FSH Menopause Test (Midstream)

For self-testing and in vitro diagnostic use only

CE 0197

INTENDED USE

The FSH Test is an immunochromatographic one step assay designed for in vitro qualitative determination of FSH in human urine to evaluate the onset of menopause in women at concentration of 25mIU/ml or higher.

SUMMARY

Follicle Stimulating Hormone is a peptide hormone produced in the pituitary gland of the brain. It is normally present in the blood or urine varying in concentration with the stage of the menstrual cycle. When estrogen levels drop, FSH is released from the pituitary gland indicating that either a woman in mid-menstrual cycle or indicating the onset of perimenopause. During early menopause, changes take place in the balance of hormones that regulate and control menstrual cycles. As a woman grows older and passes out of child bearing stage of life, the ovaries gradually make less of the hormone estrogen and FSH increases. FSH normally regulates the growth and complete, FSH production is stopped and it returns to normal. As the body decreases estrogen production with age, more FSH is made. Over time these hormone changes cause menstrual periods to stop completely and "menopause"has occurred. Health risks that can come with menopause usually include osteoporosis, increased blood cholesterol and increased risk of heart disease. The slow change in ovary function can happen between 2 and 10 years before the final period. This early stage before menopause is called Perimenopause. During this stage, the levels of FSH may rise to positive levels and slowly return to normal, causing irregular or missed periods. The testing for FSH should, therefore, be performed twice to help identify the levels of FSH throughout a menstrual cycle.

The FSH Test is a one step assay for the rapid qualitative determination of FSH in the urine. The immunological specificity of the test kit virtually eliminates cross reactivity and interference to structurally related glycoprotein hormones such as hLH, HCG and hTSH.

PRINCIPLE

The FSH Test is a qualitative, two-site sandwich immuno-assay for the determination of human follicle stimulating hormone(FSH) in urine. The membrane was pre-coated with FSH specific antibodies on the test region. During the test, the urine specimen is allowed to react with the FSH monoclonal antibody-colloid gold conjugate, which was pre-dried on the test strip. The mixture then moves upward on the membrane chromatographically by the capillary action. For a positive specimen, the conjugate binds to the FSH forming an antibody-antigen complex. This complex binds to the FSH antibody as a capture regents in the test region and produces a colored band that is equal to or more intensive than that of control band when FSH concentration is equal to or greater than 25 mIU/ml. If the color intensity of the test band is less than that of control band, it suggests a negative result. To serve as a procedural control, a colored band at control region will always apprear regardless the presence of FSH.

REAGENTS

Each FSH Test strip individually sealed in a foil pouch. Ingredients: Test device Containing test strip with Capture anti-hFSH antibody coated membrane and colored anti-hFSH antibody pad.

MATERIALS PROVIDED

1.One FSH Test strip
2.One desiccant.
3.One Instruction.

WARNING AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not use beyond the labeled expiration date imprinted on the outside of the foil pouch.
3. Do not reuse the test devices. Discard it in the dustbin after single use.
4. Read directions for use carefully before performing this test. Pay attention to the position of the C and T line
5. Do not touch the membrane locate in the windows.
6. The instructions must be followed to obtain accurate results.
7. Do not open foil pouch until specimen is collected and ready to be tested.

STORAGE

The test should be stored at temperature 2-30℃ the sealed pouch for the duration of the shelf time (24 months). Do the test in 1 hour when you open the pouch. DO NOT FREEZE.

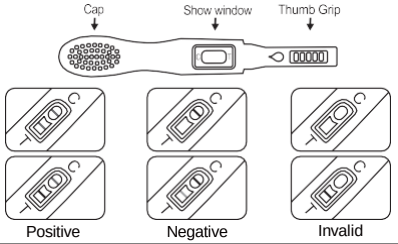
SAMPLE COLLECTION

The FSH Test is formulated for use with fresh urine specimens. The test should be used right after the specimen collection. The urine does not require any special pretreatment. 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. For best results, test the first morning urine.

TEST PROCEDURE

Allow the test, urine specimen and/or controls to equilibrate to room temperature (15-30℃) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the test midstream from the sealed pouch and use it as soon as possible.
2. Remove the Cap to show the absorbent tip.
3. Hold the midstream by the Thumb Grip with the exposed absorbent tip pointing downward. Urinate on the absorbent tip directly till it is thoroughly wet (at least 3 seconds).
   NOTE: Be careful do not urinate in the Show Window.
4. Lay the midstream on a flat surface with window on top.
5. Wait for pink-colored lines to appear. Read the results 5 minutes later. Do not read result after 10 minutes.



INTERPRETATION OF RESULTS

Positive: If the test band(T) is more intensive than or equivalent to that of control band(C),the specimen is likely at or arount the Perimenopause stage.

Negative: If the color intensity of the test band(T) is less than that of control band(C), the specimen is likely at its

basal FSH levels.

