ASTAM DIAGNOSTICS

PRODUCT INSERT

REF FSHD

PRATHAM® FSH (Menopause) Test Kit

For the qualitative detection of FSH (Follicle Stimulating Hormone) in human urine

INTENDED USE

PRATHAM® FSH Test Kit is a lateral flow through immunochromatographic test for the qualitative determination of Follicle Stimulating Hormone (FSH) in urine specimens as an aid for detection of menopause in female. For professional use only.

INTRODUCTION

Menopause is the permanent cessation of menstruation but is usually no scientifically diagnosed until one full year after a women'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 (Follicle Stimulating Hormone), which normally regulates the development of a female's eggs. 1,2,3 Therefore, testing for FSH can help determine whether a women is in the perimenopause stage. If a women knows she is premenopausal, she can take the appropriate steps to keep her body healthy and avoid the health risks associated with menopasue, which include osteoporosis, increased blood pressure and cholesterol, and increased risk of heart disease. Pratham FSH Test Kit (Urine) is a rapid test that qualitatively detects the FSH level in urine specimen at the sensitivity of 30mIU/mL. The test utilizes a combination of antibodies including a monoclonal anti-FSH antibody to selectively detect elevated levels of FSH. At the level of claimed sensitivity, the FSH One Step Menopause Test Device (Urine) shows no cross-reactivity interference from the structurally related glycoprotein hormones hCG, hLH and hTSH at high physiological levels.

TEST PRINCIPAL

PRATHAM® FSH Test Kit is a lateral flow through immunochromatographic test for the qualitative determination of Follicle Stimulating Hormone (FSH) in urine specimens as an aid for detection of menopause in female. The test utilizes a combination of antibodies including a monoclonal anti-FSH antibody to selectively detect elevated levels of FSH. The assay is conducted by adding a urine specimen to the specimen well of the test device and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate. Positive specimens react with the specific antibody FSH colored conjugate to form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wacking has occurred.

KIT COMPONENTS

1. Pouch contents: Test cassette, Sample dropper, Desiccant
2. Instruction for use

MATERIAL REQUIRED BUT NOT PROVIDED

Timer and Urine collection container etc.

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 2-30ºC till the duration of shelf life as indicated on the pouch. Do not freeze. Once the pouch is opened, test card must be used immediately.

PRECAUTIONS

1. For professional in vitro diagnostic use only.
2. Do not use after the expiration date.
3. The test device should remain in the sealed pouch until use.
4. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
5. The test device should be discarded in a proper biohazard container after testing.

SPECIMEN COLLECTION AND STORAGE

The urine specimen must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of FSH; however, urine specimens collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing. Urine specimens may be stored at 2-8ºC for upto 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20ºC. Frozen specimens should be thawed and mixed before testing.

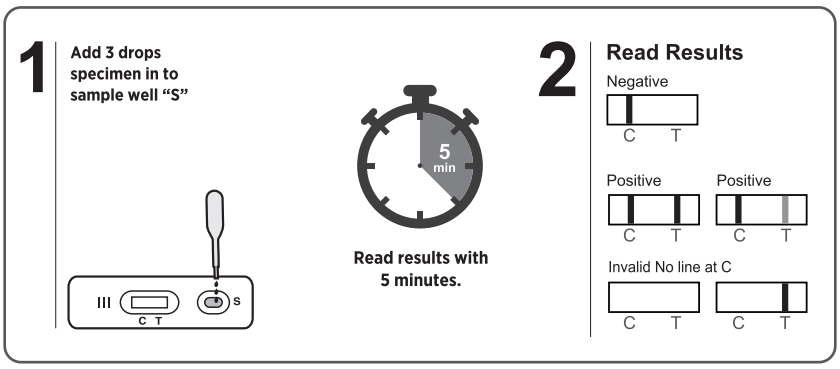
WHEN TO TEST

If the subject is having monthly periods, perform the first test during the first week of the menstrual cycle (Days 2-7, with day 1 being the first day of menstruation). Repeat with the second test 1 week later. If the subject is no longer having regular periods, perform the test at any time during the month and repeat with the second test 1 week later.

TEST PROCEDURE

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Check the packaging is not damaged. If damaged, discard the test and use another test.
3. Open the pouch & check the desiccant. If color of desiccant does not show any change (Remove blue) you can use the test. If color changes then discard the test and use another test.
4. Add 3 drops of urine specimen into the sample well (S) using the disposable sample dropper in kit.
5. Wait for 5 minutes and read result. Do not interpret result after 10 minutes.
6. Discard used card in a biomedical waste container after interpreting the results.

INTERPRETATION OF RESULTS



Negative:

Appearance of two lines at "T" region and "C" region, the result should be considered positive. A positive result indicates that FSH levels are higher than normal and the subject you may be experiencing perimenopause.

Positive:

Appearance of only one colored band at Control line region 'C'. The result should be considered negative. A negative result indicates theat the subject is probably not experiencing perimenopause in this cycle.

Invalid:

Appearance of no colored band at the Control line region 'C', the result should be considered as invalid. Repeat the test with a new test card.

INTERNAL QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. External controls are not supplied with this kit. It is recommended that positive and negative controls should be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Handle the negative and positive controls in the same manner as patient specimens.

PERFORMANCE CHARACTERISTICS

1. Sensitivity: 99.9%
2. Specificity: 98.5%
3. Average Surge level is 30 mIU / ml of urine.

LIMITATION OF THE TEST

1. For professional in vitro diagnostic use.
2. Oral contraceptives may affect the test and produce inaccurate results.
3. The test may not be used to determine fertility. It cannot be used to determine the subject's ability to become pregnant.
4. Contraceptive decisions should not be made based on the results of this test. Please contact a doctor for contraceptive advice.

DISPOSAL

Consider all test devices run with human specimen as potentially infectious and discard using standard biosafety practices.

DISCLAIMER:

Every precaution has been taken to ensure diagnostic ability and accuracy of this product. This product is used outside the control of manufacturer and distributors. Various factors including storage temperature, environment conditions, and procedural errors may affect the result. A person who is subject of the diagnosis should consult a doctor for further confirmation.

WARNING

The Manufacturer and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative in the use of this product.

BIBLOGRAPHY OF SUGGESTED READING

1. Speroff L, Glass RH, Kase NG, Clinical Gynecologic Endocrinology and Infertility 5th Ed, Williamsand Wilkins, Baltimore, MD. 1994;588.
2. Jacobs DS, Dmott DR, Grady HJ, Horvat RT, Huestis DW, Kasten BL, Laboratory Test Handbook 4th ED, Lippincott Williams and Wilkins, Baltimore, MD. 1996.
3. Turkington CA. The Perimenopause Sourcebook. Contemporary Books, New York, NY. 1998.
4. Perry S, O'Hanlan K. Natural Menopause: The Complete Guide. Reading, MA, Addison-Westley, 1997.
5. 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.

SYMBOLS

Read instructions for use	Name of Manufacturer	For single use only
No. of test	Expiry Date of Kit.	Date of manufacturing of IVD Kit
IVD In-vitro diagnostic use	Keep away from Sunlight	REF Reference Catalogue Number
Storage Condition		

ASTAM DIAGNOSTICS

Manufactured By:
ASTAM DIAGNOSTICS PVT. LTD.
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Alwar, Rajasthan-301019 (INDIA)
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