Blood Spot Test Specifications

Testosterone

Clinical Information

In men, levels of testosterone begin to decline with age, usually beginning around the mid-40s. In the Hypogonadism in Males (HIM) study, hypogonadism, determined by low testosterone levels and symptoms of androgen deficiency, was diagnosed in 38.7% of men over 45 years old. The decline in testosterone production by the testes can be more precipitous in some men than others. Excessive weight gain, stress, lack of exercise, and many medications can further reduce testosterone levels, leading to symptoms that include low libido, irritability, depression, loss of muscle mass and strength, weight gain, erectile dysfunction, osteoporosis, and adverse changes in the blood lipid profile. In women, high testosterone, often caused by ovarian cysts, leads to conditions such as excessive facial and body hair, acne, and oily skin and hair. Low testosterone in postmenopausal women, seen particularly after surgical removal of the ovaries, leads to female symptoms of androgen deficiency including loss of libido, thinning skin, vaginal dryness, and loss of bone and muscle mass. Reference ranges for blood spot testosterone levels in men are age dependent: age 20-29, 231—1039 ng/dL; age 30-39, 332—924 ng/dL; age 40-49, 216—726 ng/dL; age 50-59, 168—670 ng/dL. Optimum levels are 400—1200 ng/dL. For women, luteal phase levels range between 20—130 ng/dL, while normal postmenopausal levels are 10—45 ng/dL.

References:

Mulligan T, Frick MF, Zuraw QC, Stemhagen A, McWhirter C. Prevalence of hypogonadism in males aged at least 45 years: the HIM study. Int J Clin Pract. 2006;60:762-9.

Miller KK. Androgen deficiency in women. J Clin Endocrinol Metab. 2001;86:2395-401.

Howe CJ, Handelsman DJ. Use of filter paper for sample collection and transport in steroid pharmacology. Clin Chem. 1997;43:1408-15.

Shirtcliff EA, Reavis R, Overman WH, Granger DA. Measurement of gonadal hormones in dried blood spots versus serum: verification of menstrual cycle phase. Horm Behav. 2001;39:258-66.

Worthman CM, Stallings JF. Hormone measures in finger-prick blood spot samples: new field methods for reproductive endocrinology. Am J Phys Anthropol. 1997;104:1-21.

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 Testosterone Concentration (ng/dL)	Standard Deviation	Coefficient of Variation (C.V. %)
25	3.5	14.1
65	5.7	8.8
187	11.0	5.9

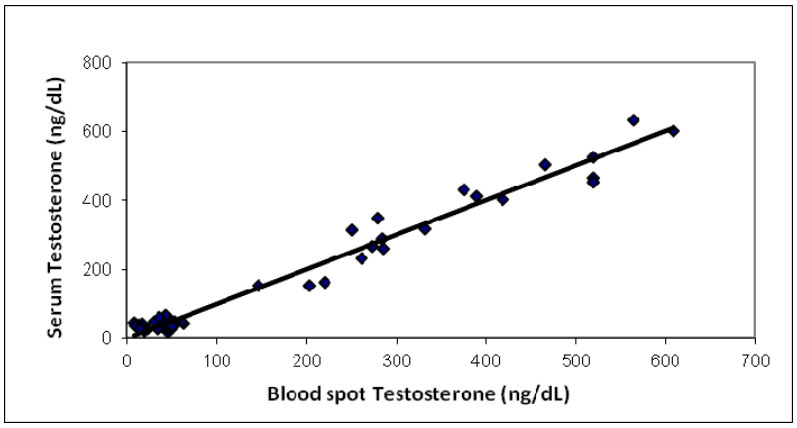
Inter-assay Precision

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 Testosterone Concentration (ng/dL)	Standard Deviation	Coefficient of Variation (C.V. %)
139	18.0	13.0
345	25.0	7.3
667	58.7	8.8

Accuracy

To test the accuracy of the dried blood spot assay for testosterone, 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.