Invalid: If control band (c) does not appear on the membrane, the test should be voided since improper test procedure or deterioration of reagents probably occurred. If you are experiencing Menopause symptoms plus you have had no menstrual cycle for the past 12 months:

1. Positive result: it indicates menopause has most likely occurred.You may want to repeat the test, but consult your doctor to discuss your results first.
2. Negative result: it indicates FSH maybe normal. But if you have the absence of your period together with the presence of other Menopause symptoms which suggests that you may be in menopause, you may want to repeat the test, but consult your doctor to discuss your results first.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing on the control region (C) is considered an internal positive procedural control, indicating proper performance and reactive reagents. A clear background in the membrane is considered an internal negative procedural control. If the test has been performed correctly and reagents are working properly, the background will clear to give a discernible result.

PERFERMANCE CHARACTERISTIC

ANALYTICAL SENSITIVITY & DIAGNOSTIC SENSITIVITY

The FSH Test has been designed to produce a definitive color band at test region when tested with 25mIU/ml or higher of hFSH at room temperature. During the evaluation of the FSH Test, samples containing 25mIU/ml of hFSH was tested 100 times, and definitive color bands at test region were detected and were equivalent to that of the control band 100% of times.

SPECIFICITY

Specificity of The FSH Test was determined from cross reaction studies with known amounts of Luteinizing Hormone(hLH), Thyroid Stimulating Hormone(hTSH) and chorionic gonadotropin(HCG). Samples containing 200mIU/ml hLH, 250μlU/ml hTSH and 1000mIU/ml HCG yielded color less intensive than that of 25mIU/ml FSH Reference.

ACCURACY

Correlation with a Qualitative Visual Test: 350 urine specimens from 70 menstrual cycles were analyzed by The FSH Test procedure in parallel with a commercial available visual method. In laboratory studies, the overall accuracy of FSH Test has been proven to be 99%.

REPRODUCIBILITY

FSH standard solution was added to normal male urine to achieve concentrations at 0mIU/ml ,12.5mIU/ml (50% below cutoff level), 25mIU/ml (cutoff level), 37.5mIU/ml (50% above cutoff level), and 50mIU/ml (100% above cutoff level). Each specimen , at each concentration of analyte, was tested four times daily, in duplicate, for five consecutive days, A total of 40 samples at each concentration were tested. The result shows that the reproducibility of the FSH Test is 100%.

VARIABILITY

FSH standard solution was added to normal male urine to achieve concentrations at 0mIU/ml, 12.5mIU/ml(50% below cutoff level), 25mIU/ml(cutoff level), 37.5 mIU/ml(50% above cutoff level), and 50mIU/ml(100% above cutoff level). Test sample from three lots were obtained and each specimen, at each concentration of anylyte, was tested four times daily, in duplicate. A total of 120 samples were tested. No variable result was observed.

INTERFERENCE TESTING

The following substances at certain concentrations do not interfere with the FSH Test in the assay.

Acetaminophen	20μg/ml
Acetylsalicylic Acid	20μg/ml
Ascorbic Acid	20μg/ml
Atropin	20μg/ml
Caffeine	20μg/ml
Gentesic Acid	20μg/ml
Glucose	2mg/ml
Hemoglobin	1μg/ml

LIMITATIONS

1. If a specimen is too diluted (i.e. low specific gravity), it may not contain representative levels of FSH. It is highly recommended that the first morning urine be tested, since it generally contains the highest concentration of FSH. FSH concentrations less than 25mIU/ml will be detected as negative.
2. Oral contraceptives, hormone replacement therapy, and estrogen supplements may affect FSH levels and could yield a false negative result. Ovarian and pituitary tumors can result in decreases FSH levels, which may cause a false negative result in the test. As is true with any diagnostic procedure, the physician should evaluate the data obtained by the use of this test in light of other clinical information.
3. This test must not be used to determine fertility. Contraception decisions should not be made based on the results of this test. This test will not determine ovulation or pregnancy status.

REFERENCES

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2. AACE Medical Guidelines for Clinical Practice for Management of Menopause, Endocrine Practice, Vol.5 No.6,Nov/Dec. 1999.
3. Mayeaux, E.J .,Jr.,Menopause/Perimenopause: Issues/Symptoms/Treatment, Lecture at Primary Care in Women's Health-1999.
4. Greendale,G.,Lee, N., Arriola, E., The Menopause, The Lancet,Vol.353,Feb.13,1999.

INDEX OF SYMBOLS

	Do not re-use		Manufacturer
IVD	In vitro diagnostic medical device		Use-by date
	Store at 2-30℃		Consult instructions for use
UK REP	Authorized representative in the United Kingdom	LOT	Batch code
Σ n	Contains sufficient for <n>tests	CE 0197	CE Mark

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