BLOOD SPOT TEST SPECIFICATIONS

High Sensitivity C–Reactive Protein

Clinical Information

C-reactive protein (CRP) is an established marker of inflammation and has recently been suggested to be an important contributor to the pro-inflammatory and pro-thrombotic elements of cardiovascular disease (CVD) risk. Extremely high CRP levels are seen in acute inflammatory states, but the small elevations that are indicative of the pro-inflammatory and pro-thrombotic states implicated in the metabolic syndrome require high sensitivity assays, and are thus referred to as hs-CRP levels.

Studies have shown correlations between elevated hs-CRP and increased risk of future heart attacks, ischemic stroke, and peripheral arterial disease. Overweight, obese, insulin resistant, and diabetic individuals typically have elevated hs-CRP levels; elevations in hs-CRP levels have also been found to predict the development of diabetes. Lifestyle changes such as aerobic exercise, weight loss, and smoking cessation lower hs-CRP levels.

Levels below 3.0 mg/L are considered to be normal; 3.1—10 mg/L is elevated, in the context of CVD risk, and above 10 mg/L is very high, more likely indicating an acute inflammatory event due to infection or trauma.

References:

Kapur S, Kapur S, Zava D. Cardiometabolic risk factors assessed by a finger stick dried blood spot method. J Diabetes Sci Technol 2008;2:236-241.

McDade TW, Burhop J, Dohnal J. High sensitivity enzyme immunoassay for C-reactive protein in dried blood spots. Clin Chem 2004; 50:652-4.

Marques-Vidal P, Mazoyer E, Bongard V, et al. Prevalence of insulin resistance syndrome in southwestern France and its relationship with inflammatory and hemostatic markers. Diabetes Care 2002;25:1371-7.

Pradhan AD, Manson JE, Rifai N, Buring JE, Ridker PM. C-reactive protein, interleukin 6, and risk of developing type 2 diabetes mellitus. JAMA 2001;286:327-34.

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Assay Method: ELISA

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 hs-CRP Concentration (mg/L)	Standard Deviation	Coefficient of Variation (C.V. %)
5.24	0.34	6.50
1.04	0.05	4.77
2.40	0.15	6.46

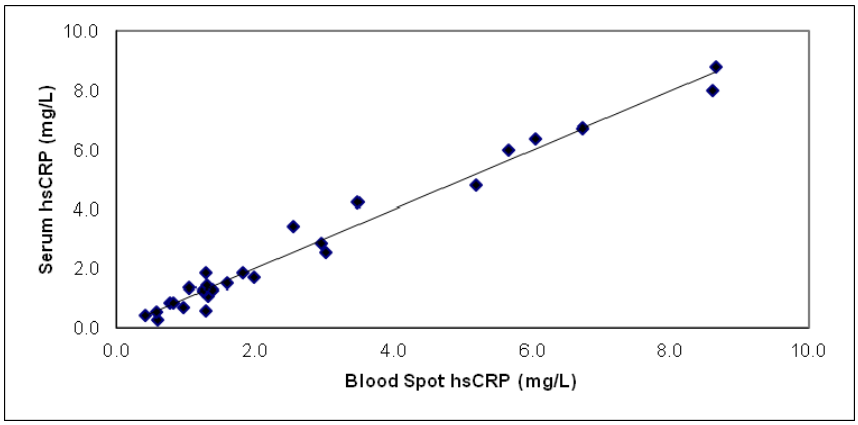
Inter-assay Precision

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

Mean hs-CRP Concentration (mg/L)	Standard Deviation	Coefficient of Variation (C.V. %)
5.56	0.32	5.79
0.60	0.05	7.90
0.38	0.02	4.86

Accuracy

To test the accuracy of the dried blood spot assay for hs-CRP, 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 = 0.99):



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.