SCREEN

SCREEN IFA TEST FSH
(Whole Blood/Serum/Plasma)
Package Insert

REF: SC-1385	English

A test for the diagnosis of follicle stimulating hormone (FSH) to detect follicle stimulating hormone (FSH) in Whole Blood/Serum/Plasma with the use of SCREEN® fluorescence Immunoassay Analyzer.
For professional in vitro diagnostic use only.

INTENDED USE

The FSH Test Cassette (Whole Blood/Serum/Plasma) is intended for in vitro quantitative determination follicle stimulating hormone (FSH) in Whole Blood, Serum or Plasma as an aid in the diagnosis of menopause.

SUMMARY

Menopause is the permanent cessation of menstruation but is usually not scientifically diagnosed until one full year after a woman's menstrual periods have stopped. The period leading up to menopause, and the 12 months following, is known as perimenopause. Many women experience symptoms during this time including hot flashes, irregular menstrual cycles, sleep disorders, vaginal dryness, hair loss, anxiety and mood swings, short-term memory loss and fatigue. The onset of perimenopause is caused by changes in the levels of hormones in the female body that regulate the menstrual cycle. As the body produces less and less estrogen, it increases its production of FSH, which normally regulates the development of a female's eggs.1-3
Therefore, testing for FSH can help determine whether a woman is in the perimenopause stage. If a woman knows she is perimenopausal, she can take the appropriate steps to keep her body healthy and avoid the health risks associated with menopause, which include osteoporosis, increased blood pressure and cholesterol, and increased risk of heart disease.4,5
The FSH Test cassette is a rapid test that quantitatively detects the FSH level in Whole Blood, Serum or Plasma specimen. The test utilizes a combination of antibodies including a monoclonal anti-FSH antibody to selectively detect elevated levels of FSH. The minimum detection level is 10mIU/mL.

PRINCIPLE

The FSH Test Cassette (Whole Blood/Serum/Plasma) is based on Fluorescence Immunoassay for the detection of FSH human Follicle Stimulating Hormone in Whole Blood /Serum/Plasma to evaluate the onset of menopause in women. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains FSH, it attaches to the fluorescent microspheres-conjugated anti-FSH antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of FSH in the sample correlates linearly with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and standard curve, the concentration of FSH in the sample can be calculated by SCREEN® Analyzer to show FSH concentration in specimen.

REAGENTS

The test contains anti-FSH antibody conjugated fluorophores and capture reagents coated on the membrane.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Leggere l'intera procedura attentamente prima di effettuare il test.
9. Read the entire procedure carefully prior to any testing.

The FSH Test Cassette should only be used with the SCREEN® Analyzer by approved medical professionals

STORAGE AND STABILITY

1. The kit should be stored at 4-30 °C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. **Do not freeze.**
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND PREPARATION

Preparation
1. Before performing the test, please make sure that all components are brought to room temperature (15-30℃). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
2. Take a tube with buffer solution out of the kit. Document patients name or ID on it.

Sample Handling
1. Collect the specimen according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 1 day, for long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be used within 1 day of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
4. EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as the coagulant tube for collecting the blood specimen.

Sample Dilution
1. The specimen (**75ul of serum/plasma/whole blood**) can be added directly with the micro pipette into the buffer.
2. Close the tube and shake the sample by hand for approximately **10 seconds** so sample and dilution buffer mix well.
3. Let the diluted sample homogenize for approximately **1 minute**.
4. It is best to place the diluted sample on an ice pack and leave the sample at room temperature for no more than 8 hours.

MATERIALS

Materials Provided
- Test Cassettes
- Specimen Collection Tubes with Extraction Buffer
- ID Card
- Package Insert

Materials Required But Not Provided
- Timer
- Centrifuge
- SCREEN® Fluorescence Immunoassay Analyzer
- Pipette

DIRECTIONS FOR USE

Refer to SCREEN® Fluorescence Immunoassay Analyzer Operation Manual for the complete instructions on use of the Test. The test should be conducted in room temperature.
1. **Portare test, campione, buffer e/o controlli a temperatura ambiente (15-30°C) prima del test**.
2. Turn on the Analyzer power. Then according to the need, select "Standard Test" or "Quick Test" mode.
3. Take out the ID card and insert it into the Analyzer ID Card Slot.
4. Squeeze **75µl Whole Blood/Serum/Plasma** into the buffer tube by pipette; mix the specimen and the buffer well
5. **Add diluted specimen with a Pipette:** Pipette **75µl diluted specimen** into the sample well of the test cassette. Start the timer at the same time.
6. There are two test modes for SCREEN® Fluorescence Immunoassay Analyzer, Standard Test mode and Quick Test mode. Please refer to the user manual of SCREEN® Fluorescence Immunoassay Analyzer for details.

