immunoshop

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Sector-11, CBD, Belapur,
Navi Mumbai-400 614, INDIA
Toll Free No : 1800-222-330
IMMUNOSHOP INDIA PVT. LTD.

Calibration Certificate of LifeDX HBPro

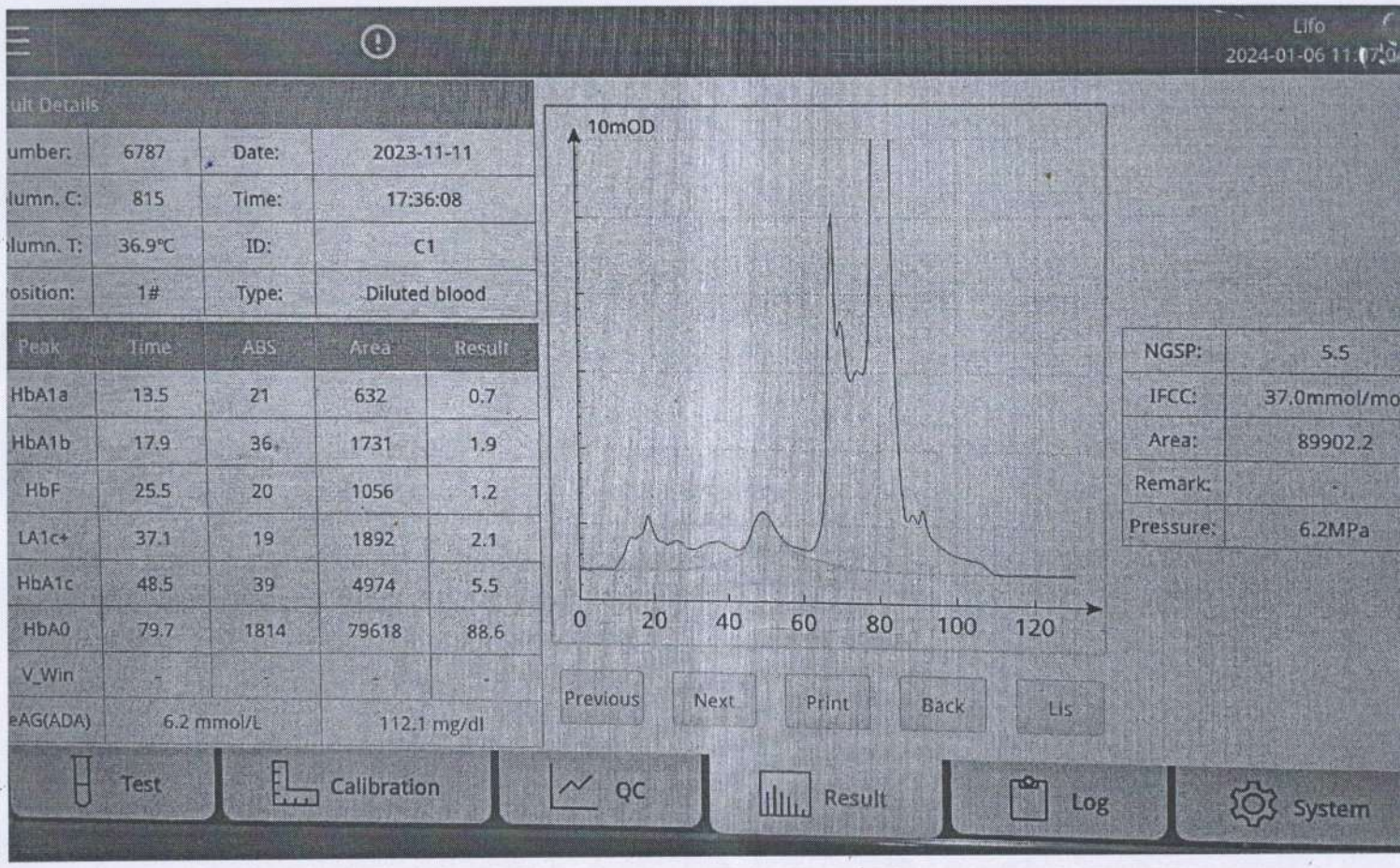
HPLC based Fully Automated HbA1c Analyser

Customer Name	Medray Clinics Pvt Ltd
Customer Address	Indiranagar, Bangalore, Karnataka
Analyser Model	LifeDX HBPro
Serial No.	I02F00000861
Next Calibration Due on	July 21st, 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, 2024 and calibration of the instrument and all other values have been found within the limit.

