

# BIOSAFE Laboratories, Inc.

Technical Bulletin

## High Density Lipoprotein (HDL) Cholesterol

Enhanced Blood Collection and Transport System

Performance Characteristics

# BIOSAFE<sup>®</sup>

The World's Window To Health

### Within-Run Precision

Within-run precision was determined by assaying dried blood spots containing various concentrations of HDL 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 HDL - Cholesterol (mg/dL)	Standard Deviation	% Coefficient of Variation
42.6	1.3	3.0%
79.5	2.7	3.3%

### Between-Run Precision

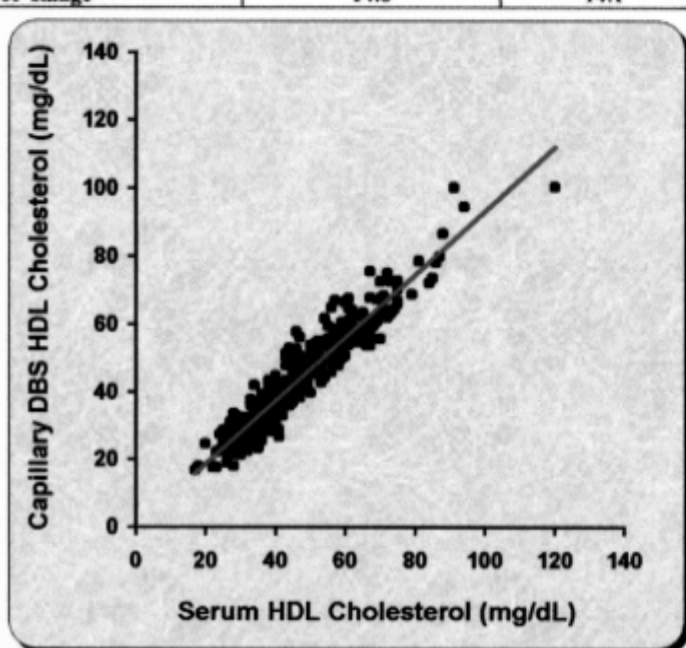
Between-run precision was determined by a series of duplicate measurements of two different samples over a series of twenty different runs (n=20). The data are presented below.

Mean Total HDL - Cholesterol (mg/dL)	Standard Deviation	% Coefficient of Variation
42.6	2.7	6.4%
79.5	3.4	4.3%

### Accuracy

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

N = 352		
Correlation Coefficient	0.95	
Slope	0.985	
Intercept	0.004	
	Dried Blood HDL-C	Comparable Serum Methodology
Mean HDL-C (mg/dL)	45.3	46.0
Standard Deviation of Range	14.6	14.1



### Total Error Determination

Total error is a measure of the overall analytical performance of an assay, a 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 HDL Cholesterol Assay was calculated using the linear regression formula, derived from the comparison of the dried blood HDL 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 HDL Cholesterol assay at both low and high HDL Cholesterol levels are presented below.

HDL-Cholesterol (mg/dL)	% Bias	Total % CV	Total Error % HDL Cholesterol
42.6	-1.5%	7.0%	15.2%
79.5	-1.5%	5.4%	12.1%

### Specimen Requirements

The BIOSAFE Laboratories Dried Blood Spot HDL 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 HDL 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 HDL 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. HDL Cholesterol results returned within days.

### BIOSAFE Laboratories, Inc.

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To place an order or for additional information, call:

1-888-700-TEST