

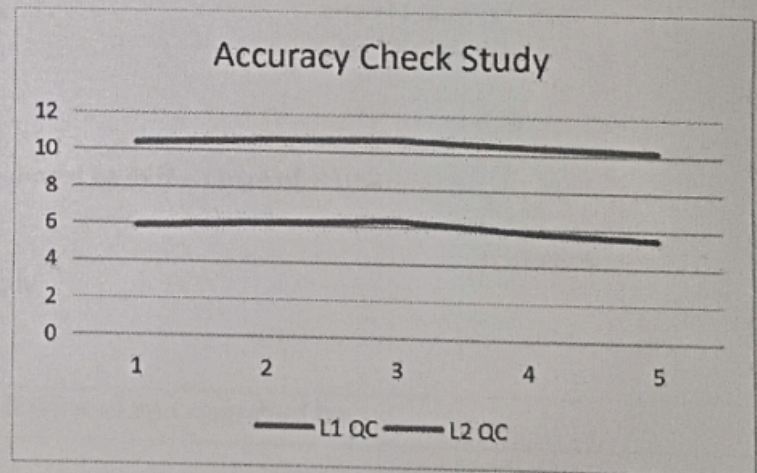
Calibration Certificate of LifeDX HBPro HPLC based Fully Automated HbA1c Analyser

Customer Name	Medray Clinics Pvt Ltd
Customer Address	Indiranagar, Bangalore, Karnataka
Analyser Model	LifeDX HBPro
Serial No.	I02F00000861
Next Calibration Due on	21 st , July 2024

This is to certify that LifeDX HBPro HPLC based Fully Automated HbA1c instrument bearing Sr. No. I02F00000861 has been validated from July 18th to July 22nd, 2022 and calibration of the instrument and all other values have been found within the limit.

Criteria 1 – Accuracy Check Study

LifeDX HBPro : Accuracy Check Study		
Date	L1 QC	L2 QC
18.07.2023	5.9	10.4
19.07.2023	6.1	10.6
20.07.2023	6.3	10.7
21.07.2023	5.8	10.4
22.07.2023	5.5	10.2
Std Deviation	0.303315018	0.194935887
Mean	5.92	10.46
%CV	5.123564489	1.863631806
Target Range	5.8	10.3
Remark	Accepted	

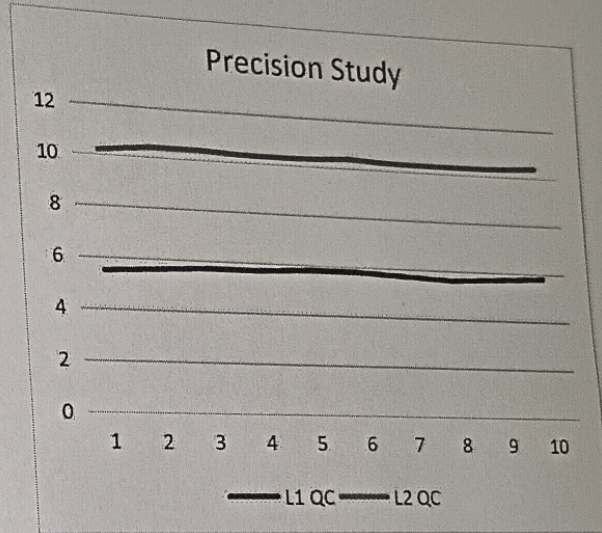


Criteria 2 - Calibration Details

	HbA1c		HbF	
	C1	5.2	5.3	0.9
C2	9.5	9.6	1.3	1.3
Remark	Accepted			
Validation Criteria	% Bias should be in the range of $\pm 10\%$			

Criteria 3 - Precision Check Study

LifeDX HBPro : Precision Study		
	L1 QC	L2 QC
22.07.2023	5.5	10.2
	5.6	10.4
	5.7	10.4
	5.7	10.3
	5.8	10.3
	5.8	10.4
	5.7	10.3
	5.6	10.3
	5.7	10.3
	5.8	10.4
Std Deviation	0.099442893	0.067494856
Mean	5.69	10.33
%CV	1.747678253	0.653386794
Target Range	5.8	10.3
Remark	Accepted	



