Aina Blood Monitoring System

Analytical Performance Summary

The Aina Blood Monitoring System is a high quality and versatile multi-parameter in-vitro diagnostic platform designed and manufactured by Jana Care. Headquartered in Boston, Jana Care's CE marked diagnostics platform enables biomarker testing for Diabetes and Cardiometabolic conditions.

When used by clinicians to manage chronic diseases, the Aina Blood Monitoring System is:

- Safe and reliable – manufactured under the highest quality standards in a ISO 13485 compliant environment.
- Clinically proven – clinically validated at numerous reputed clinical sites across the world.
- Mobile and cloud ready – compatible with iOS and Android platforms. Ready for secured information technology integration.
- Accurate and precise – performance at par with industry gold standard, laboratory and point-of-care equipments.

CE

CERTIFIED ISO 13485

HSA Health Sciences Authority

ifcc International Federation of Clinical Chemistry and Laboratory Medicine

JanaCare

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Intended Use

The Aina HbA1c Monitoring System is intended to be used for the quantitative measurement of Glycosylated Hemoglobin (HbA1c) levels in capillary fingerstick and venous whole blood samples. This system is intended for clinical laboratory and point-of-care use to monitor long term glycemic control of persons previously diagnosed with diabetes. This test can also be used as an aid for screening or diagnosis of diabetes.

Test Principle

The Aina HbA1c Test utilizes the boronate affinity method. The Aina HbA1c Test Kit consists of test strips, reagents, wash buffers, capillary tubes for sample collection, and pipette tips. The reagent contains a lysing agent and a blue boronic acid conjugate. When blood is added to the reagent, the erythrocytes are lysed and all hemoglobin precipitates. The boronic acid conjugates binds to the glycosylated hemoglobin. An aliquot of the reaction mixture is applied to the test strip and all the precipitated hemoglobin, conjugate-bound and unbound, remains on top of the filter. Any unbound boronate is removed with the wash buffer.

Specifications

Measuring range:
4 to 15% HbA1c

Supported hemoglobin range:
10 to 20 g/dL

Test time:
3 minutes

Operating temperature:
18 to 40°C

Blood volume:
5 µL (whole blood capillary or venous)

Performance Summary

The Aina HbA1c Monitoring System is a CE marked product manufactured in compliance with ISO 13485 and is traceable to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Reference Method for Measurement of HbA1c. The Aina HbA1c Monitoring System is clinically validated at numerous reputed clinical sites across the world such as National Health Group Diagnostics in Singapore, Fu Wai Hospitals in China and Narayana Health Hospitals in India.

The accuracy and precision achieved by the system are comparable to gold standard analyzers such as Bio-Rad D-10, Tosoh G8 and Alere Afinion AS100.

A summary table of CVs across the HbA1c measuring range is provided below:

Mean %HbA1c	Total Precision	
	%CV	SD
5.2	2.5	0.13
6.5	3.0	0.19
10.1	2.4	0.24
11.9	2.8	0.34
13.4	1.8	0.24

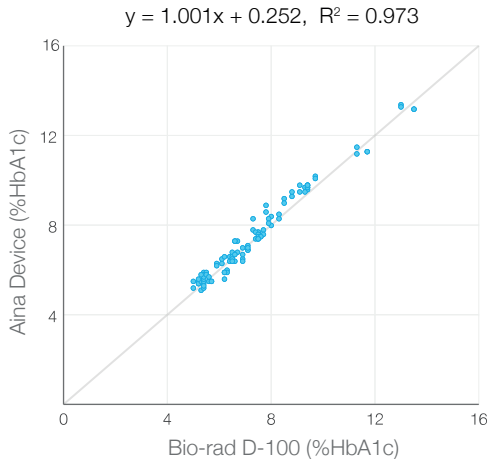
Clinical studies

I. National Health Group Diagnostics (Singapore)

Reference method: Bio-Rad D-100
Number of subjects: 50

The Aina HbA1c Monitoring System showed good correlation versus the Bio-Rad D-100 reference analyser, with $R^2 = 0.973$. 91.0% of the individual HbA1c measurements were within 10% of the Bio-Rad D-100 reference analyser values.

Accuracy Evaluation Performed Using Venous Whole Blood Samples



Comparison of performance between Aina Device and Bio-Rad D-100

Precision Evaluation

A precision study was carried out using two levels of control solutions. Each level of control solution was tested in five replicates, once a day, for 6 days for a total of 30 measurements per level.

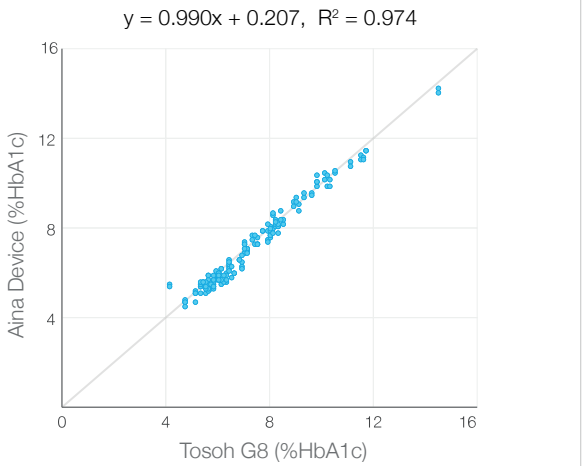
Control Level	Mean %HbA1c	Within Day		Total Precision	
		%CV	SD	%CV	SD
L1	6.5	2.9	0.19	3.2	0.21
L2	11.9	2.3	0.27	2.8	0.34

II. Fu Wai Hospitals (Beijing, China)

Reference method: Tosoh G8
Number of subjects: 80

The Aina HbA1c Monitoring System showed good correlation versus the Tosoh G8 reference analyser, with $R^2 = 0.974$. 98.8% of the individual HbA1c measurements were within 10% of the Tosoh G8 reference analyser values.

Accuracy Evaluation Performed Using Venous Whole Blood Samples



Comparison of performance between Aina Device and Tosoh G8

Precision Evaluation

A precision study was carried out using two levels of blood samples. Each blood sample was tested in duplicates, twice a day, for 5 days for a total of 20 measurements per level.

