Aina Blood Monitoring System

Analytical Performance Summary

The Aina Blood Monitoring System is a high quality and versatile multi-parameter diagnostic platform that is CE-marked and approved for sale in Europe, India, Singapore, and Malaysia.

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 13485:2012 certified environment.
- Clinically proven – clinically validated at numerous reputed clinical sites across the world.
- Proactive and personalized – integrated with a patient-facing disease management platform.

Revision 2.2
Last Updated : 27 July, 2017

JanaCare

Table of Content

HbA1c

Blood Glucose

Hemoglobin

Lipids

HbA1c

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)

Clinical studies

I. Narayana Health Hospitals (Bangalore, India)

Reference method: Variant II Turbo (Bio-Rad)
Number of subjects: 100

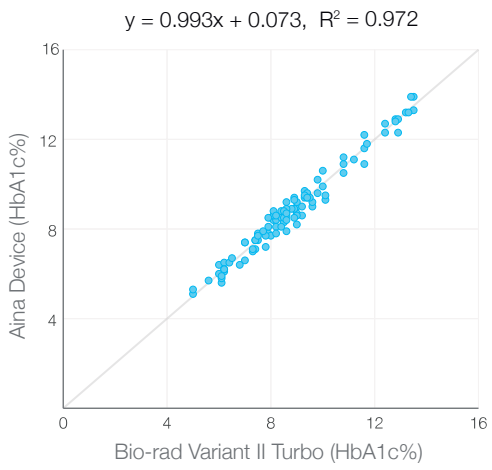

Figure 1. Comparison of performance between Aina Device HbA1c and Bio-Rad Variant II Turbo HbA1c

Precision Evaluation

A precision evaluation was performed using venous whole blood samples and showed a CV under 3% at all HbA1c levels.

	Level 1	Level 2	Level 3	Level 4
HbA1c Mean (%)	5.3	6.2	9.0	11.4
SD (%HbA1c)	0.11	0.15	0.24	0.29
CV (%)	2.16	2.34	2.66	2.56

II. Narayana Health Hospitals (Bangalore, India)

Reference method: Alere Afinion AS100
Number of subjects: 63

All samples measured on the Aina HbA1c Monitoring System were found to be within 10% of the reference and showed great linearity (R^2 = 0.976).

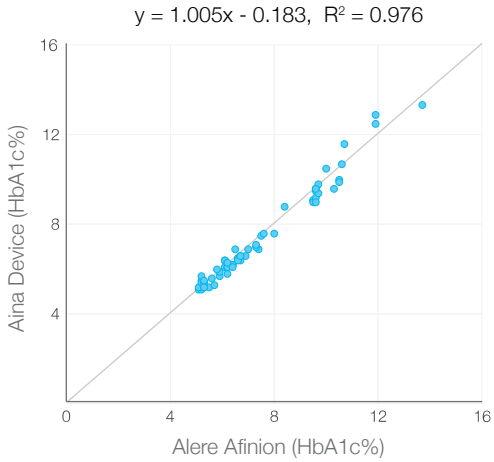

Figure 2. Comparison of performance between Aina Device HbA1c and Alere Afinion AS100 HbA1c

Precision Evaluation

A precision evaluation was performed using venous whole blood samples and showed a CV under 4% at all HbA1c levels.

Control Level	Mean Value	Within Run		Total %CV	
		%CV	95% CI	%CV	95% CI
L1	5.68	2.53	1.96 - 3.58	3.92	3.19 - 6.00
L2	13.08	2.53	1.95 - 3.58	2.85	2.50 - 3.77

III. 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 linearity (R^2 = 0.971).

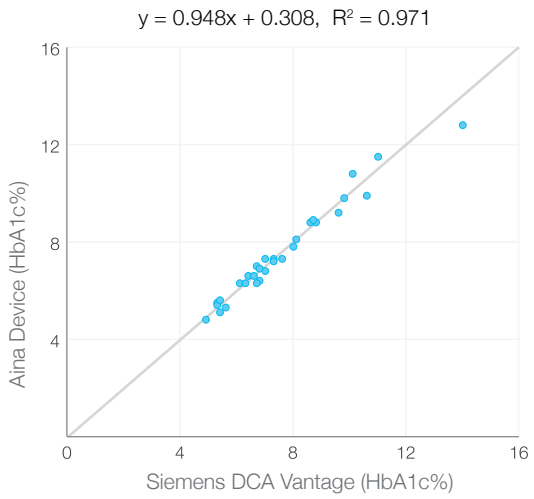

Figure 3. Comparison of performance between Aina Device HbA1c and DCA Vantage (Siemens) HbA1c

