



Bio-Rad
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(A wholly owned subsidiary)

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CIN No :- U32109DL1996PTC078494

Calibration Certificate

The **D10 Hemoglobin** system installed at LIKHITHA DIAGNOSTICS, ECIL has been calibrated by checking following procedure.

Hardware Calibration.

- **Pump flow rate**

Actual flow= 2.0 ml/min Measured flow rate=2.0 ml/min

(Flow checked by using volumetric variant sample cups with visible observation)

- **Column Temperature**

Actual Temp =35 degree C Measured Temp =34.98 C

(Temp checked by using D10 internal inbuilt temp sensor)

- **Optical Detector**

Calibrated as per the attached standard test procedure.

Fludic Calibration.

System Calibrated by using NGSP certified Bio-Rad calibrator and performance has been verified by running Quality Control

We certify that the **D10 Hemoglobin System** bearing Serial No. DC2A648010 is working as per the specification.

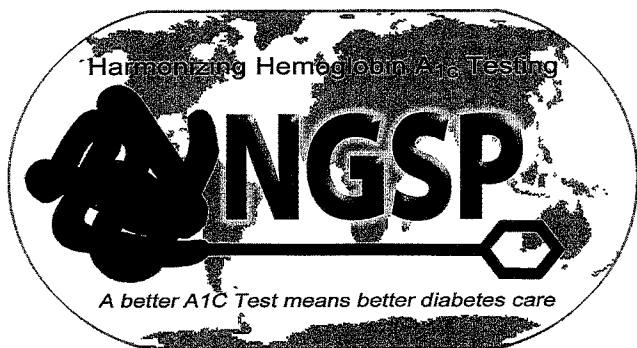
The next calibration due will be on: 25.03.2022

A. Thulasim



Bio-Rad Service

Date: 26.03.2021



Certificate of Traceability

Manufacturer Certification

This certifies that **Bio-Rad Laboratories, Inc.**, using **D-10 HbA1c (12000949)** has participated in and successfully completed the NGSP certification for manufacturers and is traceable to the **Diabetes Control and Complications Trial** Reference method. The comparison was performed with: **University of Missouri SRL#9**

The system evaluated was:

Instrument: D-10 Hb Testing System	Calibrator Lot: AA10364, AA10365	Column Lot: R90055D
Reagent Lot: AA10352, AA10353, AA10298	Calibrator Assigned Values: 5.4%, 10.5%	

Date of Certification: January 1, 2022

Certification Expires: January 1, 2023

NGSP Steering Committee Chair

NGSP Network Coordinator

SRL director/ supervisor



D-10 Installation, Operational and Performance Verification Report

Date <small>(dd mmmm, yyyy)</small>		Serial Number		Work Order	
Customer					
Software version		Firmware version		Service Activity	
Engineer		Assay		Cartridge lot #	
Buffer A lot#		Buffer B lot #		Wash lot #	
Checks			Lowest	Highest	Minimum
					Maximum
HP Pump Pressure stable: Variances less than $\pm (5\% + 0.2\text{kg/cm}^2)$ for 2 minutes					
					Unit
					Kg/cm ²
					✓ = Pass
External waste bottles fluidic and electronic connections in working order					
Preventive Maintenance Schedule is current					
Check for absence of crystallization or signs of leakage at the, HP Pumps, Transducer, Injector valve and Cartridge Holder					
Pinch valves tubing not clamped and positioned correctly					
Needle is straight and clean					
Verify all tubing behind the HPLC tray is routed correctly and not pinched between the HPLC tray and the chassis.					
Verify the HPLC tray is secured in place					
All covers secure					
All "System-Checks" pass					
LIS connection operational (optional)					
Computer network and connection operational (optional)					
BRiCare operational (optional)					
Network printer operational (optional)					

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This document does not contain Linearity, Precision, Dilution / Gradient Accuracy, or Correlation tests.



D-10 Installation, Operational and Performance Verification Report

A1c Assay Testing Results

Work Order

A calibration is required for the following reasons: If a HP pump or the Detector have been serviced, or the cartridge has been replaced, or the instrument has been producing poor quality control results prior to the service call.

