observed on the same,Package was kept in good Condition as per the directional indicators like not tilt, indicating the system has not been subjected to mechanical shocks or stored in any manner, so as to cause any damage to the same.

Found all the required accessories as required.

Intallation Procedure And Checklist Attached for the records.

External Requirement for Installation

1. Input voltage of 100-240AC, 50 - 60Hz.
2. Recommended operating Temperature is 10-30 degree Celsius, with in Relative Humidity 10%-85% and Atmospheric pressure 86kPa~106kPa.



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INSTALLATION QUALIFICATION

Carried out all the installation procedures as per the installation procedure and checklists.

Carried out all the necessary checks and alignments.

Carried out all the necessary system checks and tests.

Handover the Instrument for operators Training And Qualifications

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Technical Services Department

G. Sathish Kumar

Name : **G.Sathish Kumar**

Designation : Service Engineer



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PERFORMANCE QUALIFICATION

Calibration Parameters

Checked and found all the control parameters to be within the acceptable CV limits and in range.

Checked and found all controls to be within The acceptable SD.

System Certification

Study data has determined that the system described in this document either meets the necessary criteria outlined in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included.

The system is ready for Specific Usage.

Protocol Performed By

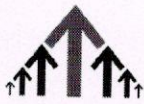
Name : **MR KRISHNKANT BELIYA**

Designation : **Service Engineer**

Performance Qualification Done By

Name : **MR KRISHNKANT BELIYA**

Designation : **Service Engineer**



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OPERATIONAL QUALIFICATION

System Certification

Study data has determined that the system described in this document either meets all criteria outlined in this Operational Protocol, or exceptional conditions have been identified and documentation included.

Exceptional Conditions, If any Have been Addressed.

The System is ready for specific usage.

Protocol Performed by : **MATRIX LABS CHENNAI**

Name: **MR KRISHNKANT BELIYA**

Designation: Service Engineer

Customer Authorization : **REDCLIFFE LABS**

: GROUND FLOOR E 7/137 HIG ARERA COLONY 10-1/2 NO SQR
BHOPAL (MP) 462016

Name : **DR. SAKAR SAXENA**

Designation : Incharge and consultant pathologist

Company Representative Name And Sign

Krishnkant Beliya
AC Beliya

Date: 06-01-2023

Customer Name And Sign

Date: 06-01-2023



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OPERATIONAL QUALIFICATION

1. Verified all the Mechanical Movements : Done
2. Verified Light Source : Done
3. Verified Electrical Systems : Done
4. Verified the all reagents Systems : Done

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Technical Services Department

G. Sathish Kumar

Name : **G.Sathish Kumar**
Designation : Service Engineer

Installation Process

Installation Preparation

1. Ask department director whether to open packages for checking instruments, if yes, open them and check whether reagents are normal.
2. Ask department director the place for installation, pay attention to matters such as enough space all around for instrument, avoiding direct sunlight, avoiding shocking, avoiding centrifuge etc.
3. Ask department director whether three power supplies, whether grounding protection, if yes, turn on the power to start up and confirm if resetting successfully.

Installation debugging



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1. Preparation for consumables: Open packages of reagents, check them whether normal, if yes, insert ID card to read it.
2. Preparation for quality control: If have control materials with random goods, conduct dissolution and wait for testing. If no, test with standard fluorescent color card and check the result whether similar to the target value.

Train for operation

1. Ask department director the starting time for training; gather teachers in front of instruments for representation. Notice not shielding instruments.
2. Train all the teachers with simplification, demonstrate with sample and make teacher operate it, observe whether mistakes or not and answer questions raised by teachers. Emphasize the common problems.
3. Ask the teacher in charge of instruments and tell him/her the matters and common problems clearly, add WeChat number with each other for communication.
4. Fill in the acceptance of installation and test and sign it by director.

Operational Inspection

1. Checked and found Mechanical Movements OK.
2. Checked and found Sensors OK.
3. Checked and found Electrical OK.
4. Checked with Controls And Samples, Results Are found OK.

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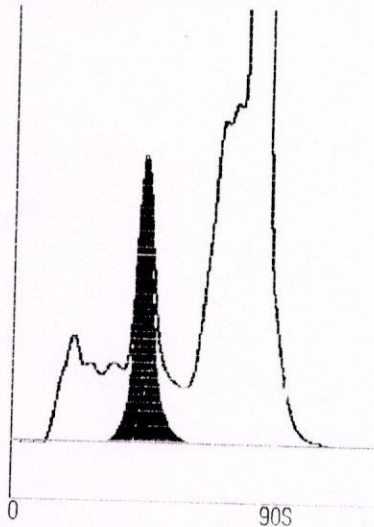
Technical Services Department

G. Sathish Kumar

Name : **G.Sathish Kumar**
Designation : Service Engineer

HbA1c

Time: 08:34:35
 Date: 2023-06-23
 Type: QC
 Rack No.: 0002
 Rack Position: 03
 Sample ID: 9SX1230010
 Running No.: 0004



Peak	Time	ABS	Area	Area%
HbA1a	12	0.0012	0.043	0.3
HbA1b	16	0.0043	0.188	1.5
HbF	22	0.0040	0.229	1.9
LA1c	37	0.0138	0.177	1.4
HbA1c	39	0.0135	1.403	10.8
HbA0	71	0.1992	10.011	84.1
V_Win	0	0.0000	0.000	0.0

Total Area: 12.051

HbA1c	10.8% ↑	NGSP
HbA1c	94.5mmol/mol	IFCC
eAG	14.5mmol/l	ADA
eAG	262.4mg/dl	ADA

Reference Range: 4.0%-5.7%

Operator:

Lab Name:

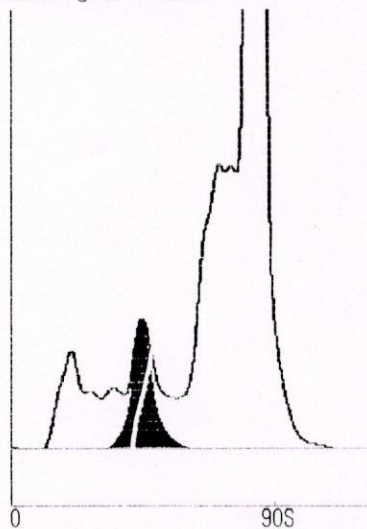
Lab Address:

Lab Telephone:

Avikash

HbA1c

Time: 14:12:32
 Date: 2023-06-23
 Type: QC
 Rack No.: 0006
 Rack Position: 02
 Sample ID: 9SX1230J10
 Running No.: 0020



Peak	Time	ABS	Area	Area%
HbA1a	12	0.0012	0.041	0.3
HbA1b	16	0.0041	0.174	1.6
HbF	22	0.0028	0.179	1.6
LA1c	37	0.0064	0.129	1.2
HbA1c	39	0.0063	0.757	6.0
HbA0	72	0.1580	9.257	89.3
V_Win	0	0.0000	0.000	0.0

Total Area: 10.537

HbA1c	6.0% ↑	NGSP
HbA1c	42.0mmol/mol	IFCC
eAG	6.9mmol/l	ADA
eAG	125.1mg/dl	ADA

Reference Range: 4.0%-5.7%

Operator:

Lab Name:

Lab Address:

Lab Telephone:

Avikash