Blood Level	Mean %HbA1c	Within Run		Total Precision	
		%CV	SD	%CV	SD
L1	6.0	2.3	0.14	3.1	0.19
L2	11.4	1.8	0.21	2.2	0.25

A precision study was carried out using two levels of control solutions. Each control solution was tested in duplicates, twice a day, for 5 days for a total of 20 measurements per level.

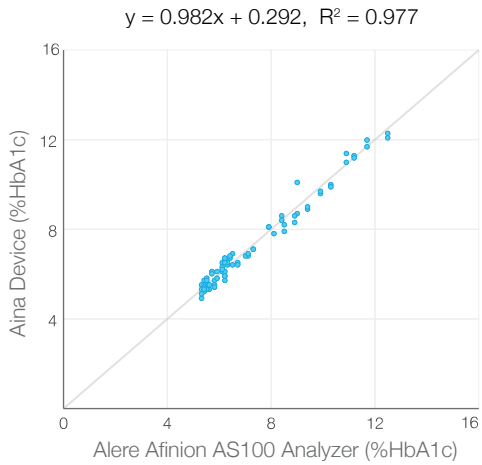
Control Level	Mean %HbA1c	Within Run		Total Precision	
		%CV	SD	%CV	SD
L1	5.2	1.9	0.10	2.5	0.13
L2	13.4	1.4	0.19	1.8	0.24

III. Narayana Health Hospitals (Bangalore, India)

Reference method: Alere Afinion AS100 and Bio-Rad D-10 Analyzer
Number of subjects: 41

The Aina HbA1c Monitoring System showed excellent correlation and agreement when compared to the Alere Afinion AS100 and Bio-Rad D-10 analyzer for both capillary and venous blood samples.

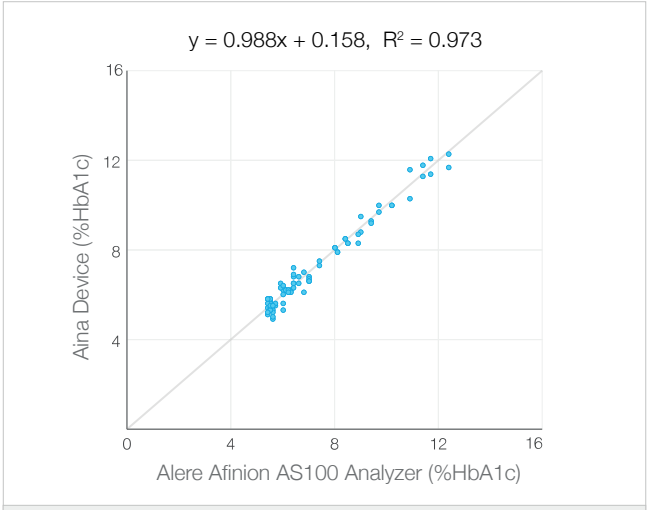
Accuracy Evaluation Performed Using Capillary Whole Blood Samples Against Alere Afinion AS100



Comparison of performance between Aina Device and Alere Afinion AS100 Analyzer

- The Aina HbA1c Monitoring System versus the Alere Afinion AS100 had a correlation of 0.977.
- 94.9% of individual measurements measured on the Aina HbA1c Monitoring System were within 10% of the reference method (Alere Afinion AS100).
- 100% of individual measurements measured on the Aina HbA1c Monitoring System were within 15% of the reference method (Alere Afinion AS100).

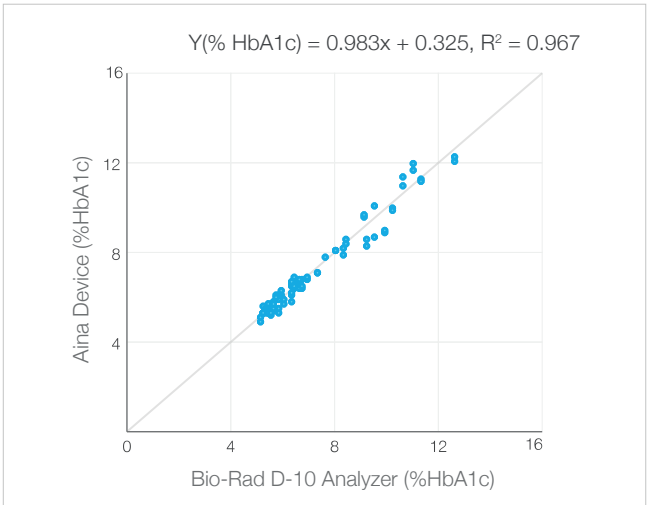
Accuracy Evaluation Performed Using Venous Whole Blood Samples Against Alere Afinion AS100



Comparison of performance between Aina Device and Alere Afinion AS100 Analyzer

- The Aina HbA1c Monitoring System versus the Alere Afinion AS100 had a correlation of 0.973.
- 96.3% of individual measurements measured on the Aina HbA1c Monitoring system were within 10% of the reference method (Alere Afinion AS100).
- 100% of individual measurements measured on the Aina HbA1c Monitoring system were within 15% of the reference method (Alere Afinion AS100).

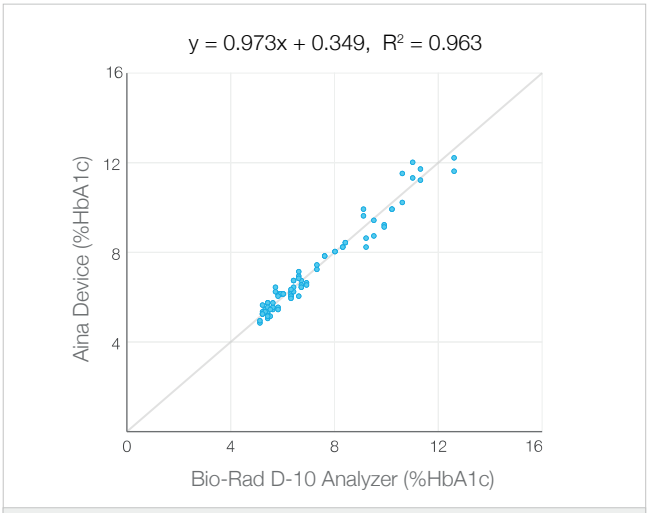
Accuracy Evaluation Performed Using Capillary Whole Blood Samples Against Bio-Rad D-10



Comparison of performance between Aina Device and Bio-Rad D-10 Analyzer

- The Aina HbA1c Monitoring System versus the Bio-Rad D-10 had a correlation of 0.967.
- 93.7% of individual measurements measured on Aina HbA1c Monitoring System were within 10% of the reference method (Bio-Rad D-10).
- 100% of individual measurements measured on Aina HbA1c Monitoring System were within 15% of the reference method (Bio-Rad D-10).

