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**“See Now” FSH CassetteTest**



**Urine**

For in vitro Diagnosis Use

Product Code: SN 1.6

**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 device 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 Device, 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 15-25°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.

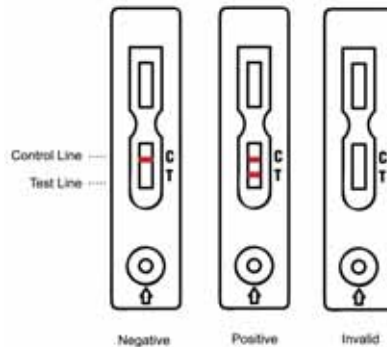
**TEST PROCEDURE**

- Remove the test device from pouch when ready to perform the test. Label the test device with patient or control identification
- Remove the test device from the sealed pouch by tearing at

the notch. Then place the testing device on a level surface

- Holding the sample dropper vertically, add 4 drops of specimen without air bubbles into the sample well that is make with an arrow on the testing device
- Wait for colored bands to appear and read results after 10 minutes.

**INTERPRETATION OF RESULTS**



**Negative**

Only one pink colored band appears at the control region.

**Positive**

Distinct pink colored bands appear at the control and test line regions.

**Invalid**

No visible band at the control region. Repeat with a new test

device. If test still fails, please contact the distributor with the lot number.

**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.