A1c Calibration Required of any assay that reports A1c Results			Lot number:		New Slope		New Intercept	
Low Level A1c Target Value	Actual Low Level A1c Value	Low level A1c Retention time	Low level Ao Retention time		High Level A1c Target Value	Actual High Level A1c Value	High Level A1c Retention time	High Level Ao Retention time

A1c Quality Control	Required of any assay that reports A1c Results					Lot number	
	Target A1c values		Actual A1c Value	A1c Retention Time	Ao Retention Time	Baseline Stable	Total Area
	Minimum	Maximum					
QC Low							
QC Mid-Range (Liquicheck Only)							
QC High							

A1c Primary Tube Samples: A1c and Dual Kit Short Assays require 10 primary tube samples

	Sample identification	A1c Result value	A1c Retention Time	Ao Retention time	Baseline Stable	Total area
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

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D-10 Installation, Operational and Performance Verification Report

β-thalassemia Assay Testing Results

A calibration is required for the following reasons: If a HP pump or the Detector have been serviced, or the cartridge has been replaced, or the instrument has been producing poor quality control results prior to the service call.

Hb F and A2 Calibration (Perform, if necessary, on systems running Dual kit Extended Assay)

Lot number:		New Hb F Slope		New Hb F Intercept		New A2 Slope		New A2 Intercept	
Low Level Hb F Target Value	Actual Low Level Hb F Value	Hb F Retention time		Low Level Hb A2 Target Value	Actual Low Level Hb A2 Value	Hb A2 Retention time		Total Area	
High Level Hb F Target Value	Actual High Level Hb F Value	Hb F Retention time		High Level Hb A2 Target Value	Actual HighLevel Hb A2 Value	Hb A2 Retention time		Total Area	

Hb F and A2 Quality Control				Required on systems running Dual Kit Extended Assay				Lot number		
	Target Hb F values		Actual Hb F Value	HB F Retention Time	Target A2 values		Actual Hb A2 Value	Hb A2 Retention Time	Baseline Stable	Total Area
	Minimum	Maximum			Minimum	Maximum				
Low QC										
High QC										

F / A1c / A2 Primary Tube Samples: 5 Primary tube samples are required on systems running Dual kit Extended Assay

	Sample identification	Hb F Result value	Hb F Retention Time	Hb A1c Result value	Hb A1c Retention Time	Hb A2 Result value	Hb A2 Retention time	Baseline Stable	Total area
1									
2									
3									
4									
5									

Comments

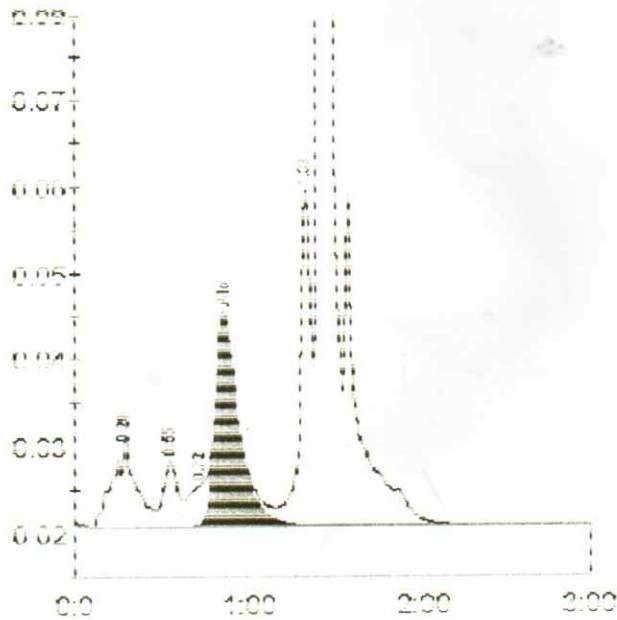
If necessary, add the chromatograms :

Work Order number	Bio-Rad Representative Printed Name	Bio-Rad Representative Signature

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Calibration report

Pic-Red DATE: 02/10/2022
 D-10 TIME: 10:31 AM
 SAI: #DC2A648010 Software version: 4.30-2
 Calibrator ID: AA10032
 Injection date: 01/24/2022 07:47 PM
 Injection # 13 Method: HbA1c
 Rack# --- Rack position: 3



Peaktable - ID: CAL2

Peak	Retention Time	Height	Area	Area %
A1b	0.20	10531	92615	3.0
F	0.55	7647	44297	1.5
LA1d/CHb-2	0.72	4599	31503	1.1
A1c	0.88	24142	224986	10.3
D2	1.33	38600	172902	6.0
A0	1.41	829313	2302117	80.3

