

Total Cholesterol, DBS

Self-Collection Capillary Blood Microsample Method.

Performance Characteristics

● Within-Run Precision

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

Cholesterol (mg/dL)	Standard Deviation	Coefficient of Variation (%)
218.9	4.3	2.0
157.8	1.5	0.9

● Clinical Sensitivity and Specificity

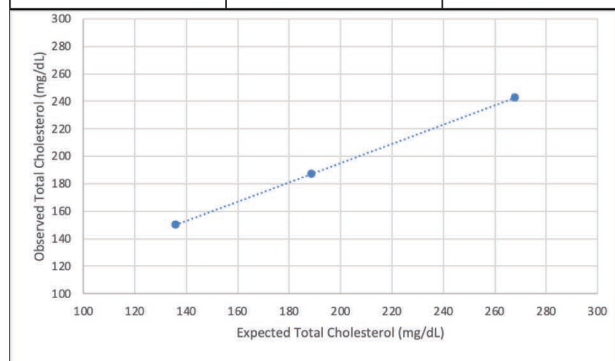
Clinical sensitivity and specificity were determined by testing paired venous samples and capillary blood microsamples from 50 donors and the results evaluated at a cut-off value of 240 mg/dL:

N=50	Capillary Chol ≥ 240 mg/dL	Capillary Chol < 240 mg/dL
Venous Cholesterol ≥ 240 mg/dL	13	4
Venous Cholesterol < 240 mg/dL	1	32

● Linearity

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

Observed Cholesterol (mg/dL)	Expected Cholesterol (mg/dL)	Recovery (%)
150.2	135.9	110.5
187.2	188.5	99.3
242.7	267.8	90.6



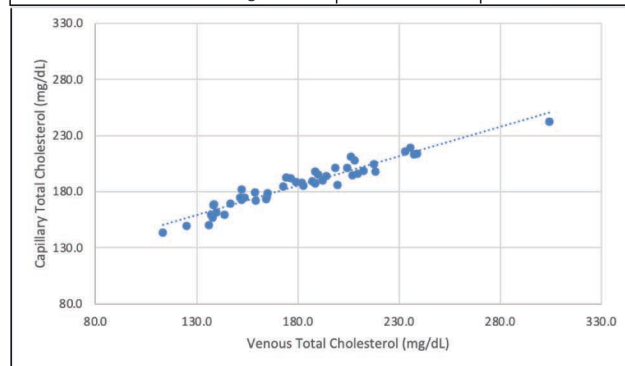
● Microsample Stability

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

N=50		
Correlation Coefficient	0.9200	
Slope	0.5251	
Intercept	91.137	
	Microsample	Comparable Standard Method
Mean Value of Cholesterol	186.1	180.8
Standard Deviation of Range	20.3	37.2



● Sample Requirements

The Cholesterol 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

Total Cholesterol levels greater than 240 mg/dL are associated with an increased risk of cardiovascular disease.