IV. Khoo Teck Puat Hospital (Singapore)

Reference method: c501 (Cobas)
Number of subjects: 41

The Aina HbA1c Monitoring System showed great linearity versus the laboratory reference (R2 = 0.982). In addition, 92.7% of the samples were within 10% of the reference.

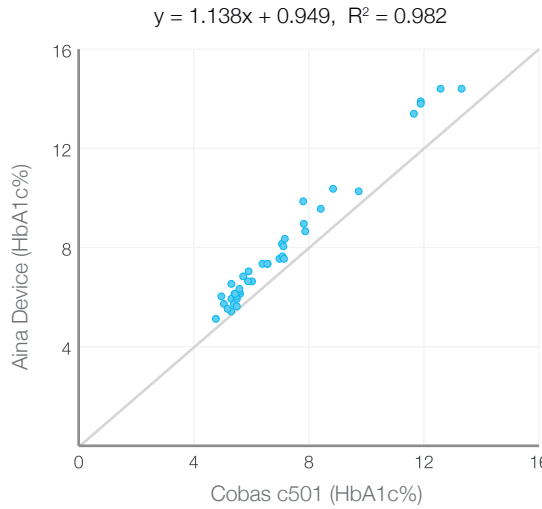

Figure 4. Comparison of performance between Aina Device HbA1c and c501 (Cobas) HbA1c

V. CARE Hospitals (Hyderabad)

Reference method: Unicel DxC (Beckman Coulter)
Number of subjects: 100

The Aina HbA1c Monitoring System showed great linearity versus the laboratory reference (R^2 = 0.963). In addition, 96% of the samples were within 10% of the reference.

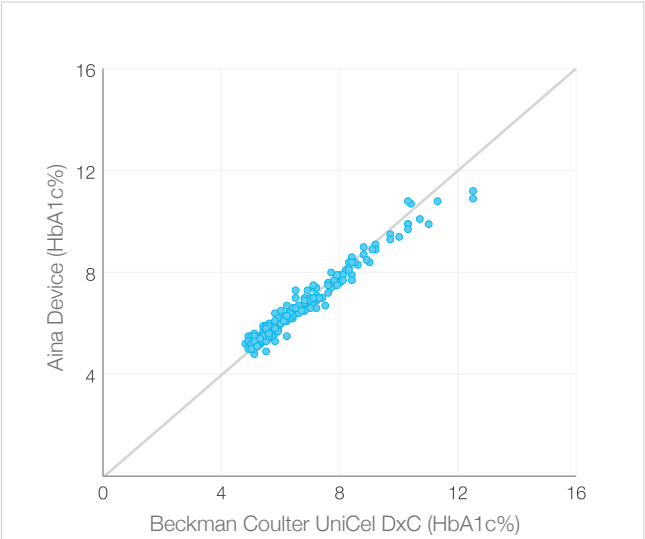

Figure 5. Comparison of performance between Aina Device HbA1c and UniCel DxC (Beckman Coulter) HbA1c

VI. 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 laboratory gold standard for both capillary and venous blood samples.