Interpretation: LifeDX HBPro Calibration done successfully.

Prepared, Reviewed and approved by	
Name :	Ganagadhar
Title:	Service Engineer
Date :	23-07-2023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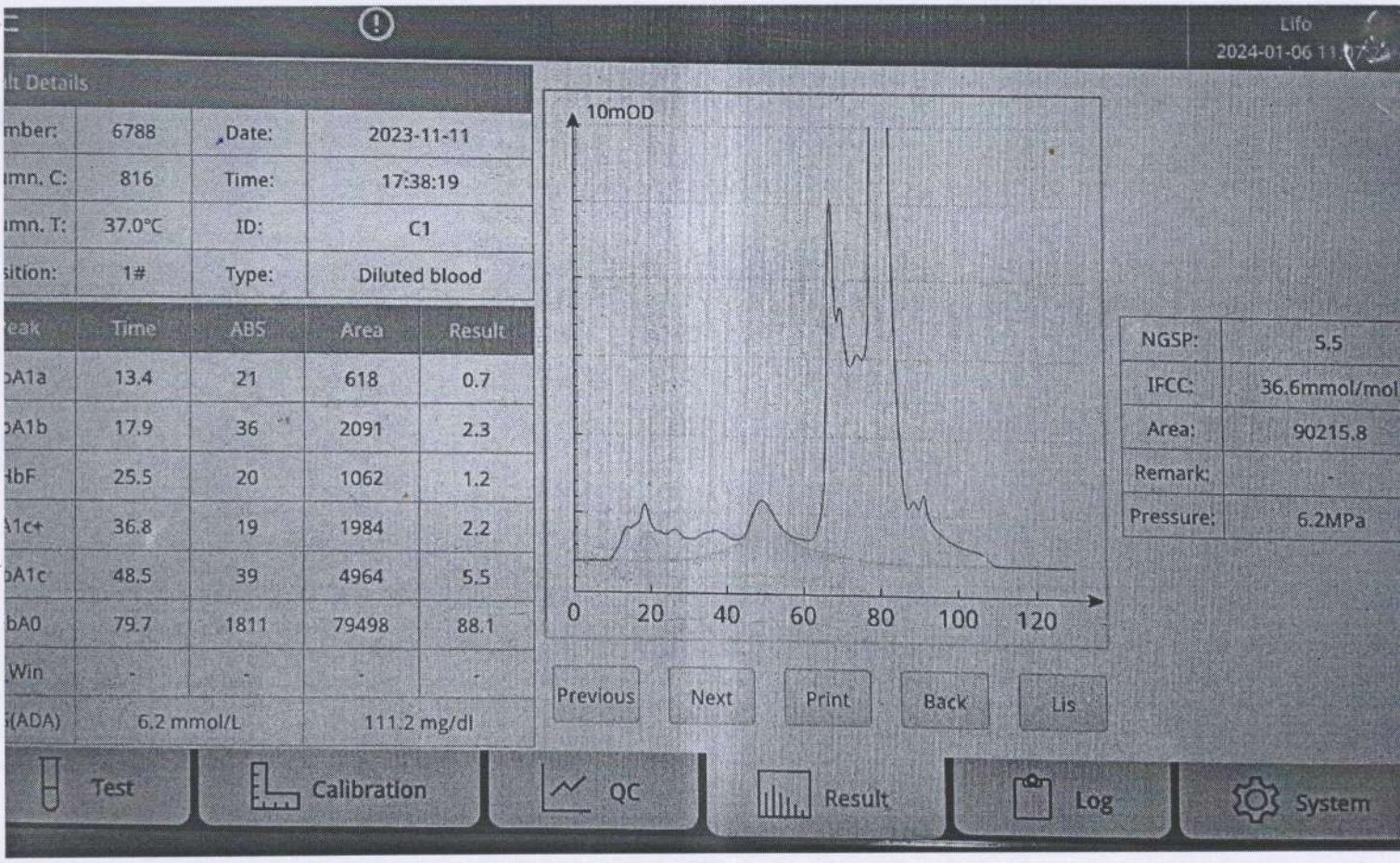
Date: 2023-11-11
lumn. C: 815
Time: 17:36:08
lumn. T: 36.9℃
ID: C1
osition: 1#
Type: Diluted blood
Peak Time ABS Area Result
HbA1a 13.5 21 632 0.7
HbA1b 17.9 36 1731 1.9
HbF 25.5 20 1056 1.2
LA1c+ 37.1 19 1892 2.1
HbA1c 48.5 39 4974 5.5
HbA0 79.7 1814 79618 88.6
V_Win - - - -
eAG(ADA) 6.2 mmol/L 112.1 mg/dl
10mOD
0 20 40 60 80 100 120
NGSP: 5.5
IFCC: 37.0mmol/mo
Area: 89902.2
Remark: -
Pressure: 6.2MPa
Previous
Next
Print
Back
Lis
Test
Calibration
QC
Result
Log
