

BLOOD SPOT TEST SPECIFICATIONS

Estradiol

Clinical Information

Estradiol is the predominant, and the most potent, circulating estrogen. It is mostly bound to sex hormone binding globulin in the blood. In reproductive age women, an excess of estradiol, relative to progesterone, can explain many symptoms including endometrial hyperplasia, pre-menstrual syndrome, fibrocystic breasts, and uterine fibroids. Women approaching menopause, whose estrogen levels swing from high to low while progesterone levels decline, can also experience symptoms of estrogen dominance, which include weight gain, fibrocystic and tender breasts, uterine fibroids, irritability, water retention, and thyroid problems. Estrogen dominance can lead to cancers of the uterus and breasts, and insulin resistance. With the onset of menopause, when ovarian estrogen and progesterone production decline, low estradiol levels lead to hot flashes, night sweats, vaginal dryness, sleep disturbances, foggy thinking, and bone loss. In men, too much estradiol, relative to testosterone levels, leads to feminizing effects such as breast enlargement. In healthy young men, testosterone is at its highest level and estradiol is very low. However, as men age, this shifts to a higher estradiol/testosterone ratio. Even if testosterone levels are normal, men can experience symptoms indicative of a functional testosterone deficiency because of the effects of higher than normal estradiol levels. The reference range for blood spot estradiol levels is 43—180 pg/mL in premenopausal women during the luteal phase; <10—49 pg/mL in postmenopausal women; and 12—56 pg/mL in men.

References:

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.
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.
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.

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 Estradiol Concentration (pg/mL)	Standard Deviation	Coefficient of Variation (C.V. %)
39	6.4	16.4
66	5.6	8.5
108	3.4	3.1

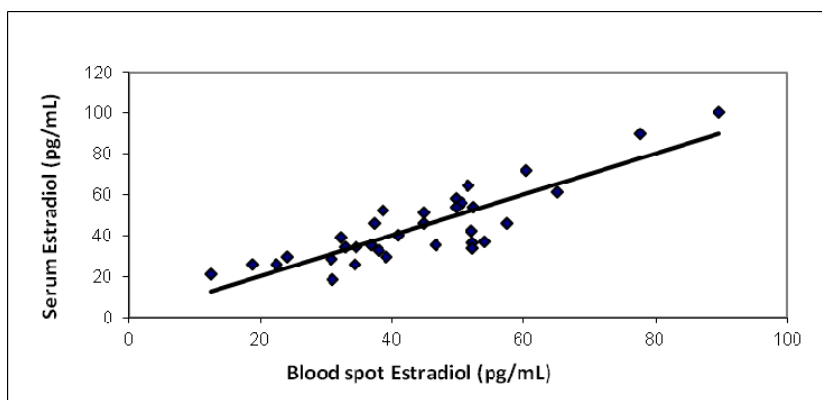
Inter-assay Precision

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 Estradiol Concentration (pg/mL)	Standard Deviation	Coefficient of Variation (C.V. %)
49	6.7	13.6
110	8.5	7.8
188	7.9	4.2

Accuracy

To test the accuracy of the dried blood spot assay for estradiol, dried blood spot samples collected at the same time as corresponding serum samples were analyzed by linear regression. Resulting correlation data are shown below ($R = 0.86$):



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.