



# D-10 Installation, Operational and Performance Verification Report

Date (dd mmmm, yyyy)	25 July, 2024	Serial Number	DJ23B10801	Work Order	WO-01900522	
Customer	Lupin Diagnostics , Chennai					
Software version	5.00-2	Firmware version	5.00-2	Service Activity	I.Q.-O.Q.	
Engineer	Abhishek S	Assay	A1c	Cartridge lot #	R00345BG	
Buffer A lot#	AA40029	Buffer B lot #	AA40030	Wash lot #	AA40037	
Checks		Lowest	Highest	Minimum	Maximum	Unit
HP Pump Pressure stable: Variances less than $\pm$ (5% +0.2kg/cm <sup>2</sup> ) for 2 minutes		27.4	28.4	24.5	31.3	Kg/cm <sup>2</sup>
						✓ = 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 are shown below

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.

WO-01900522

A1c Calibration				Lot number:	S30274	New Slope		New Intercept	
Required of any assay that reports A1c Results									
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	
5.3	5.3	0.80	1.39		10.5	10.5	0.79	1.40	

A1c Quality Control		Required of any assay that reports A1c Results				Lot number	655964
	Target A1c values		Actual A1c Value	A1c Retention Time	Ao Retention Time	Baseline Stable	Total Area
	Minimum	Maximum					
QC Low	4.7	7.0	5.6	0.81	1.40	✓	1,795,396
QC Mid-Range (Liquicheck Only)							
QC High	9.0	13.6	11.3	0.80	1.40	✓	1,633,102

## 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	BIO2063763	7.9	0.84	1.40	✓	2,743,195
2	HA00889014	7.3	0.87	1.41	✓	2,010,332
3	BIO2063139	7.5	0.87	1.41	✓	2,431,233
4	HA00881384	5.3	0.85	1.39	✓	4,387,720
5	BIO2062580	8.0	0.87	1.40	✓	2,244,894
6	BIO2061753	6.0	0.88	1.41	✓	1,861,561
7	BIO2063591	10.6	0.84	1.40	✓	3,211,643
8	BIO2063893	8.3	0.87	1.40	✓	2,306,630
9	BIO2063739	8.5	0.83	1.40	✓	4,809,650
10	BIO2063869	5.8	0.85	1.39	✓	4,743,744

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# D-10 Installation, Operational and Performance Verification Report

## $\beta$ -thalassemia Assay Testing Results are not reported on this instrument

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 High Level 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										

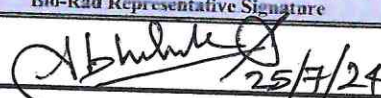
**F / A1c / A2 Primary Tube Samples:** 5 Primary tube samples are required on systems running Dual kit Extended Assay

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**

IQ OQ PQ performed and all results found satisfactory.

If necessary, add the chromatograms:

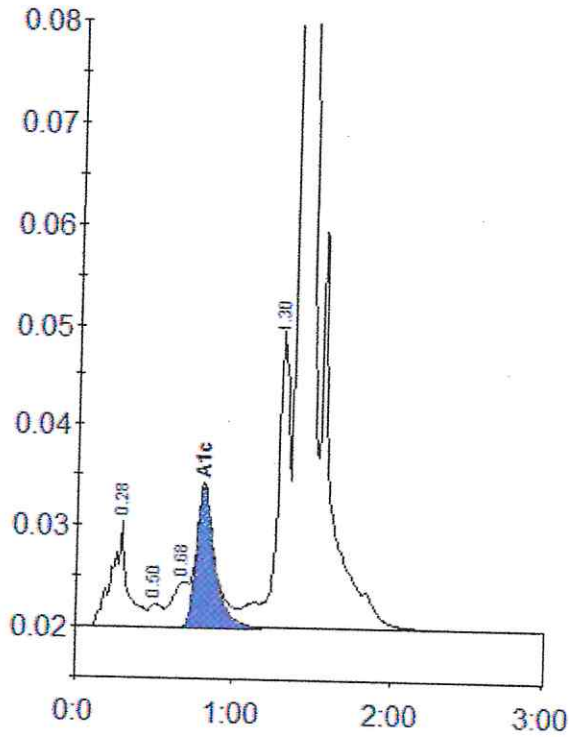
Work Order number	Bio-Rad Representative Printed Name	Bio-Rad Representative Signature
WO-01900522	Abhishek S	 25/7/24