System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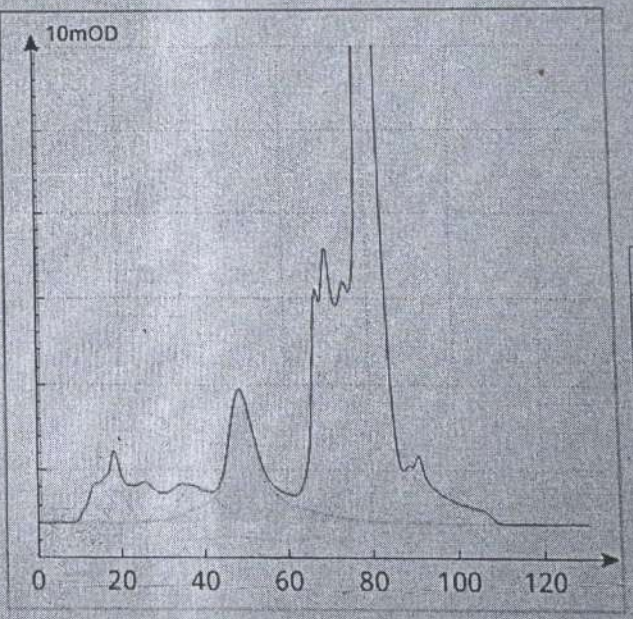
lt Details
mber: 6788 Date: 2023-11-11
mn. C: 816 Time: 17:38:19
mn. T: 37.0℃ ID: C1
sition: 1# Type: Diluted blood
eak Time ABS Area Result
A1a 13.4 21 618 0.7
A1b 17.9 36 2091 2.3
bF 25.5 20 1062 1.2
1c+ 36.8 19 1984 2.2
A1c 48.5 39 4964 5.5
bA0 79.7 1811 79498 88.1
Win - - - -
(ADA) 6.2 mmol/L 111.2 mg/dl
10mOD
0 20 40 60 80 100 120
NGSP: 5.5
IFCC: 36.6mmol/mol
Area: 90215.8
Remark: -
Pressure: 6.2MPa
Previous
Next
Print
Back
Lis
Test
Calibration
QC
Result
Log
System

Lifo
2024-01-06 11:07

ult Details

mber:	6789	Date:	2023-11-11
umn. C:	817	Time:	17:40:29
umn. T:	37.0℃	ID:	C2
sition:	2#	Type:	Diluted blood

