1. VivaChek Ino Blood Glucose Test Strips

Raw Material	Quantity	Description
Glucose Oxidase	<25Iu	1 test
Mediator	<300ug	
Buffer Solution	< 1.5mg	
Non-reactive Ingredient	<50ug	

2 VivaChek Ino Blood Glucose Meter

Material name	%
ABS (Shell)	38.9%
Silicone (Rubber Button)	3.4%
PMMA (Lens)	9.1%
Steel (Screw)	1.2%
E-glass, oxide, chemicals (PCB)	25.0%
SiO_2 (LCD)	21.2%
Stainless Steel (Battery Contact)	0.6%
Paper, Printing Ink, Other	0.6%

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Specification

Test range	10-600 mg/dL (0.6-33.3 mmol/L)
Result calibration	Plasma-equivalent
Sample type	Fresh capillary whole blood
Enzyme	Glucose Oxidase
Sample size	About 0.5 μL
Testing time	About 5 seconds
Operation temperature	5°C - 45°C (41°F - 113°F)
Operation humidity	10% - 90%
Hematocrit range	20-70%
Battery	2 x coin batteries
Battery life	Over 1,000 tests
Memory	900 results with time and date
Data transfer port	Micro USB

Limitations

The VivaChek™ Ino meter, test strips and control solution have been designed, tested and proven to work together effectively to provide accurate blood glucose measurements. Do not use components from other brands.

Fresh capillary blood may be collected into test tubes containing sodium heparin, lithium heparin if the blood is used within 10 minutes. Do not use sodium fluoride/oxalate or other anticoagulants or preservatives.

Use only with whole blood. Do not use with serum or plasma samples.

Very high (above 70%) and very low (below 20%) hematocrit levels can cause false results. Talk to your doctor or health care professional to find out your hematocrit level.

Abnormally high levels (above 3 mg/dL) of vitamin C and other reducing substances will produce false high blood glucose measurements.

The system is tested to accurately read the measurement of glucose in whole blood within the range of 10 to 600 mg/dL (0.6-33.3 mmol/L).

Fatty substances (triglycerides up to 3,000 mg/dL (166.7 mmol/L) or cholesterol up to 500 mg/dL (27.7 mmol/L) have no major effect on blood glucose test results.

The VivaChek™ Ino Blood Glucose Monitoring System has been tested and shown toNwork properly up to 10,000ft (3,048 meters).

Severely ill persons should not run the glucose test with the VivaChek™ Ino Blood Glucose Monitoring System.

Patients using oxygen therapy are not recommended for testing with VivaChek™ Ino Blood Glucose Monitoring System.

Blood samples from patients in shock, or with severe dehydration or from patients in a hyperosmolar state (with or without ketosis) have not been tested and are not recommended for testing with VivaChek™ Ino Blood Glucose Monitoring System.

Dispose of blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow proper precautions and obey all local regulations when disposing of materials.

PERFORMANCE CHARACTERISTICS

The VivaChek™ Ino meter is calibrated by using YSI (Model 2300 STAT PLUS) Glucose Analyzer reference instrument, which is traceable to NIST reference standard.

Repeatability, Precision

Repeatability-Blood		
Interval	Glucose concentration	Standard Deviation (SD) or Coefficient of Variation (CV)
1	40 mg/dL (2.2 mmol/L)	1.5 mg/dL (0.083 mmol/L)
2	80 mg/dL (4.4 mmol/L)	2.6 mg/dL (0.14 mmol/L)
3	130 mg/dL (7.2 mmol/L)	2.5%
4	200 mg/dL (11.1 mmol/L)	3.0%
5	325 mg/dL (18.1 mmol/L)	2.6%
Intermediate Precision-Control Solution		
Interval	Glucose concentration	Standard Deviation (SD) or Coefficient of Variation (CV)
1	40 mg/dL (2.2 mmol/L)	2.0 mg/dL (0.11 mmol/L)
2	120 mg/dL (6.7 mmol/L)	2.8%
3	350 mg/dL (19.4 mmol/L)	2.6%

System Accuracy

The capillary blood glucose measurements from 120 participants were taken by a trained technician using the VivaChek™ Ino Blood Glucose Meter (y). Capillary blood samples were obtained from fingertip, palm and forearm sampling sites for the VivaChek™ Ino Blood Glucose Meter testing. Fingertip samples from the same subjects were also analyzed with YSI Model 2300 STAT PLUS Glucose Analyzer (x). The results were compared.

Linear Regression Results: VivaChek™ Ino (y) vs. YSI Reference (x)				
Sample Site	Slope	Intercept (mg/dL)/ (mmol/L)	R	N
Fingertip	0.9847	1.4981/0.0832	0.9969	240
Palm	1.0101	-0.0441/-0.0025	0.9950	202
Forearm	1.0034	-0.0706/-0.0039	0.9935	202

Fingertip samples were used for YSI reference measurement.

The sample range was 23.3 to 534 mg/dL (1.3 to 29.7 mmol/L) for VivaChek™ Ino Blood Glucose Meter testing with blood sampled from fingertip sites. The sample range was 50.4 to 376 mg/dL (2.8 to 20.9 mmol/L) for VivaChek™ Ino Blood Glucose Meter testing with blood sampled from palm and forearm sites.

Fingertip Site: System Accuracy Results for Glucose Concentration ≥ 100 mg/dL (5.5 mmol/L)		
Within ± 5%	Within ± 10%	Within ± 15%
142/178 (79.8%)	177/178 (99.4%)	178/178 (100%)
Fingertip Site: System Accuracy Results for Glucose Concentration < 100 mg/dL (5.5 mmol/L)		
Within ± 5 mg/dL (0.28 mmol/L)	Within ± 10 mg/dL (0.56 mmol/L)	Within ± 15 mg/dL (0.83 mmol/L)
56/62 (90.3%)	62/62 (100%)	62/62 (100%)

Palm Site: System Accuracy Results for Glucose Concentration ≥ 100 mg/dL (5.5 mmol/L)		
Within ± 5%	Within ± 10%	Within ± 15%
122/160 (76.3%)	149/160 (93.1%)	159/160 (99.4%)
Palm Site: System Accuracy Results for Glucose Concentration < 100 mg/dL (5.5 mmol/L)		
Within ± 5 mg/dL (0.28 mmol/L)	Within ± 10 mg/dL (0.56 mmol/L)	Within ± 15 mg/dL (0.83 mmol/L)
30/42 (71.4%)	42/42 (100%)	42/42 (100%)

Forearm Site: System Accuracy Results for Glucose Concentration ≥ 100 mg/dL (5.5 mmol/L)		
Within ± 5%	Within ± 10%	Within ± 15%
115/160 (71.9%)	147/160 (91.9%)	158/160 (98.8%)
Forearm Site: System Accuracy Results for Glucose Concentration < 100 mg/dL (5.5 mmol/L)		
Within ± 5 mg/dL (0.28 mmol/L)	Within ± 10 mg/dL (0.56 mmol/L)	Within ± 15 mg/dL (0.83 mmol/L)
31/42 (73.8%)	39/42 (92.9%)	42/42 (100%)