

Site name:	Prima Diagnostics Center
Address:	Yelahanka Satellite Town - Bangalore
Province-Postal code	560064
Contact Name	Dr.Seema Umarji

Calibration Certificate

Date	27/08/2021 <small>(dd mmmm, yyyy)</small>	Instrument Model	D-10 Hb Analyzer	Instrument Serial Number	DJ7H110301
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We certify that the Bio-Rad instrument specified above and installed in your lab is calibrated and the performance was found satisfactory.

High Pressure Pump Flow Rate Reference: Service Manual: Section 7.7.3

Measured with <small>(Device manufacturer and model)</small>	Device Serial Number	Device Calibration date <small>(dd mmmm, yyyy)</small>
Measuring Cylinder	2129	21/11/2020

Specified Range@ 1.5ml/Minute	Measured Value
1.425 – 1.575 ml/minute	1.490

Column Holder temperature Reference: Service Manual: Section 7.9

Measured with <small>(Device manufacturer and model)</small>	Device Serial Number	Device Calibration date <small>(dd mmmm, yyyy)</small>
Fluke 179	36020106	17/12/2020

Specified Range @ 35°C	Measured Value
33.4°C – 36.4°C	34.9


Detector log value**Reference: Service Manual: Section 7.2 or Field Bulletin D-10-081**

Measured with	Specified Range	Measured Value
Instrument Service Software	0.018 – 0.022 AU	0.02068

The next calibration is due on	Aug 2022	<small>(dd mmmm, yyyy)</small>
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For Bio-Rad Laboratories India Pvt Limited

Authorized Signatory:





Bio-Rad
Laboratories (India) Pvt. Ltd.



EMAAR Digital Greens,
 9th Floor, Tower A, Sector 61
 Gurugram - 124 102, Haryana - India
 Tel: (91) 124 - 4029300
 E-mail : support.india@bio-rad.com

Institute: Pima Diagnostics
 Contact name: Mr. Madhu Kumar
 Dept/Div: Biotechnology
 Address: Selaksanka, New Town
Boagachuri Pin Code:
 City:
 Tel:
 Email:

S.No. **313622** SER-OR-09 (Revision 03)

FIELD SERVICE REPORT

Service Territory: INSRUS FSR No.: 313622
 Case Log No.: 02269895 Case Log Date: 28/03/21
 Work Order No.: 01079358
 Event Occurrence Date/Time:
 Contract /Reference No.:

Instrument: D10 Serial No.: D5FH110301
 S/W Version: 4.30-8 F/W Version: 4.30-8

Division/Group
 CDG - CSD/IDD/IHD/CID/Others:
 LSG - LAD/PFD/GXD/QLB/CBB/Others:

Complaint: Re installation
 Complaint Analysis: Reproducible (Y/N):
 Action Taken: D10 instrument was re-installed. Reagents were loaded. System
Push given. Printer was run
 Checks Performed: Re-calibration & controls. Results were found within
the range. Instrument is working fine.
 Remarks:

Service Job Classification

Service Activity	Billing Type
<input type="checkbox"/> Repair	<input type="checkbox"/> Warranty
<input type="checkbox"/> Preventative Maintenance	<input type="checkbox"/> Reagent Rental
<input type="checkbox"/> Installation	<input type="checkbox"/> Contract
<input type="checkbox"/> Validation	<input type="checkbox"/> Upgrade
<input type="checkbox"/> Depot Repair	<input type="checkbox"/> Installation
<input type="checkbox"/> SW/HW Upgrade	<input checked="" type="checkbox"/> Billable
<input type="checkbox"/> Relocation	<input type="checkbox"/> S G & A
<input type="checkbox"/> Demo / Training	<input type="checkbox"/> Overhead
<input type="checkbox"/> Application Support	Others: <u></u>
<input checked="" type="checkbox"/> Re-Installation	
<input type="checkbox"/> De-Installation	

Parts Used / Recommended

Part No.	Description	Warehouse	Cost Component	Qty	Cost (INR)

Utilization

Date	Time In	Time Out	Labor Hrs	Travel Hrs
<u>24/03/21</u>	<u>10:30</u>	<u>12:30</u>	<u>3.0</u>	

Measuring Device Details (For Validation only):

Service job has been completed satisfactorily

Customer Comments:
 Customer (Name, Signature & Stamp): M Nagarajan
 Date: 24/03/21