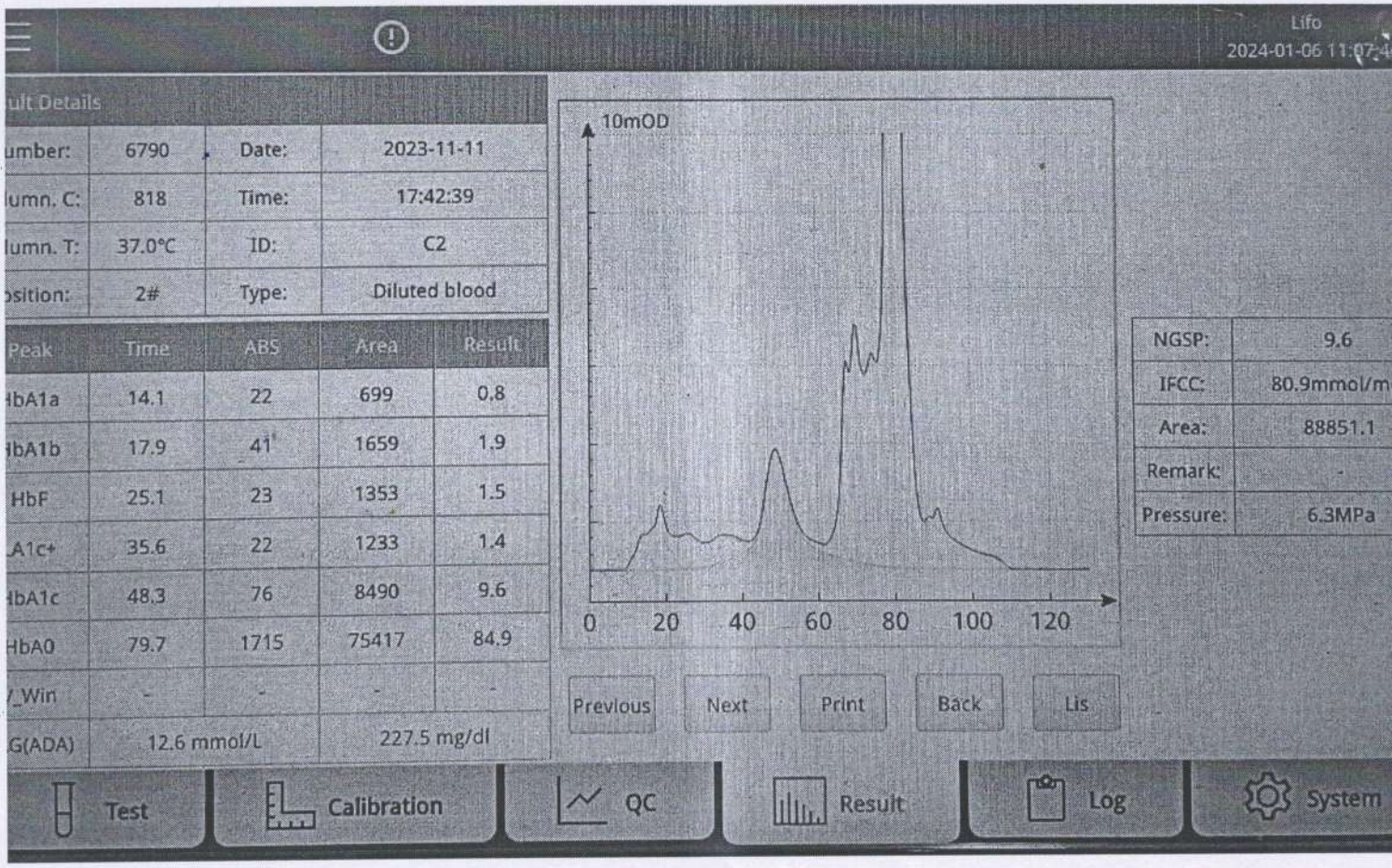
Peak	Time	ABS	Area	Result
bA1a	13.5	23	572	0.6
bA1b	17.9	42	1895	2.1
HbF	25.1	23	1381	1.5
A1c+	34.7	22	2131	2.4
bA1c	48.3	77	8596	9.5
bA0	79.7	1745	75605	83.8
_Win	-	-	-	-
(ADA)	12.6 mmol/L		226.9 mg/dl	



