Blood Spot Test Specifications

Prostate-Specific Antigen

Clinical Information

Prostate-specific antigen (PSA) is a serine protease in the kallikrein family, which is produced primarily in the prostate gland. It is an established marker for proliferation of prostate tissue: high levels can indicate the presence of benign prostatic hypertrophy or advancing prostate cancer. As prostate cells start to become crowded, they produce more PSA, which acts to suppress angiogenesis and therefore reduce the blood supply to the surrounding tissue to prevent it from further growth. High levels are therefore seen only as a result of rapid growth. Although used widely as a screening test for prostate cancer, it is important to include other risk factors alongside PSA in the assessment. PSA levels can indicate prostate problems contraindicating testosterone treatment, and should be assessed prior to starting testosterone therapy. PSA is also produced by breast tissue, and has been found to be useful in the assessment of benign breast disease and in predicting hormone-responsiveness and better prognosis of breast cancer. It is elevated during pregnancy and in women with excess androgen. Recent research has suggested a role for PSA in the evaluation of patients with acute myocardial infarction (MI): patients whose PSA becomes elevated during acute MI have been found to have more severe and frequent coronary lesions than in those whose levels diminish. The reference range for blood spot PSA in men is <0.5—4.0 ng/mL.

References:

Nanri M, Nanri K, Fujiyama C, et al. Prostate-specific antigen assay using whole blood samples spotted on filter paper and its application to mass screening for prostate cancer. Int J Urol. 2007;14:505-9.

Balk SP, Ko YJ, Bubley GJ. Biology of prostate-specific antigen. J Clin Oncol. 2003;21:383-91.

Thompson IM, Ankerst DP. Prostate-specific antigen in the early detection of prostate cancer. CMAJ. 2007;176:1853-8.

Black MH, Diamandis EP. The diagnostic and prognostic utility of prostate-specific antigen for diseases of the breast. Breast Cancer Res Treat.2000;59:1-14.

Patanè S, Marte F. Prostate-specific antigen and acute myocardial infarction: A possible new intriguing scenario. Int J Cardiol. 2009;134:e147-9.

Assay Method: Chemiluminescent Immunoassay

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 PSA Concentration (ng/mL)	Standard Deviation	Coefficient of Variation (C.V. %)
0.8	0.026	3.2
2.2	0.169	7.7
14.8	0.471	3.2

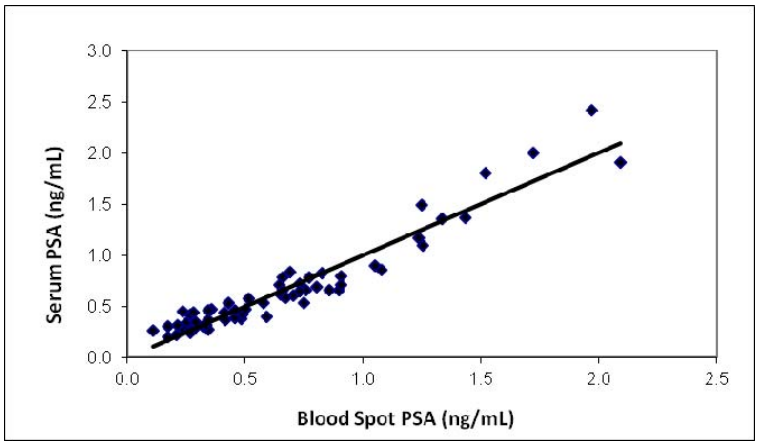
Inter-assay Precision

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 PSA Concentration (ng/mL)	Standard Deviation	Coefficient of Variation (C.V. %)
0.7	0.07	10.5
1.4	0.11	8.2
2.2	0.12	5.5

Accuracy

To test the accuracy of the dried blood spot assay for PSA, 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 = 0.96):



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.