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# Calibration report

Bio-Rad  
D-10  
S/N: #DJ23B10801  
Calibrator ID:  
Injection date  
Injection #: 1  
Rack #: ---

DATE: 07/25/2024  
TIME: 03:14 PM  
Software version: 4.30-2  
AA30424  
07/25/2024 02:05 PM  
Method: HbA1c  
Rack position: 1



Peak table - ID: CAL1

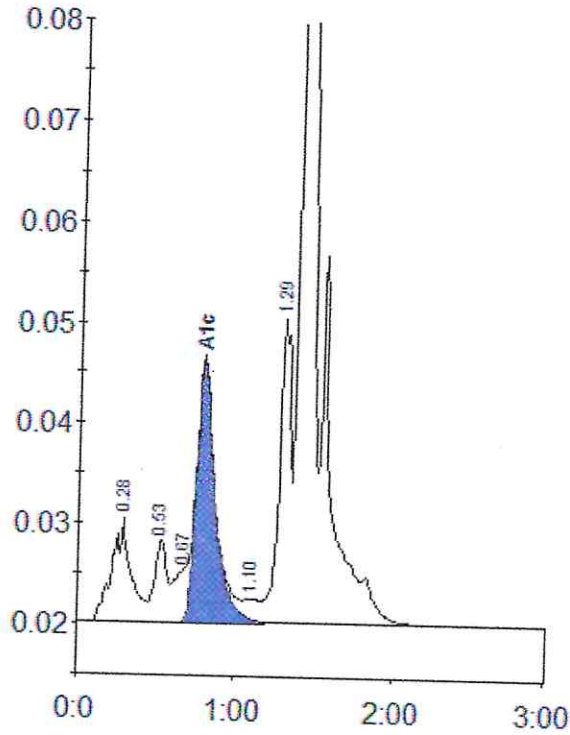
Peak	R.time	Height	Area	Area %
A1b	0.28	10469	73776	2.5
F	0.50	2365	14143	0.5
LA1c/CHb-2	0.68	4483	27164	0.9
A1c	0.80	13750	111407	5.3
P3	1.30	29781	163002	5.6
A0	1.39	886164	2519321	86.6
Total Area:		2908813		

Concentration:	%
A1c	5.3

*Abdul*  
25/7/24

# Calibration report

Bio-Rad DATE: 07/25/2024  
 D-10 TIME: 03:14 PM  
 S/N: #DJ23B10801 Software version: 4.30-2  
 Calibrator ID: AA30425  
 Injection date 07/25/2024 02:08 PM  
 Injection #: 2 Method: HbA1c  
 Rack #: --- Rack position: 2



Peak table - ID: CAL2

Peak	R.time	Height	Area	Area %
A1b	0.28	10359	87660	3.3
F	0.53	8185	44144	1.7
LA1c/CHb-2	0.67	5121	30466	1.1
A1c	0.79	26039	212732	10.5
Unknown	1.10	2432	17769	0.7
P3	1.29	30521	157419	5.9
A0	1.40	786953	2116831	79.4
Total Area:		2667020		

Concentration:	%
A1c	10.5

Calibration Passed

Analyte	Old Slope	Old Intercept	New Slope	New Intercept

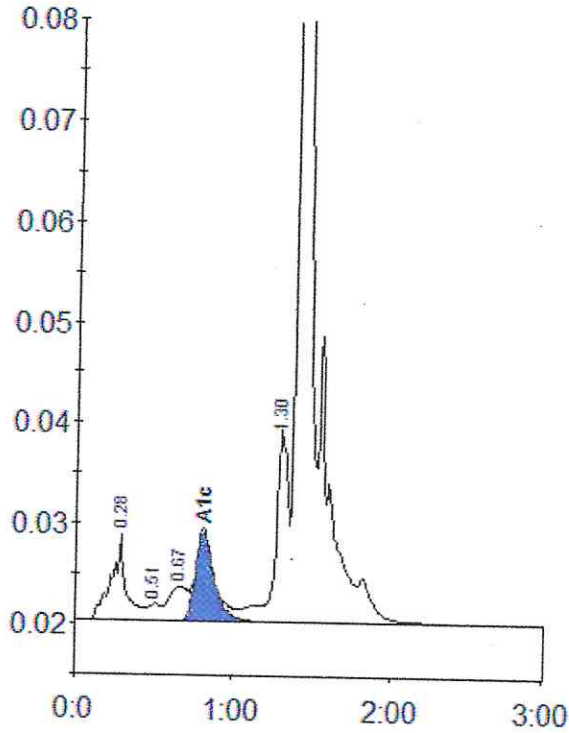
*Abhishek*  
 25/7/24

Alc 1.24 0.70 1.22 0.60

Abhijit  
25/7/24

# Control report

Bio-Rad DATE: 07/25/2024  
D-10 TIME: 03:14 PM  
S/N: #DJ23B10801 Software version: 4.30-2  
Control ID: 2380HA1  
Injection date 07/25/2024 02:11 PM  
Injection #: 3 Method: HbA1c  
Rack #: -- Rack position: 3