NGSP:	9.5
IFCC:	80.7mmol/m
Area:	90180.5
Remark:	-
Pressure:	6.2MPa

Previous | Next | Print | Back | Lis

Test | Calibration | QC | Result | Log | System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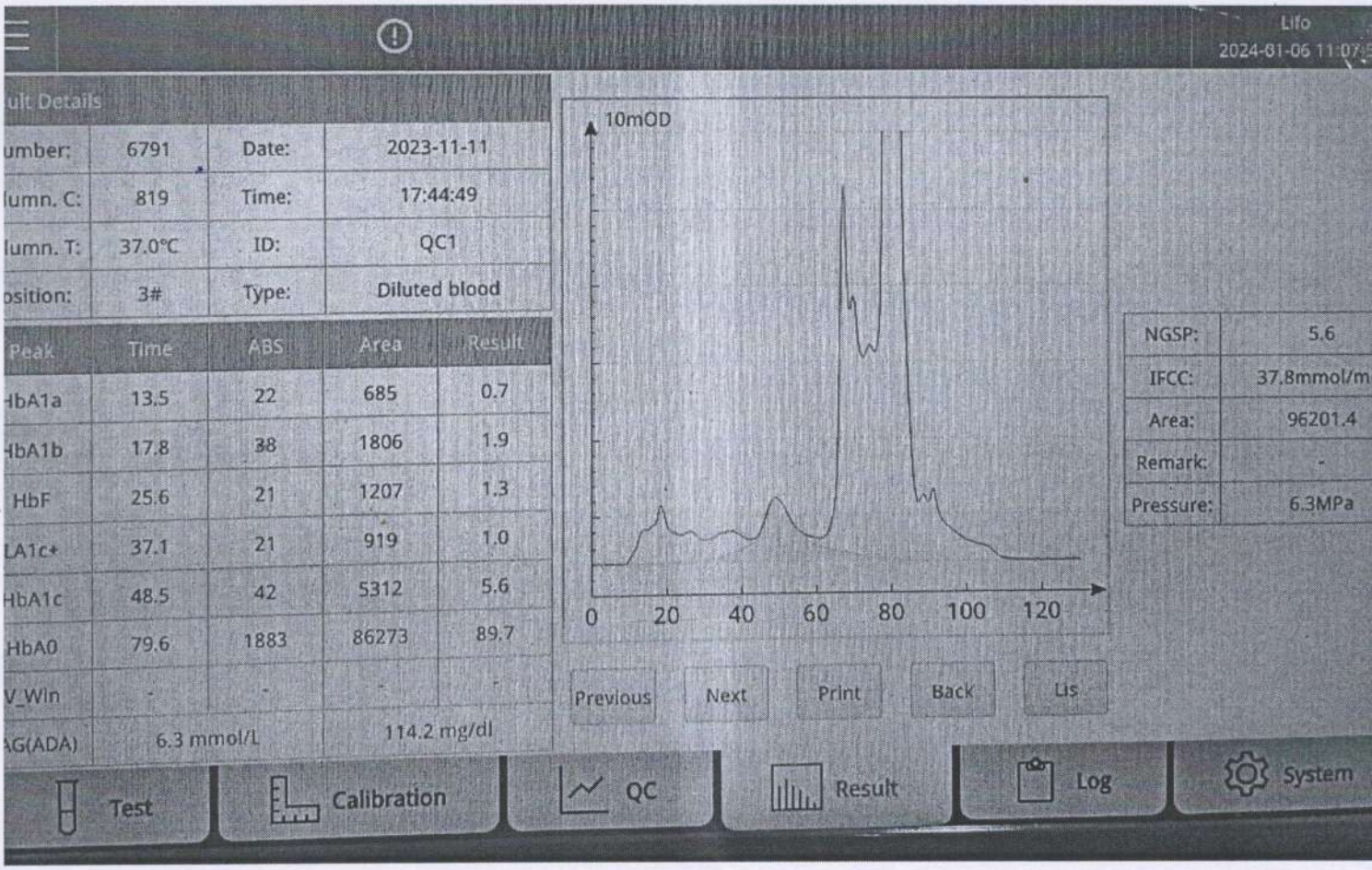
Time: 17:42:39
lumn. T: 37.0℃
ID: C2
sition: 2#
Type: Diluted blood
Peak Time ABS Area Result
HbA1a 14.1 22 699 0.8
HbA1b 17.9 41 1659 1.9
HbF 25.1 23 1353 1.5
A1c+ 35.6 22 1233 1.4
HbA1c 48.3 76 8490 9.6
HbA0 79.7 1715 75417 84.9
/_Win - - - -
G(ADA) 12.6 mmol/L 227.5 mg/dl
10mOD
0 20 40 60 80 100 120
NGSP: 9.6
IFCC: 80.9mmol/m
Area: 88851.1
Remark: -
Pressure: 6.3MPa
Previous
Next
Print
Back
Lis
Test
Calibration
QC
Result
Log
System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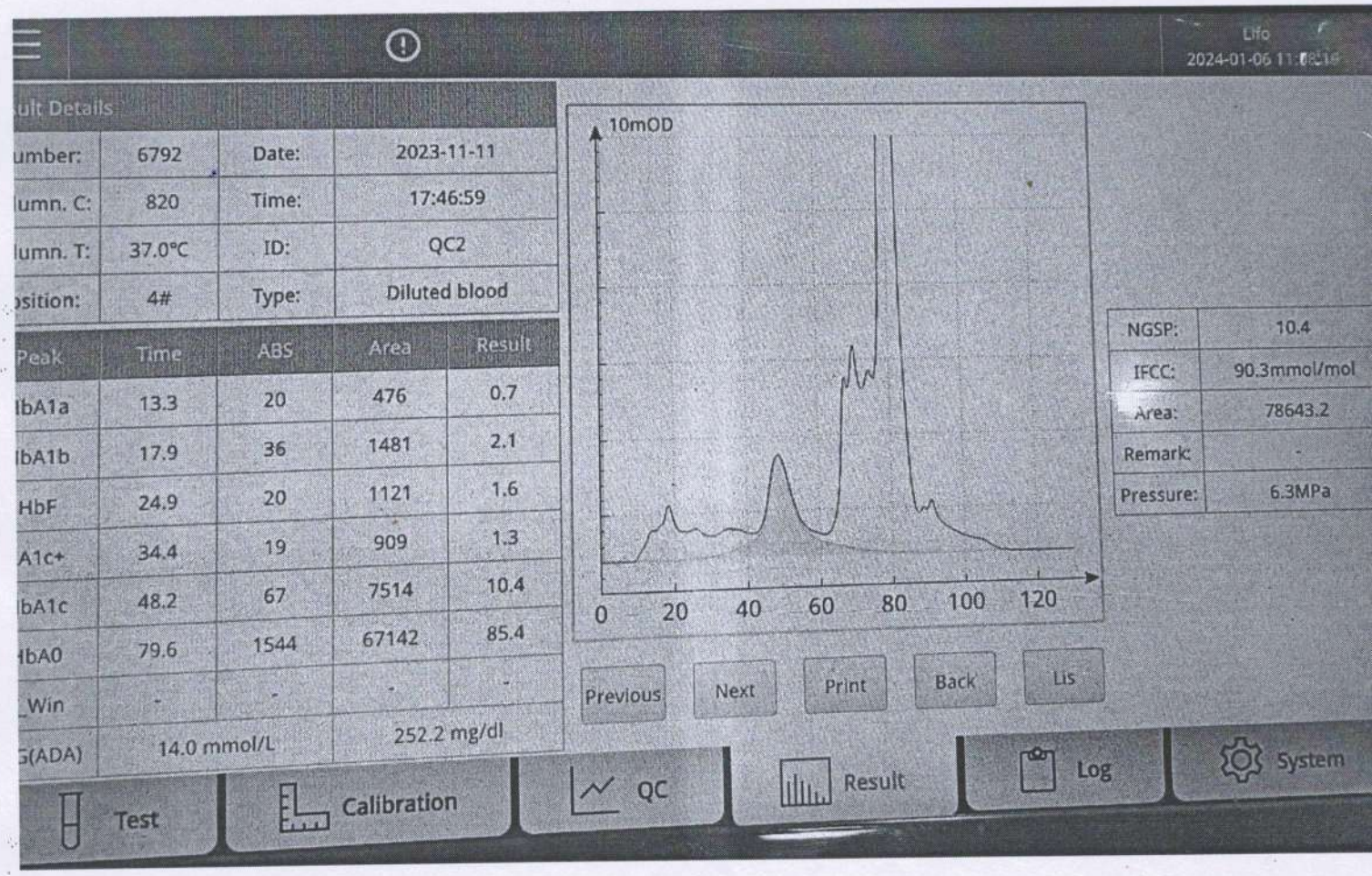
Date: 2023-11-11
lumn. C: 819
Time: 17:44:49
lumn. T: 37.0℃
ID: QC1
osition: 3#
Type: Diluted blood
Peak
Time
ABS
Area
Result
HbA1a 13.5 22 685 0.7
HbA1b 17.8 38 1806 1.9
