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FSH-11210009000 FSH-11200104000 FSH-11200203000

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# Follicle Stimulating Hormone (FSH) tests

(Menopause tests)

#### **INTENDED USE**

Follicle Stimulating Hormone (FSH) tests are single use, rapid immunoassay for the qualitative detection of Follicle Stimulating Hormone (FSH) in urine to aid in the detection of menopause. It is intended for use by the lay users.

## PRINCIPLE

Antibodies to FSH are precoated onto membrane as a capture reagent on the test zone. During the test, specimen is allowed to react with the colloidal gold particles, which have been labeled with antibodies to FSH. If FSH is present, a purple colored line will develop on the membrane in proportion to the amount of FSH present in the specimen. To serve as a procedural control, red colored line in the control zone will always appear regardless of the presence of FSH.

FSH is a kind of glycoprotein hormone secreted by the basophil in the anterior pituitary, regulates the development, growth, adolescent sexual maturity of the human body, and a series of physiological processes related to reproduction, in particular to stimulate the maturation of germ cells. The determination of FSH content, can understand the pituitary endocrine function, but also indirectly understand the functional status of the hypothalamus and ovaries. In the clinical, level of FSH significantly and continued to increase is one of the major indicators to determine the emergence of female menopause.

## COMPONENTS

## **REAGENTS AND MATERIALS PROVIDED**

Each kit contains:

- 1. Each pouch contains one strip with one desiccant bag
- 2. Instruction for use
- 3. Urine cup

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer or stopwatch

## WARNING AND PRECAUTIONS

- 1. For in vitro diagnostic use only.
- 2. Do not use beyond the labeled expiration date.
- 3. Do not use the test if the pouch has been perforated.
- 4. Do not modify the test procedure.

5. Do not reuse the test devices. Discard it in the dustbin after single use.

6. Urine that has been chemically treated, heated, diluted, or otherwise modified may give inaccurate results.

7. Always interpret the results under good light conditions to avoid misreading of the results.

8. If desiccant bag is not present in the pouch, DO NOT USE the test.

9. Always add accurate volume of specimen by following the instruction.

10. This test should not be used as a basis for fertility and contraception, nor to determine ovulation and pregnancy.

11. 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 decreased 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.

## STORAGE

Follicle Stimulating Hormone (FSH) tests should be stored at room temperature (4-30°C, do not freeze) for 24 months from the date of manufacture. Keep the test strip in sealed pouch until use. Once you have taken the test strip out of the pouch, perform the test as early as possible (within 1 hour) to avoid test strip from becoming moist.

#### SAMPLE COLLECTION AND TEST PREPARATION

1. First morning urine typically contains the highest concentration of FSH and is therefore the best sample for performing the urine test. However, any urine specimen may be used.

2. Collect the urine specimen in a clean container. Do not use preservatives.

3. If the specimen is not used immediately following collection, should be refrigerated at 4°C.

## **EXAMINATION PROCEDURE**

Allow the test, urine specimen and/or controls to reach room temperature prior to testing.

1. Before opening, allow the test strip to reach room temperature. Use it immediately after opening.

2. See the illustration below, immerse the test strip vertically in the urine specimen for 5 seconds. Do not pass the maximum line (MAX) on the test strip when immersing the strip.

3. Place the test strip on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. Read results at 5-10 minutes. Do not interpret the result after 10 minutes.



#### **INTERPRETATION OF RESULTS**

1. *Negative:* No purple lines appear within 10 minutes in the test zone (T), only a purple line in the control zone (C), which this indicates that the specimen does not contain a detectable level of FSH.

2. *Positive:* Two lines are visible, but the line in test zone (T) is the same as or darker than the one in the control zone (C).

3. *Invalid:* If no purple lines appear the control zone (C), the test is invalid. Discard the test and repeat with new specimen and new strip.

## **Built-In Control**

Follicle Stimulating Hormone (FSH) tests have a built in procedural control that demonstrates assay validity. A red line appearing adjacent to the control zone (C) indicates that the test runs correctly.

## LIMITATION

1. If specimen is too diluted, it may not contain representative levels of hFSH. The first morning urine generally contains the highest concentration of FSH should be obtained 48-72 hours later and retested. The concentration of hFSH less than 25mIU/mL will be detected as negative.

2. This test must not be used to determine fertility. Contraception decisions should not be made based on the results of this test.

#### PERFORMANCE CHARACTERISTICS

Analytic Sensitivity: 25mIU/mL

Analytic Specificity

The specificity was determined from cross-reaction studies with known amounts of human hormones commonly founded in normal human urine.

Human Luteinizing Hormone (hLH)300mIU/mLHuman Thyroid Stimulating Hormone (hTSH)250µIU/mLInterference Testing250µIU/mL

The following substances were shown not to interfere with the Follicle Stimulating Hormone (FSH) tests at or below the following concentration.

Acetaminoph	20mg/dL	Caffeine	20mg/dL	Estriol (E-3)	25ng/mL
Ascorbic Acid	20mg/dL	Cortisol	200ng/mL	Gentisic Acid	20mg/dL
Acetylsalicyli	20mg/dL	Albumin	2000mg/dL	Glucose	2000mg/dL
Ampicillin	20mg/dL	DHEAS	500ng/mL	Tetracycline	20mg/dL
Atropine	20mg/dL	Estradiol (E-2)	25ng/mL	Uric Acid	10mg/dL

#### **Table 1 Interference substances**

#### Precision

Intra-assay: In the study, two replicate assays were performed with each of three specimens containing 0, 25mI-U/mL FSH. Correct negative and positive results were registered in 100% of the assays.

Inter-assay: The study involved the same five specimens containing 0, 25mIU/mL FSH. The samples were analyzed in 12 independent assays with the Follicle Stimulating Hormone (FSH) tests originating from three different lots at different times during two months. Again, expected negative and positive results were registered in 100% of the assays.

#### Clinical Study

This clinical study selected 60 cases of irregular menstrual and menopausal symptoms in women (positive group), 60 cases of non-menstrual and menopausal symptoms in women (positive group) and 120 cases without symptoms of menopause women (negative group) test, continuous monitoring for 4 weeks, at the same time with the company agent and has achieved the qualifications listed at the same time. The coincidence rate of test results was more than 98%.

#### REFERENCE

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**INDEX OF SYMBOLS** 

2	Do not re-use		
REF	Catalogue number		
IVD	For In Vitro Diagnostic medical device		
Х	Use by date		
Z	Date of manufacture		
4 C - 30 C	Temperature limitation		
	Consult instructions for use		
EC REP	Authorized Representative in the European Community		
LOT	Batch code		
$\sum_{n}$	Contains sufficient for < n > tests		
<b>C €</b> 0123	CE Mark		
	Manufacturer		

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