

LipidPlus® Professional Test Strip Information

NOTE : Please carefully read detailed information included in the package insert for each type of LipidPlus® Professional Test Strip.

LIMITATIONS OF SYSTEM (for Lipid profile test):

Lipid Profile Test Strips provide accurate results when the following constraints are observed:

- Do not use neonate samples

Physicians - Please note the following factors that may affect test results:

- For use with capillary whole blood.
- Extremes in hematocrit may affect test results. Hematocrit levels less than 30% may cause falsely high readings and hematocrit levels greater than 55% may cause falsely low readings.
- Total cholesterol may be decreased by Dopamine and Gentisic acid.
- Triglycerides may be decreased by Dopamine, Methylopa and L-ascorbic-acid.
- HDL-cholesterol may be decreased by Dopamine and Gentisic acid.
- EDTA, Heparin containing tubes are recommended as an anticoagulant tube.

Performance Characteristics:

Performance for the Lipid Profile Test Strips was evaluated in laboratory and in clinical testing (Please refer to strip instructions for more detailed information). Testing Range: The test range for LipidPlus® Professional is 100~400mg/dL for Total Cholesterol, 25~80 mg/dL for HDL-Cholesterol and 70~600mg/dL for Triglycerides.

1) Accuracy

The accuracy of lipid profile results obtained with the LipidPlus® Professional Test System were compared to results obtained with a reference device. Lipid profile levels were measured for 1200 capillary whole blood specimens at three different centers.

Total Cholesterol

Sample Type	Slope	y-intercept	R ²
Capillary	1.0013	2.2025	0.9933

HDL-Cholesterol

Sample Type	Slope	y-intercept	R ²
Capillary	0.9935	1.2036	0.9935

Triglycerides

Sample Type	Slope	y-intercept	R ²
Capillary	1.0169	-0.2810	0.9983

2) Precision

- The precision of Total Cholesterol, HDL-Cholesterol and Triglycerides test results was measured over 20 days with three different levels in venous whole blood samples.

Total Cholesterol

Mean Conc. (mg/dL)	120.0	231.8	349.7
SD (mg/dL)	1.9	3.2	4.0
CV (%)	1.6	1.4	1.1

Triglycerides

Mean Conc. (mg/dL)	130.0	357.2	530.1
SD (mg/dL)	1.9	5.0	6.1
CV (%)	1.4	1.4	1.2

HDL-Cholesterol

Mean Conc. (mg/dL)	30.9	51.9	73.0
SD (mg/dL)	0.8	1.1	1.6
CV (%)	2.5	2.1	2.2

Lipid Profile

	Level 1			Level 2			Level 3		
	TC	TG	HDL	TC	TG	HDL	TC	TG	HDL
Mean(mg/dL)	118.9	128.5	31.5	236.0	357.6	50.2	348.0	529.0	71.2
SD(mg/dL)	2.1	2.2	0.7	3.4	4.3	1.1	5.0	6.0	1.5
CV(%)	1.8	1.7	2.3	1.4	1.2	2.2	1.4	1.1	2.1

- The precision of Total Cholesterol, HDL-Cholesterol and Triglycerides test results was measured with two control solutions for 20 days.

Total Cholesterol

Mean Conc. (mg/dL)	150.3	250.6
SD (mg/dL)	2.2	3.6
CV (%)	1.5	1.4

HDL-Cholesterol

Mean Conc. (mg/dL)	59.9	29.9
SD (mg/dL)	1.3	0.8
CV (%)	2.1	2.7

Triglycerides

Mean Conc. (mg/dL)	120.5	250.5
SD (mg/dL)	2.9	2.8
CV (%)	2.4	1.1

LipidPlus® Professional Test Strip Information

NOTE: Please carefully read detailed information included in the Instructions for Use for each type of LipidPlus® Professional Test Strip

LIMITATIONS OF SYSTEM (for Glucose test):

The LipidPlus® Professional Glucose Test Strips provide accurate results when the following constraints are observed:

- Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- Inaccurate low results may occur for individuals experiencing a hyperglycemic hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
- Use only the LipidPlus® Professional Glucose Test Strips with the LipidPlus® Professional Meter.
- Use fresh capillary whole blood only.
- Do not use neonate samples.
- Test Strips are for single use only. Do not reuse.
- Dehydration may be a cause of higher test results.
- Using glucose test strip above an altitude of 10,000 feet will have an effect on test results.