Accuracy Evaluation Performed Using Venous Whole Blood Samples Against Bio-Rad D-10



Comparison of performance between Aina Device and Bio-Rad D-10 Analyzer

- The Aina HbA1c Monitoring System versus the Bio-Rad D-10 had a correlation of 0.963.
- 91.4% of individual measurements measured on the Aina HbA1c Monitoring System were within 10% of the reference method (Bio-Rad D-10).
- 98.8% of individual measurements measured on the Aina HbA1c Monitoring System were within 15% of the reference method (Bio-Rad D-10).

Precision Evaluation

A precision study was carried out using three levels of blood samples. Each blood sample was tested in triplicates, twice a day, for 10 days across two test kit lots for a total of 120 measurements per level.

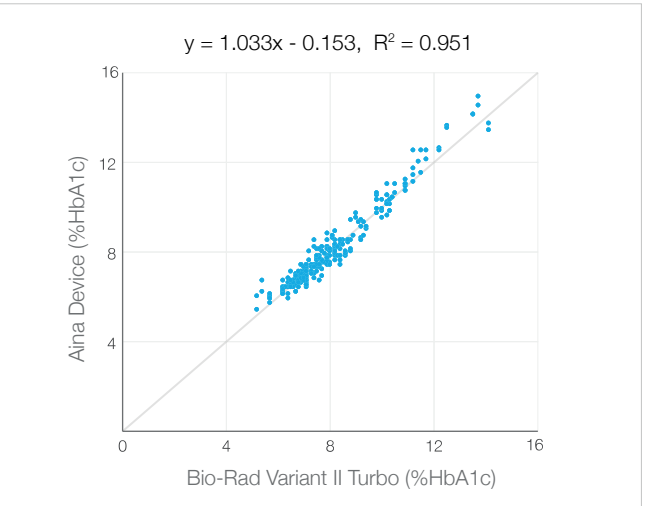
Blood Level	Mean %HbA1c	Total Precision	
		%CV	SD
L1	5.1	2.9	0.15
L2	6.5	3.0	0.19
L3	10.1	2.4	0.24

IV. Dr. Mohan's Diabetes Specialities Center (Chennai, India)

Reference method: Variant II Turbo (Bio-Rad)
Number of subjects: 131

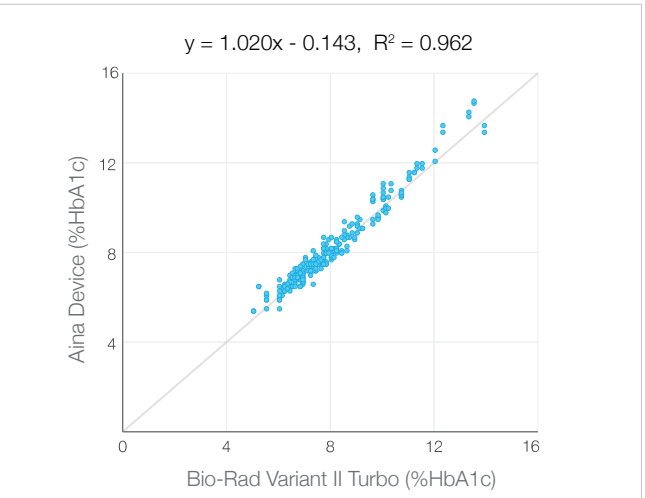
The Aina HbA1c Monitoring System showed excellent correlation and agreement when compared to the Bio-Rad Variant II Turbo for both capillary and venous blood samples.

Accuracy Evaluation Performed Using Capillary Whole Blood Samples



Comparison of performance between Aina Device and Bio-Rad Variant II Turbo

Accuracy Evaluation Performed Using Venous Whole Blood Samples



Comparison of performance between Aina Device and Bio-Rad Variant II Turbo

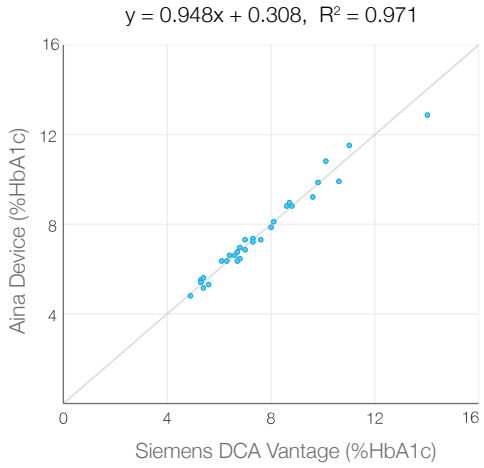
- The Aina HbA1c Monitoring System versus the Bio-Rad Variant II Turbo had a correlation of 0.951 for capillary samples and 0.962 for venous samples.
- 94.5% of individual measurements measured on the Aina HbA1c Monitoring System were within 10% of the reference method (Bio-Rad Variant II Turbo) for capillary samples.
- 98.3% of individual measurements measured on the Aina HbA1c Monitoring System were within 15% of the reference method (Bio-Rad Variant II Turbo) for capillary samples.
- 97.6% of individual measurements measured on the Aina HbA1c Monitoring System were within 10% of the reference method (Bio-Rad Variant II Turbo) for venous samples.
- 99.2% of individual measurements measured on the Aina HbA1c Monitoring System were within 15% of the reference method (Bio-Rad Variant II Turbo) for venous samples.

V. Study against the Siemens DCA Vantage (Bangalore, India)

Reference method: DCA Vantage (Siemens)
Number of subjects: 30

A total of 30 samples were included in the study. Measurements were taken in duplicates for all samples. All samples measured on the Aina HbA1c Monitoring System were found to be within 10% of the reference and showed great correlation (R^2 = 0.971).

