DRG® Follicle Stimulating Hormone (FSH) Rapid Test (RAP-4153)
(Dipstick)

Revised 4 Jan. 2011 rm (Vers. 2.1) **IVD**

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

For *in vitro* diagnostic use

INTENDED USE
The DRG FSH Rapid Test is intended for detecting the presence of FSH in urine specimens in a qualitative format sensitive to 25 mIU/ml. This test is for in vitro screenning use in obtaining a visual qualitative result for FSH in urine to predict the time of menopausal.

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 in mid-menstrual cycle or indicating the onset of perimenopause. 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 childbearing 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 Perimenopause. 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 (CIA) 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 DRG FSH Rapid Test is a qualitative, two site sandwich immunoassay for the determination of human follicle stimulating hormone (FSH) in urine specimens. The membrane was precoated with FSH specific antibodies on the test region. During the test, the specimen is allowed to react with the FSH monoclonal antibody-colloid gold conjugate which was pre-dried on the test strip. The mixture then moves upward on the membrane chromatographically by the 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 regents on the test region and produces a colored band when FSH concentration is equal to or greater than 25 mIU/ml. Absence of this colored band in the test region suggests a negative result. To serve as a procedural control, a colored band at control region will always appeared regardless the presence of FSH.

STORAGE AND STABILITY
The DRG FSH Rapid Test can be store refrigerated or at room temperature (2-30 ºC) in sealed pouch.
Avoid freezing.

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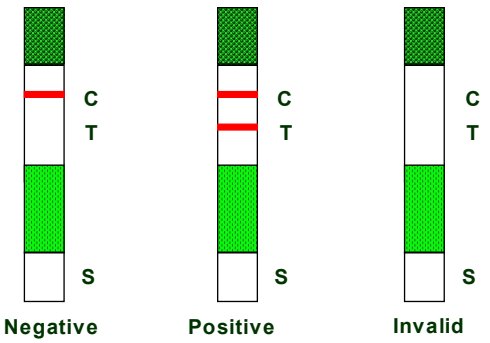
PRECAUTION
1.For *in vitro* diagnostic use.
2.Do not use after expiration date.
3.Test device should remain sealed until ready for use.
4.The reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azide build up. Specimens should be considered hazardous and handled appropriately.

SPECIMEN COLLECTION
Collect and storage 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 ºC 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 ºC. 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.

ASSAY PROCEDURE
For Dipstick Test
1.Remove the strip from pouch and label the device with specimen identification.
2.Carefully place the white end (sample pad) of the reaction strip into the specimen vial. Make sure that the absorbent patch (white end of the strip) is underneath the surface of the sample liquid. A 10 to 30 second dip into the sample is sufficient.
3.Remove end of the test strip from the reaction vial and start the watch or timer.
4.Within 5 minutes, a colored band will appear at the top of the test region, indicating the reaction is completed.



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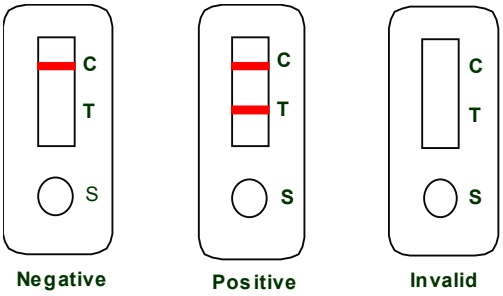
For Card Test
1.Remove the device from pouch and label the device with specimen identification.
2.Add 3 or 4 drops (150 µl) of urine to the sample well (S).
3.Observe the result within 5 minutes, no longer than 10 minutes.



INTERPRETATION OF RESULT
Negative: Only one colored band appears on the control region (C). No colored band in the test region (T).
Positive: In addition to the control band, a distinct colored band also appears in the test region (T).
Invalid: If no bands appear after 10 minute, the result is invalid. The protocol may not have been performed correctly, or the test is deteroirated. The assay should be repeated using a new test device.
Note: Do not interpret result after 10 minutes.

QUALITY CONTRIL
The procedural control is included in the test. A colored band appearing on the control region indicates proper performance and reactive reagents.
Good laboratory practices include the use of 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 thire 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 prepare its own urine pools using known menopausal urine (30-50 mIU/ml) as a positive, and a pre-menopause or pregnant female urine (<15 mIU/ml) as a negative.

LIMITATION
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. If hFSH concentrations less than 25 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

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test. This test will not determine ovulation or pregnancy status.

PERFORMANCE AND CHARACTERISTIC

Sensitivity:
The analytical sensitivity of the DRG FSH Rapid Test has been set at 25 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 certain concentrations do not interfere with the FSH rapid test in the assay.

Acetaminophen	20 mg/dl
Acetysalicylic Acid	20 mg/dl
Ascorbic Acid	20 mg/dl
Atropine	20 mg/dl
Caffeine	20 mg/dl
Gentesic Acid	20 mg/dl
Glucose	2.0 g/dl
Hemoglobin	1.0 mg/dl

REFERENCE

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