GENETRACK Diagnostics

Follicle-Stimulating Hormone (FSH)

WHAT IS FOLLICLE-STIMULATING HORMONE (FSH)?

Follicle-stimulating hormone (FSH) is a hormone produced in the pituitary gland in both males and females. It works with luteinizing hormone (LH) to regulate development, growth, pubertal maturation, and reproductive processes (1). In males, FSH activates Sertoli cells for spermatogenesis and inhibin B secretion. In females, FSH initiates follicular growth, particularly for the development of the female gamete in the ovaries (2).

FSH levels fluctuate during each menstrual cycle in women of reproductive age, Levels are typically 2 – 12 IU/L during the follicular phase, 4 – 36 IU/L at the mid-cycle peak, and 1 – 9 IU/L during the luteal phase (3).

FSH levels typically remain high in menopause, and may contribute to postmenopausal osteoporosis and cardiovascular disease (4).

Males generally have FSH levels between 0.95 and 11.95 IU/L (5). Normally children have low FSH levels until they reach puberty (6).

PURPOSE OF AN FSH TEST

FSH tests are most commonly requested for the following reasons:

- For determining why a couple can't get pregnant
- As an indirect measurement of ovarian reserve (reproductive potential) in females
- For evaluating a male's low sperm count
- For evaluating menstrual problems in females (e.g., irregular or absent menstruation)
- Confirming the start of menopause
- For evaluating early or delayed puberty in young boys and girls
- Helping in the diagnosis of some pituitary gland disorders (e.g., tumor)

ABNORMAL FSH LEVELS

Elevated FSH levels are an indication of subfertility and/or infertility. Abnormally high FSH levels in females of reproductive age can occur due to premature menopause, poor ovarian reserve, gonadal dysgenesis, Turner syndrome, and lupus (2). High FSH levels in males can occur in Klinefelter syndrome, castration, and gonadal dysgenesis (7).

Low FSH levels can also be an indication of infertility. This can result in low sperm production in males, and cessation of menstruation in females. There are various conditions that result in low FSH, including polycystic ovarian syndrome, Kallmann syndrome, hypothalamic suppression, hypopituitarism, and hyperprolactinemia (2).

TEST PROCEDURE

Correct specimen collection and handling is required for optimal assay performance. Samples should be collected on the third day of your menstrual cycle (third day of menstruation) for optimum results.

This test requires a blood sample from a finger prick. All supplies for sample collection are provided in this kit. First wash and dry hands. Warm hands aid in blood collection. Clean the finger prick site with the alcohol swab and allow to air dry. Use the provided lancet to puncture the skin in one quick, continuous and deliberate stroke. Wipe away the first drop of blood (as it may be contaminated with tissue fluid or skin debris). Massage finger to increase blood flow at the puncture site and hold in a position that gravity facilitates the collection of blood on the fingertip. Transfer the blood to the blood collection card or blood collection tube (microtainer).

Avoid squeezing or 'milking' the finger excessively. If blood flow stops, perform a second skin puncture on another finger if more blood is required.

Dispose of all sharps safely and return sample to the laboratory in the provided prepaid return shipping envelope.

Upon receipt at the laboratory, the blood sample is analyzed by the fully automated Alinity I FSH chemiluminescent microparticle immunoassay on the Alinity ci series analyzer. This assay measures FSH levels by binding to monoclonal anti-β FSH coated microparticles. The amount of FSH in the blood sample is measured in relative light units by a chemiluminescent reaction. This assay has a precision value of <3 %CV.

SPECIAL INSTRUCTIONS

For fertility testing in females, the samples should be collected on the third day of the menstrual cycle (third day of menstruation) for optimum results.

TEST INTERPRETATION

This assay will provide accurate FSH values for the tested specimen. This value is to be used in conjunction with other clinical and laboratory information for analyses of women's health and fertility.

DISCLAIMERS/LIMITATIONS

These results should be interpreted in conjunction with other laboratory and clinical information.

Assay interference may occur in specimens from individuals routinely exposed to animals or to animal serum products. Additional clinical or diagnostic information may be required for these specimens.

Certain medications (e.g., birth control pills and cimetidine), hormone therapy, recent test using a radioactive substance (e.g., bone scan), and heavy cigarette smoking may affect FSH test results. In addition, FSH levels fluctuate throughout each menstrual cycle in reproductive age females, so the timing of sample collection may influence the interpretation of the FSH level.

Additional testing is recommended if FSH results are inconsistent with clinical evidence.

False results may occur in specimens from individuals that have received preparations of mouse monoclonal antibodies for diagnosis or therapy. Additional clinical or diagnostic information may be required for these specimens.

Correct specimen collection and handling is required for optimal assay performance. The assay is unaffected (≤ 10% interference) by hemoglobin (500 mg/dL), bilirubin (20 mg/dL), triglycerides (3000 mg/dL), and protein (12 g/dL).

REFERENCES

(1) Ulloa-Aguirre A, Reiter E, & Crépieux P. (2018). FSH Receptor Signaling: Complexity of Interactions and Signal Diversity. *Endocrinol*, 159 (8), 3020-3035.

(2) Knudtson J. (2019) Female Reproductive Endocrinology. *Merck Manual Professional Version*. https://www.merckmanuals.com/en-ca/professional/gynecology-and-obstetrics/female-reproductive-endocrinology/female-reproductive-endocrinology

(3) Endocrine Society Laboratory Reference Ranges

(4) Zhu D, et al. (2018). Extragonadal Effects of Follicle-Stimulating Hormone on Osteoporosis and Cardiovascular Disease in Women during Menopausal Transition. *Trends Endocrinol Metab*, 29 (8), 571-580.

(5) Alinity i FSH Reagent Kit.

(6) Soldin OP, et al. (2005) Pediatric reference intervals for FSH, LH, estradiol, T3, free T3, cortisol, and growth hormone on the DPC IMMULITE 1000. *Clin Chim Acta*, 355 (0), 205-210.

(7) Simoni M, et al. (1999) Role of FSH in male gonadal function. *Ann Endocrinol (Paris)*, 60 (20), 102-106.