Peak table - ID: A1CTRL

Peak	R.time	Height	Area	Area %
A1b	0.28	8578	58135	3.2
F	0.51	1724	9115	0.5
LA1c/CHb-2	0.67	3441	22042	1.2
A1c	0.81	8853	73140	5.6
P3	1.30	19152	109401	6.1
A0	1.40	565605	1523562	84.9
Total Area:		1795396		

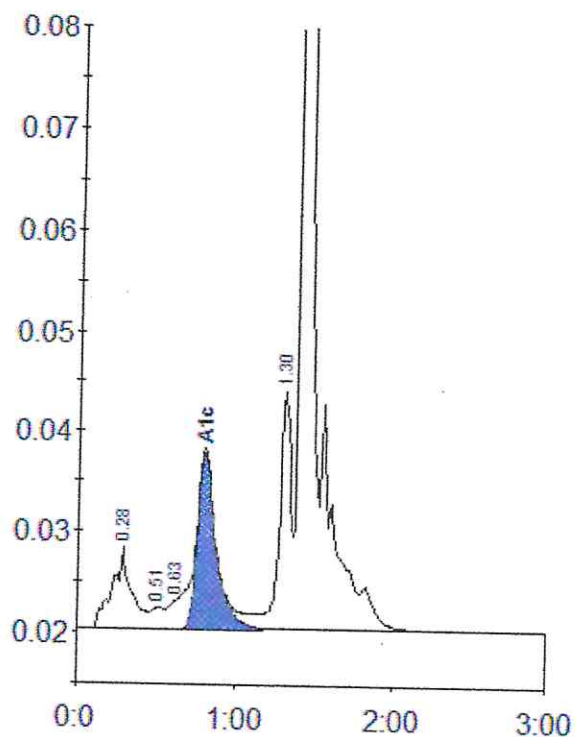
Concentration:	%
A1c	5.6

Control OK

*Abhishek*  
25/7/24

# Patient report

Bio-Rad                      DATE: 07/25/2024  
D-10                            TIME: 03:14 PM  
S/N: #DJ23B10801        Software version: 4.30-2  
Sample ID:                    A2CTRH  
Injection date              07/25/2024 02:14 PM  
Injection #: 4                Method: HbA1c  
Rack #: ---                    Rack position: 4



Peak table - ID: A2CTRH

Peak	R.time	Height	Area	Area %
A1b	0.28	7975	68048	4.2
F	0.51	2143	10684	0.7
LA1c/CHb-1	0.63	2841	13568	0.8
A1c	0.80	17562	141204	11.3
P3	1.30	23778	113273	6.9
A0	1.40	475397	1286328	78.8
Total Area:		1633102		

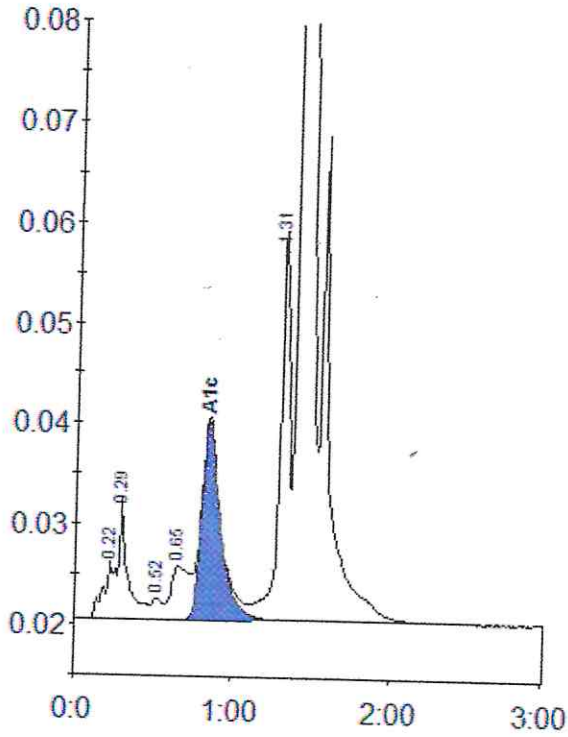
Concentration:	%
A1c	11.3

*Abhishankar*  
25/7/24



# Patient report

Bio-Rad DATE: 07/25/2024  
D-10 TIME: 03:14 PM  
S/N: #DJ23B10801 Software version: 4.30-2  
Sample ID: BI02063763  
Injection date: 07/25/2024 02:22 PM  
Injection #: 5 Method: HbA1c  
Rack #: --- Rack position: 1