Accuracy Evaluation Performed Using Capillary Whole Blood Samples

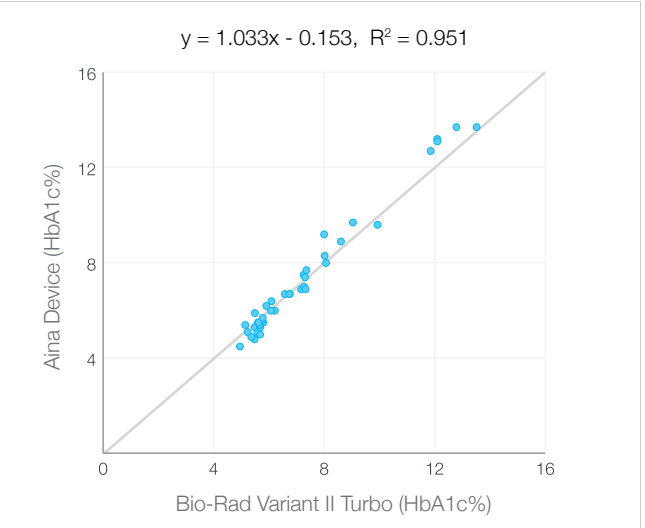

Figure 6. Accuracy Evaluation Performed Using Capillary Whole Blood Samples

- The Aina HbA1c Monitoring System versus the gold standard revealed a correlation of 0.974 and a kappa agreement of 0.98.
- 94.5% of individual measurements measured on Aina HbA1c Monitoring system were within 10% of reference method (Variant II Turbo, Bio-rad).
- 98.3% of individual measurements measured on Aina HbA1c Monitoring system were within 15% of reference method (Variant II Turbo, Bio-rad).

Accuracy Evaluation Performed Using Venous Blood Samples

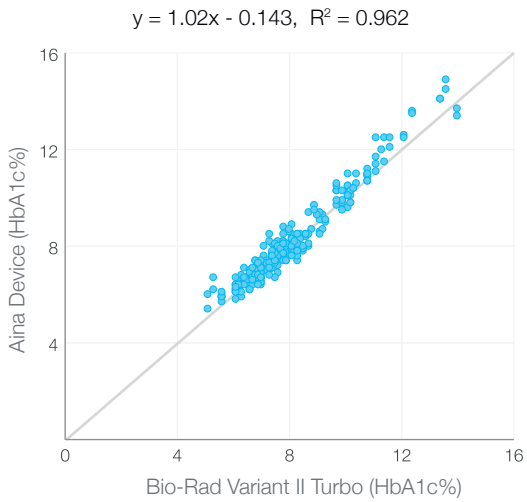

Figure 7. Accuracy Evaluation Performed Using Venous Blood Samples

- The Aina HbA1c Monitoring System versus the gold standard revealed a correlation of 0.984 and a kappa agreement of 0.988.
- 97.6% of individual measurements measured on Aina HbA1c Monitoring system were within 10% of reference method (Variant II Turbo, Bio-rad).
- 99.2% of individual measurements measured on Aina HbA1c Monitoring system were within 15% of reference method (Variant II Turbo, Bio-rad).

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)

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: Y(mg/dL) = 0.9659x - 0.9925 with R^2 = 0.9941.

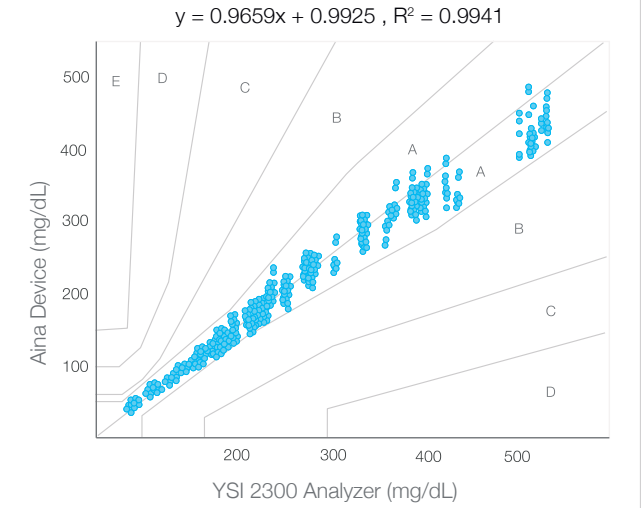

Figure 8. Comparison of performance between Aina Device Blood Glucose and YSI 2300 Analyzer

Table 1: 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	181/204	204/204
57.4	88.7	100.0

Table 2: System accuracy results for glucose concentration ≥ 5.55 mmol/L (≥100 mg/dL)

Within ± 5%	Within ± 10%	Within ± 15%
269/552	452/552	528/552
48.7	81.9	95.7

Table 3: System accuracy results for all combined glucose concentration

System accuracy results for glucose concentrations between 38.9 mg/dl and 486 mg/dL		
Total number of samples	Total number of passing samples	System accuracy
48.7	731	97.5%

A total of 126 subjects participated in this study. Aina Blood Glucose Monitoring System vs YSI 2300D Stat Plus met the EN ISO 15197:2013 standard accuracy requirements.

