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.

FDA CE CERTIFIED ISO 13485 HSA Health Sciences Authority ifcc International Federation of Clinical Chemistry and Laboratory Medicine NGSP

Jana Care

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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. The system is intended for clinical laboratory and point-of-care use to monitor long term glycemic control of persons previously diagnosed with diabetes or as an aid in the diagnosis of diabetes.

Test Principle

The Aina HbA1c Test utilizes the boronate affinity method. 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 glycated 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. The precipitate is evaluated by measuring the blue (glycated hemoglobin) and the red (total hemoglobin) color intensity respectively with the Aina Device, the ratio between them being proportional to the percentage of the glycated hemoglobin in the sample.

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	0.1
6.5	3.0	0.2
10.1	2.4	0.2
11.9	2.8	0.3
13.4	1.8	0.2

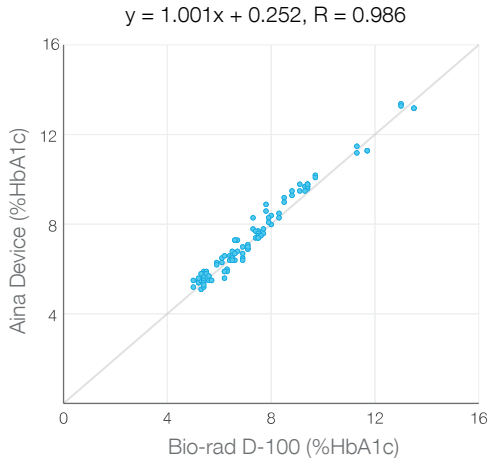
Clinical studies

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 = 0.986. 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.

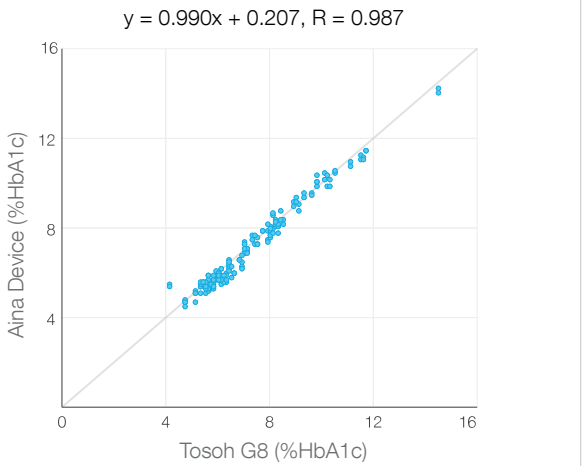
Control Level	Mean %HbA1c	Within Day		Total Precision	
		%CV	SD	%CV	SD
L1	6.5	2.9	0.2	3.2	0.2
L2	11.9	2.3	0.3	2.8	0.3

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 = 0.987. 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	0.1	3.1	0.2
L2	11.4	1.8	0.2	2.2	0.3

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.

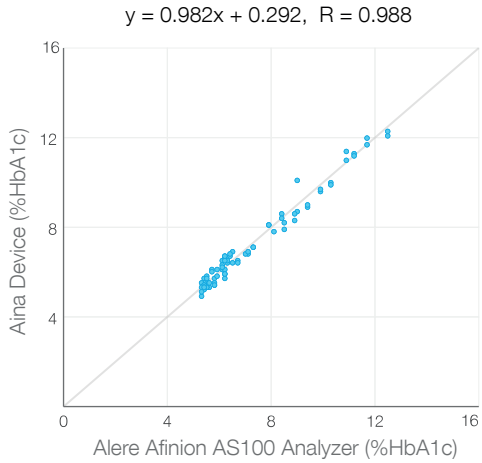
Control Level	Mean %HbA1c	Within Run		Total Precision	
		%CV	SD	%CV	SD
L1	5.2	1.9	0.1	2.5	0.1
L2	13.4	1.4	0.2	1.8	0.2

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.

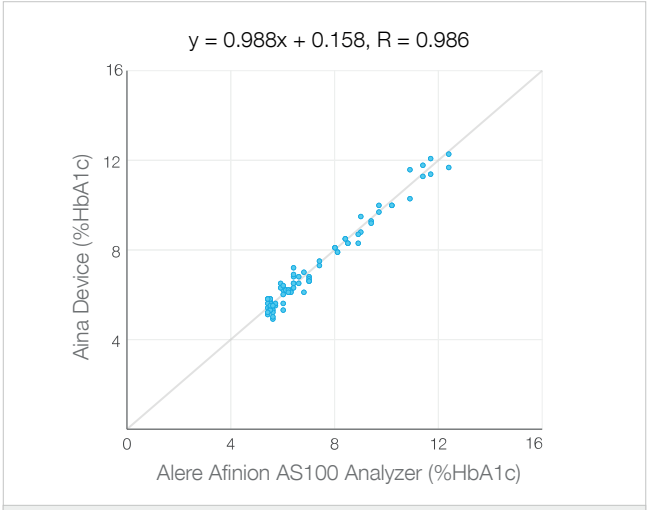
Accuracy Evaluation Performed Using Capillary Whole Blood Samples Against Alere Afinion AS100



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 R = 0.988.
- 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).