Total Area: 2888420

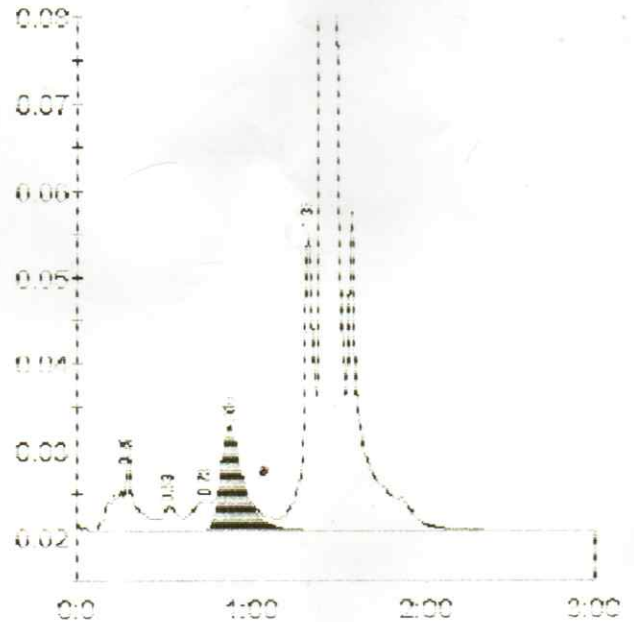
Concentration	%
A1c	110.31

Analyte	Passed		New	
	Slope	Intercept	Slope	Intercept
A1c	1.21	0.55	1.21	0.54

Naveen
 24/01/2022

Calibration report

Pic-Red DATE: 02/10/2022
 D-10 TIME: 10:31 AM
 SAI: #DC2A648010 Software version: 4.30-2
 Calibrator ID: AA10031
 Injection date: 01/24/2022 07:44 PM
 Injection # 12 Method: HbA1c
 Rack# --- Rack position: 1



Peaktable - ID: CAL1

Peak	Retention Time	Height	Area	Area %
A1b	0.20	9516	82208	2.3
F	0.53	2706	16951	0.6
LA1d/CHb-2	0.72	3562	23984	0.9
A1c	0.88	11720	104951	5.4
D2	1.33	24224	149550	5.6
A0	1.41	789216	2322017	85.7

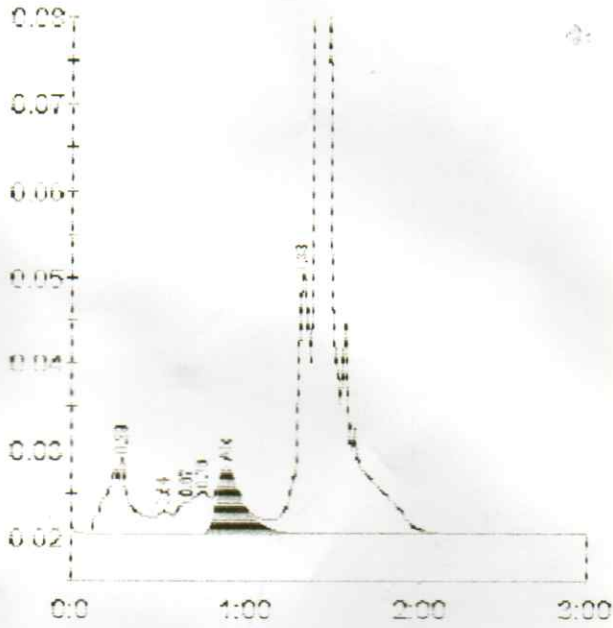
Total Area: 2690659

Concentration	%
A1c	15.4

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 24/01/2022

Patient report

Bio-Rad DATE: 02/01/2022
 D-10 TIME: 10:51 AM
 S/N: #DC2A648010 Software version: 4.30-2
 Sample ID: L1
 Injection date: 01/24/2022 08:16 PM
 Injection #: 14 Method: HbA1c
 Rack #: --- Rack position: 1



Peaktable - ID: L1

Peak	R.time	Height	Area	Area %
A1b	0.29	9727	93664	3.9
F	0.54	2594	15098	0.7
LA1d/CHb-1	0.67	2777	27099	1.7
LA1d/CHb-2	0.76	4765	24992	1.6
A1c	0.90	7278	72623	4.7
D2	1.33	30022	150129	6.9
A0	1.41	648611	1920287	82.2