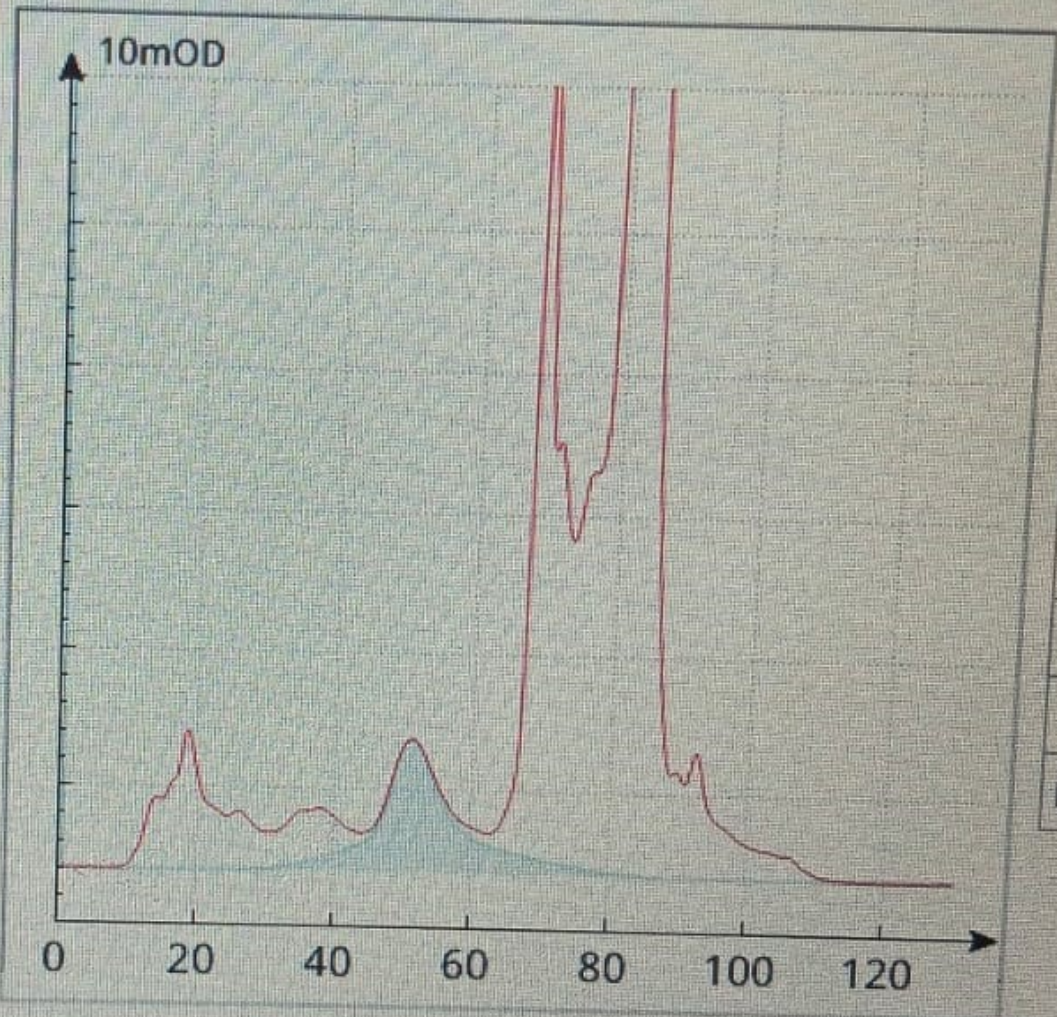
Acceptance Criteria: Accuracy of level 1, level 2 : Bias% should be in the range of $\pm 10\%$.

Interpretation: LifeDX HBPro Calibration done successfully.

