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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 midstream with one desiccant bag
2. Instruction for use

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 midstream in sealed pouch until use. Once you have taken the test midstream out of the pouch, perform the test as early as possible (within 1 hour) to avoid test midstream from becoming moist.

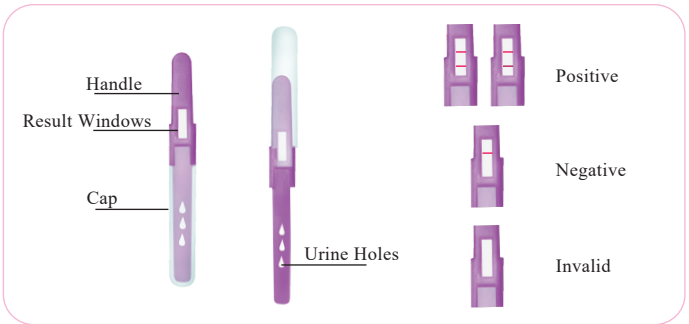
SAMPLE COLLECTION AND TEST PREPARATION

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. Urine specimen could be collected 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 midstream to reach room temperature. Use it immediately after opening.
2. Take off the clear cap from sample end of test midstream and put it to other end of test midstream to cover window area.
3. Hold the end of cap and put the urine holes in urinating stream for 3-5 seconds.
4. Re-cap the test midstream and place it on a clean, dry flat surface, start the timer and wait for the colored line(s) to appear. Read results at 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 midstream.

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.

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/mL
Human Thyroid Stimulating Hormone (hTSH) 250μIU/mL

Interference Testing

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

Table 1 Interference substances

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

Precision

Intra-assay: In the study, two replicate assays were performed with each of three specimens containing 0, 25mIU/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

1. Cobin R H. AACE medical guidelines for clinical practice for management of menopause[J]. Endocrine Practice, 1999:354-366.
2. Cauchon E, Liu S, Percival M D, et al. Development of a homogeneous immunoassay for the detection of angiotensin I in plasma using AlphaLISA acceptor beads technology[J]. Analytical biochemistry, 2009, 388(1): 134-139.
3. Poulsen F, Jensen K B. A luminescent oxygen channeling immunoassay for the determination of insulin in human plasma[J]. Journal of biomolecular screening, 2007, 12(2): 240-247.
4. Backer L C, Rubin C S, Marcus M, et al. Serum follicle-stimulating hormone and luteinizing hormone levels in women aged 35-60 in the U.S. population: the Third National Health and Nutrition Examination Survey (NHANES III, 1988-1994).[J]. Menopause-the Journal of the North American Menopause Society, 1999, 6(1):29-35.
5. Beaudet L, Bédard J, Breton B, et al. Homogeneous assays for single-nucleotide polymorphism typing using AlphaScreen[J]. Genome research, 2001, 11(4): 600-608.
6. McGiven J A, Sawyer J, Perrett L L, et al. A new homogeneous assay for high throughput serological diagnosis of brucellosis in ruminants[J]. Journal of immunological methods, 2008, 337(1): 7-15.

INDEX OF SYMBOLS

	Do not re-use
REF	Catalogue number
IVD	For In Vitro Diagnostic medical device
	Use by date
	Date of manufacture
4°C 30°C	Temperature limitation
	Consult instructions for use
EC REP	Authorized Representative in the European Community
LOT	Batch code
Σ n	Contains sufficient for < n > tests
CE 0123	CE Mark
	Manufacturer

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