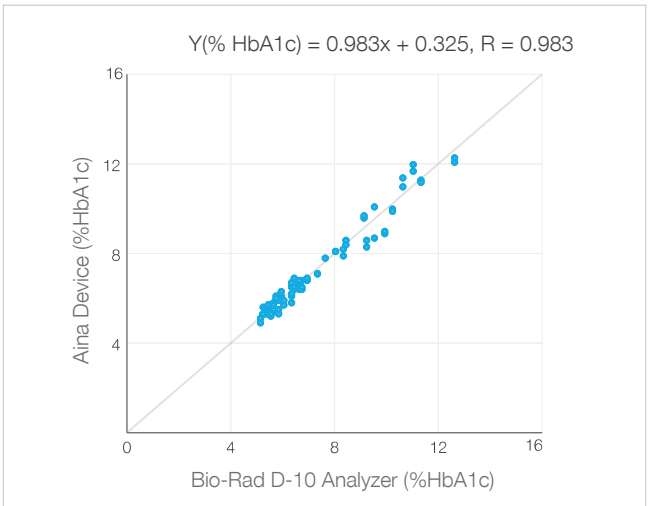
Accuracy Evaluation Performed Using Venous Whole Blood Samples Against Alere Afinion AS100



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 R = 0.986.
- 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).

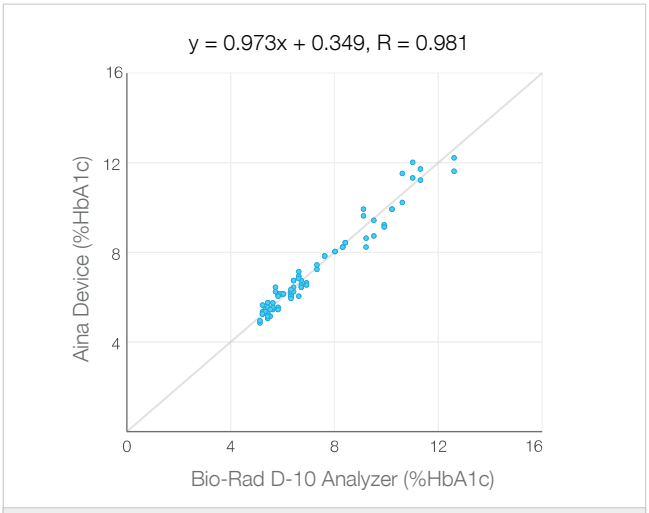
Accuracy Evaluation Performed Using Capillary Whole Blood Samples Against Bio-Rad D-10



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 R = 0.983.
- 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 R = 0.981.
- 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.

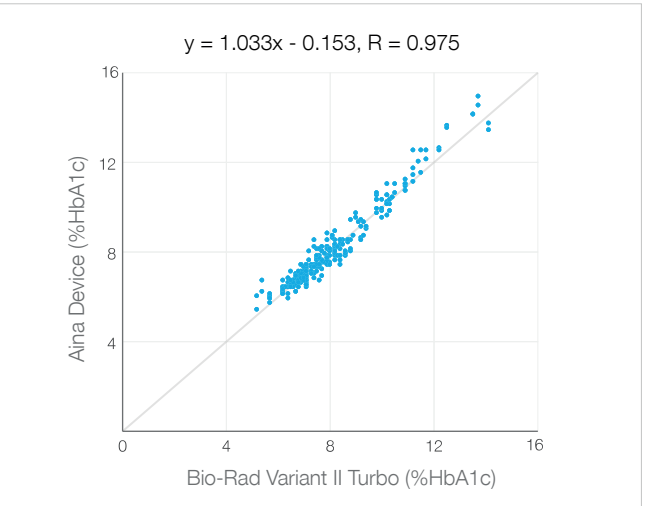
Blood Level	Mean %HbA1c	Total Precision	
		%CV	SD
L1	5.1	2.9	0.2
L2	6.5	3.0	0.2
L3	10.1	2.4	0.2

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

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

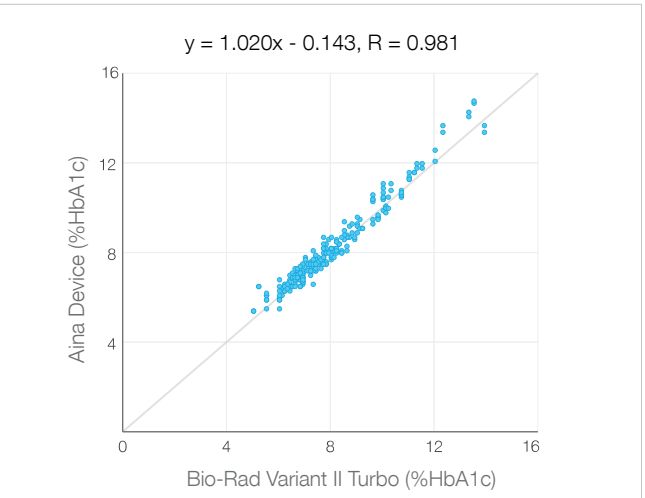
The Aina HbA1c Monitoring System showed excellent correlation and agreement when compared to the Bio-Rad Variant II Turbo for both capillary and venous blood samples.