Peak table - ID: BI02063763

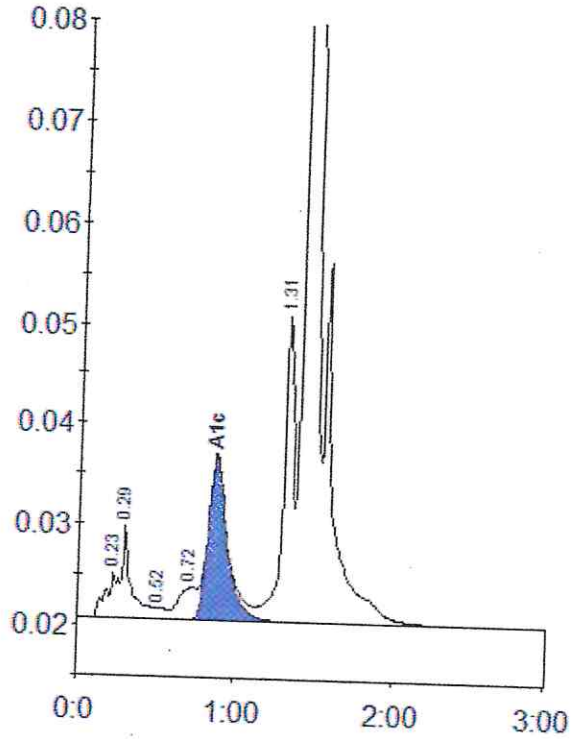
Peak	R.time	Height	Area	Area %
A1a	0.22	5793	29577	1.1
A1b	0.29	12116	46201	1.7
F	0.52	2166	10750	0.4
LA1c/CHb-1	0.65	5351	42078	1.5
A1c	0.84	19654	163179	7.9
P3	1.31	39136	165840	6.0
A0	1.40	898751	2285571	83.3
Total Area:		2743195		

Concentration:	%
A1c	7.9

*Abhishit*  
25/7/24

# Patient report

Bio-Rad                      DATE: 07/25/2024  
 D-10                         TIME: 03:14 PM  
 S/N: #DJ23B10801        Software version: 4.30-2  
 Sample ID:                 BI02063139  
 Injection date             07/25/2024 02:28 PM  
 Injection #: 7             Method: HbA1c  
 Rack #: ---                Rack position: 3



Peak table - ID: BI02063139

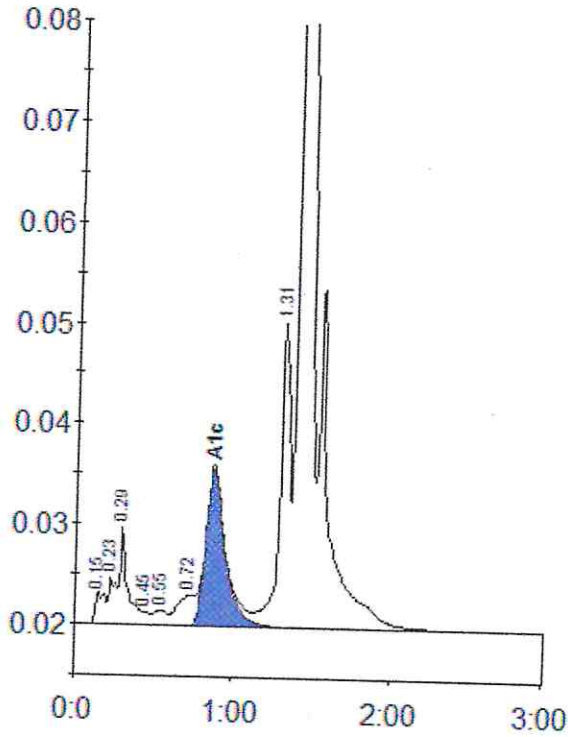
Peak	R.time	Height	Area	Area %
A1a	0.23	4601	19675	0.8
A1b	0.29	9349	42522	1.7
F	0.52	1162	6390	0.3
LA1c/CHb-2	0.72	3213	20632	0.8
A1c	0.87	16075	136999	7.5
P3	1.31	30799	132539	5.5
A0	1.41	810940	2072476	85.2
Total Area:		2431233		