HbF 25.6 21 1207 1.3
LA1c+ 37.1 21 919 1.0
HbA1c 48.5 42 5312 5.6
HbA0 79.6 1883 86273 89.7
V_Win - - - -
AG(ADA) 6.3 mmol/L 114.2 mg/dl
10mOD
0 20 40 60 80 100 120
NGSP: 5.6
IFCC: 37.8mmol/m
Area: 96201.4
Remark: -
Pressure: 6.3MPa
Previous
Next
Print
Back
Lis
Test
Calibration
QC
Result
Log
System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ult Details
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lumn. C: 820
Time: 17:46:59
lumn. T: 37.0°C
ID: QC2
sition: 4#
Type: Diluted blood
Peak | Time | ABS | Area | Result
lbA1a | 13.3 | 20 | 476 | 0.7
lbA1b | 17.9 | 36 | 1481 | 2.1
HbF | 24.9 | 20 | 1121 | 1.6
A1c+ | 34.4 | 19 | 909 | 1.3
lbA1c | 48.2 | 67 | 7514 | 10.4
bA0 | 79.6 | 1544 | 67142 | 85.4
_Win | - | - | - | -
(ADA) | 14.0 mmol/L | | 252.2 mg/dl
10mOD
0 20 40 60 80 100 120
NGSP: 10.4
IFCC: 90.3mmol/mol
Area: 78643.2
Remark: -
Pressure: 6.3MPa
Previous
Next
Print
Back
Lis
Test
Calibration
QC
Result
Log
System

