

BLOOD SPOT TEST SPECIFICATIONS

Luteinizing Hormone

Clinical Information

Luteinizing hormone (LH), a glycoprotein hormone produced by the anterior pituitary, is essential for reproduction in both men and women. In women, controlled by a negative feedback loop involving several ovarian hormones, gonadotropin-releasing hormone (GnRH) is secreted in pulses from the hypothalamus, which stimulates LH production from the pituitary gland. In a normal menstrual cycle, a surge of LH production lasting around 48 hours occurs at the end of the follicular phase. This sudden burst of LH causes luteinization of the ovarian follicles and triggers ovulation. In men, LH acts on the Leydig cells of the testes to stimulate production of testosterone, which is necessary for sexual function as well as spermatogenesis. LH levels are useful for the clinical assessment of infertility: low levels in men can result in hypogonadism and insufficient sperm production, while in women LH levels are used to determine the occurrence of ovulation for couples trying to conceive. High LH levels are seen in polycystic ovarian syndrome, and in precocious puberty levels are similar to those seen in reproductive age individuals instead of the lower levels normally seen in children. LH levels can also be used in the diagnosis of pathologies of the hypothalamus or pituitary. As women enter menopause, LH levels rise as ovarian hormone production declines, reducing the negative feedback effect on GnRH production. LH testing can help evaluate a woman's menopausal status. Ranges for blood spot LH in premenopausal women (luteal phase) are 0.5–12.8 U/L, in premenopausal women (follicular phase) 1.6–9.3 U/L, in postmenopausal women 15–64 U/L, and in men 1.0–8.4 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 LH Concentration (U/L)	Standard Deviation	Coefficient of Variation (C.V. %)
1.2	0.09	6.9
12.8	0.97	7.6
61.5	3.10	5.0

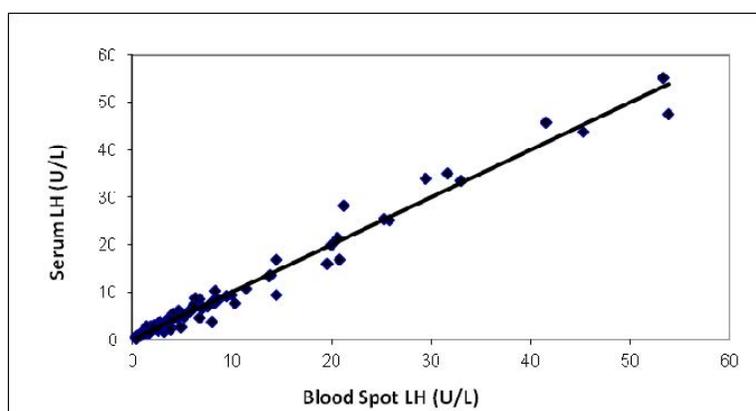
Inter-assay Precision

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 LH Concentration (U/L)	Standard Deviation	Coefficient of Variation (C.V. %)
6.7	0.53	7.8
19.5	1.07	5.5
50.3	3.82	7.6

Accuracy

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