Prepared, Reviewed and approved by	
Name :	Devan S
Title:	Service Engineer
Date :	22-07-2023

r:	1763	Date:	2022-12-22
C:	554	Time:	14:03:46
T:	34.9°C	ID:	C1
n:	1#	Type:	Diluted blood

	Time	ABS	Area	Result
a	13.6	26	691	0.6
b	18.1	51	2901	2.5
	25.5	21	1046	0.9
+	37.4	23	2554	2.2
c	50.5	49	6012	5.2
D	80.9	2411	101892	88.5
n	-	-	-	-
DA)	5.7 mmol/L		103.2 mg/dl	



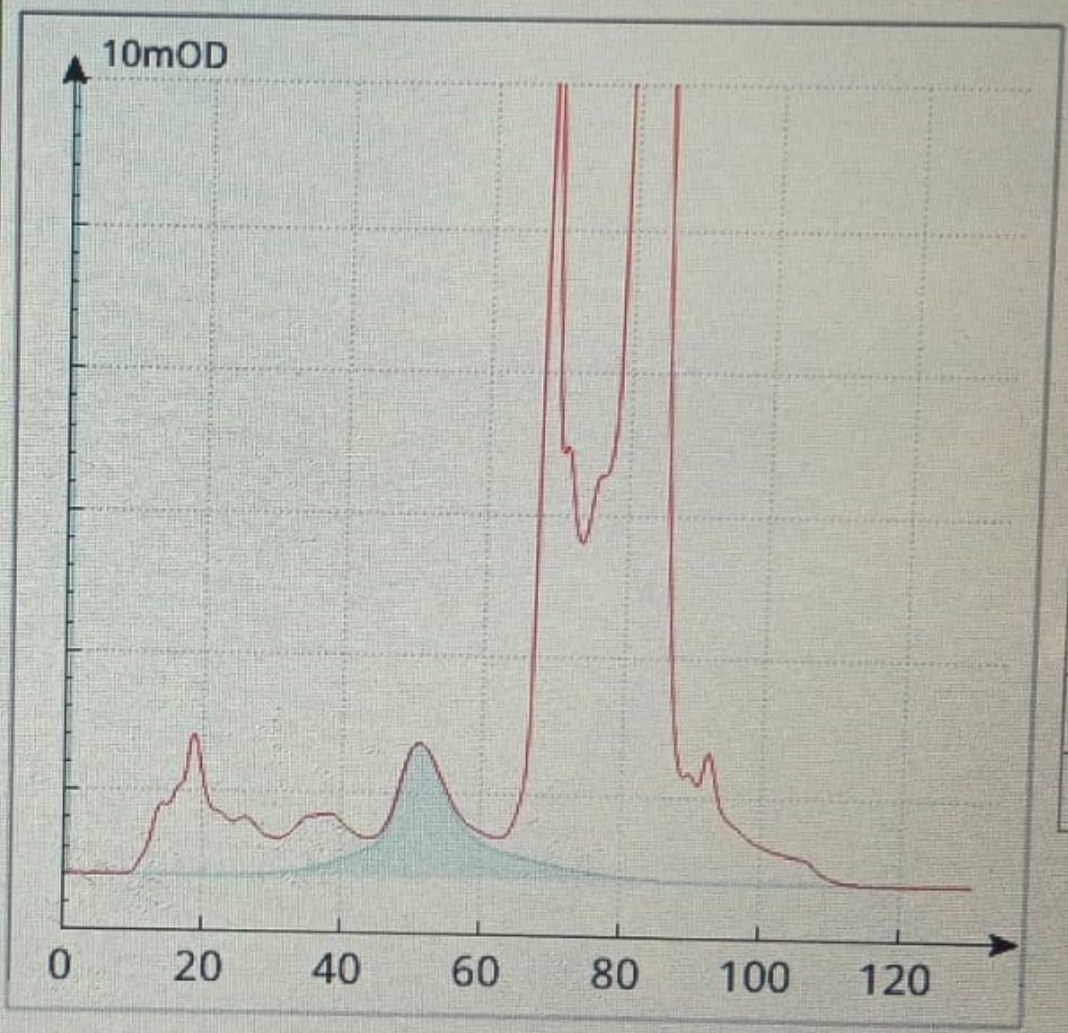
NGSP:	
IFCC:	
Area:	
Remark:	
Pressure:	

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Test Details

Number:	1764	Date:	2022-12-22
Run. C:	555	Time:	14:05:56
Run. T:	34.9°C	ID:	C1
Position:	1#	Type:	Diluted blood