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

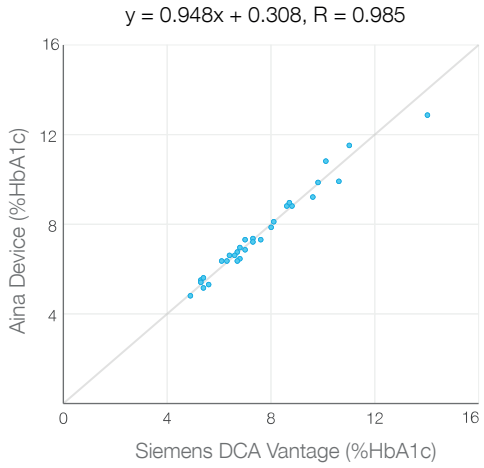
- The Aina HbA1c Monitoring System versus the Bio-Rad Variant II Turbo had a correlation of R = 0.975 for capillary samples and R = 0.981 for venous samples.
- 94.5% of individual measurements measured on the Aina HbA1c Monitoring System were within 10% of the reference method (Bio-Rad Variant II Turbo) 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 = 0.985).

Accuracy Evaluation Performed Using Capillary Whole Blood Samples



Comparison of performance between Aina Device and Siemens DCA Vantage

Aina HbA1c Monitoring System 2

The Aina HbA1c Monitoring System 2 is a FDA approved product manufactured in compliance with ISO 13485. The system is certified by the National Glycohemoglobin Standardization Program (NGSP) 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 2 is clinically validated at numerous reputed clinical sites across the world.

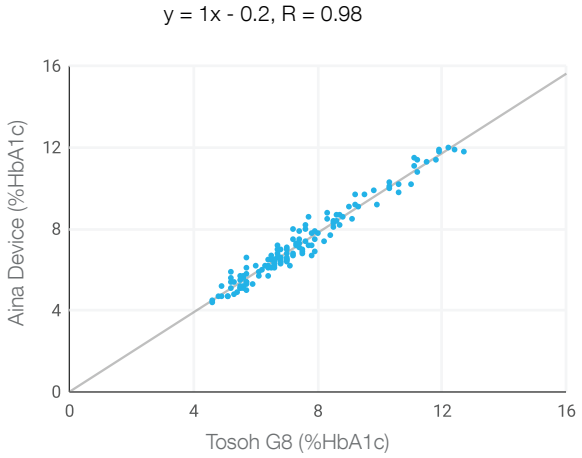
Clinical studies

A method comparison study was performed at three clinical sites in the United States. A total of 6 operators participated in the study and three systems were used.

Reference method: Tosoh G8
Number of subjects: 132

The Aina HbA1c Monitoring System 2 showed good correlation versus the Tosoh G8 reference analyser, with R = 0.98. 92% 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

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. The Aina Lipids Monitoring System is intended for clinical laboratory and point-of-care use to measure lipids for the diagnosis and treatment of disorders involving excess cholesterol in the blood as well as for lipid and lipoprotein metabolism disorders. This system is intended for clinical laboratory and point-of-care use by trained professionals.

Test Principle

The Aina Lipids Monitoring System is based on the 'Trinder method'. The intensity of the colour produced from this reaction is proportional to the levels of total cholesterol, HDL cholesterol and triglycerides in the blood.

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)

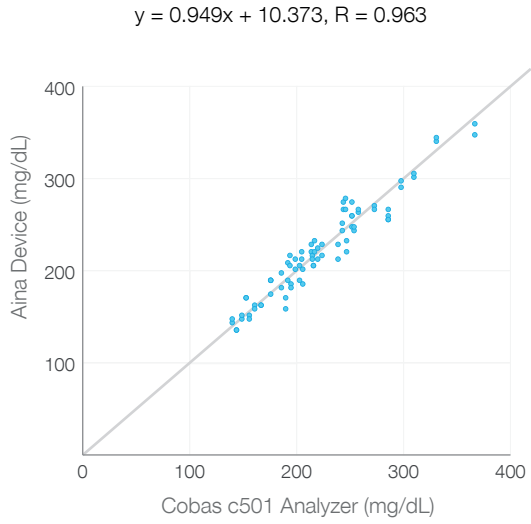
Clinical studies

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 = 0.963).
- 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).

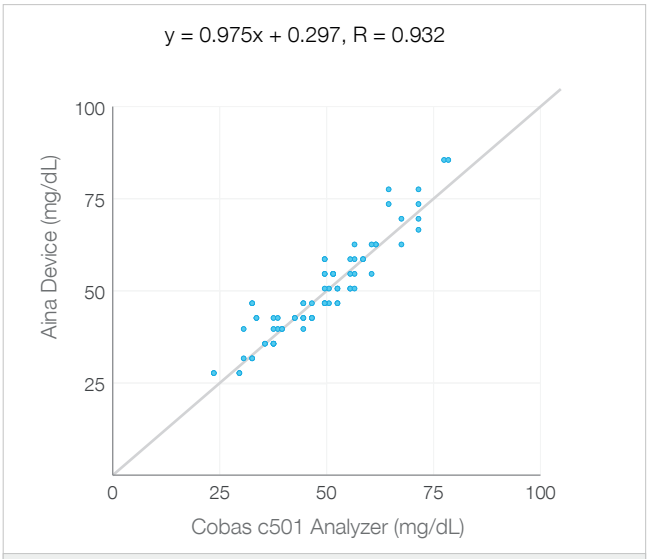
Precision Evaluation

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).