1. More than 95% (97.5%) of the measure 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 49.6, 85.8, 130.2, 203.1 and 306.2 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)	49.6	85.8	130.2	203.1	306.2
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 (Roche Diagnostics) and AU2700 (Beckman Coulter)

Number of subjects: 129

Accuracy Study Performed Using Capillary Whole Blood Samples

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 EN ISO 15197:2013 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	

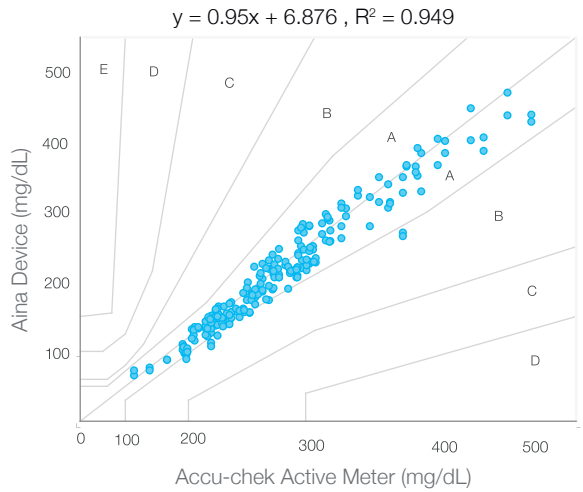

Figure 9. Comparison of performance between Aina Device Blood Glucose and Accu-chek Active Meter

Accuracy Evaluation Performed Using Venous Whole Blood Samples

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 EN ISO 15197:2013 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	

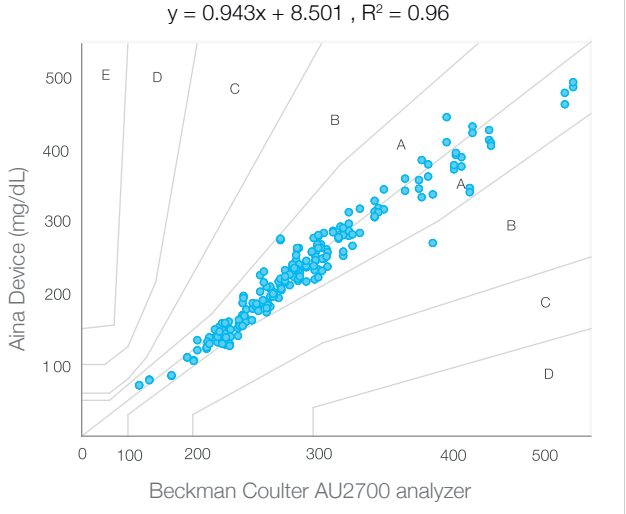

Figure 10. Comparison of performance between Aina Device Blood Glucose and Beckman Coulter AU2700 analyzer

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)

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 laboratory reference (R^2 = 0.97).
In addition, 94.4% of the samples were within 10% of the reference and 97.2% were within 15% of the reference.

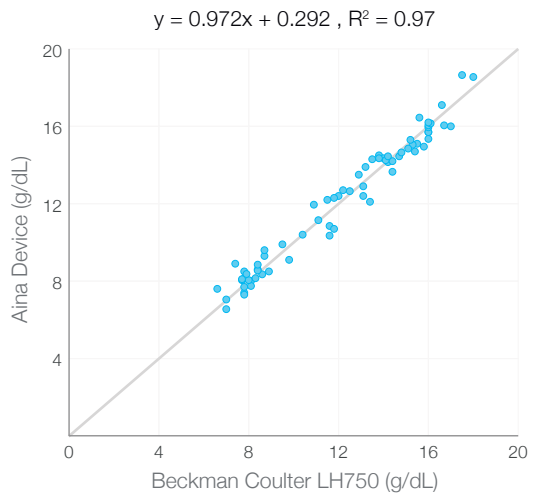

Figure 11. Comparison of performance between Aina Device Hemoglobin and Beckman Coulter LH750r

Precision Evaluation

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

Control Level	Mean Value	Within Run		Total %CV	
		%CV	95% CI	%CV	95% CI
L1	7.92	3.15	2.58 - 4.03	4.13	3.69 - 5.08
L2	13.77	1.04	0.85 - 1.33	1.88	1.61 - 2.46
L3	17.46	0.75	0.62 - 0.96	1.33	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).
In addition, 97.6% of the samples were within 10% of the reference.