Peak	Time	ABS	Area	Result
bA1a	13.8	25	705	0.6
bA1b	18.1	51	2452	2.2
HbF	25.5	21	1082	1.0
A1c+	37.7	23	2422	2.1
bA1c	50.4	48	5961	5.3
bA0	80.9	2378	100783	88.9
_Win	-	-	-	-
G(ADA)	5.8 mmol/L		104.1 mg/dl	



NGSP:
IFCC:
Area:
Remark:
Pressure:

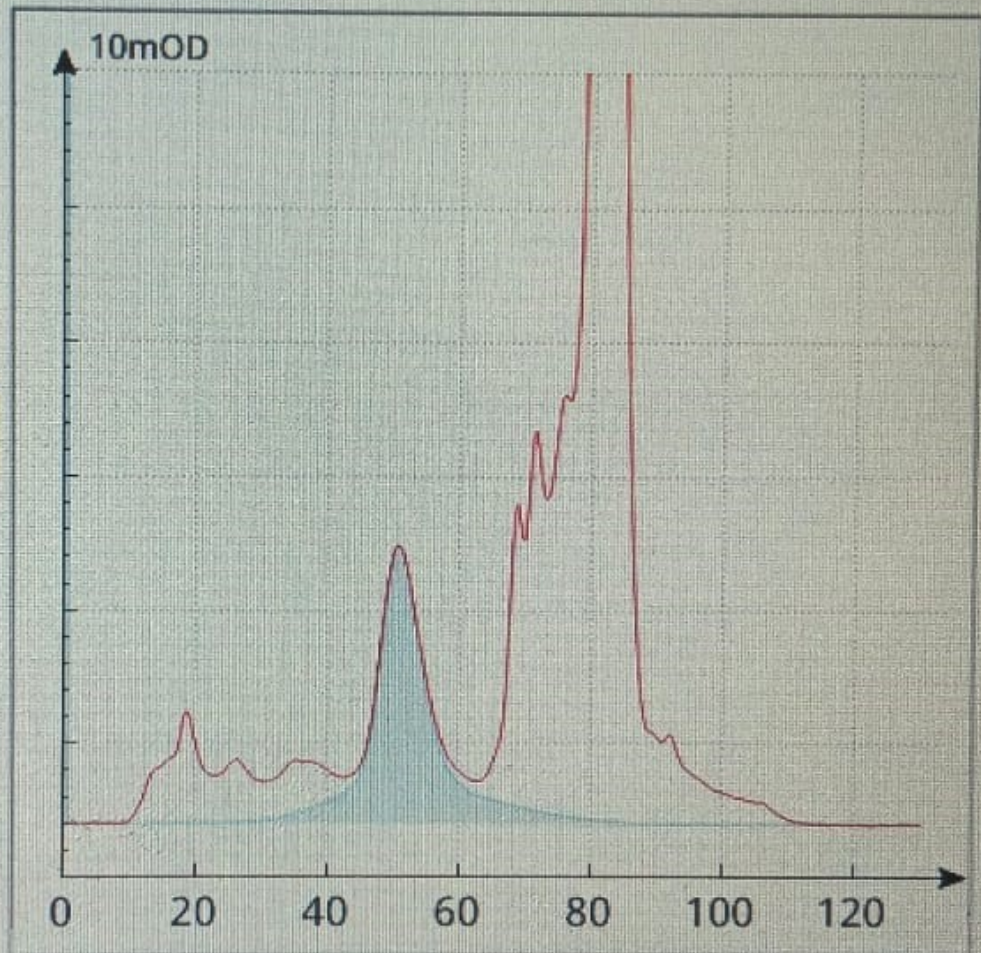
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Details

Number:	1765	Date:	2022-12-22
Run. C:	556	Time:	14:08:06
Run. T:	34.9°C	ID:	C2
Run. I:	2#	Type:	Diluted blood

Peak	Time	ABS	Area	Result
A1a	12.5	17	249	0.2
A1b	18.1	42	1782	1.5
A1c	25.7	24	1488	1.3
A1d	34.8	24	1201	1.0
A1e	50.2	104	11316	9.5
A1f	81.0	2512	102460	86.5
Win	-	-	-	-
ADA)	12.6 mmol/L		227.4 mg/dl	



NGSP:	
IFCC:	80.9n
Area:	11
Remark:	
Pressure:	9.