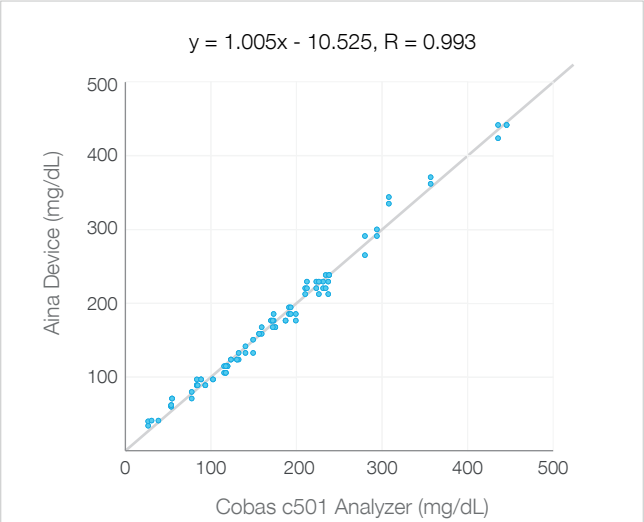
Precision Evaluation

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 = 0.993).
- 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.

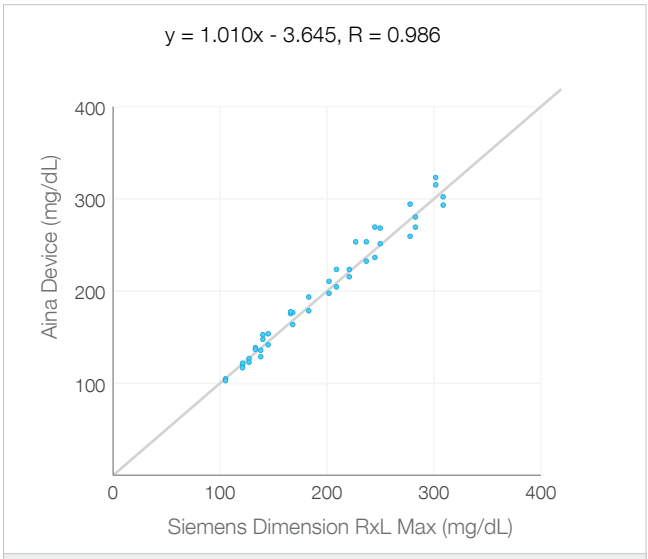
Control Level	Mean Value (mg/dL)	Within Day		Total Precision	
		%CV	SD	%CV	SD
L1	149	3.1	4.7	4.7	7.0
L2	235	3.6	8.4	4.7	11.1

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 = 0.986). 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.

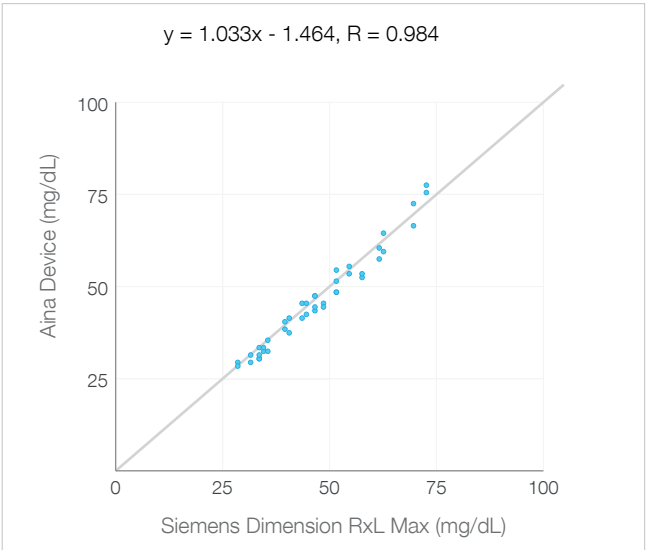
Blood Level	Mean Value (mg/dL)	Total Precision	
		%CV	SD
L1	128	3.9	5.0
L2	217	4.2	9.0

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 = 0.984). 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.