Accuracy Evaluation Performed Using Capillary Whole Blood Samples



Comparison of performance between Aina Device and Siemens DCA Vantage

Lipids

Intended Use

The Aina Lipids System is intended to be used for quantitative measurement of total cholesterol, HDL cholesterol and triglycerides in capillary fingerstick and venous whole blood samples. This testing system is intended to measure lipids for the diagnosis and treatment of disorders involving excess cholesterol in the blood or for lipid and lipoprotein metabolism disorders. This system is intended for professional use only.

Test Principle

Test results are based on the instrument reading light reflected off a test strip that has changed color after blood has been placed on it. The darker the color, the higher the analyte concentration. The instrument converts this reading into a result that it displays. This procedure is based on the "Trinder Method" for the determination of lipids

Performance Summary

The Aina Lipids Monitoring System is a CE marked product and manufactured in compliance with the highest quality standards in a ISO 13485 certified environment. The Aina Lipids Monitoring System is clinically validated at numerous reputed clinical sites across the world such as National Health Group Diagnostics in Singapore, Narayana Health Hospitals in India and FuWai Hospitals in China.

The accuracy and precision achieved by the system are comparable to gold standard analyzers such as Cobas c501, Siemens Dimension RxL Max and Hitachi 008AS.

Summary tables of CVs across the total cholesterol, HDL cholesterol and triglycerides measuring ranges are provided below:

Total Cholesterol	
Mean Value (mg/dL)	Total Precision (%CV)
128	3.9
156	2.6
202	4.1
243	3.7

Trigycerides	
Mean Value (mg/dL)	Total Precision (%CV)
110	3.5
145	4.7
235	4.7
333	3.7

HDL Cholesterol	
Mean Value (mg/dL)	Total Precision (%CV)
29	3.0
35	6.6
48	3.6

Specifications

Measuring range:

Types	Measuring range (in mg/dL)	Measuring range (in mmol/L)
Total Cholesterol	100 to 400	2.59 to 10.34
HDL Cholesterol	25 to 85	0.65 to 2.20
Triglycerides	50 to 450	0.56 to 5.08

Supported hematocrit (PCV) range:

Types	PCV range
Total Cholesterol & Triglycerides	30 - 50%
HDL Cholesterol	33 - 49%

Test time:
Approximately 2 minutes

Operating temperature:
10 to 40°C

Blood volume:
15 µL (whole blood capillary or venous)

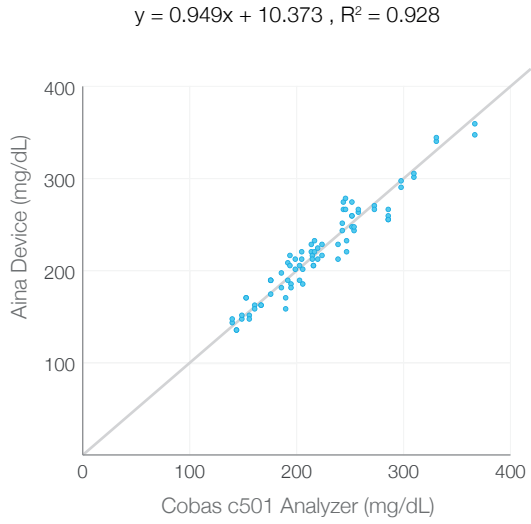
Clinical studies

I. National Health Group Diagnostics (Singapore)

Reference method: Cobas c501 analyzer
Number of subjects: 40

Total Cholesterol

Accuracy Evaluation Performed Using Venous Whole Blood Samples



Comparison of performance between Aina Device and Cobas c501 Analyzer

- The Aina Lipids Monitoring System for total cholesterol showed great correlation versus the laboratory reference (R^2 = 0.928).
- 98.8% of individual measurements measured on Aina Lipids Monitoring System for total cholesterol were within 15% of the reference method (Cobas c501 analyzer).
- 100% of individual measurements measured on Aina Lipids Monitoring System for total cholesterol were within 20% of the reference method (Cobas c501 analyzer).

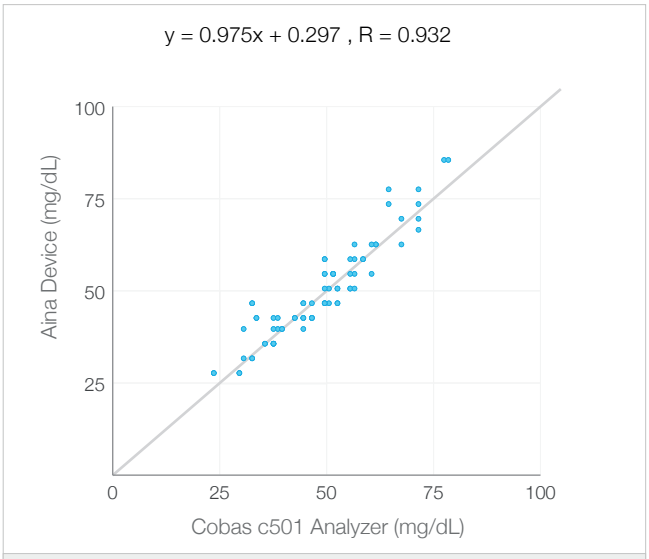
Precision Evaluation

A precision study was carried out using two levels of control solutions. Each control solution was tested in five replicates, once per day, for 6 days for a total of 30 measurements per level and showed a CV under 5% at all total cholesterol concentrations.

Control Level	Mean Value (mg/dL)	Within Day		Total Precision	
		%CV	SD	%CV	SD
L1	143	3.2	4.5	4.3	6.1
L2	202	3.4	6.9	4.1	8.3

HDL Cholesterol

Accuracy Evaluation Performed Using Venous Whole Blood Samples



Comparison of performance between Aina Device and Cobas c501 Analyzer

- The Aina Lipids Monitoring System for HDL cholesterol showed great correlation versus the laboratory reference (R= 0.932).
- 96.2% of individual measurements measured on the Aina Lipids Monitoring System for HDL cholesterol were within 10 mg/dL of the reference method (Cobas c501).
- 100% of individual measurements measured on the Aina Lipids Monitoring System for HDL cholesterol were within 15 mg/dL of the reference method (Cobas c501).

