

HEALTH-CHEM DIAGNOSTICS LLC

3341 S.W 15th ST. POMPANO BEACH, FL 33069- USA - Tel: (954) 979-3845 – Fax: (954) 979-7997 - www.healthchemdiagnostics.com

DIPSTREAM™ ONE STEP FSH

For the rapid detection of Follicle Stimulating Hormone (hFSH) in human urine specimens (Menopause Testing)

INTENDED USE

The ONE STEP FSH is intended for detecting the presence of FSH in human urine specimens in a qualitative format sensitive to 40 mIU/ml. This test is for in vitro screening use in obtaining a visual, qualitative determination of FSH in urine.

INTRODUCTION

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 is in mid-menstrual cycle or indicating the onset of pre-menopause. 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 the child bearing stage of life, the ovaries gradually make less of the hormone estrogen and FSH increases. FSH normally regulates the growth and development of an egg. Once this part of the monthly cycle is 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. The slow change in ovary function can happen between 2 and 10 years before the final period. This early stage before menopause is called pre-menopause. 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 ONE STEP FSH Test is a chromatographic immunoassay 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 ONE STEP FSH is a qualitative, two site sandwich immunoassay for the determination of human Follicle Stimulating Hormone (FSH) in urine specimens. The membrane is pre-coated with FSH specific antibodies on the test region. During the test, the specimen is allowed to react with the FSH monoclonal antibody-colloidal gold conjugate which was lyophilized on the test strip. The mixture then moves upward on the membrane chromatographically by 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 reagent on the test region and produces a red to purple colored band when FSH concentration is equal to, or greater than 40mIU/ml. Presence of this colored band in the test region suggests a positive result. To serve as a procedural control, a



For in vitro diagnostic use only

colored band at the control region will always appear, regardless of the presence of FSH.

STORAGE AND STABILITY

The ONE STEP FSH can be stored refrigerated, or at room temperature (2-28 °C) in its sealed pouch. Avoid freezing.

PRECAUTIONS

1. For in vitro diagnostic use.
2. Do not use after expiration date.
3. Test device should remain sealed until ready for use.
4. Keep out of reach of children.

ASSAY PROCEDURE

Remove the 2-way DipStream from the foil packet; chose only one way of testing below:

✦ Using the test as a MidStream

Using the wide handle, hold the test so that the fiber tip is in your urine stream for at least 6 seconds.

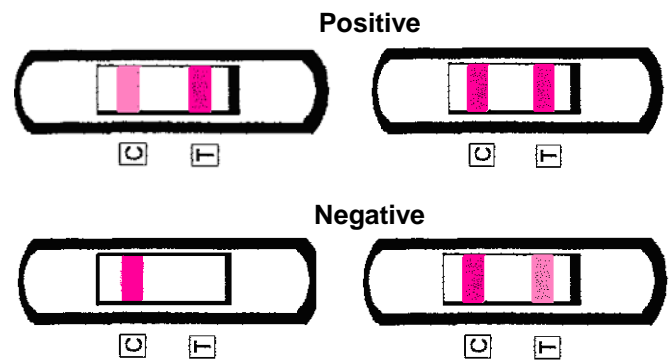
✦ Using the test as a Dip Test

Collect your urine in a clean glass container, then dip the test into the urine container for 6 to 10 seconds.

Note: Even if the plastic is waterproof, do not submerge the plastic part of the test.

- ✦ Read results 5 minutes after adding your urine.

Note: To avoid confusion, discard the test device after interpreting your results and do not read the test results after ten (10) minutes.



SPECIMEN COLLECTION

Collect and store specimens following standard clinical procedures.

1. The urine specimen must be collected in a clean dry container, either plastic or glass, without preservative. No centrifugation or filtration of urine is required. However, if the performance of the test is hindered by high turbidity, or presence of particulates in the specimen, it should be centrifuged to remove solids, prior to performing the test.

2. The test can be performed at anytime during the day, however, for best results, the urine sample for the test should be collected at about the same time each day. It is highly recommended that the first morning urine be tested, since it generally contains the highest concentration of FSH. Urine collected during the day will dilute the FSH level and may cause a false negative result.