Total Area: 2214699

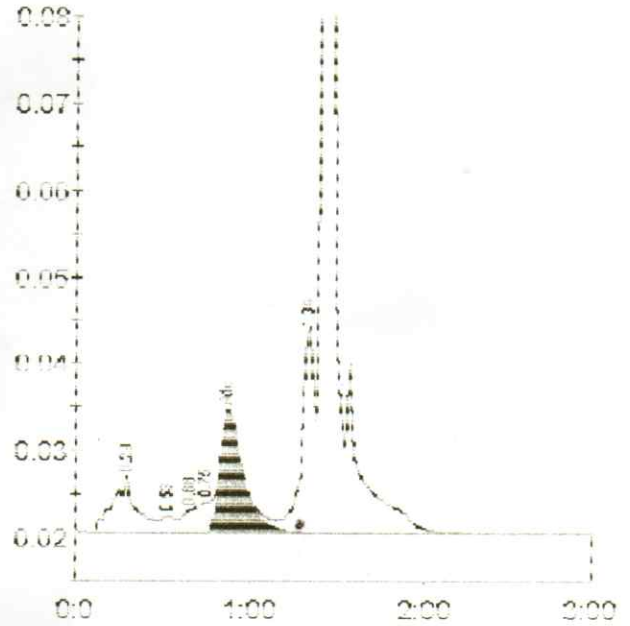
Concentration: %	
A1c	4.7

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Patient report

Bio-Rad DATE: 02/01/2022
 D-10 TIME: 10:51 AM
 S/N: #DC2A648010 Software version: 4.30-2
 Sample ID: L2
 Injection date: 01/24/2022 08:19 PM
 Injection #: 15 Method: HbA1c
 Rack #: --- Rack position: 2



Peaktable - ID: L2

Peak	R.time	Height	Area	Area %
A1b	0.29	6484	61336	3.5
F	0.53	1964	11216	0.6
LA1d/CHb-1	0.66	2629	10993	0.6
LA1d/CHb-2	0.75	3657	24153	1.4
A1c	0.89	13886	125278	9.4
D2	1.34	23638	116997	6.6
A0	1.41	509897	1412104	80.1

Total Area: 1781996

Concentration: %	
A1c	9.4

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24/01/2022

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Daily summary

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DATE: 02/19/2022

D 10

TIME: 02:26 PM

SN: #DC2A648010 Software version: 4.30.2

Method: HBA1c

Injection date: 02/19/2022

R#	I#	Sample ID	NGSP HBA1c %
1	L1		5.0
2	L1		4.9
3	L1		4.7
4		000025700800	0.0
5	L1		4.9
6	L1		4.7
7	L2		9.9
8	L2		9.0
9	L2		9.0
10	L2		9.0
11	L2		9.1
12		000910731703	7.4
13		000911043603	10.5
14		000910732203	5.7
15		000910731603	6.1
16		000910732003	7.5

BIO-RAD USA

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Likhithas Diagnostics and Speciality Lab, ECIL, Hyderabad

HbA1c (D-10) Precision Study

Equipment : D-10 Biorad

Control : Diabetes Control , Biorad

Lot No: 85830, Exp : 30.09.2023

Date : 18.02.2022

Equipment Serial No. DC2A648010

S.N.	Level 1	Level 2
1	5.0	8.80
2	4.8	9.00
3	4.7	8.90
4	4.8	8.90
5	4.7	9.10
Mean	4.80	8.94
SD	0.12	0.11
%CV	2.55	1.28

