

BLOOD SPOT TEST SPECIFICATIONS

HDL Cholesterol

Clinical Information

Cholesterol bound to high-density lipoprotein (HDL) in the blood is known as HDL cholesterol. A low level of circulating HDL cholesterol is one of the established criteria for the diagnosis of metabolic syndrome, and has long been regarded as a powerful predictor of cardiovascular disease in both diabetics and non-diabetics. In a large cohort from the Framingham Study, a high total cholesterol/HDL cholesterol or LDL cholesterol/HDL cholesterol ratio were associated with increased coronary heart disease risk, and a high HDL cholesterol level was associated with reduced risk, in both men and women. Currently, the LDL cholesterol/HDL cholesterol ratio is regarded as a reliable tool for the evaluation of cardiovascular disease risk. While absolute values of each are still considered by the National Cholesterol Education Program (NCEP) as the optimal diagnostic indicators, the ratios that are currently accepted by doctors and researchers are as follows: total cholesterol:HDL cholesterol ratio – optimally below 4; LDL cholesterol:HDL cholesterol ratio – optimally below 3. The current NCEP recommendation to reduce risk of cardiovascular disease is to maintain an HDL cholesterol level >40 mg/dL in both men and women.

References:

NCEP Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). Third Report of the 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.

Boden WE. High-density lipoprotein cholesterol as an independent risk factor in cardiovascular disease: assessing the data from Framingham to the Veterans Affairs High-Density Lipoprotein Intervention Trial. *Am J Cardiol.* 2000;86:19L-22L.

Ingelsson E, Schaefer EJ, Contois JH, et al. Clinical utility of different lipid measures for prediction of coronary heart disease in men and women. *JAMA.* 2007;298:776-85.

Fernandez ML, Webb D. The LDL to HDL cholesterol ratio as a valuable tool to evaluate coronary heart disease risk. *J Am Coll Nutr.* 2008;27:1-5.

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 HDL-Cholesterol Concentration (mg/dL)	Standard Deviation	Coefficient of Variation (C.V. %)
33	2.89	8.7
54	3.80	7.0
103	8.22	8.0

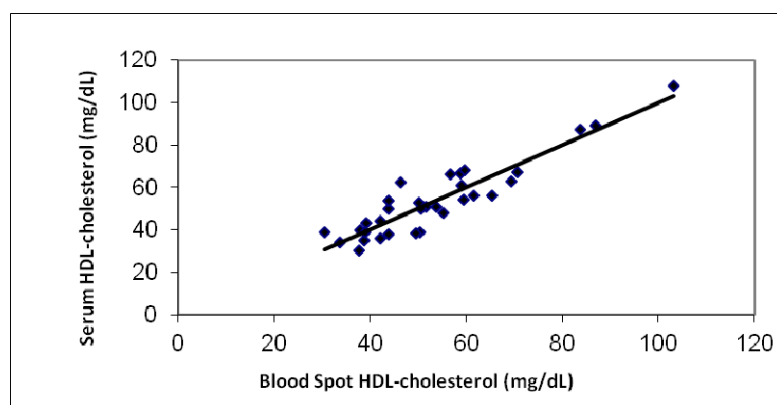
Inter-assay Precision

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 HDL-Cholesterol Concentration (mg/dL)	Standard Deviation	Coefficient of Variation (C.V. %)
34	3.77	11.1
66	6.41	9.7
95	12.27	12.9

Accuracy

To test the accuracy of the dried blood spot assay for HDL-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 = 0.92):



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.