3. If specimens cannot be tested after collection, they should be stored refrigerated at 2-8°C for 24 hours. If samples are refrigerated, they must be equilibrated to room temperature before testing. If testing is delayed more than 24 hours, the specimen should be frozen at -20 °C. Do not use a frost-free freezer, which may allow the specimens to go through freeze-thaw cycles that may denature the FSH and cause spurious results. The frozen specimen must be thawed, brought to room temperature and thoroughly mixed before testing. Avoid repeated thawing and freezing.

INTERPRETATION OF RESULTS

Positive: If the Test band is *of equal or greater intensity (equal or darker)* than the control band, this is a positive result and a good indication that the woman is in menopause.

Negative: If the test band is of lesser intensity (lighter) than the control band or cannot be seen, this means the FSH level of the sample is at or near its basal (normal) level and that the woman is not in menopause.

Invalid: If no control band appears within five minutes, the result is invalid and should be ignored. A visible control band is needed in all cases to confirm proper test operation. No control band indicates either the test procedures were not followed correctly, or the test reagents failed. Carefully review the test procedures and retest with a fresh (unused) test device.



QUALITY CONTROL

A procedural control is included in the test. A colored band appearing on the control region indicates proper performance and reactive reagents. Good Laboratory Practice includes the use of a control to ensure proper test performance. FSH negative and positive controls are available commercially (Bio-Rad Laboratories Liquichek™ Immunoassay Plus Control). Each laboratory should establish their own criteria for interpretation of results as baseline FSH levels and patterns of FSH secretion can vary among individuals. The use of control samples is advised to assure the performance of the test and reactivity of the reagents. It is recommended that the laboratory prepares its own urine pools using known menopausal urine (30-50 mIU/ml) as a positive, and a pre-menopausal, or pregnant female urine (<15 mIU/ml) as a negative.

LIMITATIONS

1. If a specimen is too diluted (i.e. low specific gravity), it may not contain representative levels of hFSH. It is highly recommended that the first morning urine be tested, since it generally contains the highest concentration of FSH. hFSH concentrations less than 40 mIU/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 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.

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.

PERFORMANCE AND CHARACTERISTICS

Sensitivity: The analytical sensitivity of the FSH Rapid Test has been set at 40 mIU/ml or higher.

Specificity: The specificity was determined from cross reaction studies with known amounts of Chorionic Gonadotropin Hormone (hCG), Luteinizing Hormone (hLH), and Thyroid Stimulating Hormone (hTSH). 250 IU/ml hCG, 500mIU/ml hLH and 250 mIU/ml hTSH all gave negative results.

Interference Testing: The following substances at stated concentrations do not interfere with the FSH rapid test in the assay.

Acetaminophen	20 mg/dl
Acetylsalicylic Acid	20 mg/dl
Ascorbic Acid	20 mg/dl
Atropine	20 mg/dl
Caffeine	20 mg/dl
Gentisic Acid	20 mg/dl
Glucose	2.0 g/dl
Hemoglobin	1.0 mg/dl

REFERENCES

1. AACE Medical Guidelines for Clinical Practice for Management of Menopause, Endocrine Practice, Vol. 5 No. 6, Nov / Dec. 1999.
2. Greendale, G., Lee, N., Arriola, E., The Menopause, The Lancet, Vol. 353, Fe b. 13, 1999.
3. .Mayeaux, E.J., Jr., Menopause/Pre-menopause: Issues/Symptoms/ Treatment, Lecture at Primary Care in Women's Health -1999.
4. Backer, I., 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), Menopause, Vol. 6, No. 1, 1999. MPC-DXU-WI-1-023-38-B; November 2003
5. Dahl, K.D., Stone, M.P. J. Androl.13:11-22 (1992)
6. Simoni, M., Nieschlag, E. Endocrinol.Invest.14:983-997 (1991)
7. Sairam, M.R., In Li, C.H.Ed.Hormonal proteins and peptides, New York Academic Press, 1, 1983.
8. Maderbacher, S., Shu-Chen, T., Schwarz, S., Dirnhofer, S., Wick, G., Berger, P. Clin.Chem.39:1435-1439 (1993)
9. Desai, M.P., Khatkhatay, M.I., Sankolli, G.M., Joshi, U.M. Immunoassay 12:83-98 (1991)

Manufactured by Health-Chem Diagnostics LLC
3341 SW 15th Street, Pompano Beach, Florida, USA

www.healthchemdiagnostics.com

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