

INTENDED USE

Sensit FSH Rapid test Kit is an in-vitro immunochromatographic assay designed for qualitative determination of FSH (follicle-stimulating hormone) produced by the pituitary gland that plays a crucial role in reproductive health in both males and females, stimulating the growth of follicles in women and sperm production in men. The test provides a visual, qualitative result, and all positive specimens are advised to be confirmed with other qualified assays.

SUMMARY & TEST DESCRIPTION

Follicle-Stimulating Hormone (FSH) is a hormone produced by the pituitary gland, located at the base of the brain. It plays a crucial role in reproductive health by stimulating the growth and development of ovarian follicles in women and supporting sperm production in men. In women, FSH levels fluctuate throughout the menstrual cycle, with the highest levels occurring at the beginning of the cycle to promote follicular growth. FSH testing is commonly used to assess ovarian function and fertility. High levels of FSH may indicate diminished ovarian reserve, meaning fewer viable eggs are available for fertilization. The FSH test is often used in conjunction with other fertility tests to evaluate reproductive health, especially in women experiencing irregular cycles or difficulty conceiving.

Menopause means the end of menstruation, but it is usually not diagnosed until one year after the end of menstrual bleeding. The period that precedes menopause and continues for 12 months after it is called perimenopause. Many women experience symptoms during this period, including hot flashes, irregular periods, sleep disturbances, vaginal dryness, hair loss, anxiety and mood swings, transient memory loss and exhaustion. The onset of perimenopause is caused by changes in the levels of hormones that regulate the menstrual cycle in a woman's body. As the body produces less and less estrogen, the production of follicle-stimulating hormone (FSH) increases. FSH normally regulates the development of a woman's eggs. Therefore, testing for FSH can help determine whether a woman is in perimenopause. If a woman knows she is in perimenopause, she can act accordingly to keep her body healthy and avoid the health risks associated with menopause (e.g. osteoporosis, high blood pressure and cholesterol, and increased risk of heart disease)

The FSH test can be performed using a urine sample, similar to an LH test, to detect hormone levels and provide insight into ovarian function. Testing for FSH is typically done on the third day of the menstrual cycle (Day 3), as this is when baseline hormone levels are most accurately measured. The sensitivity of the FSH Rapid Test Kit is 25 mIU/mL (International Standard Value), with a specificity of 99%.

For the most reliable results, FSH testing should be conducted in the morning with the first urine of the day, as FSH levels are more stable at that time. If you are using an FSH test to assess fertility, consult your doctor for further interpretation of your results, especially if you have irregular cycles or are trying to conceive.

PRECAUTION & WARNING

- 1) Use within 10 minutes after opening pouch.
- 2) Do not touch result window.
- 3) Use only the buffer supplied along with the kit.
- 4) Do not mix components from different kits.
- 5) Do not use with specimen containing precipitates

MATERIALS PROVIDED

1. Each Kit contains 30 test devices, each sealed in a foil pouch containing following items:
 - a. One test card
 - b. Dropper
 - c. Desiccant
2. Instruction Leaflet

MATERIAL REQUIRED BUT NOT SUPPLIED

Specimen collection containers.

STORAGE & STABILITY

Store the test kit between 4-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

SPECIMEN COLLECTION

1. Urine specimen may be collected at any time in a clean, dry container either plastic or glass without preservatives.
 2. If specimen cannot be assayed immediately, it can be stored at 2-8°C for up to 48 hours prior to testing frozen at -20° C for longer period of time.
 3. Specimens should be equilibrated to room temperature before testing if they were refrigerated or frozen.
 4. Urine specimen exhibiting visible precipitates should be filtered, centrifuged, and settled so that clear aliquots can be obtained for testing.
- Choose a convenient time of the day to collect urine. Try to collect urine at about the same time each day for the entire cycle.*

TEST PROCEDURE

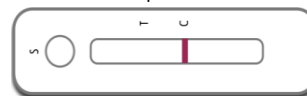
1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 5 drops of the specimen to the sample hole (marked S) on the test card.
3. Wait for 5-10 minutes and interpret results. The result is considered invalid after 20 minutes. All results where control band does not appear are considered invalid.

INTERPRETATION OF TEST RESULT

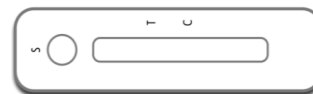
Positive: Color bands at position C and T.




Negative: Color band at position C.



Invalid: Color band at C does not appear



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