Concentration:	%
A1c	7.5

*Abdul*  
 25/7/24

# Patient report

Bio-Rad DATE: 07/25/2024  
 D-10 TIME: 03:14 PM  
 S/N: #DJ23B10801 Software version: 4.30-2  
 Sample ID: BI02062580  
 Injection date 07/25/2024 03:08 PM  
 Injection #: 16 Method: HbA1c  
 Rack #: --- Rack position: 2



Peak table - ID: BI02062580

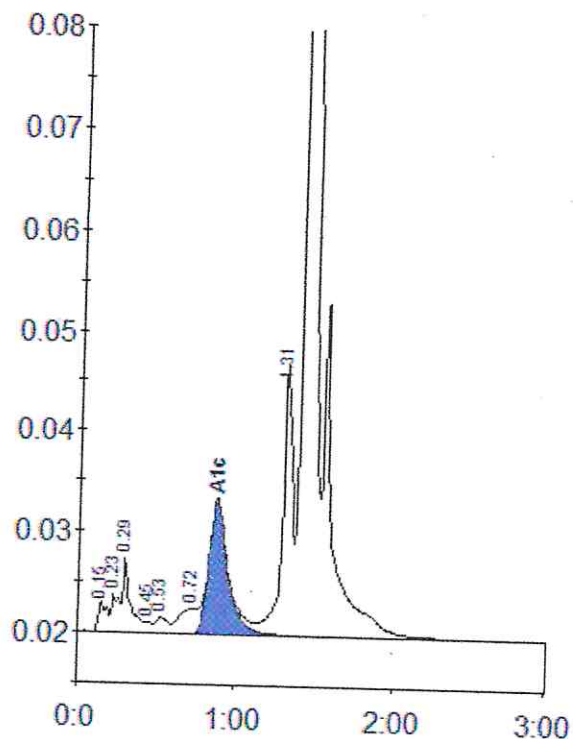
Peak	R.time	Height	Area	Area %
Unknown	0.15	3219	13179	0.6
A1a	0.23	4625	15061	0.7
A1b	0.29	9826	34871	1.6
Unknown	0.45	1254	3605	0.2
F	0.55	1426	9085	0.4
LA1c/CHb-2	0.72	3033	19602	0.9
A1c	0.87	15677	135123	8.0
P3	1.31	30256	133469	5.9
A0	1.40	781675	1880900	83.8
Total Area:			2244894	

Concentration:	%
A1c	8.0

*Abdulhadi S*  
 25/7/24

# Patient report

Bio-Rad                      DATE: 07/25/2024  
 D-10                            TIME: 03:14 PM  
 S/N: #DJ23B10801        Software version: 4.30-2  
 Sample ID:                    HA00889014  
 Injection date                07/25/2024 03:11 PM  
 Injection #: 17                Method: HbA1c  
 Rack #: ---                    Rack position: 3



Peak table - ID: HA00889014

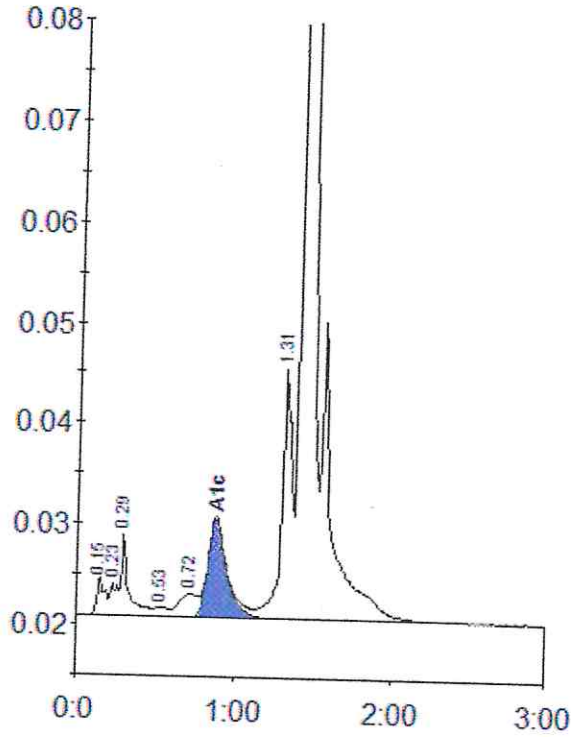
Peak	R.time	Height	Area	Area %
Unknown	0.15	2971	11047	0.5
A1a	0.23	3788	12133	0.6
A1b	0.29	7328	26379	1.3
Unknown	0.45	1003	3427	0.2
F	0.53	1529	8542	0.4
LA1c/CHb-2	0.72	2559	16318	0.8
A1c	0.87	13021	110063	7.3
P3	1.31	26860	114263	5.7
A0	1.41	680207	1708160	85.0
Total Area:			2010332	