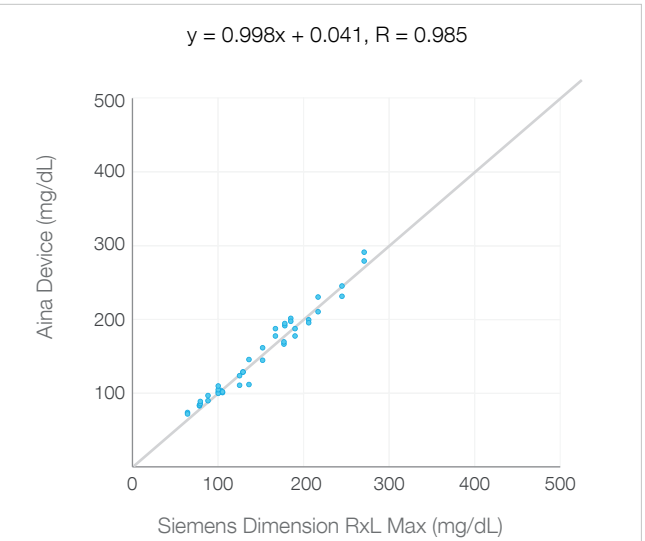
Blood Level	Mean Value (mg/dL)	Total Precision	
		%CV	SD
L1	29	3.0	0.9
L2	48	3.6	1.8

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 = 0.985). 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.

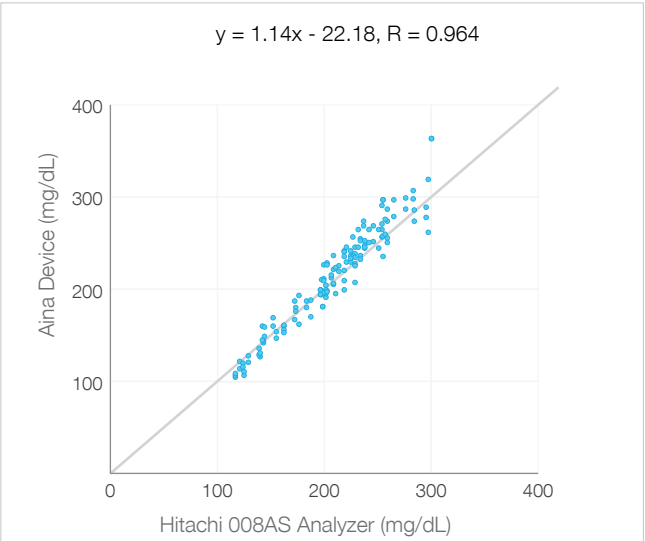
Control Level	Mean Value (mg/dL)	Within Day	Total Precision
		%CV	%CV
L1	145	4.7	4.7
L2	220	5.8	6.4

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 = 0.964).
- 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 Mini Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood from the finger and venous whole blood as an aid in monitoring the effectiveness of blood glucose control. The Aina Mini Blood Glucose Monitoring System is meant for in vitro diagnostic use by healthcare professionals in clinical settings and people with diabetes at home. The system is not intended for use in diagnosis or screening of diabetes mellitus. The system is not intended for testing neonate cord blood samples.

Specifications

Measuring range:
20 to 600 mg/dL
(1.1 to 33.3 mmol/L)

Test time:
Less than 10 seconds

Operating temperature:
10 to 35°C

Sample volume:
0.6 µL whole blood capillary or venous

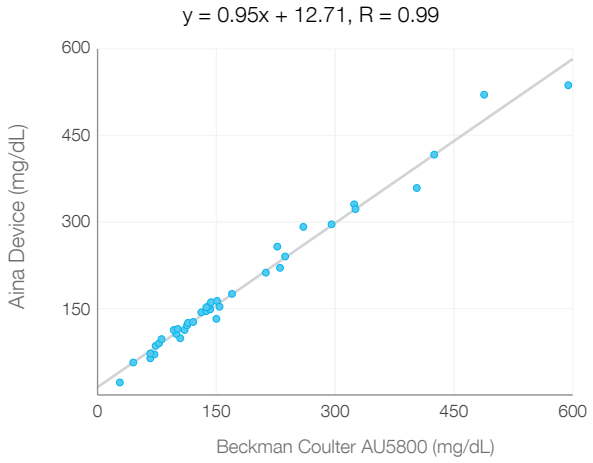
Test Principle

The Aina Mini Blood Glucose test is based on the measurement of electrical current caused by the reaction of glucose with the reagents on the electrode of the strip. The blood sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with FAD glucose dehydrogenase (FAD-GDH) and potassium ferricyanide. Electrons are generated, producing an electrical current that is proportional to the glucose in the sample. After the reaction time, the glucose concentration in the sample is displayed.

Performance Summary

The Aina Mini Blood Glucose Monitoring System is a CE marked product and manufactured in compliance with the highest quality standards in an ISO 13485 certified environment. The Aina Mini Blood Glucose Monitoring System is clinically validated at numerous reputed clinical sites such as National University Hospital, Singapore and Xiangya Hospital, China. The accuracy and precision achieved by the system are comparable to gold standard analyzers such as YSI 2300D STAT Plus and Beckman Coulter AU5800. A summary table of CVs across the glucose measuring range is provided below:

Mean Value (pg/mL)	SD	%CV
97	2.6	1.8
140	4.5	3.2
218	5.4	2.7
245	7.6	3.1
373	10.8	2.9
492	11.9	2.4



Comparison of performance between Aina Mini Blood Glucose Monitoring System and Beckman Coulter AU5800 for venous whole blood

A total of 40 subjects participated in this study, Aina Mini Blood Glucose Monitoring System vs Beckman Coulter AU5800 met the ISO 15197:2015 standard accuracy requirements with 100% of the measurements are within 15% or mg/dL of the reference measurement. The Aina Mini Blood Glucose Monitoring System showed a good correlation with R = 0.99 versus the Beckman Coulter AU5800.

