

BIOSAFE Laboratories, Inc.

Technical Bulletin

Triglycerides

Enhanced Blood Collection and Transport System

Performance Characteristics

BIOSAFE®

The World's Window To Health

Within-Run Precision

Within-Run precision was determined by assaying dried blood spots containing various concentrations of triglycerides. Each of the dried blood spot specimens was assayed in replicates of two in twenty different runs. The data is presented below.

Mean Triglyceride Concentration	Standard Deviation	% Coefficient of Variation
126 mg/dL	7.7	6.1%
352 mg/dL	19.2	5.5%

Between-Run Precision

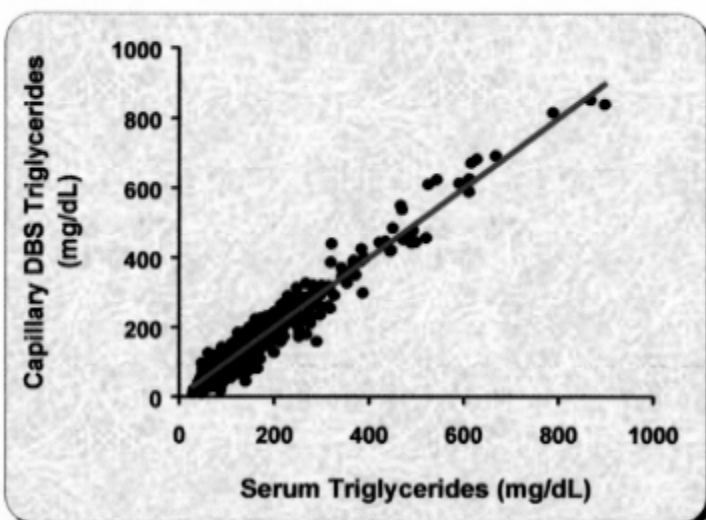
Between-run precision was determined by a series of duplicate measurements of two different samples over a series of twenty different runs (n=20). The data is presented below.

Mean Triglyceride Concentration	Standard Deviation	% Coefficient of Variation
126 mg/dL	7.2	5.7%
352 mg/dL	21.2	6.0%

Accuracy

Paired dried blood spot samples containing varying concentrations of triglycerides were analyzed. Triglyceride concentrations observed for the capillary dried blood spot specimens versus serum were analyzed by linear regression. The data is presented below.

N=356		
Correlation Coefficient		.97
Slope		1.001
Intercept		0.31
	Dried Blood Triglyceride	Comparable Serum Methodology
Mean Triglycerides (mg/dL)	185.4	184.6
Standard Deviation of Range	138.8	133.8



Total Error Determination

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

Mean Triglyceride Concentration	% Bias	Total CV	Total Error
126 mg/dL	-0.4%	8.3%	16.7%
352 mg/dL	-0.2%	8.1%	16.1%

Specimen Requirements

The BIOSAFE Laboratories Dried Blood Spot Triglyceride Assay requires three(3) 50uL drops of capillary whole blood placed onto a specialized paper card. The blood is allowed to dry in open air and subsequently placed into envelope and finally into a shipping bag containing desiccant. It is then sent via regular mail to BIOSAFE Laboratories for testing.

Specimen Stability

Dried blood spot triglyceride specimens are stable for more than 14 days when stored at room temperature and 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 Triglyceride Assay 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 the provided mailer.
4. Triglyceride results returned to patient within days.

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To place an order or for additional information, call

1-888-700-TEST