Concentration:	%
A1c	7.3

*Abdulhadi*  
 25/7/24

# Patient report

Bio-Rad DATE: 07/25/2024  
 D-10 TIME: 03:14 PM  
 S/N: #DJ23B10801 Software version: 4.30-2  
 Sample ID: BI02061753  
 Injection date 07/25/2024 02:37 PM  
 Injection #: 10 Method: HbA1c  
 Rack #: --- Rack position: 6



Peak table - ID: BI02061753

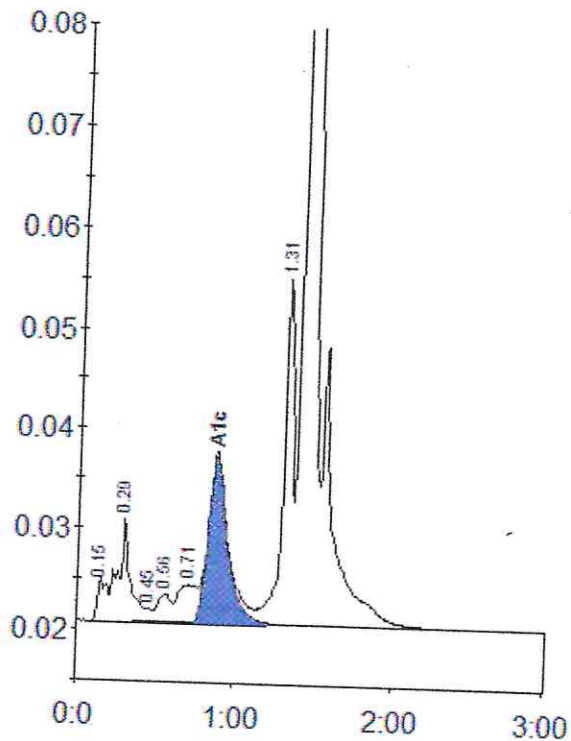
Peak	R.time	Height	Area	Area %
Ala	0.15	3838	12965	0.7
Unknown	0.23	3379	6687	0.4
Alb	0.29	8301	32750	1.8
F	0.53	964	5727	0.3
LA1c/CHb-2	0.72	2400	15472	0.8
A1c	0.88	9814	82760	6.0
P3	1.31	24772	107455	5.8
A0	1.41	646561	1597745	85.8
Total Area:		1861561		

Concentration:	%
A1c	6.0

*Abubakar*  
 25/7/24

# Patient report

Bio-Rad                      DATE: 07/25/2024  
 D-10                         TIME: 03:14 PM  
 S/N: #DJ23B10801        Software version: 4.30-2  
 Sample ID:                 BI02063893  
 Injection date             07/25/2024 03:05 PM  
 Injection #: 15            Method: HbA1c  
 Rack #: ---                Rack position: 1