Clinical studies

I. National University Hospital, Singapore

Method Comparison
Reference method: Beckman Coulter AU5800
Number of subjects: 40

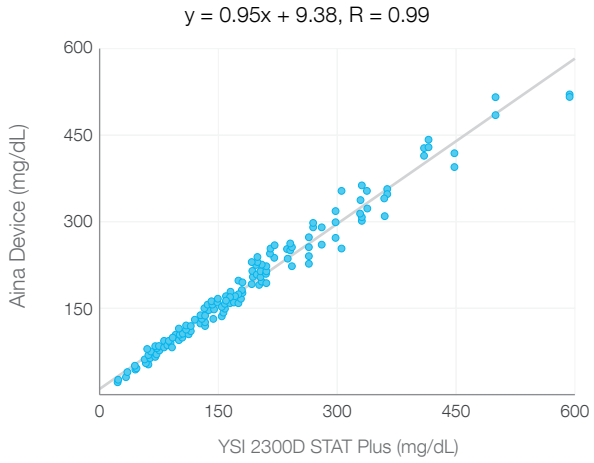
Precision Evaluation

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 5 days for a total of 25 measurements per level.

Control Level	Mean Value (mg/dL)	Within Day Precision		Total Precision	
		%CV	SD	%CV	SD
L1	97	1.0	1.8	2.6	1.8
L2	218	2.5	5.4	2.7	5.4

II. Xiangya Hospital, Changsha, China

Method Comparison
Reference method: YSI 2300D STAT Plus
Number of subjects: 100



Comparison of performance between Aina Mini Blood Glucose Monitoring System and YSI 2300D STAT Plus for capillary whole blood

A total of 100 subjects participated in this study and the data were collected in duplicates. The Aina Mini Blood Glucose Monitoring System vs YSI 2300D STAT Plus met the ISO 15197:2015 standard accuracy requirements with 96.5% of the measurements are within 15% or mg/dL of the average measured values of the reference measurement. The Aina Mini Blood Glucose Monitoring System showed a good correlation with R = 0.99 versus the YSI 2300D STAT Plus.

Precision Evaluation

A precision evaluation was performed with venous whole blood samples tested in 10 replicates and showed a CV under 4% at all Glucose concentrations.

Mean Value (mg/dL)	SD	%CV
41	2.5	-
92	3.2	3.5
140	4.5	3.2
245	7.6	3.1
373	10.8	2.9
492	11.9	2.4

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 by trained professionals 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:
4.5 to 23 g/dL

Test time:
30 seconds

Operating temperature:
10 to 40°C

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

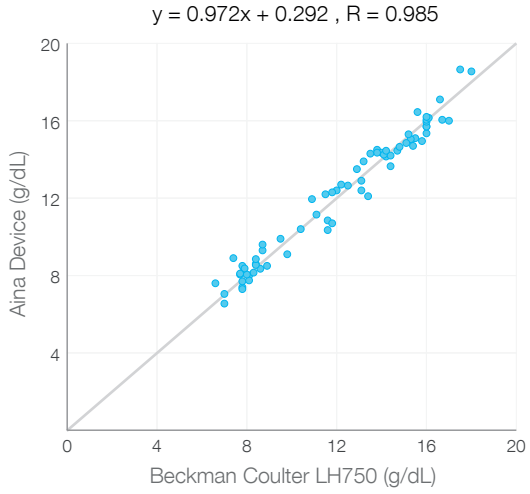
Performance Summary

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 = 0.985). 94.4% of the samples were within 10% of the reference and 97.2% were within 15% of the reference.

Precision Evaluation

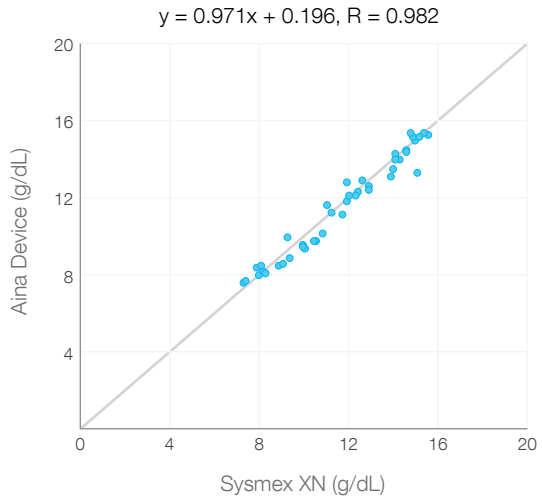
A precision evaluation was performed with control solutions for 20 days and showed a CV under 5% at all hemoglobin concentrations.

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 = 0.982). 97.6% of the samples were within 10% of the reference.



Comparison of performance between Aina Device and Sysmex XN

NT-proBNP

Intended Use

The Lambda NT-proBNP Monitoring System is intended to be used for the quantitative determination of N-terminal pro b-type natriuretic peptide (NT-proBNP) in human capillary fingerstick whole blood, venous whole blood, and plasma. The device may be used in conjunction with clinical evaluation as an aid in assessing the prognosis of patients diagnosed with heart failure (HF). This system is intended for clinical laboratory and point-of-care use by trained professionals.