Processed By : Mr. Ch. Vamshi, Sr. Lab Technician

Verified By : Quality Manager

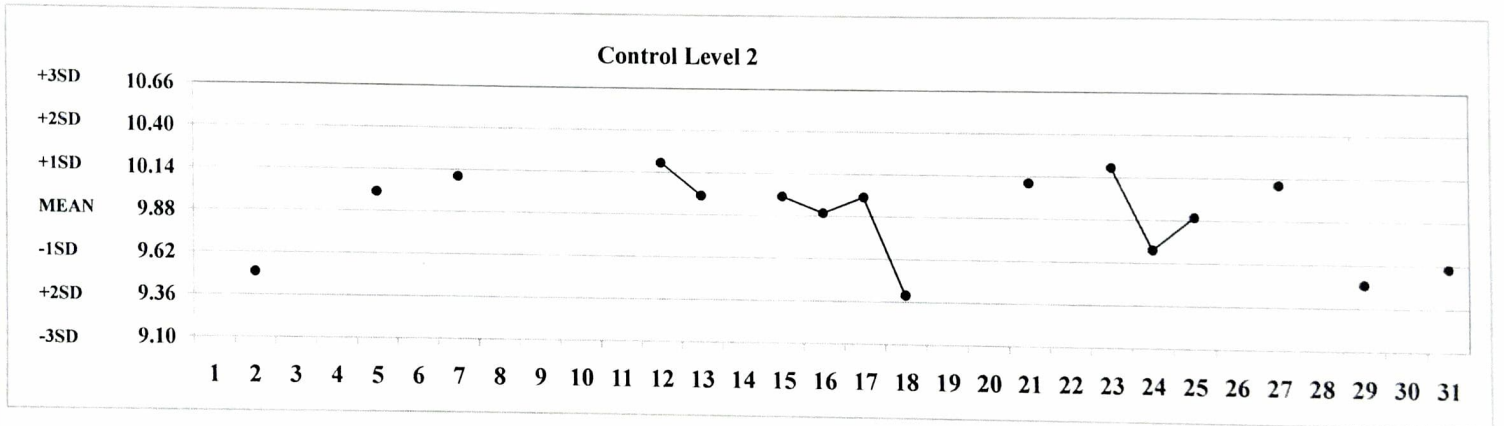
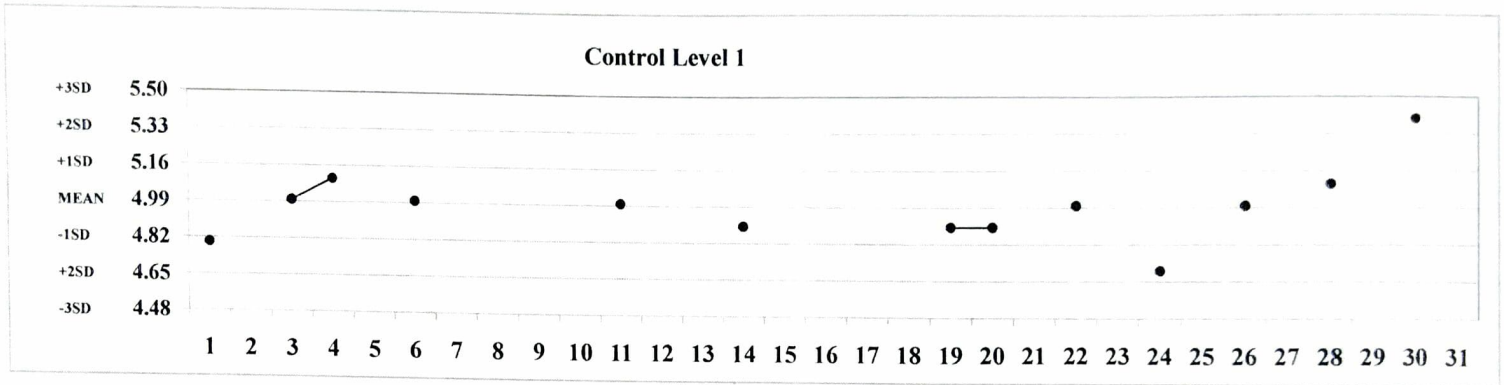


Levey Jenning Chart - HbA1c %

Control Level	Mfg Mean	Low	SD	Lab Mean	Bias%	SD	3SD	-3SD	+3SD	%CV	MU	TEa %
Level 1	5.2	4.6	0.30	5.0	-4.3	0.17	0.50	4.48	5.49	3.36	6.59	± 10%
Level 2	9.8	8.6	0.60	9.9	0.9	0.26	0.79	9.10	10.68	2.66	5.21	

Jan-22

Date	Level 1	Level 2
1	4.8	
2		9.5
3	5.0	
4	5.1	
5		10.0
6	5.0	
7		10.1
8		
9		
10		
11	5.0	
12		10.2
13		10.0
14	4.9	
15		10.0
16		9.9
17		10.0
18		9.4
19	4.9	
20	4.9	
21		10.1
22	5.0	
23		10.2
24	4.7	9.7
25		9.9
26	5.0	
27		10.1
28	5.1	
29		9.5
30	5.4	
31		9.6
Mean	5.0	9.9
SD	0.17	0.26
CV%	3.36	2.66



D. Indu Mythili

HOD Laboratory

[Signature]
Quality Manager