Peak table - ID: BI02063893

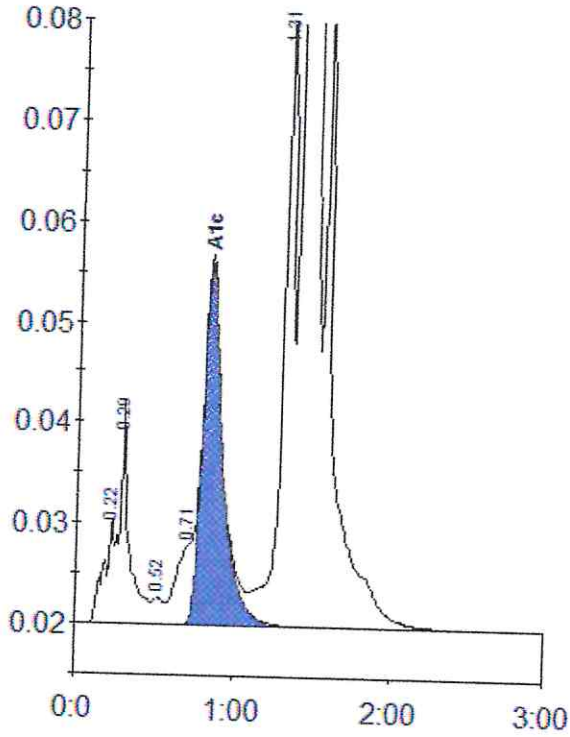
Peak	R.time	Height	Area	Area %
A1a	0.15	4268	16115	0.7
A1b	0.29	10306	56488	2.4
Unknown	0.45	1311	3149	0.1
F	0.56	2842	16245	0.7
LA1c/CHb-2	0.71	3746	24761	1.1
A1c	0.87	16582	144268	8.3
P3	1.31	34786	144531	6.3
A0	1.40	778112	1901074	82.4
Total Area:			2306630	

Concentration:	%
A1c	8.3

*Abhishek*  
 25/7/24

# Patient report

Bio-Rad                      DATE: 07/25/2024  
 D-10                         TIME: 03:14 PM  
 S/N: #DJ23B10801        Software version: 4.30-2  
 Sample ID:                 BI02063739  
 Injection date             07/25/2024 02:46 PM  
 Injection #: 13             Method: HbA1c  
 Rack #: ---                 Rack position: 9



Peak table - ID: BI02063739

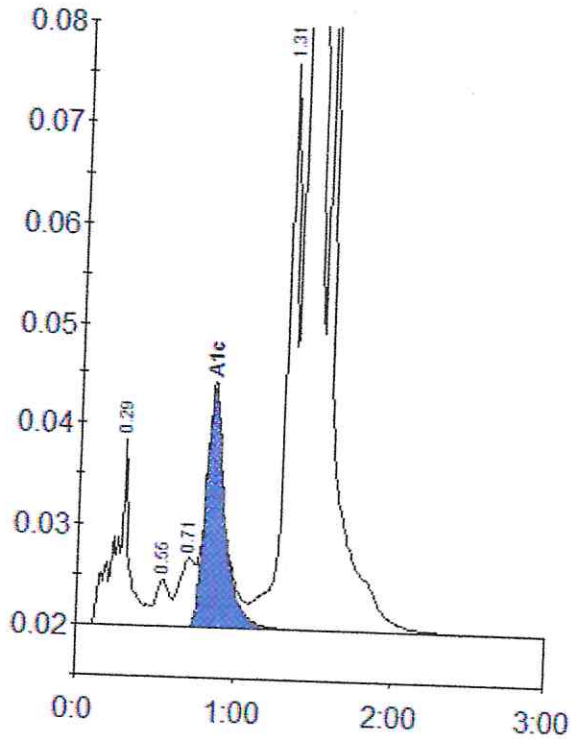
Peak	R.time	Height	Area	Area %
A1a	0.22	10509	43820	0.9
A1b	0.29	22021	97643	2.0
F	0.52	2686	13360	0.3
LA1c/CHb-2	0.71	8104	51272	1.1
A1c	0.83	36079	317037	8.5
P3	1.31	62803	279190	5.8
A0	1.40	1432382	4007328	83.3
Total Area:			4809650	

Concentration:	%
A1c	8.5

*Abdulhadi*  
 25/7/24

# Patient report

Bio-Rad                      DATE: 07/25/2024  
D-10                            TIME: 03:14 PM  
S/N: #DJ23B10801        Software version: 4.30-2  
Sample ID:                    BI02063869  
Injection date                07/25/2024 02:49 PM  
Injection #: 14                Method: HbA1c  
Rack #: ---                    Rack position: 10



Peak table - ID: BI02063869

Peak	R.time	Height	Area	Area %
A1b	0.29	18430	118846	2.5
F	0.55	4637	27819	0.6
LA1c/CHb-2	0.71	6915	43742	0.9
A1c	0.85	23673	202508	5.8
P3	1.31	56134	228300	4.8
A0	1.39	1517328	4122530	86.9
Total Area:			4743744	

