

# BIOSAFE Laboratories, Inc.

Technical Bulletin

## Total Cholesterol

Enhanced Blood Collection and Transport System  
Performance Characteristics

### Within-Run Precision

Within-run precision was determined by assaying dried blood spots containing various concentrations of cholesterol. Each of the dried blood spot specimens was assayed in replicates of two in twenty individually calibrated runs. The data are presented below.

Mean Total Cholesterol (mg/dL)	Standard Deviation	% Coefficient of Variation
153	5.1	3.3%
196	7.3	3.7%
263	10.1	3.8%

### Between-Run Precision

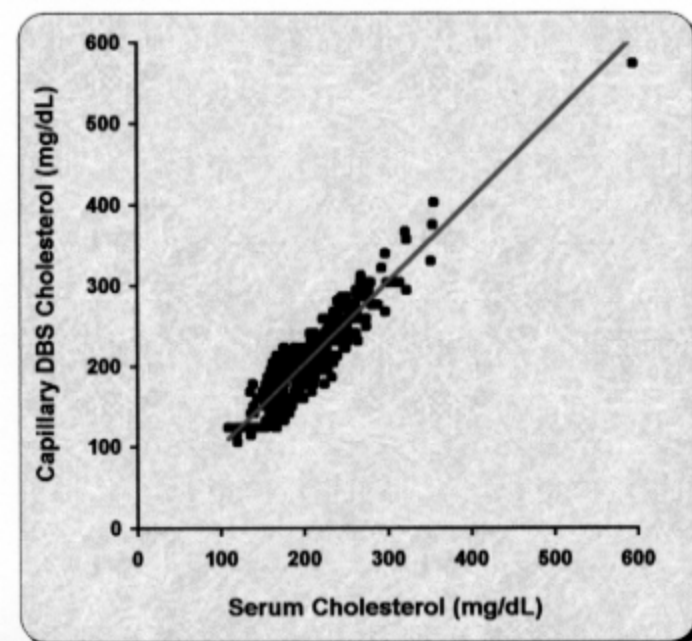
Between-run precision was determined by a series of duplicate measurements of three different samples over a series of twenty different runs (n=20). The data are presented below.

Mean Total Cholesterol (mg/dL)	Standard Deviation	% Coefficient of Variation
153	5.7	3.7%
196	7.6	3.6%
263	8.4	3.2%

### Accuracy

Paired serum and dried blood spot samples containing varying concentrations of cholesterol were analyzed. Total cholesterol concentrations observed for the dried blood spot (DBS) specimens versus serum (enzymatic methodology) were analyzed by the linear regression method.

N = 358		
Correlation Coefficient	.975	
Slope	1.02	
Intercept	-1.6	
	Dried Blood Total Cholesterol	Comparable Serum Methodology
Mean Chol. (mg/dl)	210.2	208.8
Standard Deviation of Range	47.7	45.3



### Total Error Determination

Total error is a measure of the overall analytical performance of an assay, and combines both accuracy and precision. Total error is equal to the % Bias + (1.96 x Total C.V.). The % Bias of the BIOSAFE Dried Blood Cholesterol Assay was calculated using the linear regression formula, derived from the comparison of the dried blood Cholesterol concentration versus the comparable serum methodology. Total C.V. =  $(CV_B^2 + CV_W^2)^{1/2}$ , where  $CV_W$  is the coefficient of variation for within-run precision, and  $CV_B$  is the coefficient of variation for between-run precision. The results of the total error analysis for the BIOSAFE dried blood Cholesterol assay at both low and high Cholesterol levels are presented below at low, normal and elevated Total Cholesterol levels.

Total Cholesterol (mg/dL)	% Bias	Total % CV	Total Error (% Total Cholesterol)
153	0.90%	4.9%	10.5%
196	-1.1%	5.1%	11.1%
263	-1.3%	4.9%	10.9%

### Specimen Requirements

The BIOSAFE Laboratories Dried Blood Spot Total Cholesterol Assay requires three (3) 50µL drops of capillary whole blood placed onto specialized paper card. The blood is dried and placed into a waterproof outer envelope for shipping via regular mail to BIOSAFE Laboratories for testing.

### Specimen Stability

Dried blood spot total cholesterol specimens are stable for more than 14 days when stored at room temperature and for greater than 21 days when stored at -20°C.

### Convenient and Simple to Administer

Simple instructions guide the patient through self-collection of a capillary blood sample onto a collection card using a finger lancet. The BIOSAFE Cholesterol Detection System requires only four simple steps:

1. Collection kit provided to patient.
2. Patient applies blood sample onto collection card.
3. Blood sample sent to BIOSAFE Laboratories in provided mailer.
4. Total Cholesterol results returned within days.

BIOSAFE Laboratories, Inc.  
8600 W. Catalpa  
Chicago, IL 60656  
CLIA Registration No. 14D0928217

To place an order or for additional information, call:

1-888-700-TEST