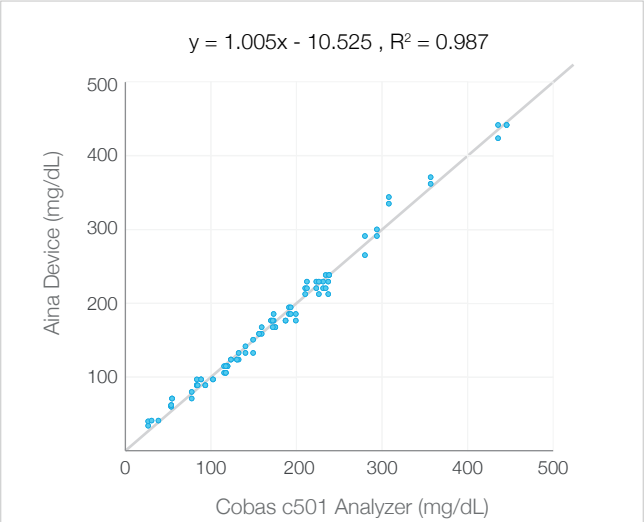
Precision Evaluation

A precision study was carried out using one level of control solution. The control solution was tested in five replicates, once per day, for 6 days for a total of 30 measurements per level and showed a CV under 7% at that HDL cholesterol concentration.

Control Level	Mean Value (mg/dL)	Within Day		Total Precision	
		%CV	SD	%CV	SD
L2	35	3.9	1.4	6.6	2.3

Triglycerides

Accuracy Evaluation Performed Using Venous Whole Blood Samples



Comparison of performance between Aina Device and Cobas c501 Analyzer

- The Aina Lipids Monitoring System for triglycerides showed great correlation versus the laboratory reference (R^2 =0.987).
- 92.5% of individual measurements measured on the Aina Lipids Monitoring System for triglycerides were within 15 mg/dL or 15% of the reference method (Cobas c501).
- 100% of individual measurements measured on the Aina Lipids Monitoring System for triglycerides were within 20 mg/dL or 20% of the reference method (Cobas c501).

Precision Evaluation

A precision study was carried out using two levels of control solutions. Each control solution was tested in five replicates, once per day, for 6 days for a total of 30 measurements per level and showed a CV under 5% at all triglyceride concentrations.

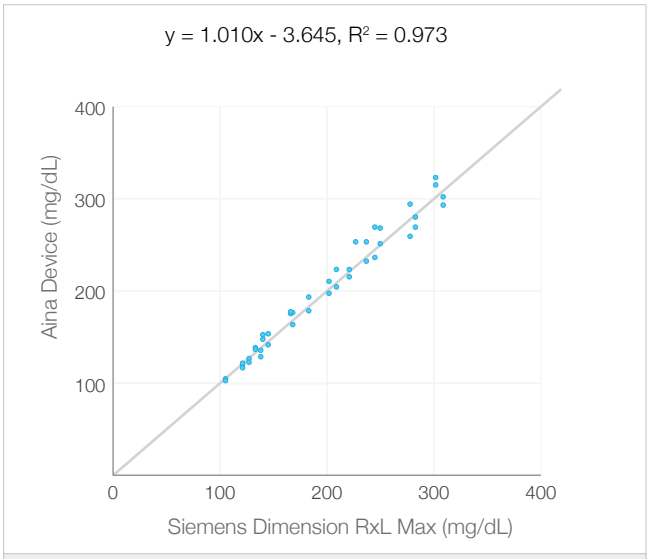
Control Level	Mean Value (mg/dL)	Within Day		Total Precision	
		%CV	SD	%CV	SD
L1	149	3.1	4.7	4.7	7.0
L2	235	3.6	8.4	4.7	11.1

II. Narayana Health Hospitals (Bangalore, India)

Reference method: Dimension RxL Max (Siemens)
Number of subjects: 42

Total Cholesterol

Accuracy Evaluation Performed Using Venous Whole Blood Samples



Comparison of performance between Aina Device and Siemens Dimension RxL Max

The Aina Lipids Monitoring System for total cholesterol showed great correlation versus the laboratory reference (R^2 = 0.973). 100% of the samples were within 15% of the reference analyzer.

Precision Evaluation

A precision evaluation was performed with venous whole blood samples tested in 20 replicates and showed a CV under 5% at all total cholesterol concentrations.

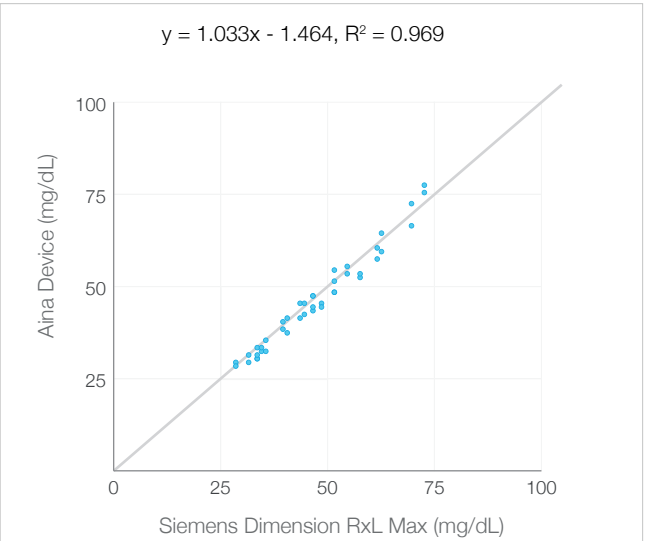
Blood Level	Mean Value (mg/dL)	Total Precision	
		%CV	SD
L1	128	3.9	5.0
L2	217	4.2	9.0

A precision evaluation was performed with control solutions tested in duplicates, over 20 days, with 2 runs per day, and showed a CV under 6% at all total cholesterol concentrations.

Control Level	Mean Value (mg/dL)	Within Day	Total Precision
		%CV	%CV
L1	156	2.6	3.4
L2	220	4.3	5.5

HDL Cholesterol

Accuracy Evaluation Performed Using Venous Whole Blood Samples



Comparison of performance between Aina Device and Siemens Dimension RxL Max

The Aina Lipids Monitoring System for HDL cholesterol showed great correlation versus the laboratory reference (R^2 = 0.969). 100% of the samples were within 15 mg/dL of the reference analyzer.

Precision Evaluation

A precision evaluation was performed with venous whole blood samples tested in 20 replicates and showed a CV under 4% at all HDL cholesterol concentrations.