Specifications

Measuring range:
- Whole blood: 500 - 10,000 pg/mL
- Serum/Plasma: 250 - 10,000 pg/mL

Test time:
13 minutes

Operating temperature:
20 to 30°C

Sample volume and types:
80 µL whole blood (capillary or venous), serum or plasma

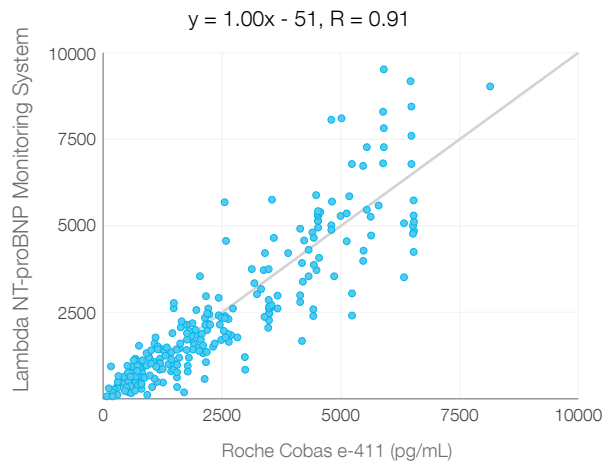
Test Principle

The Lambda NT-proBNP Test is a colloid gold-based immunoassay utilizing a double-antibody sandwich format. When sample is added to sample port, analyte in the sample reacts with anti NT-proBNP immunogold conjugate on the conjugate pad and forms an immune complex, which then flows onto the nitrocellulose. When the immunogold complex reaches the test band, it reacts with the anti NT-proBNP antibody pre-coated on the nitrocellulose and is fixed on the test band of the nitrocellulose. Signal intensity at the test line is directly proportional to the amount of NT-proBNP in the sample.

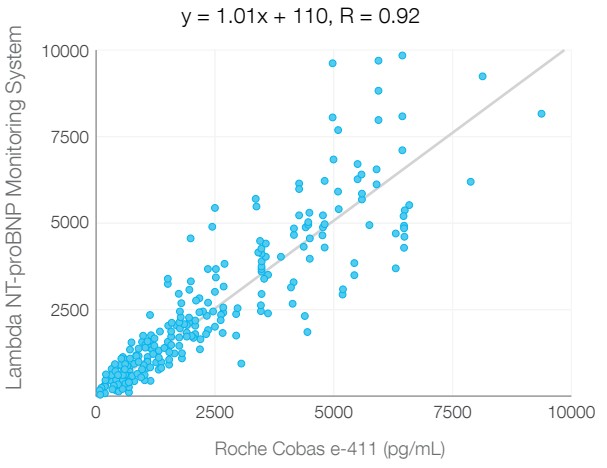
Clinical studies

Narayana Health Hospitals (Bangalore, India)

Method Comparison
Reference method: Roche Cobas e-411
Number of subjects: 615 (291 whole blood, 324 plasma)



Comparison of performance between Lambda NT-proBNP Monitoring System and the Roche Cobas e-411 for whole blood



Comparison of performance between Lambda NT-proBNP Monitoring System and the Roche Cobas e-411 for plasma

The Lambda NT-proBNP Monitoring System shows comparable performance to the Roche Cobas e-411 with a correlation of 0.91 and 0.92 for the whole blood and plasma samples respectively.

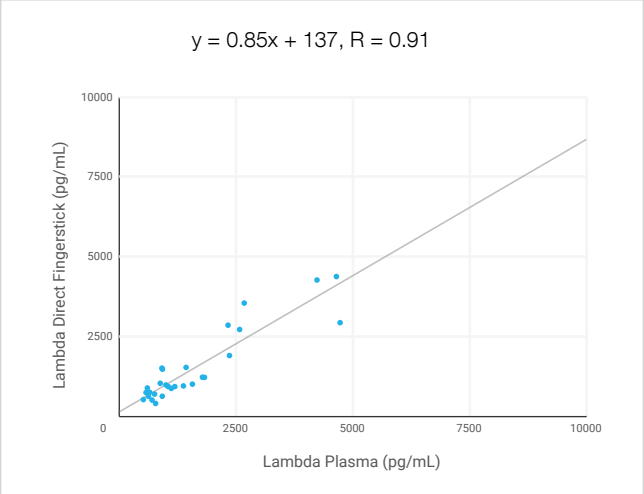
Precision Evaluation

A within-run precision evaluation was performed with venous whole blood and plasma samples in a single day and showed a CV under 12% at all NT-proBNP concentrations.