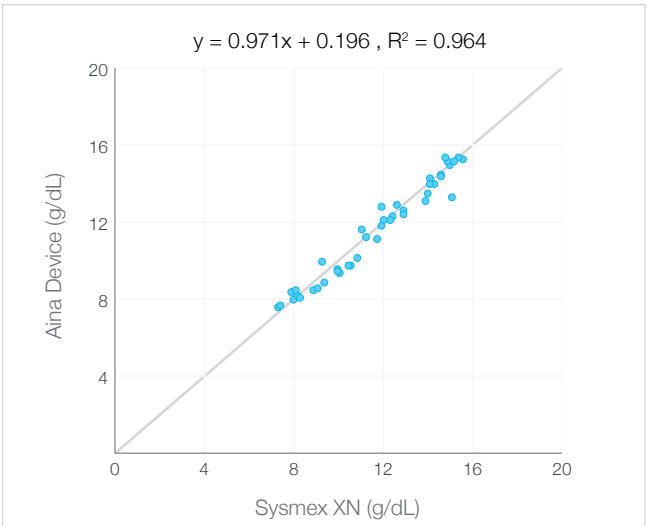

Figure 12. Comparison of performance between Aina Device Hemoglobin and Sysmex XN

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.

Specifications

Measuring range:

Types	Measuring range (in mg/dL)	Measuring range (in mmol/L)
Total Cholesterol	100 to 300	2.59 to 7.76
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. Narayana Health Hospitals (Bangalore, India)

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

Total Cholesterol

Accuracy Evaluation

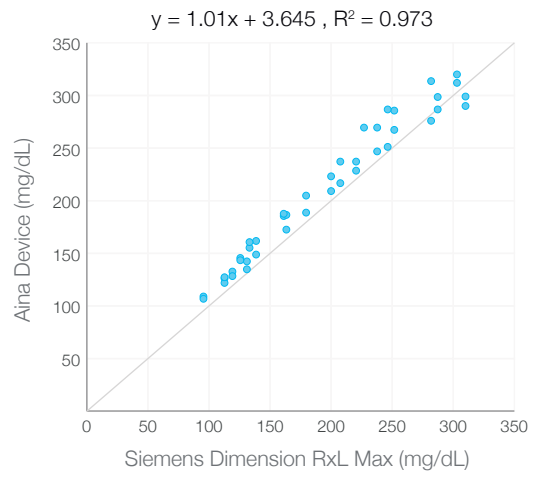

Figure 13. Comparison of performance between Aina Device Total Cholesterol and Siemens Dimension RxL Max

Precision Evaluation

A precision evaluation was performed with venous whole blood samples with 3 operators in a single day and showed a CV under 5% at all Total Cholesterol concentrations.

Precision across operators		
Mean (mg/dL)	SD (mg/dL)	%CV
137.2	4.5	4.29
208.4	7.0	3.36

A precision evaluation was performed with control solutions over 15 days, with 2 runs per day and using 2 Aina Devices, and showed a CV under 5% at all Total Cholesterol concentrations.

