



Bio-Rad
Laboratories (India) Pvt Ltd
(A wholly owned subsidiary)

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CIN No : - U32109DL1996PTC078494

CALIBRATION CERTIFICATION

*This is to certify that Bio-Rad D-10 HbA1c System (Serial No DC2K758111) which is installed at **Bioline Laboratory, Calicut, Kerala** has been calibrated using by checking following procedures.*

Hardware Calibration.

*Column temperature values are calibrated as per our standard procedure and verified by traceable Digital Multimeter/Thermometer (**Make: Fluke, Model: 179, No: No:31090107**). These values are within their limit. Traceability Certificate attached.*

*Set value – 35.0 Deg C
Measured Value – 35.2 Deg C*

Calibration Verification.

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

*We certify that the D-10 Hemoglobin system bearing Serial number **DC2K758111** is working as per the specification.*

Calibration done on 15.09.2021

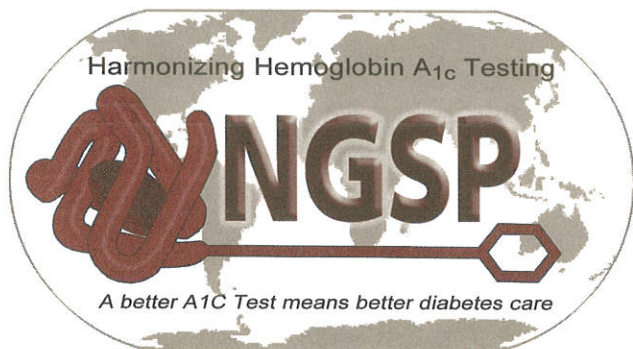
The next calibration due will be on 14.09.2022

For Bio-Rad Laboratories (India) Pvt Ltd



Authorized Signatory

Date: 15.09.2021



Certificate of Traceability

Manufacturer Certification

This certifies that **Bio-Rad Laboratories, Inc.**, using **D-10 HbA1c** 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	Calibrator Lot: AA00135, AA00136	Column Lot #: D90234A
Reagent Lot: AA00217, AA00218, AA00142	Calibrator Assigned Values: 5.4%, 10.1%	

Date of Certification: January 1, 2021

Certification Expires: January 1, 2022

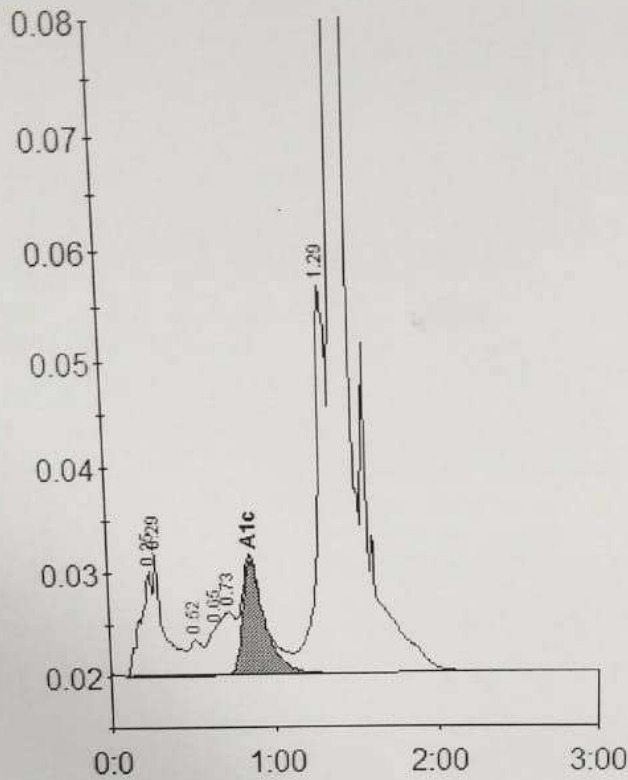
NGSP Steering Committee Chair

NGSP Network Coordinator

SRL director/ supervisor

Control report

Bio-Rad
D-10
S/N: #DC2K758111
Control ID: default
Injection date: 09/15/2021 10:26 AM
Injection #: 1
Rack #: ---
DATE: 03/23/2022
TIME: 03:43 PM
Software version: 4.30-2
Method: HbA1c
Rack position: 1



Peak table - ID: A1CTRL

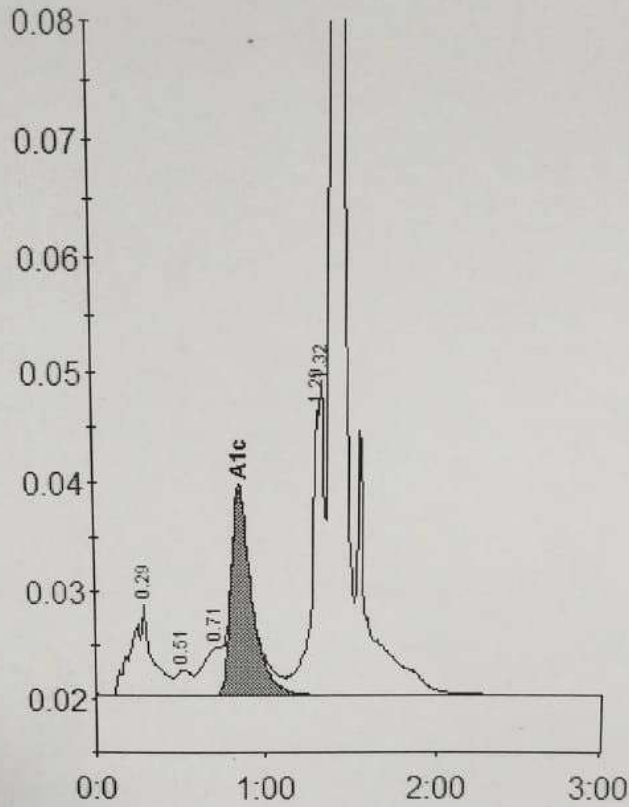
Peak	R.time	Height	Area	Area %
Unknown	0.25	10098	51855	1.8
A1b	0.29	12157	52817	1.8
F	0.52	3374	17973	0.6
LA1c/CHb-1	0.65	4654	40605	1.4
LA1c/CHb-2	0.73	6043	41152	1.4
A1c	0.86	10978	101417	4.8
P3	1.29	36868	182525	6.4
A0	1.37	896179	2375745	82.9
Total Area:		2864088		

Concentration:	%
A1c	4.8

Control OK

Control report

Bio-Rad DATE: 03/23/2022
D-10 TIME: 03:43 PM
S/N: #DC2K758111 Software version: 4.30-2
Control ID: default
Injection date 09/15/2021 10:29 AM
Injection #: 2 Method: HbA1c
Rack #: --- Rack position: 2



Peak table - ID: A1CTRH

Peak	R.time	Height	Area	Area %
A1b	0.29	8702	74142	3.3
F	0.51	2437	14625	0.6
LA1c/CHb-2	0.71	4546	28438	1.3
A1c	0.85	19092	160142	9.1
P3	1.29	26345	76389	3.4
Unknown	1.32	28209	66649	2.9
A0	1.38	674541	1853312	81.5
Total Area:		2273697		

Concentration:	%
A1c	9.1

Control OK