Blood Spot Test Specifications

Progesterone

Clinical Information

Progesterone's primary function during the menstrual cycle is to induce a secretory endometrium ready for implantation of a fertilized egg. Levels therefore increase during the luteal phase of the cycle after ovulation. If no implantation occurs, progesterone returns to follicular phase levels. If a pregnancy results, progesterone continues to rise to very high levels and carries out a variety of functions necessary to sustain the pregnancy. In some patients with infertility, ovulation may occur but luteal phase levels of progesterone are inadequate. Luteal phase deficiency is a result of inadequate progesterone production by the corpus luteum. During menopause, ovarian progesterone production dwindles, resulting in postmenopausal levels similar to those seen in men. Progesterone has wide-ranging physiological effects, including neuroprotection, maintenance of skin elasticity, and development of bone tissue. Progesterone also counteracts the proliferative effects of estrogen on the endometrium. Blood spot and serum levels are normally identical, but when samples are collected after transdermal application of progesterone, finger stick blood spot progesterone levels are higher than serum , suggesting a rapid distribution of progesterone to tissues including the capillary beds of the fingertips. Reference range progesterone levels in premenopausal women (luteal phase) are 3.3—22.5 ng/mL, and in postmenopausal women and men <0.1—0.8 ng/mL.

References:

Du JY, Sanchez P, Kim L, Azen CG, Zava DT, Stanczyk FZ. Percutaneous progesterone delivery via cream or gel application in postmenopausal women: a randomized cross-over study of progesterone levels in serum, whole blood, saliva, and capillary blood. Menopause. 2013;20:1169-75.

Edelman A, Stouffer R, Zava DT, Jensen JT. A comparison of blood spot vs. plasma analysis of gonadotropin and ovarian steroid hormone levels in reproductive-age women. Fertil Steril. 2007;88:1404-7.

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.

Petsos P, Ratcliffe WA, Heath DF, Anderson DC. Comparison of blood spot, salivary and serum progesterone assays in the normal menstrual cycle. Clin Endocrinol (Oxf). 1986;24:31-8.

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 Progesterone Concentration (ng/mL)	Standard Deviation	Coefficient of Variation (C.V. %)
0.9	0.2	17.6
7.0	1.2	16.6
13.9	1.3	9.1

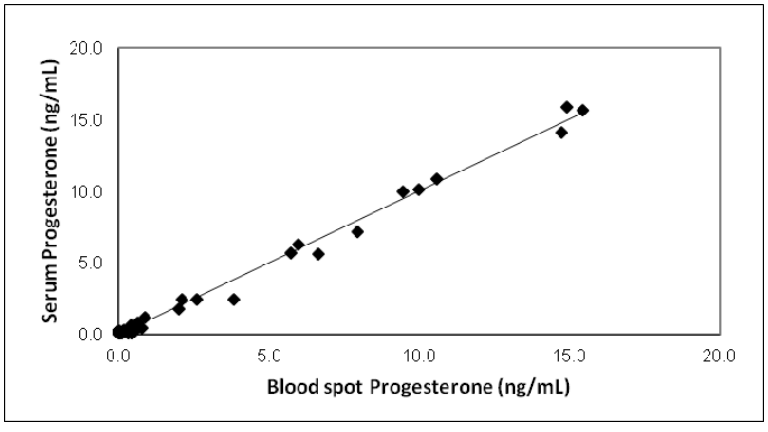
Inter-assay Precision

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 Progesterone Concentration (ng/mL)	Standard Deviation	Coefficient of Variation (C.V. %)
0.7	0.2	19.2
9.5	1.1	12.0
28.2	3.4	12.0

Accuracy

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