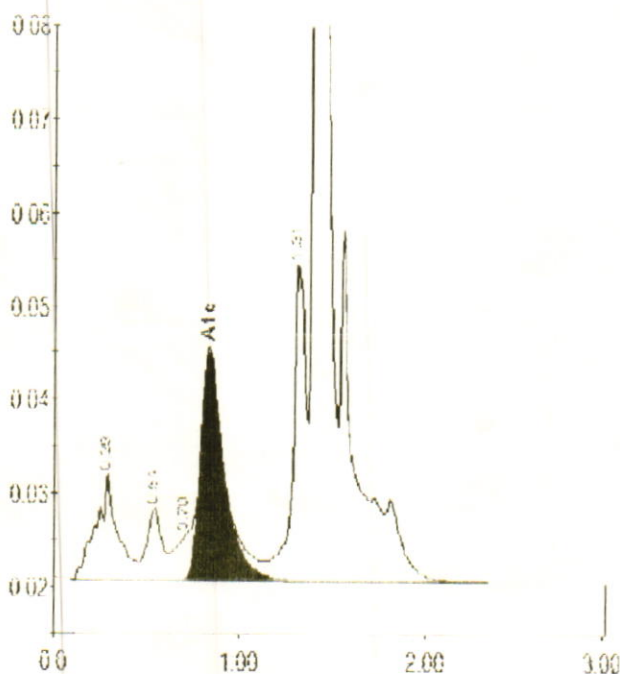
M Nagarajan
 BIO-RAD REPRESENTATIVE
 SIGNATURE

1st WHITE: OFFICE COPY
 2nd LIGHT YELLOW: CUSTOMER COPY

Regional Offices: Bangalore: 91-80-23128253 / 41489367, Chennai: 91-44-42034047 / 42924949, Kolkata: 91-33-22266564 / 22266598 / 22266599, Mumbai: 91-22-66989015 / 29254437

Calibration report

Bio-Rad DATE: 03/24/2021
 D-10 TIME: 01:18 PM
 S/N: #DJ711110301 Software version: 4.30-2
 Calibrator ID: AA00051
 Injection date: 03/24/2021 01:17 PM
 Injection #: 3 Method: HbA1c
 Rack #: --- Rack position: 2



Peak table - ID: CA1.2

Peak	R time	Height	Area	Area %
A1b	0.29	11504	91625	3.4
F	0.54	7662	43994	1.7
LA1c/CHb	20.70	4195	27422	1.0
A1c	0.83	24177	215237	10.2
P3	1.31	34300	165222	6.2
A0	1.41	729879	2115758	79.6
Total Area:		2659257		

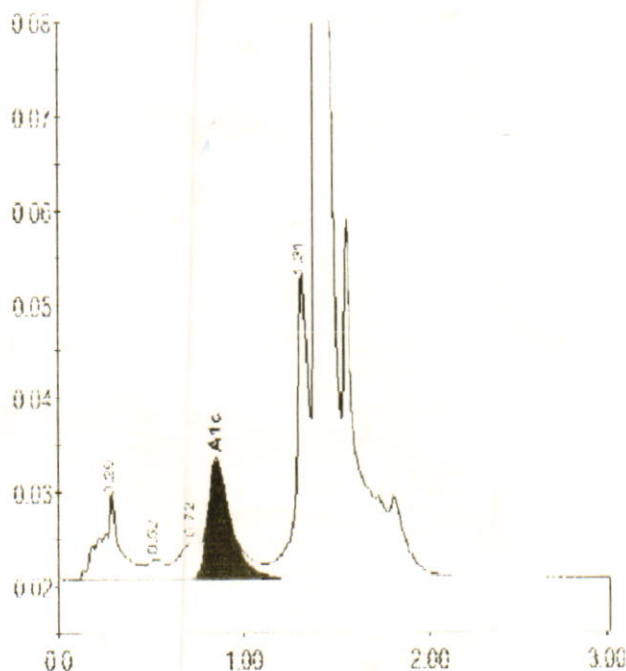
Concentration	%
A1c	10.2

Calibration Passed

Analyte	Old Slope	Old Intercept	New Slope	New Intercept
A1c	1.23	0.68	1.12	1.00

Calibration report

Bio-Rad
 D-10
 S/N: #DJ711110301 Software version: 4.30-2
 Calibrator ID: AA00050
 Injection date: 03/24/2021 01:14 PM
 Injection #: 2 Method: HbA1c
 Rack #: --- Rack position: 1