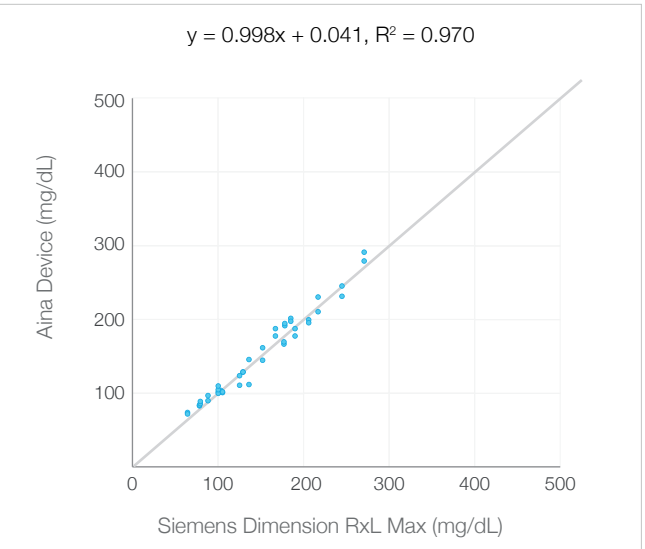
Blood Level	Mean Value (mg/dL)	Total Precision	
		%CV	SD
L1	29	3.0	0.9
L2	48	3.6	1.8

A precision evaluation was performed with control solutions tested in duplicates, over 20 days, with 2 runs per day, and showed a CV under 7% at all HDL cholesterol concentrations.

Control Level	Mean Value (mg/dL)	Within Day	Total Precision
		%CV	%CV
L1	29	5.6	6.3
L2	44	5.5	7.0

Triglycerides

Accuracy Evaluation Performed Using Venous Whole Blood Samples



Comparison of performance between Aina Device and Siemens Dimension RxL Max

The Aina Lipids Monitoring System for triglycerides showed great correlation versus the laboratory reference (R^2 = 0.970). 97.6% of the samples were within 15 mg/dL or 15% of the reference analyzer.

Precision Evaluation

A precision evaluation was performed with venous whole blood samples tested in 20 replicates and showed a CV under 4% at all triglycerides concentrations.

Blood Level	Mean Value (mg/dL)	Total Precision	
		%CV	SD
L1	110	3.5	6.3
L2	333	3.7	12.4

A precision evaluation was performed with control solutions tested in duplicates, over 20 days, with 2 runs per day, and showed a CV under 6.5% at all triglycerides concentrations.

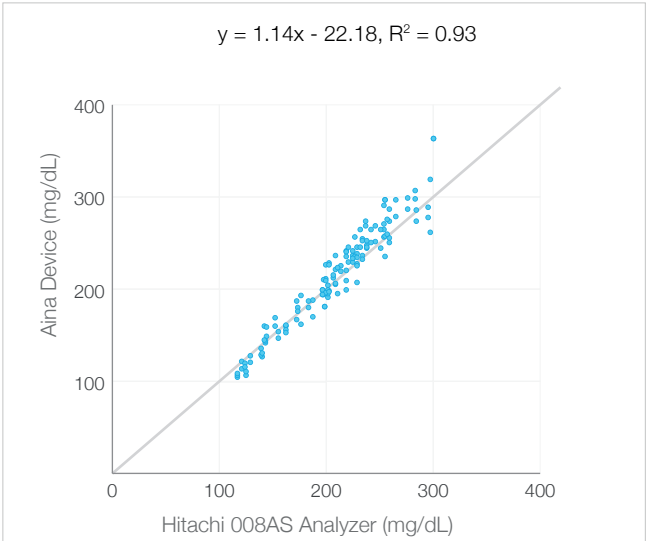
Control Level	Mean Value (mg/dL)	Within Day	Total Precision
		%CV	%CV
L1	145	4.7	4.7
L2	220	5.8	6.4

III. Fu Wai Hospitals (Beijing, China)

Reference method: Hitachi 008AS Analyzer
Number of subjects: 68

Total Cholesterol

Accuracy Evaluation Performed Using Venous Whole Blood Samples



Comparison of performance between Aina Device and Hitachi 008AS Analyzer

- The Aina Lipids Monitoring System for total cholesterol showed great correlation versus the laboratory reference (R^2 = 0.93).
- 96.3% of individual measurements measured on Aina Lipids Monitoring System for total cholesterol were within 15% of the reference method (Hitachi 008AS Analyzer).
- 98.5% of individual measurements measured on Aina Lipids Monitoring System for total cholesterol were within 20% of the reference method (Hitachi 008AS Analyzer).

Precision Evaluation

A precision study was carried out using two levels of control solutions. Each control solution was tested in duplicates, twice a day, for 5 days for a total of 20 measurements per level and showed a CV under 5% at all total cholesterol concentrations.

Control Level	Mean Value (mg/dL)	Within Day		Total Precision	
		%CV	SD	%CV	SD
L1	159	4.2	6.7	4.2	6.7
L2	243	2.5	6.1	3.7	9.1

Blood Glucose

Intended Use

The Aina Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip. The Aina Blood Glucose Monitoring System is intended for both over-the-counter (OTC) for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes controls or for point-of-care (POC) use by a trained health care professional. It is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

Test Principle

The test employs glucose oxidase, peroxidase and the chromogen 3,3',5,5' - Tetramethylbenzidine along with non reactive ingredients to produce a colour change that is directly proportional to the amount of D-glucose in the blood sample.

Specifications

Measuring range:
10 to 500 mg/dL
(0.55 to 27.7 mmo/L)

Supported hematrocit (PCV) range:
25 to 55%

Test time:
Approximately 5 seconds

Operating temperature:
5 to 45°C

Blood volume:
At least 2 µL (whole blood capillary)

Performance Summary

The Aina Blood Glucose Monitoring System is a CE marked product and manufactured in compliance with the highest quality standards in a ISO 13485 certified environment.
The Aina Blood Glucose Monitoring System is clinically validated at numerous reputed clinical sites such as Narayana Health Hospitals and Dr. Mohan's Specialities Center.

The accuracy and precision achieved by the system are comparable to gold standard analyzers such as YSI 2300D STAT Plus and Beckman Coulter AU2700.