Quick Test" mode: After **15 minutes** of adding sample, Insert the test cassette into the Analyzer, click "**QUICK TEST**", fill the test information and click "**NEW TEST**" immediately. The Analyzer will automatically give the test result after a few seconds.
"Standard Test" mode: Insert the test cassette into the Analyzer immediately after adding specimen, click "**STANDARD TEST**", fill the test information and click **"NEW TEST"** at the same time, The Analyzer will automatically countdown 1**5 minutes**. After the countdown, the Analyzer will give the result at once.

INTERPRETATION OF RESULTS

Results read by SCREEN® Fluorescence Immunoassay Analyzer.
The result of tests for FSH is calculated by SCREEN® Fluorescence Immunoassay Analyzer and display the result on the screen. For additional information, please refer to the user manual of SCREEN® Fluorescence Immunoassay Analyzer.
Linearity range of FSH Test is 10-80 mIU/mL.
Reference value: 3~25mIU/mL.

QUALITY CONTROL

Each FSH Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test cassette was inserted and read properly by SCREEN® Fluorescence Immunoassay Analyzer. An invalid result from the internal control causes an error message on SCREEN® Fluorescence Immunoassay Analyzer indicating that the test should be repeated. An invalid result from the internal control causes an "N/A" message on SCREEN® Fluorescence Immunoassay Analyzer. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The FSH Test Cassette (Whole Blood/Serum/Plasma) is for professional in vitro diagnostic use, and should only be used for the quantitative detection of FSH. The test works only when the test procedures are precisely followed.
2. The FSH Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of FSH in the specimen and the test may not be used to determine fertility. It cannot be used to determine the ability to become pregnant. Contraception decisions should not be made based on the results of this test alone.
3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. Oral contraceptive and pregnancy may affect the test and produce inaccurate results.
5. The results of FSH Tests are based on measuring the levels of FSH in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.
6. Keep out of the reach of children.

EXPECTED VALUES

Concentrations	Clinical Reference
> 25 mIU/mL	Menopause has most likely occurred. Test may be repeated. Discuss with patient methods and therapies to promote good health after menopause.
< 25 mIU/mL	Most likely not experiencing perimenopause this cycle.

PERFORMANCE CHARACTERISTICS

1. Accuracy
The test deviation is ≤±15%.
2. Sensitivity
The FSH Test Cassette (Whole Blood/Serum/Plasma) can detect levels of FSH as low as 10 mIU/mL in Whole Blood/Serum/Plasma.
3. Detection range

10~80 mIU/mL

4. Linearity range

10~80 mIU/mL, R≥0,990

5. Cross- reactivity

The FSH Test Cassette (Whole Blood/Serum/Plasma) minimum detection level is 10mIU/mL. The addition of LH (1,000 mIU/mL), hCG (100 IU/mL), and TSH (1,000 µIU/mL) to negative (0 mIU/mL FSH) and positive (25 mIU/mL FSH) specimens showed no cross-reactivity.

6. Interfering Substances

The following potentially interfering substances were added to FSH negative and positive specimens, respectively.

Acetaminophen:20 mg/dL	Caffeine:20 mg/dL
Acetylsalicylic Acid:20 mg/dL	Gentisic Acid:20 mg/dL
Ascorbic Acid:20mg/dL	Glucose 2 g/dL
Acetoacetic Acid:2 g/dL	Hemoglobin:500 mg/dL
Bilirubin:100mg/dL	

None of the substances at the concentration tested interfered in the assay.

BIBLIOGRAFY

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2. Perry S, O'Hanlan K. Natural Menopause: The Complete Guide. Reading, MA, Addison-Wesley, 1997.
3. Stanford, JL, Weiss NS, et al. Combined Estrogen and Progestin Hormone Replacement Therapy in Relation to Risk of Breast Cancer, J. Am. Med. Assoc. 1995; 274(2): 137-142.
4. Speroff L, Glass RH, Kase NG, Clinical Gynecologic Endocrinology and Infertility 5th Ed, Williams and Wilkins, Baltimore, MD. 1994; 588.
5. Jacobs DS, Demott DR, Grady HJ, Horvat RT, Huestis DW, Kasten BL, Laboratory Test Handbook 4th Ed, Lippincott Williams and Wilkins, Baltimore, MD. 1996.

INDEX OF SYMBOLS

	Consult Instructions for Use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by	2	Do not reuse
4°C 30°C	Store between 4-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		

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