Control Level	Precision across operators		
	Mean (mg/dL)	SD (mg/dL)	%CV
L1	174.5	7.6	4.38
L2	237.7	11.7	4.91

HDL Cholesterol

Accuracy Evaluation

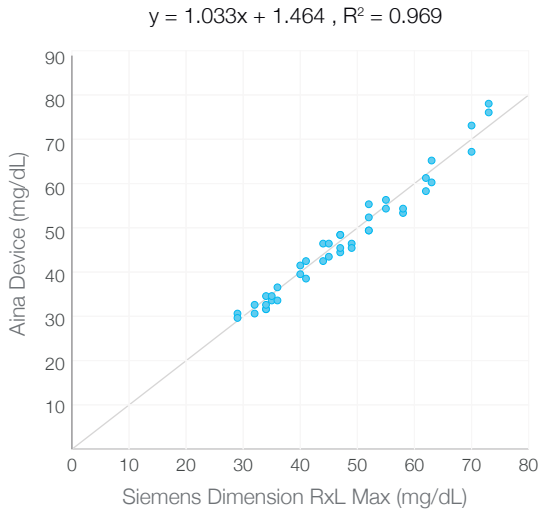

Figure 14. Comparison of performance between Aina Device HDL Cholesterol and Siemens Dimension RxL Max

Precision Evaluation

A precision evaluation was performed with venous whole blood samples with 3 operators in a single day and showed a CV under 5% at all HDL Cholesterol concentrations.

Precision across operators		
Mean (mg/dL)	SD (mg/dL)	%CV
32.4	1.4	4.41
50.6	1.8	3.51

A precision evaluation was performed with control solutions over 15 days, with 2 runs per day and using 2 Aina Devices, and showed a CV under 5.5% at all HDL Cholesterol concentrations.

Control Level	Precision across operators		
	Mean (mg/dL)	SD (mg/dL)	%CV
L1	27.0	1.2	4.45
L2	39.5	2.0	5.08

Triglycerides

Accuracy Evaluation

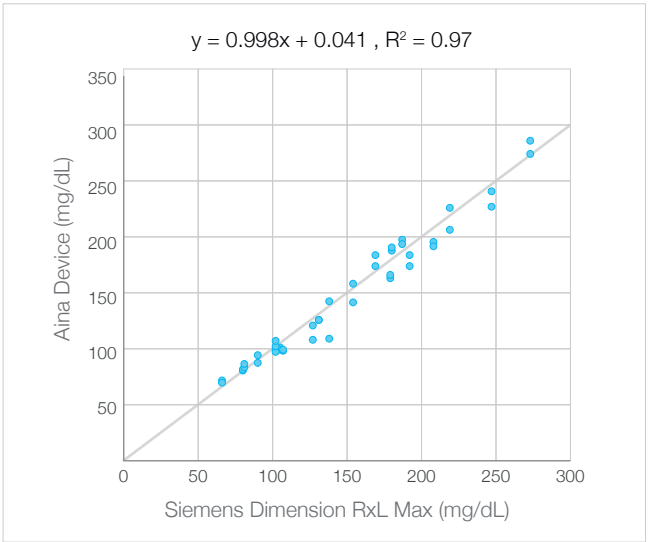

Figure 15. Comparison of performance between Aina Device Triglycerides and Siemens Dimension RxL Max

Precision Evaluation

A precision evaluation was performed with venous whole blood samples with 3 operators in a single day and showed a CV under 5% at all Triglycerides concentrations.

Precision across operators		
Mean (mg/dL)	SD (mg/dL)	%CV
88.2	4.0	4.56
343.5	16.1	4.67

A precision evaluation was performed with control solutions over 15 days, with 2 runs per day, and showed a CV under 6.5% at all Triglycerides concentrations.

Precision across operators		
Mean (mg/dL)	SD (mg/dL)	%CV
127.5	5.8	4.58
194.3	12.3	6.35