A summary table of CVs across the glucose measuring range is provided below:

Mean Glucose Value (mg/dL)	%CV	SD
50	1.6	0.8
86	3.1	2.6
130	2.7	3.5
203	2.8	5.7
306	3.1	9.5

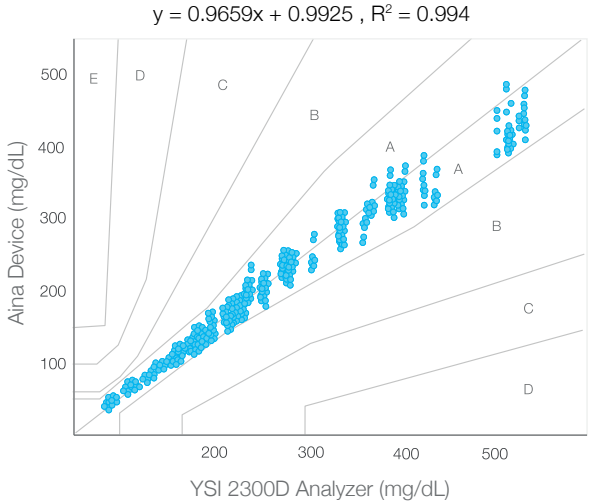
Clinical studies

I. Narayana Health Hospitals (Bangalore, India)

Reference method: 2300D STAT Plus (YSI)
Number of subjects: 126

Accuracy Evaluation

A comparison against capillary whole blood using the YSI 2300D STAT Plus analyser produced the following regression:



Comparison of performance between Aina Device and YSI 2300D Analyzer

System accuracy results for glucose concentration <5.55 mmol/L (<100 mg/dL)		
Within ± 0.28 mmol/l (Within ± 5 mg/dl)	Within ± 0.56 mmol/l (Within ± 10 mg/dl)	Within ± 0.83 mmol/l (Within ± 15 mg/dl)
117/204 (57.4%)	181/204 (88.7%)	204/204 (100%)

System accuracy results for glucose concentration ≥5.55 mmol/L (≥100 mg/dL)		
Within ± 5%	Within ± 10%	Within ± 15%
269/546 (49.3%)	452/546 (82.8%)	528/546 (96.5%)

System accuracy results for glucose concentrations between 38.9 mg/dl and 486 mg/dL Within ±0.83 mmol/L (15 mg/dL) or ±15%		
Total number of data points	Total number of passing data points	System accuracy
750	731	97.5%

A total of 126 subjects participated in this study. Aina Blood Glucose Monitoring System vs YSI 2300D Stat Plus met the ISO 15197:2015 standard accuracy requirements.

1. More than 95% (97.5%) of the measured glucose values fell within +/- 15 mg/dL of the average measured values of the reference measurement procedure at glucose concentrations < 100 mg/dL (<5.55 mmol/L) or within +/- 15% at glucose concentrations >= 100 mg/dL (>= 5.55 mmol/L).

2. More than 99% (100%) of individual glucose measured value fell within zones of A and B of the Consensus Error Grid.

Precision Evaluation

The repeatability obtained with the blood samples is shown in the following table. The table lists the pooled standard deviation and pooled CV% with 95% confidence intervals for the five levels of glucose tested (n=100). No outliers were detected and excluded from data analysis. At glucose concentrations of 50, 86, 130, 203 and 306 mg/dL coefficients of variation (CVs) of 1.6, 3.1, 2.7, 2.8 and 3.1% were obtained respectively, indicating a high degree of precision. At all glucose levels tested the coefficient of variation was below 4%.

	Level 1	Level 2	Level 3	Level 4	Level 5
Grand Mean (mg/dL)	50	86	130	203	306
Pooled SD (mg/dL)	0.8	2.6	3.5	5.7	9.5
95% CI (mg/dL)	0.5-0.9	2.0-3.0	2.5-4.0	4.7-6.5	7.6-10.7
Pooled CV%	1.6	3.1	2.7	2.8	3.1
95% CI	1.1-2.0	2.3-3.4	2.0-3.0	2.3-3.2	2.5-3.5

II. Dr. Mohan's Specialties Center (Chennai, India)

Reference method: Accu-Chek Active Blood Glucose Meter, Beckman Coulter AU2700

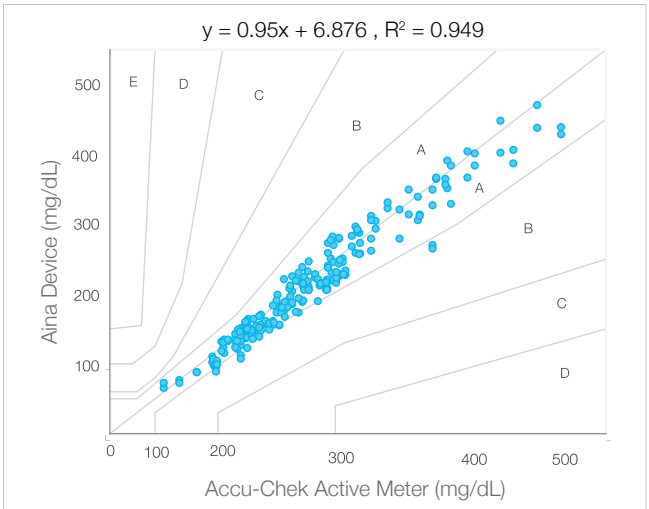
Number of subjects: 218

Accuracy Study Performed Using Capillary Whole Blood Samples Against Accu-Chek Active

A comparison of the Aina Blood Glucose Monitoring System versus the Roche Diagnostics' Accu-Chek Active Blood Glucose Meter was performed using capillary (fingerstick) whole blood samples. Testing was performed in duplicates for a total of 218 samples.

This evaluation showed a good correlation against the reference method, with the following regression: Y(mg/dL) = 0.95x + 6.876 with R^2 = 0.949, and satisfied the ISO 15197 standard accuracy requirements, as illustrated in the table and Consensus Error Grid below.

