Technical Bulletin

Blood Glucose, DBS

Self-Collection Capillary Blood Microsample Method.

Performance Characteristics

● Within-Run Precision

Within-run precision was determined by testing microsamples containing two concentrations of Glucose. Each of the microsamples was tested ten times:

Glucose (mg/dL)	Standard Deviation	Coefficient of Variation (%)
104.7	5.4	5.2
155.8	5.0	3.2

● Clinical Sensitivity and Specificity

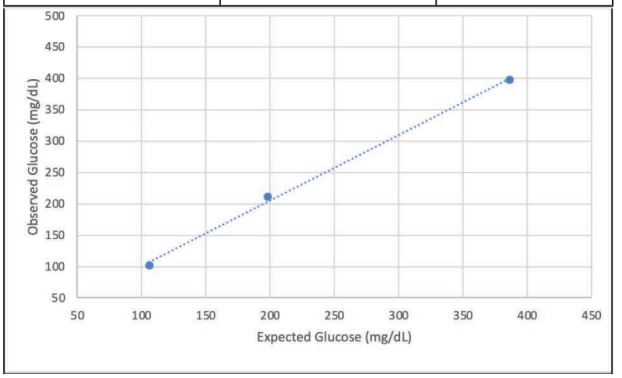
Clinical sensitivity and specificity were determined by testing paired venous samples and capillary blood microsamples from 30 donors and the results evaluated at a cut-off value of 105 mg/dL:

N=30	Capillary Glucose ≥ 105 mg/dL	Capillary Glucose < 105 mg/dL
Venous Glucose		
≥ 105 mg /dL	6	1
< 105 mg/dL	0	23

● Linearity

Capillary blood samples containing different levels of Glucose, expanding throughout the reportable range, were selected and the assay was performed in triplicate:

Observed Glucose (mg/dL)	Expected Glucose (mg/dL)	Recovery (%)
397.1	386.0	102.9
211.8	198.0	107.0
101.3	106.0	95.6



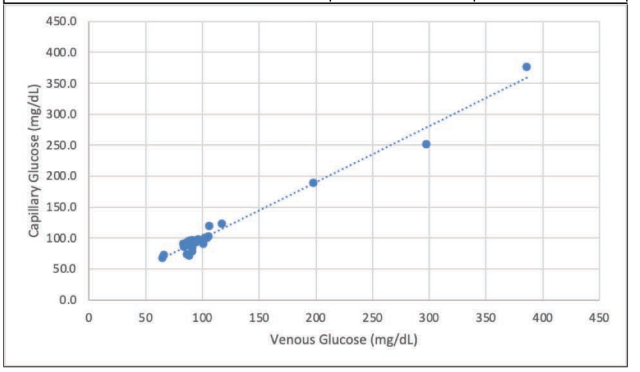
● Microsample Stability

Glucose dried blood microsamples are stable for two weeks when stored at ambient temperature during regular shipping and handling conditions.

● Accuracy

Paired venous samples, and capillary blood microsamples containing varying concentrations of Glucose, were tested. Glucose concentration observed for the dried blood microsamples versus venous (enzymatic colorimetric method) were statistically analyzed by simple regression.

N=30		
Correlation Coefficient		0.9798
Slope		0.9115
Intercept		7.58
	Microsample	Comparable Standard Method
Mean Value of Glucose	112.0	114.6
Standard Deviation of Range	64.87	70.4



● Sample Requirements

The Blood Glucose dried blood microsample test requires capillary blood placed into a Microcollection device. The device is then placed in the return box and mailed to the laboratory for analysis.

● Convenience and Simplicity

Simple stepwise instructions are provided to health awareness participants for collection of a Microsample using a finger lancet:

1. The collection kit is provided
2. Participant deposits 5 blood drops into transport device
3. The Microsample is mailed to the laboratory

● Interpretation

Blood Glucose levels greater than 105 mg/dL (fasting conditions) or 125 mg/dL (non-fasting conditions) are associated with an increased risk of developingtype II diabetes. Results may reflex to a Hemoglobin A1c test.