

Ferritin, DBS

Self-Collection Capillary Blood Microsample Method.

Performance Characteristics

● Within-Run Precision

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

Ferritin (ng/mL)	Standard Deviation	Coefficient of Variation (%)
132.1	8.9	6.7
181.7	17.6	9.7

● Clinical Sensitivity and Specificity

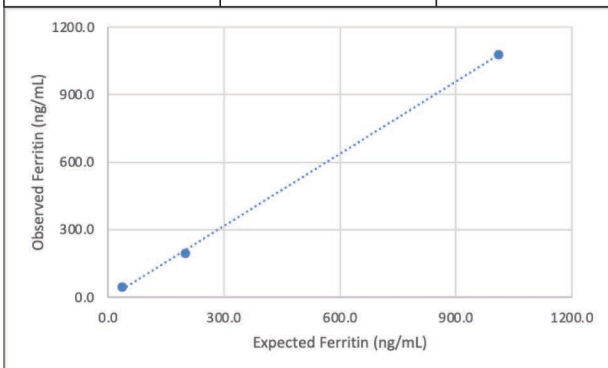
Clinical sensitivity and specificity were determined by testing paired venous samples and capillary blood microsamples from 25 donors and the results evaluated at a cut-off value of 400 ng/mL:

N=25	Capillary Ferritin ≥ 400 ng/mL	Capillary Ferritin < 400 ng/mL
Venous Ferritin ≥ 400 ng/mL	5	0
Venous Ferritin < 400 ng/mL	1	19

● Linearity

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

Observed Ferritin (ng/mL)	Expected Ferritin (ng/mL)	Recovery (%)
46.8	36.6	127.9
195.9	198.9	98.5
1078.1	1010.0	106.7



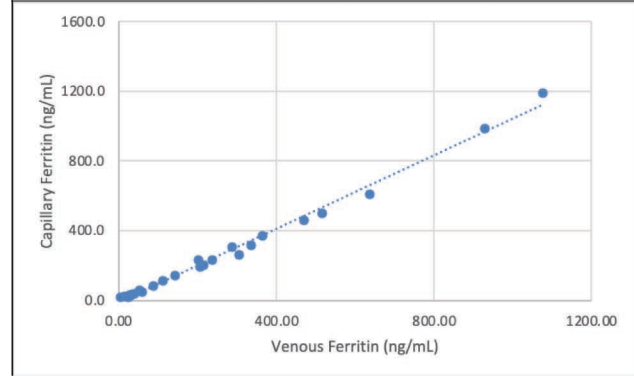
● Microsample Stability

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 Ferritin, were tested. Ferritin concentrations observed for the dried blood microsamples versus venous (enhanced chemiluminescence method) were statistically analyzed by simple regression.

N=25		
Correlation Coefficient	0.9900	
Slope	1.0600	
Intercept	- 11.2000	
	Microsample	Comparable Standard Method
Mean Value of Ferritin	259.1	256.1
Standard Deviation of Range	300.6	283.8



● Sample Requirements

The Ferritin 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

Ferritin levels under 20 ng/mL are considered deficient, and concentrations over 400 ng/mL are considered iron overload. Repeated test results over 1,000 ng/mL suggest hereditary hemochromatosis.