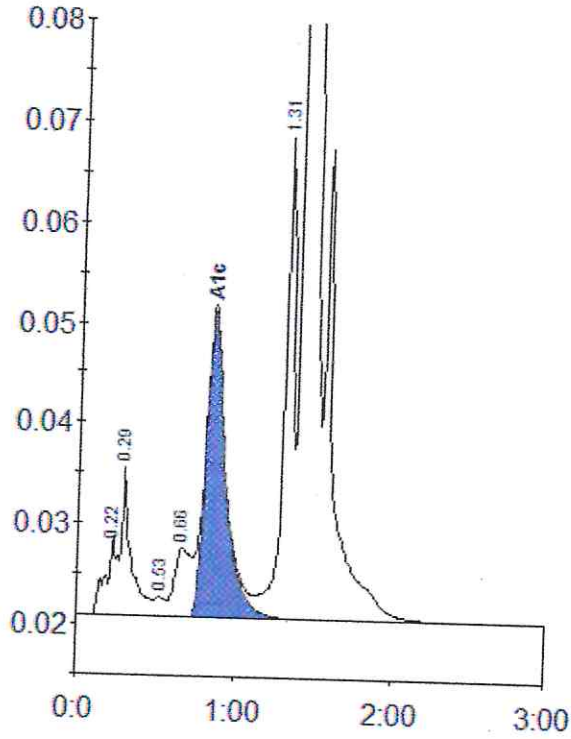
Concentration:	%
A1c	5.8

*Abhishankar*  
25/7/24



# Patient report

Bio-Rad                      DATE: 07/25/2024  
D-10                            TIME: 03:14 PM  
S/N: #DJ23B10801        Software version: 4.30-2  
Sample ID:                    BI02063591  
Injection date                07/25/2024 02:40 PM  
Injection #: 11                Method: HbA1c  
Rack #: ---                    Rack position: 7



Peak table - ID: BI02063591

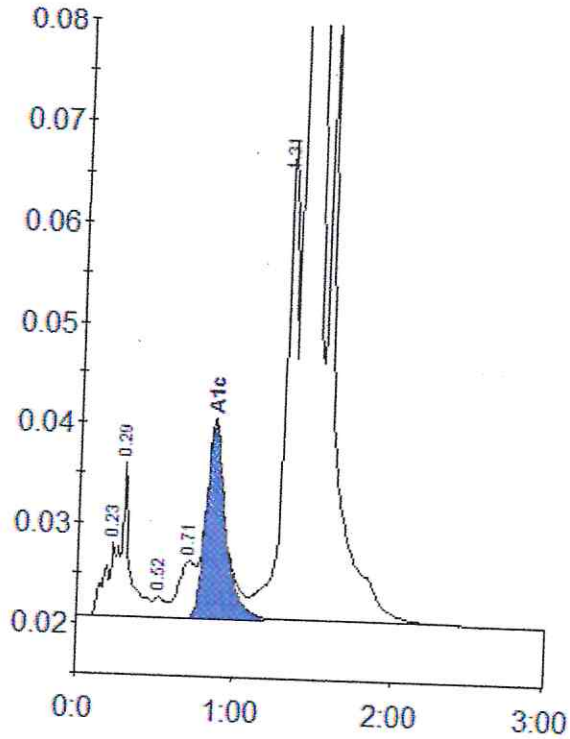
Peak	R.time	Height	Area	Area %
A1a	0.22	7960	40376	1.3
A1b	0.29	14816	63127	2.0
F	0.53	2035	10170	0.3
LA1c/CHb-1	0.66	6917	46134	1.4
A1c	0.84	30617	265016	10.6
P3	1.31	47886	190608	5.9
A0	1.40	982344	2596212	80.8
Total Area:		3211643		

Concentration:	%
A1c	10.6

*Abdul*  
25/7/24

# Patient report

Bio-Rad DATE: 07/25/2024  
 D-10 TIME: 03:14 PM  
 S/N: #DJ23B10801 Software version: 4.30-2  
 Sample ID: HA00881384  
 Injection date 07/25/2024 02:31 PM  
 Injection #: 8 Method: HbA1c  
 Rack #: --- Rack position: 4



Peak table - ID: HA00881384

Peak	R.time	Height	Area	Area %
A1a	0.23	7280	32481	0.7
A1b	0.29	15342	65807	1.5
F	0.52	2086	10784	0.2
LA1c/CHb-2	0.71	5761	37560	0.9
A1c	0.85	19363	168488	5.3
P3	1.31	47527	209359	4.8
A0	1.39	1434829	3863242	88.0
Total Area:	4387720			

Concentration:	%
A1c	5.3

*Abhishankar*  
 25/7/24