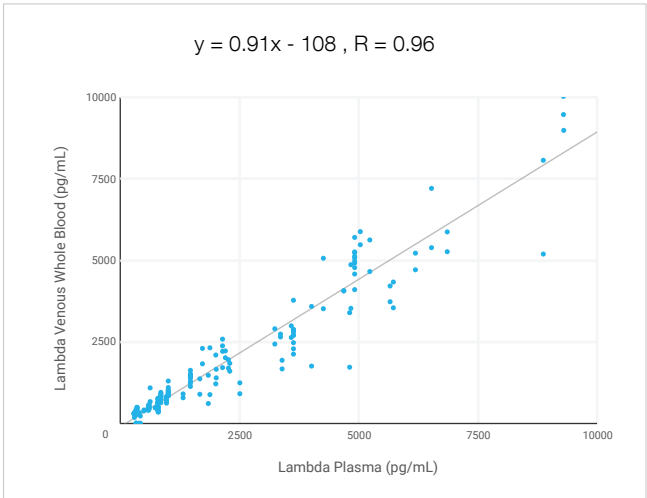
Whole blood sample level	Mean Value (pg/mL)	%CV
L1	667	7
L2	1251	7
L3	3134	11

Plasma sample level	Mean Value (pg/mL)	%CV
L1	448	7
L2	1577	7
L3	3516	9

Matrix Comparison



Comparison of Lambda NT-proBNP Monitoring System performance between direct fingerstick and plasma samples

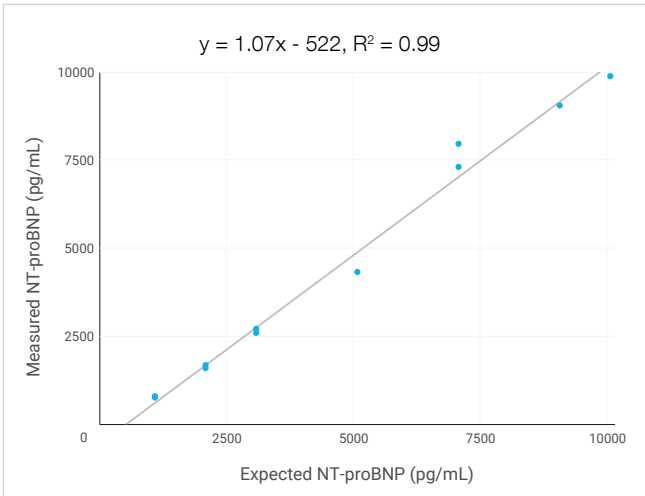


Comparison of Lambda NT-proBNP Monitoring System performance between venous whole blood and plasma samples

The Lambda NT-proBNP Monitoring System shows equivalent performance with direct fingerstick, venous whole blood and plasma samples.

Linearity Evaluation

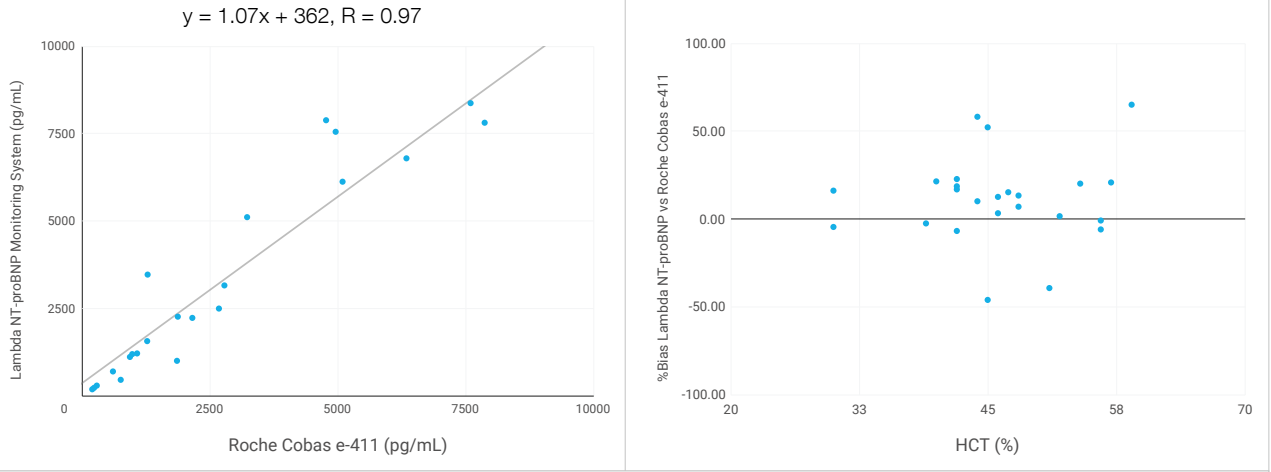
A linearity study was performed using 7 samples prepared by mixing 2 extreme samples in varying proportions. The system showed good linearity across the measuring range with an R^2 value of 0.99.



Comparison of measured and expected concentrations to evaluate the linearity of the Lambda NT-proBNP Monitoring System

Hematocrit Evaluation

Number of subjects: 25



Comparison of performance between Lambda NT-proBNP Monitoring System and the Roche Cobas e-411 with whole blood samples across various hematocrit concentrations

The performance of the Lambda NT-proBNP Monitoring System with whole blood samples against the Roche Cobas e-411 is consistent across hematocrit concentrations between 30% and 60%.

Jana Care

Jana Care, Inc.
8 Saint Mary's Street, Suite 936
Boston, MA 02215

Have a question?
Call us at
International: +1 (855) 809-9558
India: +91-8047092684 or
email us at support@janacare.com