

BLOOD SPOT TEST SPECIFICATIONS

Follicle-Stimulating Hormone

Clinical Information

Follicle-stimulating hormone (FSH) is a glycoprotein hormone secreted by the pituitary gland. Acting synergistically with luteinizing hormone, which like FSH is produced in response to gonadotropin-releasing hormone (GnRH) pulses from the hypothalamus, it regulates fertility in both men and women. In women, ovarian hormones suppress GnRH in a negative feedback loop. As estrogen and progesterone levels fall during menstruation, FSH levels rise to a peak on day 3 of the menstrual cycle, stimulating recruitment and growth of immature follicles in preparation for ovulation during the follicular phase. Levels decline again in response to inhibin B produced by the follicles. If levels remain abnormally high in the luteal phase, this can be a sign of ovarian insufficiency, while higher than normal FSH levels in the follicular phase may indicate premature ovarian failure. As a woman enters menopause, declining ovarian hormone production reduces the negative feedback on GnRH production and FSH rises to very high levels. FSH testing is therefore commonly used to assess menopausal status. Low levels are seen in polycystic ovarian syndrome. In men, FSH is essential for spermatogenesis; low levels can lead to low sperm counts resulting in infertility, while high levels can indicate primary testicular failure. Children with precocious puberty have higher levels than normal for children. FSH levels are also affected by disorders of the hypothalamus or pituitary. The reference range for blood spot FSH in premenopausal women (luteal phase) is 0.6–8.0 U/L, in premenopausal women (follicular phase) 2.4–9.3 U/L, in postmenopausal women 31–134 U/L, and in men 1.0–10.5 U/L.

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.

Worthman CM, Stallings JF. Measurement of gonadotropins in dried blood spots. *Clin Chem.* 1994;40:448-53.

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 FSH Concentration (U/L)	Standard Deviation	Coefficient of Variation (C.V. %)
2.0	0.06	3.0
24.3	1.80	7.4
112.9	4.30	3.8

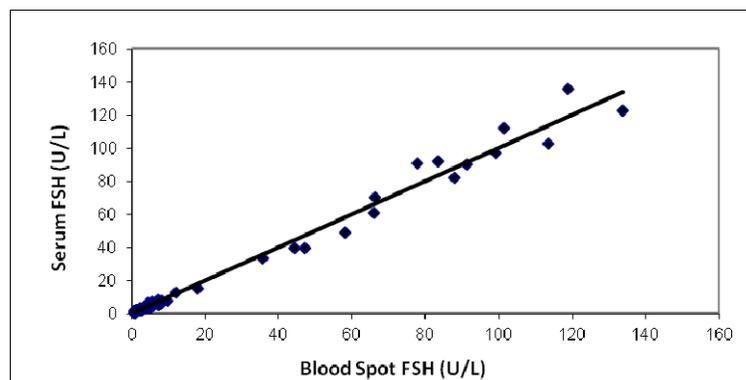
Inter-assay Precision

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 FSH Concentration (U/L)	Standard Deviation	Coefficient of Variation (C.V. %)
1.9	0.15	8.1
41.9	1.67	4.0
98.4	8.76	8.9

Accuracy

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