

Rapid FSH Urine Dipstick Test

FSH-DS0425

A rapid chromatographic immunoassay for the detection of follicle stimulating hormone (FSH) in human urine

Intended Use

Rapid FSH Urine Dipstick Test is a colloidal gold/antibody complex based immunoassay designed for the qualitative determination of follicle stimulating hormone (FSH) in human urine. It is intended for laboratory use only.

Summary and Explanation

FSH is a glycoprotein hormone weighing approximately 30,000 Da. It is composed of two polypeptide chains: the alpha and beta subunits. In response to Gonadotropin-releasing hormone (GnRH) produced by the hypothalamus, the basophilic cells of the anterior pituitary secrete FSH and Luteinizing Hormone (LH). Both these hormones control gonadal development and maintenance. FSH controls the development of the ovarian follicles in females. FSH controls spermatogenesis in males. Both LH and FSH act in a negative feedback effect on the hypothalamus, thus regulating the circulatory levels of both hormone. The FSH Urine dipstick test is helpful in identifying hypothalamic, pituitary or gonadal dysfunction.

Test Principle

The FSH Urine dipstick Test consists of a chromatographic absorbent device and an unique combination of monoclonal antibodies that selectively detect FSH in test samples with a high degree of sensitivity. In ten minutes, levels of FSH as low as 25 mIU/ml are detected.

An anti-FSH antibody is immobilized in a test zone (T) of a nitrocellulose membrane located in the middle section of the test strip. Another FSH antibody labeled with colloidal gold is supported in a different section of the test strip. When the sample addition zone the arrow pointed end is in contact with urine, the urine sample migrates through the absorbent area before it flows to the test membrane. FSH present in the specimen is bound by antibody-gold conjugate forming a labeled antibody-antigen complex. The complex is captured by anti-FSH antibody immobilized in the T zone of the membrane forming a red line. The intensity of the test line is proportional to the concentration of FSH in the urine sample. Another gold conjugate is captured by the antibody immobilized in the control zone (C) of the membrane producing another red color line, regardless of the presence or absence of FSH in the sample. The color intensity of the C line represents the T line intensity of a 25mIU/ml sample test. The level of FSH in the urine sample above or below 25mIU/ml cutoff is determined by comparing the color intensity of the T line and the C line. If the T line is absent or less intense than the C line, the test result is negative, which

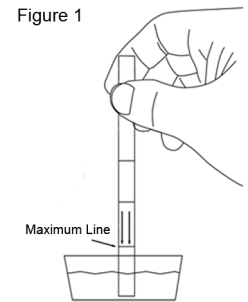
means, the FSH level of the urine sample is below the 25mIU/ml cutoff. If the T line is more intense than the C line, the test result is positive, i.e., the FSH level of the urine sample is above 25mIU/ml.

Storage and Stability

Store the test device at 2 - 28°C. Prior to use bring test device and components to room temperature.

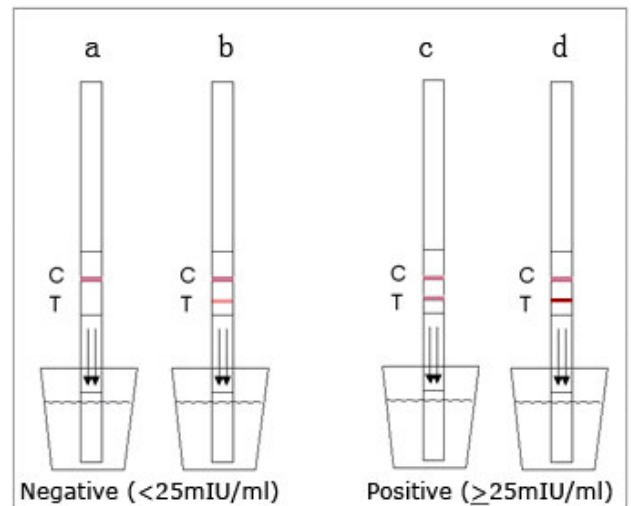
Assay Procedure

1. Bring test components including urine to room temperature.
2. Remove test strip from the pouch.
3. Dip the arrow pointed end of test strip into a container of the urine sample, ensuring that the level of the urine sample does not surpass the edge of the arrow tape. Keep contact between the test strip and the urine specimen for 10 seconds or longer.
4. Read results at 10 minutes; do not interpret results after 10 minutes. (see Figure 1).



Interpretation of Results

Figure 1. Dipstick Test Results.



1. **NEGATIVE:** A negative result is observed when there is no T line (a) or the T line is less intense (b) than the C line. A negative result indicates the FSH level of the urine sample is below the 25mIU/ml cutoff.
2. **POSITIVE:** If FSH concentration in the urine sample is equal to or above 25mIU/ml, the intensity of the T line will be equal to (c) or higher (d) than that of the C line. A second test after 5 to 7 days may be performed to confirm the first positive test.

- a. **INVALID:** If there is no rose-color line visible in the control window, then the test result is invalid. It is recommended that the urine be re-tested.

Limitations

- A positive result with the the rapid FSH Urine Test only indicates that there is an increased level of FSH present. As in the case of any diagnostic procedure, the results obtained from this test should be used in conjunction with other information available to the physician before a definitive diagnosis is made.
- Oral contraceptives, hormone replacement therapy, and estrogen supplements may affect FSH levels and cause false negative results.
- Ovarian and pituitary tumors may cause false negative results.
- This test must not be used to determine fertility. Contraception decisions should not be made based on test results.

Expected Values

FSH levels in pre-menopausal women will cycle on average from 5 to 25 mIU/ml during the normal menstrual cycle. These FSH levels will form test lines that are lighter or similar to the intensity of the control line. Many women will begin to show a surge of FSH before the onset of menopause and high levels that can reach upwards of 500 mIU/ml of FSH will continue during the menopausal period. These surge levels of FSH will lead to a test line that has stronger color intensity than that of the control line.

References

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