Physicians - Please note the following conditions that may affect test results:

- Extremes in hematocrit may affect test results. Hematocrit levels less than 30% may cause falsely high readings. Hematocrit levels greater than 55 % may cause falsely low readings.
- Interference: Acetaminophen, Uric acid, Ascorbic acid (Vitamin C), and other reducing substances when occurring in normal blood or normal therapeutic concentrations do not significantly affect results. However, abnormally high concentrations may cause inaccurately high results.
- Lipemic samples; Cholesterol up to 500 mg/dL or triglycerides up to 3000 mg/dL do not significantly affect the results. Values beyond these levels should be interpreted with caution.
- Blood samples that contain a high concentration of dissolved oxygen may lower the test result.
- EDTA containing tube is recommended as an anticoagulant tube.

Performance Characteristics:

The performance of the glucose test strips has been evaluated in laboratory and in clinical testing.

Measurement Range: The measurement range for LipidPlus® Professional Glucose Testing is 20 to 600 mg/dL.

Accuracy:

The accuracy results obtained with the LipidPlus® Professional Lipid Profile and Glucose Measuring System were compared to glucose results obtained with the Hitachi Glucose Auto meter 747, a laboratory instrument. Glucose levels were measured on 160 patients at three different clinical centers.

System accuracy results for glucose concentration < 75 mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
27/27 (100%)	27/27 (100%)	27/27 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
100/133 (75%)	130/133 (98%)	133/133 (100%)	133/133 (100%)

Alternate Site Testing Accuracy:

Glucose test results obtained from alternate sites were compared to the glucose results obtained with the Hitachi Glucose Auto Meter 747 (reference method), a laboratory instrument. Glucose levels were measured at three different clinical centers.

Test results for **DORSAL HAND** were compared to the reference method.

System accuracy results for glucose concentration < 75 mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
4/5 (80%)	5/5 (100%)	5/5 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
112/145(77%)	143/145 (99%)	145/145 (100%)	145/145 (100%)

Test results for **VENTRAL PALM** were compared to the reference method.

System accuracy results for glucose concentration < 75 mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
4/5 (80%)	5/5 (100%)	5/5 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
111/145 (77%)	143/145 (99%)	145/145 (100%)	145/145 (100%)

Test results for **UPPER ARM** were compared to the reference method.

System accuracy results for glucose concentration < 75mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
4/5 (80%)	5/5 (100%)	5/5 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
109/145(75%)	143/145 (99%)	145/145 (100%)	145/145(100%)

Test results for **FOREARM** were compared to the reference method.

System accuracy results for glucose concentration < 75mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
4/5(80%)	5/5 (100 %)	5/5 (100 %)

System accuracy results for glucose concentration ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
95/145(66%)	137/145 (94%)	143/145 (99%)	145/145(100%)

Test results for **THIGH** were compared to the reference method.

System accuracy results for glucose concentration < 75mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
3/5(60%)	5/5 (100%)	5/5 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Within ± 5mg/dL	Within ±10%	Within ±15%	Within ±20%
103/145(71%)	137/145 (94%)	144/145 (99%)	145/145(100%)

Test results for **CALF** were compared to the reference method.

System accuracy results for glucose concentration < 75mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
2/5(40%)	5/5 (100 %)	5/5 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
100/145(69%)	138/145 (95%)	145/145 (100%)	145/145(100%)

Precision:

Repeatability evaluation for venous blood samples.

Mean (mg/dL)	45.0	84.7	130.8	206.2	341.8
CV (%)	3.1	2.1	2.2	2.6	2.4

Intermediate evaluation for control solutions.

Mean (mg/dL)	49.7	100.5	300.3
CV (%)	2.3	1.7	0.7