II. CARE Hospitals (Hyderabad, India)

Reference method: Unicel DxC (Beckman Coulter)
Number of subjects: 100

Total Cholesterol

Accuracy Evaluation

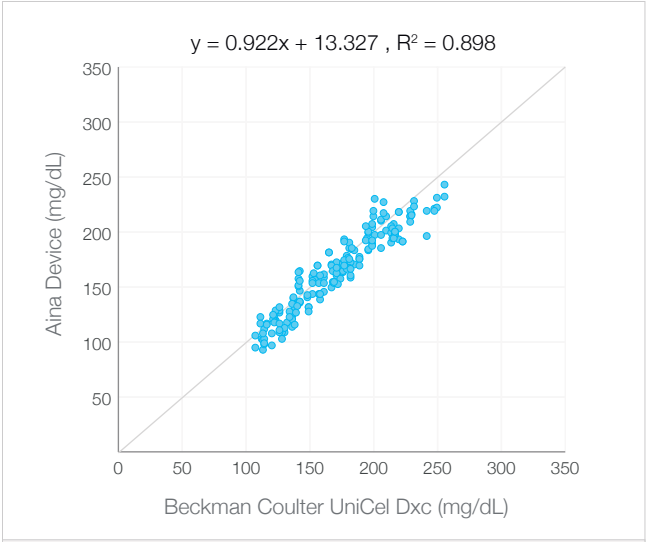

Figure 16. Comparison of performance between Aina Device Total Cholesterol and Beckman Coulter UniCel Dxc

The Aina Lipids Monitoring System for Total Cholesterol showed great linearity versus the laboratory reference (R^2 = 0.95). In addition, 100% of the samples were within 20% of the reference.

HDL Cholesterol

Accuracy Evaluation

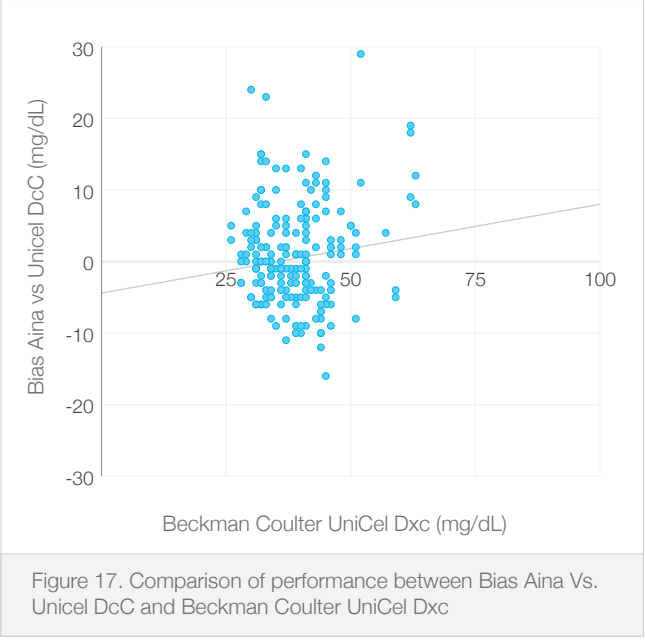

Figure 17. Comparison of performance between Bias Aina Vs. Unicel DcC and Beckman Coulter UniCel Dxc

The Aina Lipids Monitoring System for HDL Cholesterol 99% of the samples were within 15 mg/dL of the reference.

Triglycerides

Accuracy Evaluation

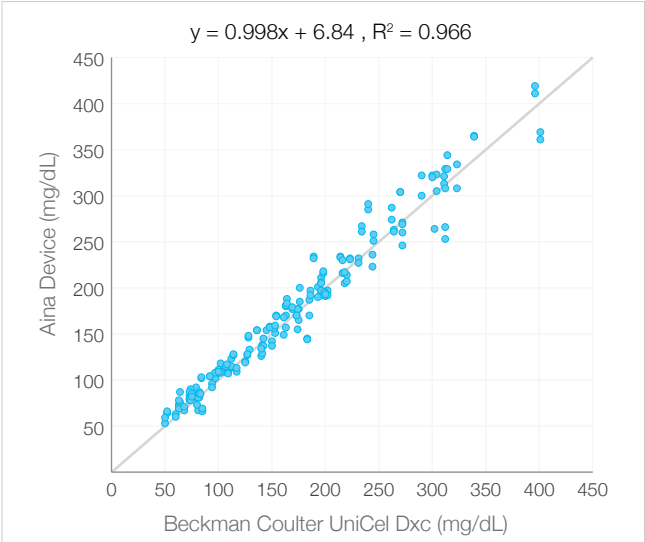

Figure 18. Comparison of performance between Aina Device Triglycerides and Beckman Coulter UniCel Dxc

The Aina Lipids Monitoring System for Triglycerides showed great linearity versus the laboratory reference (R^2 = 0.97). In addition, 95% of the samples were within 15 mg/dL or 15% of the reference.