Bin	Number of samples	% of samples
Within ± 5%	86	39
Within ± 10%	167	77
Within ± 15%	207	95
Total samples	218	



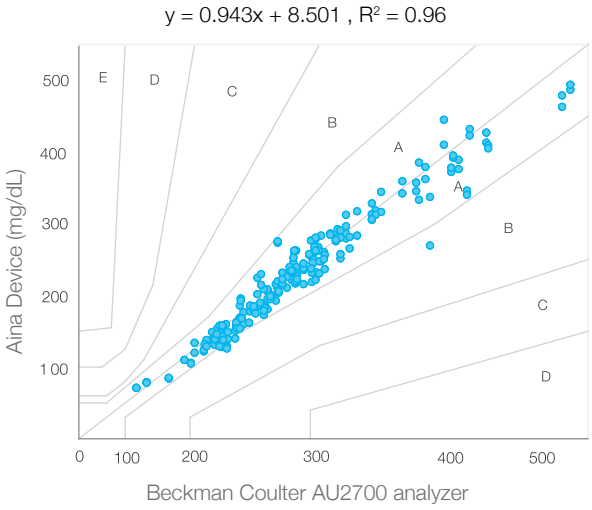
Comparison of performance between Aina Device and Accu-Chek Active Meter

Accuracy Evaluation Performed Using Venous Whole-Blood Samples Against Beckman Coulter AU2700

A comparison of the Aina Blood Glucose Monitoring System versus the Beckman Coulter AU2700 analyzer was performed using venous whole blood samples. Testing was performed in duplicates for a total of 210 samples.

This evaluation showed a good correlation against the reference method, with the following regression: Y(mg/dL) = 0.943x + 8.501 with R^2 = 0.96, and satisfied the ISO 15197:2015 standard accuracy requirements, as illustrated in the table and Consensus Error Grid below.

Bin	Number of samples	% of samples
Within ± 5%	108	51
Within ± 10%	169	80
Within ± 15%	199	95
Total samples	210	



Comparison of performance between Aina Device and Beckman Coulter AU2700 analyzer

Hemoglobin

Intended Use

The Aina Hemoglobin Monitoring System is intended to be used for the quantitative measurement of hemoglobin levels in capillary fingerstick and venous whole blood samples. This system is intended for clinical laboratory and point-of-care use to monitor anemia.

Test Principle

Erythrocytes in the specimen are lysed to release hemoglobin. The hemoglobin is converted to methemoglobin. The intensity of the color produced from this reaction is proportional to the hemoglobin concentration.

Specifications

Measuring range:
7 to 23 g/dL

Test time:
30 seconds

Operating temperature:
15 to 30°C

Blood volume:
10 µL (whole blood capillary or venous)

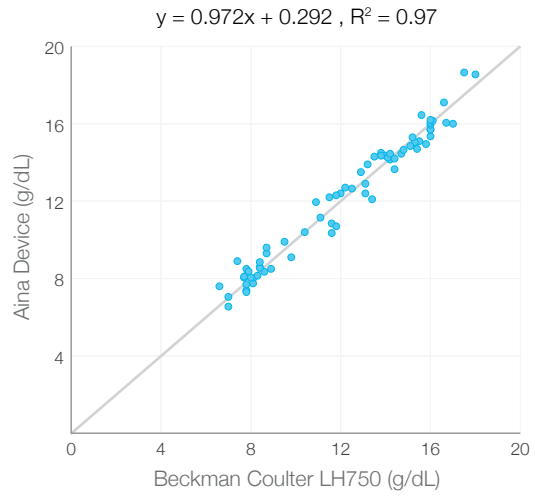
Performance Summary

The Aina Hemoglobin Monitoring System is a high quality product manufactured by in compliance with the highest quality standards in a ISO 13485 certified environment. The Aina Hemoglobin Monitoring System is clinically validated at numerous reputed clinical sites across the world such as Narayana Health Hospitals in India and Khoo Teck Puat Hospital in Singapore.

The accuracy and precision achieved by the system are comparable to gold standard analyzers such as Beckman Coulter LH750 and Sysmex XN.

A summary table of CVs across the hemoglobin measuring range is provided below:

Mean Hb Value (g/dL)	Within Run %CV	Total %CV
7.9	3.2	4.1
13.8	1.0	1.9
17.5	0.8	1.3



Comparison of performance between Aina Device and Beckman Coulter LH750

Clinical studies

I. Narayana Health Hospitals (Bangalore, India)

Reference method: LH750 (Beckman Coulter)
Number of subjects: 71

Accuracy Evaluation

The Aina Hemoglobin Monitoring System showed great linearity versus the Beckman Coulter LH750 reference (R^2 = 0.97). 94.4% of the samples were within 10% of the reference and 97.2% were within 15% of the reference.

Precision Evaluation

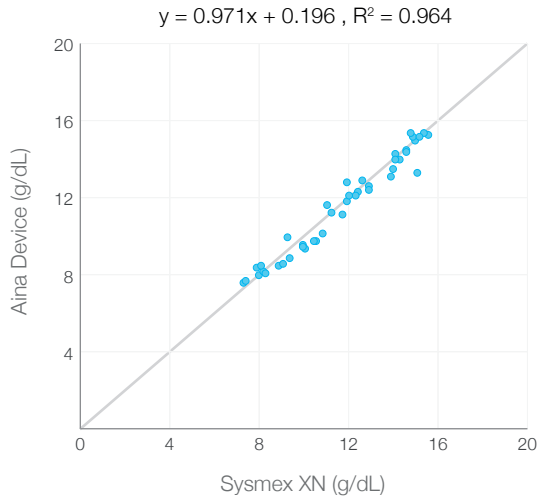
A precision evaluation was performed with control solutions for 20 days and showed a CV under 5% at all hemoglobin concentrations.

Control Level	Mean Value	Within Run		Total %CV	
		%CV	95% CI	%CV	95% CI
L1	7.9	3.1	2.58 - 4.03	4.1	3.69 - 5.08
L2	13.8	1.0	0.85 - 1.33	1.9	1.61 - 2.46
L3	17.5	0.7	0.62 - 0.96	1.3	1.13 - 1.75

II. Khoo Teck Puat Hospital (Singapore)

Reference method: XN (Sysmex)
Number of subjects: 42

The Aina Hemoglobin Monitoring System showed great linearity versus the laboratory reference (R^2 = 0.964). 97.6% of the samples were within 10% of the reference.



Comparison of performance between Aina Device and Sysmex XN

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