

HDL-Cholesterol (HDL-C), DBS

Self-Collection Capillary Blood Microsample Method.

Performance Characteristics

● Within-Run Precision

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

HDL-C (mg/dL)	Standard Deviation	Coefficient of Variation (%)
51.9	1.6	3.0
76.7	1.9	2.4

● Clinical Sensitivity and Specificity

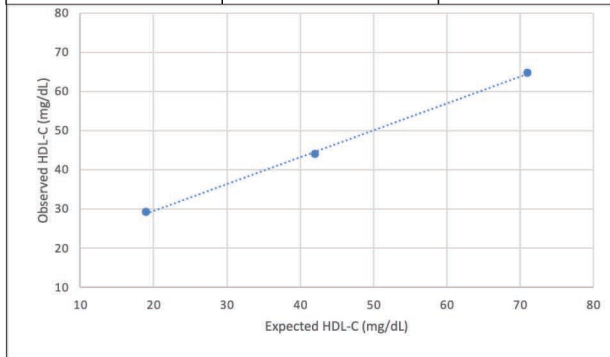
Clinical sensitivity and specificity were determined by testing paired venous samples and capillary blood microsamples from 30 donors and the results evaluated at a cut-off value of 40 mg/dL:

N=30	Capillary HDL-C ≥ 40 mg/dL	Capillary HDL-C < 40 mg/dL
Venous HDL-C ≥ 40 mg/dL	24	0
Venous HDL-C < 40 mg/dL	0	6

● Linearity

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

Observed HDL-C (mg/dL)	Expected HDL-C (mg/dL)	Recovery (%)
29.2	19.0	153.6
44.0	42.0	104.7
64.9	71.0	91.4



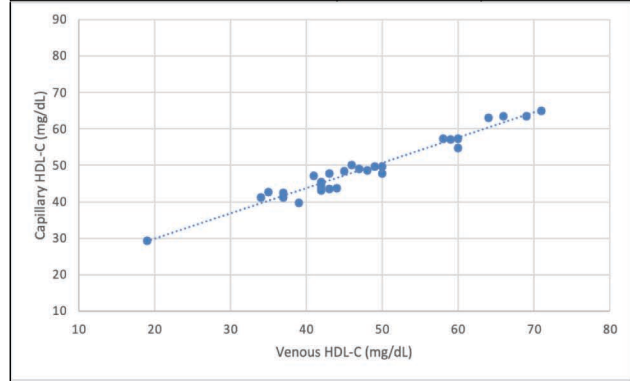
● Microsample Stability

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

N=30		
Correlation Coefficient	0.9557	
Slope	0.6963	
Intercept	15.934	
	Microsample	Comparable Standard Method
Mean Value of HDL-C	49.0	47.7
Standard Deviation of Range	8.3	11.7



● Sample Requirements

The HDL-C 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

HDL-C levels less than 40 mg/dL are associated with an increased risk of cardiovascular disease.