

BLOOD SPOT TEST SPECIFICATIONS

Total Cholesterol

Clinical Information

Cholesterol is required by the body as a precursor to steroid hormone synthesis and as a component of cell membranes. However, in excessive amounts it is a strong component of coronary heart disease risk because of its contribution to coronary atherosclerosis. Atherosclerotic plaque is largely composed of cholesterol. As with other risk factors, high blood cholesterol levels are more significant when other cardiometabolic parameters are already abnormal, or in patients who already have diabetes or cardiovascular disease.

The American Diabetes Association and the American College of Cardiology Foundation recently released a consensus statement on lipoprotein management in patients with cardiometabolic risk, which notes that elevated blood cholesterol levels are central to the prediction of the development of atherosclerosis. Total cholesterol is the sum of all forms of cholesterol in the bloodstream, including LDL, HDL and VLDL cholesterol, and provides an estimate of the levels of the atherogenic lipoproteins that transport the bulk of the cholesterol in the blood.

The current National Cholesterol Education Program recommendations for total cholesterol levels are: <200 mg/dL = desirable; 200 - 239 mg/dL = borderline high; >240 mg/dL = high.

References:

National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report. *Circulation* 2002;106:3143-421.
Brunzell JD, Davidson M, Furberg CD, Goldberg RB, Howard BV, Stein JH, Witztum JL; American Diabetes Association; American College of Cardiology Foundation. Lipoprotein management in patients with cardiometabolic risk: consensus statement from the American Diabetes Association and the American College of Cardiology Foundation. *Diabetes Care* 2008; 31:811-22.

Assay Method: Enzymatic

Intra-assay Precision

Intra-assay precision was determined by choosing three samples spanning the reference range, and analyzing them multiple times within the same run. Results are shown below:

Mean Cholesterol Concentration (mg/dL)	Standard Deviation	Coefficient of Variation (C.V. %)
142	10.13	7.1
185	10.04	5.4
250	14.02	5.6

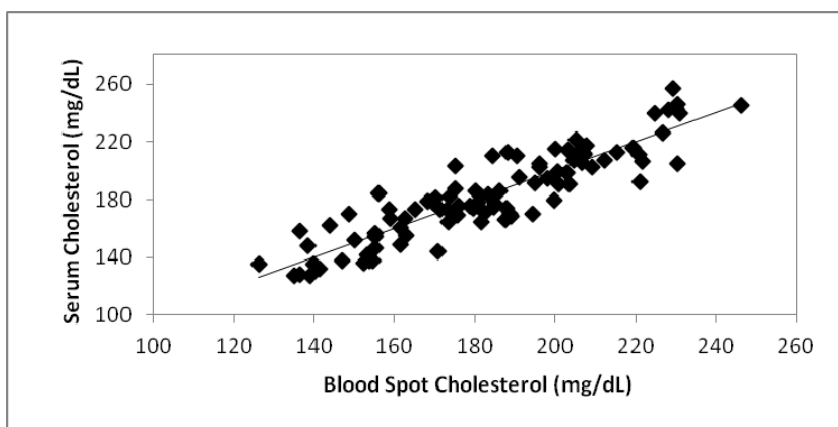
Inter-assay Precision

Inter-assay precision was determined by choosing three samples spanning the reference range, and analyzing them multiple times throughout different runs. Results are shown below:

Mean Cholesterol Concentration (mg/dL)	Standard Deviation	Coefficient of Variation (C.V. %)
140	8.55	6.1
189	10.50	5.5
248	21.92	8.9

Accuracy

To test the accuracy of the dried blood spot assay for cholesterol, dried blood spot samples collected at the same time as corresponding serum samples were analyzed by linear regression. Resulting correlation data are shown below (R = 0.90):



Analyte Stability

The dried blood spot samples are stable for more than 1 month at room temperature.

Specimen Collection

Kits for blood spot collection contain a filter paper collection card, finger lancets, an alcohol prep pad, sterile gauze, a band-aid, easy-to-follow instructions, and a mailer to return the sample for analysis.