Test

Calibration

QC

Result

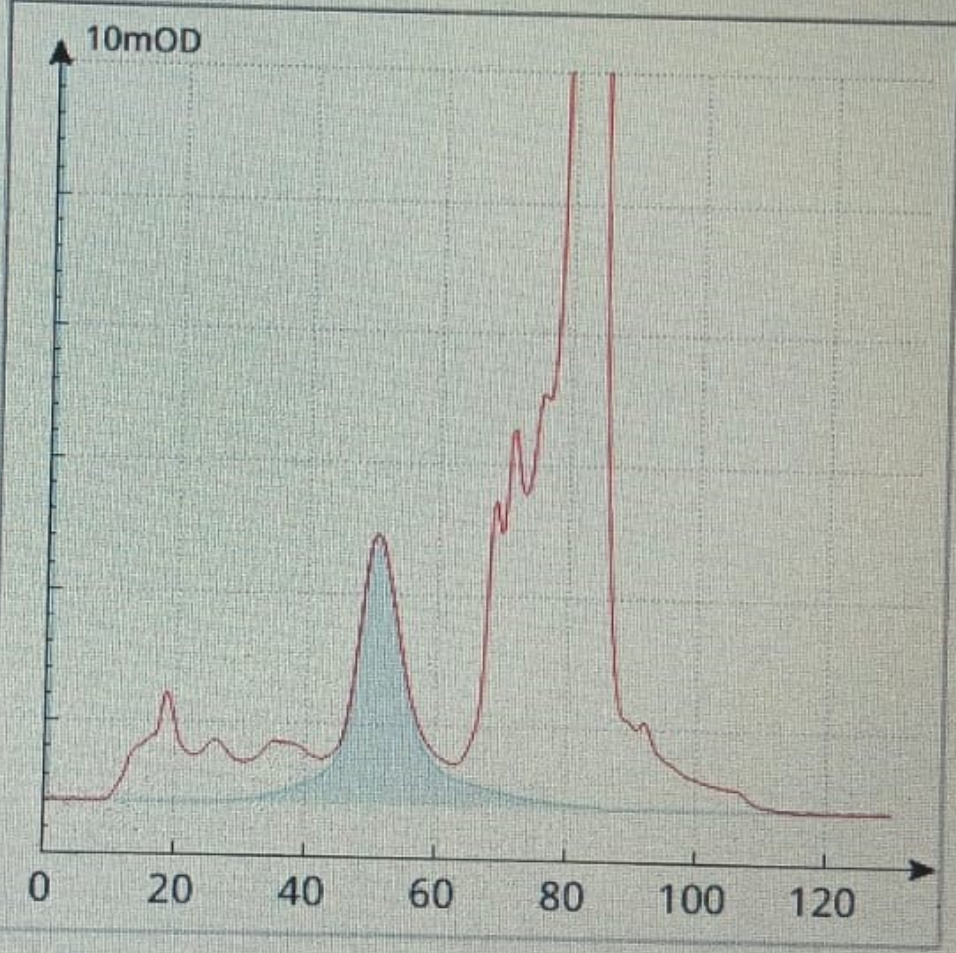
Log

Sys

Result Details

Number:	1766	Date:	2022-12-22
Column. C:	557	Time:	14:10:16
Column. T:	34.9°C	ID:	C2
Position:	2#	Type:	Diluted blood

Peak	Time	ABS	Area	Result
bA1a	12.5	17	258	0.2
bA1b	18.1	41	1736	1.5
HbF	25.6	24	1459	1.3
bA1c+	34.8	23	2423	2.1
bA1c	50.1	103	11148	9.6
bA0	80.9	2474	99618	85.4
Win	-	-	-	-
(ADA)	12.6 mmol/L		227.6 mg/dl	



NGSP:	
IFCC:	81.0n
Area:	11
Remark:	
Pressure:	9.