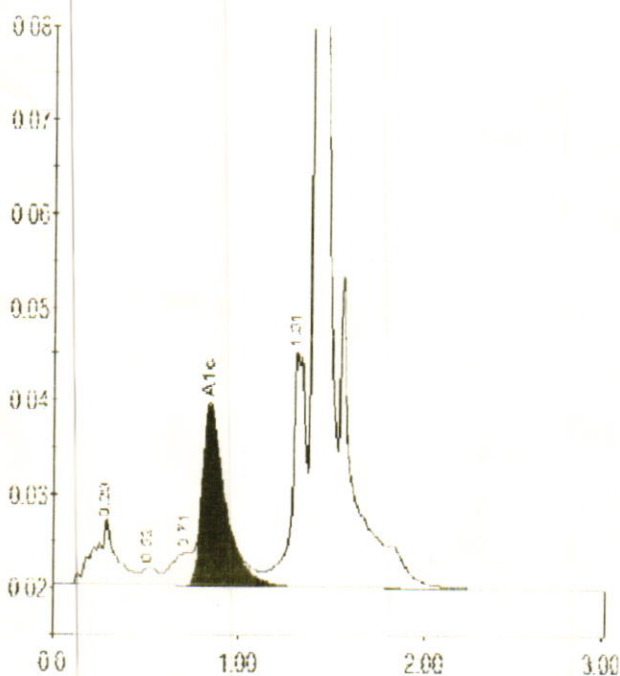
Peak table - ID: CAL1

Peak	R.time	Height	Area	Area %
A1b	0.29	9178	66464	2.5
F	0.52	2166	13078	0.5
LA1c/CHb-2	0.72	3947	25631	1.0
A1c	0.85	12333	107917	5.6
P3	1.31	32577	153314	5.8
A0	1.40	782086	2268633	86.1
Total Area:			2635037	

Concentration	%
A1c	5.6

Control report

Bio-Rad DATE: 03/24/2021
 D-10 TIME: 01:23 PM
 S/N: #DJ711110301 Software version: 4.30-2
 Control ID: 33990H
 Injection date: 03/24/2021 01:23 PM
 Injection #: 5 Method: HbA1c
 Rack #: --- Rack position: 4



Peak table - ID: A1CTRH

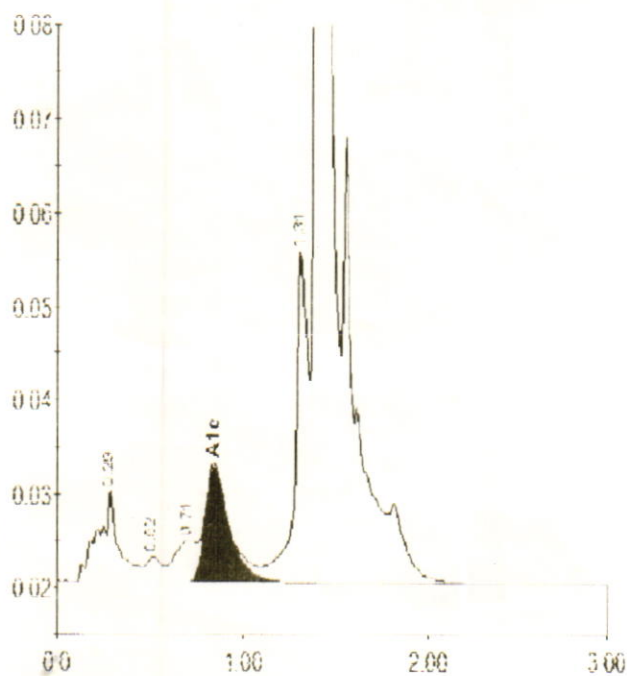
Peak	R.time	Height	Area	Area %
A1b	0.29	7125	59952	2.7
F	0.52	1993	12300	0.6
LA1c/CHb-20	0.71	3524	21847	1.0
A1c	0.84	19146	165792	9.5
P3	1.31	25502	129267	5.9
A0	1.41	673680	1811180	82.3
Total Area:			2200338	

Concentration	%
A1c	9.5

Control OK

Control report

Bio-Rad DATE: 03/24/2021
 D-10 TIME: 01:20 PM
 S/N: #DJ711110301 Software version: 4.30-2
 Control ID: 339901
 Injection date: 03/24/2021 01:20 PM
 Injection #: 4 Method: ITbA1c
 Rack #: --- Rack position: 3



Peak table - ID: A1C TRI.

Peak	R time	Height	Area	Area %
A1b	0.29	10097	77658	2.5
F	0.52	2732	16488	0.5
LA1c/CHb-2	0.71	4593	31513	1.0
A1c	0.85	12288	113686	5.1
P3	1.31	35771	168135	5.3
A0	1.40	958417	2753802	87.1
Total Area:			3161281	

Concentration	%
A1c	5.1

Control OK