HbA1c Calibrator

Packing Insert

【Intend Use】

HbA1c Calibrator is intended for the percent determination of HbA1c in human blood using High Performance Liquid Chromatography (HPLC).

【Principle】

Form correspondence between the concentration of HbA1c and the variation of peak area ratio by testing calibrator level 1 and level 2. Establish standard curve to measure the concentration of HbA1c in sample.

【Application】

It's only for use with Lifotronic GH and H series HbA1c system.

【Composition】

1. Calibrator includes hemoglobin from lyophilized whole blood, preservatives and stabilizers.
2. It's traceable to NGSP Ion Exchange Chromatography method.

【Packing Specification】

The kit includes calibrator level 1, level 2
2×0.1mL

【Expiry Date】

1. Store at 2~8°C, keep in dark place. The calibrator is provided in lyophilized form for increased stability
2. Expiry Date, shelf life is 12 months. After resolved, it will be stable for 7 days at -20°C

【Operation Step】

1. Open vial, and place at room temperature for 10~15 minutes.
2. Add 100μL deionized water with pipette to dissolve level 1 and level 2, then stand for 30 minutes.
3. Tighten the vial covers and shake them gently and thoroughly.
4. Then choose suitable centrifuge tubes to dispatch, label and use.

【Limitation of the Procedure】

Refer to the operation guide to use the calibrator. If not, the measured results are not reliable.

