

Blood Creatinine, DBS

Self-Collection Capillary Blood Microsample Method.

Performance Characteristics

● Within-Run Precision

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

Creatinine (mg/dL)	Standard Deviation	Coefficient of Variation (%)
0.8	0.01	1.3
6.0	0.06	0.9

● Clinical Sensitivity and Specificity

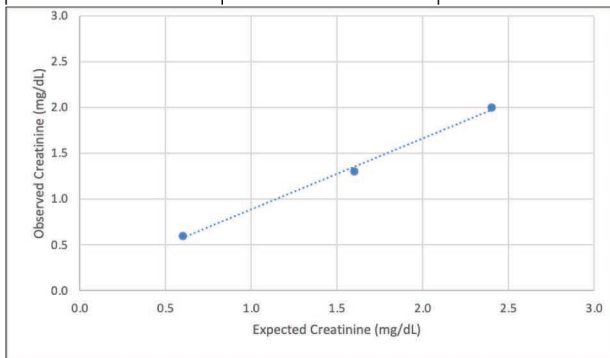
Clinical sensitivity and specificity were determined by testing paired venous samples and capillary blood microsamples from 30 donors and the results evaluated at a cut-off value of 1.4 mg/dL:

N=30	Capillary Creat ≥ 1.4 mg/dL	Capillary Creat < 1.4 mg/dL
Venous Creatinine ≥ 1.4 mg/dL	7	0
Venous Creatinine < 1.4 mg/dL	2	21

● Linearity

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

Observed Creatinine (mg/dL)	Expected Creatinine (mg/dL)	Recovery (%)
0.6	0.6	100.0
1.3	1.6	81.3
2.0	2.4	83.3



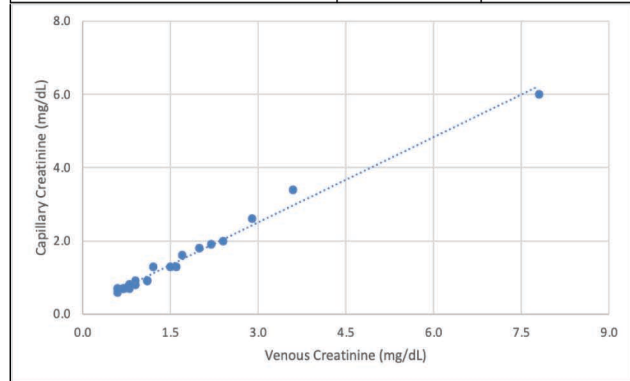
● Microsample Stability

Creatinine 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 blood Creatinine, were tested. Creatinine concentrations observed for the dried blood microsamples versus venous (enzymatic colorimetric method) were statistically analyzed by simple regression.

N=30		
Correlation Coefficient	0.9881	
Slope	0.7739	
Intercept	0.1837	
	Microsample	Comparable Standard Method
Mean Value of Creatinine	1.4	1.5
Standard Deviation of Range	1.2	1.5



● Sample Requirements

The Creatinine 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

Creatinine levels greater than 1.4 mg/dL are associated with chronic kidney damage.