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“See Now” FSH Strip Test



Urine

For in vitro Diagnosis Use

Product Code: SN 1.5

INTENDED USE

The “See Now” FSH test is a rapid and convenient immunochromatographic *in vitro* assay. It is designed for qualitative determination of follicle stimulating hormone (FSH) in urine.

PRINCIPLE

In women elevated level of FSH is associated to the symptoms and stages of menopause. FSH is produced in the pituitary gland and is responsible for the growth and maturation of ovarian follicles during the menstrual cycles. FSH levels are dependent upon menstrual cycle, but usually remain below. If FSH levels remain elevated at 25mIU/ml or greater during the entire cycle then this is evidence of menopause.

The “See Now” FSH test strip is a test for the determination of FSH level in urine. The test is positive when FSH level is 25mIU/ml or greater. If the test is positive test once more after a week to find out whether the FSH level has remained 25mIU/ml or greater. If the test is positive again, the women may have reached menopause.

MATERIALS SUPPLIED

- Test Strip, desiccant
- Test instruction

MATERIALS REQUIRED BUT NOT SUPPLIED

- Specimen collection container, Timer

STORAGE AND STABILITY

- Test device in the sealed pouch can be stored at 2-30°C up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not reuse.
- Test device should remain sealed until use.
- Do not used after the expiration date shown on the pouch.
- Keep out of children’s reach.

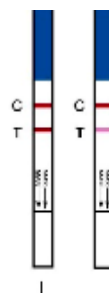
TEST PROCEDURE

- Remove the test device from pouch when ready to perform the test .Label the test device with patient or control identification
- Immerse the strip into the urine with the arrow end pointing

towards the urine. Let it stay immersed until you see liquid traveling up past the MAX word.

- Take the strip out after a minimum of 10 seconds. Lay the strip (MAX side facing up) flat on a clean, dry, non-absorbent surface
- Read the result after 10 minutes. Ensure that the background of the test area is white before interpreting the results

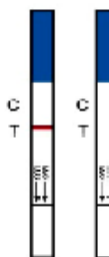
INTERPRETATION OF RESULTS



Positive: Two colored lines should be observed in the viewing window. The line in the test region (T) is the probe line; the line in the control region (C) is the control line. This indicates the FSH is present in the urine or above 25mIU/ml .In this positive case wait for a week and take the second test .If the second test is also positive ,you may have reached menopause.



Negative: The red test line (T.) is lighter than the control line or not appear at all. This indicates the FSH level of the urine is less than 25mIU/ml .You do not have to use the second the device if the test result was negative.



Invalid: No line appears in the control region. Under no circumstances should a positive sample be identified until the control line forms in the viewing area. If the control line does not form, the test result is inconclusive and the assay should be repeated.

LIMITATION OF PROCEDURE

- This test must not be used to determine ovulation, pregnancy and contraception decisions. Please discuss your contraceptive needs with your physician.
- Hormone replacement therapy, estrogen supplements and oral contraceptive they affect the test and produce inaccurate results.

PERFORMANCE CHARACTERISTICS

Specificity

The following homologues hormones are tested and did not affect the expected results

Homologous hormones	Source	Concentration tested
LH	NBSC	200 mIU/ml
hCG	NBSC	200 IU/ml
TSH	Zymed	100µIU/ml

Sensitivity

The "See Now" FSH can detect urine FSH concentration of 25 mIU/ml or greater.

Accuracy

A multi center clinical study was constructed to establish the performance of the "See Now" FSH compared results obtained from another commercially available FSH EIA ,in this study, total 217 urine specimens were collected and evaluated.