【Performance Standard】

1. Appearance:Visual inspection:be red loose dried frozen aquatic products, be red liquid after redissolving .
2. Packing volume of level 1,level 2:≥2.7g.
3. Accuracy of level 1,level 2:Bias% should be in the range of ± 10%.
4. Intra-assay precision of level 1,level 2:CV≤5%.
5. Inter-assay precision of level 1,level 2:CV≤10%.
6. Bio-safety of level 1,level 2:HBsAg,HIV antibody,HCV antibody,TP antibody are negative.

【Precautions/Warnings】

1. For In Vitro Diagnostic Use.
2. Each unit of whole blood used in the manufacturer of the calibrators was tested by CFDA approved methods and found non-reactive for HbsAg, HCV, HIV-1, HIV-2 and TP. No test method can offer complete assurance from infection. In accordance with good laboratory practice, all human source material should be considered potentially infectious; therefore, handle the calibrators with the same precautions used with patient specimens.

【Calibration Referring Value】

See the reference Value on the vial.

【Manufacturer】

Shenzhen Lifotronic Technology Co., Ltd

Add: Unit A, 4th Floor, Building 15, Yijing Estate, No.1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R.China

Mail: service@lifotronic.com

【Authorized representative in the European Community】

Shanghai International Holding Corp. GmbH (Europe)

Add: Eiffestrasse 80, 20537 Hamburg, Germany

【Version and Modification Date】

Version: A5

Modification Date: 2018-03-16

HbA1c Control Material

Packing Insert

【Intend Use】

HbA1c Control Material is intended for the system quality control for accuracy and repeatability.

【Application】

The Control Materials were made from human whole blood. It will compare the measuring results in sample test program with reference range

【Composition】

1. The Control Material includes hemoglobin from lyophilized whole blood, preservatives and stabilizers.
2. It's traceable to NGSP Ion Exchange Chromatography method.

【Packing Specification】

The kit includes Control Material Level 1, Level 2

2×0.1mL

【Expiry Date】

1. Store at 2~8°C, keep in dark place. The Control Material is provided in lyophilized form for increased stability
2. Expiry Date, shelf life is 12 months. After resolved, it will be stable for 7 days at -20°C.

【Operation Step】

1. Open vial, and place at room temperature for 10~15 minutes.
2. Add 100μL deionized water with pipette to dissolve Level 1 and Level 2, then stand for 30 minutes.
3. Tighten the vial covers and shake them gently and thoroughly.
4. Then choose suitable centrifuge tubes to dispatch, label and use.

【Reference Range】

See the reference range on the vial.

【Explanation of QC Results】

The measured QC results should be in reference range. If not, the whole system should be checked, such as the calibrator expiry date, stored condition and system status.

【Performance Standard】

1. Appearance:Visual inspection:be red loose dried frozen aquatic products, be red liquid after redissolving .
2. Packing volume of level 1,level 2:≥2.7g.
3. Accuracy of level 1,level 2:Bias% should be in the range of ± 10%.
4. Intra-assay precision of level 1,level 2:CV≤5%.
5. Inter-assay precision of level 1,level 2:CV≤10%.
6. Bio-safety of level 1,level 2:HBsAg,HIV antibody,HCV antibody,TP antibody are negative.

【Precautions/Warnings】

1. For In Vitro Diagnostic Use.
2. Each unit of whole blood used in the manufacturer of the Control Materials was tested by CFDA approved

methods and found non-reactive for HbsAg, HCV, HIV-1, HIV-2 and TP. No test method can offer complete assurance from infection. In accordance with good laboratory practice, all human source material should be considered potentially infectious; therefore, handle the Control Materials with the same precautions used with patient specimens

3.Besides the given reference range, laboratories could establish inner QC program according to real condition, and then determined reference range.

4. Use caution in disposing of the materials according to local regulations and law

【Manufacturer】

Shenzhen Lifotronic Technology Co., Ltd

Add: Unit A, 4th Floor, Building 15, Yijing Estate, No.1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R.China

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Version: A5

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