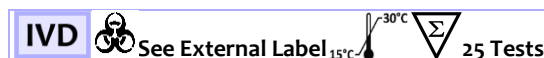




OneStep FSH Urine RapiCard™ InstaTest

REF 198220

PIC FT198220YQ1



FSH Urine RapiCard™ InstaTest	
Principle	Rapid Chromatographic Immunoassay
Detection	Qualitative
Sensitivity	40 mIU/mL

PRODUCT FEATURES

✓ **High Sensitivity and Specificity**

✓ **Built in Internal Controls**

✓ **Simplified Workflow, Non-invasive, and Safe**

✓ **Rapid and Faster Results**

INTENDED USE

The Cortez Diagnostics OneStep FSH Urine RapiCard™ InstaTest qualitative immunoassay designed to detect follicle stimulating hormone (FSH) in human urine at concentrations equal to or greater than 40 mIU/mL. This product is for health care professional use only.

SIGNIFICANCE AND SUMMARY

FSH is secreted by the β -cells of the anterior pituitary under the control of the gonadotropin releasing hormone produced in the hypothalamus. It consists of two subunits designated alpha (α) and beta (β). The α sub-units of FSH are biochemically identical with that of LH, TSH and FSH, whereas the β sub-unit of FSH is biochemically unique and confers biological and immunological specificity. The β sub-unit determines the bioactivity of FSH. FSH and LH exist in both males and females for normal sexual function. The secretory patterns are very different for males and females. In sexually mature adults, FSH and LH are secreted not in constant amounts, but in pulses that result in rapid fluctuations over the entire reference range. Concentration of FSH and LH may increase or decrease by 50 to 100%. Therefore, samples obtained within the same day from the same individual may vary, but be within the reference range. In mature females FSH initiates the growth and development of ovarian follicles. During ovulation, when is ruptured, the follicle (corpus luteum) secretes estradiol and progesterone, which control the circulating levels of FSH by a negative feedback effect on the hypothalamus. In menopause, there is a decrease in estradiol secretion due to the diminished ovarian function. As a result of the lack of a negative feedback effect, with diminished estradiol, the circulation FSH levels become significantly increased. In the mature male, FSH is associated with the stimulation and maintenance of spermatogenesis. Testosterone and estradiol have the role of providing the negative feedback signal to the hypothalamus for controlling the release of FSH. Infertility in males may be due to hypogonadism as a result of primary testicular failure. Testicular failure may be functional failure to mature or a result of germ cell damage. In those conditions, FSH levels are raising dramatically due to the lack of a negative feedback effect. Low FSH values may relate to insufficient

Gonadotropin production and pituitary or hypothalamic dysfunctions. Pituitary dysfunction is often a causative agent of secondary gonad failure, which results in decreased secretion of both FSH and LH. The net effect in both males and females is infertility. This is also occurred with central nervous system disorders and following administration of certain depressant drugs such as the phenothiazines. Although there are significant exceptions, ovarian failure is indicated when FSH concentrations exceed 40 mIU/mL.

ASSAY PRINCIPLE

This assay is a one-step lateral flow chromatographic immunoassay. The test strip includes (1) a conjugate pad containing mouse monoclonal anti-FSH antibody conjugated to colloidal gold, and (2) nitrocellulose membrane containing a test line (T line) and a control line (C line). When the proper amount of specimen is applied to the sample pad of the device, FSH in the specimen binds to the anti-FSH antibody-gold conjugate in the conjugate pad to form a complex and migrates along the membrane strip. If the specimen contains FSH at a level equal to or greater than 40 mIU/mL, the complex will bind to the capture antibody coated on the T line to develop a colored band. If the specimen does not contain FSH or the FSH level is below the detectable level, the T line will not develop. The C line is coated with goat anti-mouse antibody, which will bind to the gold-antibody conjugate and form a colored line regardless of the presence of FSH.

MATERIALS AND COMPONENTS

Materials provided with the test kit

25 Cassettes, each sealed in a foil pouch with a dropper pipette and desiccant
1 Package insert (Instructions for use)

Materials required but not provided

Specimen collection containers
Timer

Diagnostic Automation/Cortez Diagnostics, Inc.

21250 Califa St, Suite 102 and 116, Woodland Hills, CA 91367 USA Phone: 818-591-3030, Fax: 818-591-8383

Email: onestep@rapidtest.com Website: www.rapidtest.com



STORAGE AND STABILITY

Store the product at room temperature 15-30°C (59-86°F). Each device may be used until the expiration date printed on the label if it remains sealed in its foil pouch. Do not freeze and/or expose this kit to temperatures over 30°C.

SPECIMEN COLLECTION

Each urine specimen must be collected in a clean container. Specimens may be kept at room temperature for 8 hours, at 2-8°C for up to 3 days and at -20°C or lower for prolonged storage. Do not mix specimens.

PRECAUTIONS

- The instructions must be followed to obtain accurate results.
- Do not open the sealed pouch unless ready to operate the assay.
- Do not use expired devices.
- Dispose of all specimens and used assay materials in a proper biohazard container.

ASSAY PROCEDURE

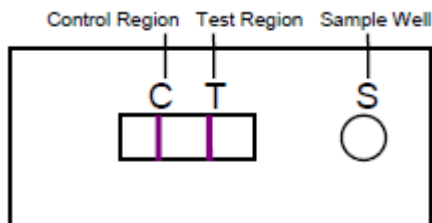
- Refrigerated specimens and other test materials, including tests, **must be equilibrated to room temperature before testing.**
- Remove the cassette from its pouch and place it on a flat surface.
- Add four drops (about 160 µL) of the specimen to the sample well marked as "S" on the cassette.
- **Note:** If migration is not observed in 30 seconds in the result window, add one or two extra drops of urine specimen.
- Strong positive results may be observed in 2-3 minutes. Weak positive results may take up to 5 minutes to develop.
- **IMPORTANT: Do not interpret the results after 10 minutes.**

RESULTS

INTERPRETATION OF RESULTS

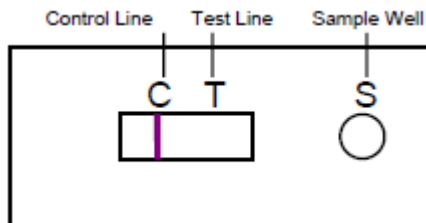
Positive:

If both the C line and T line appear, the FSH concentration of the specimen is equal to or higher than 40 mIU/mL.



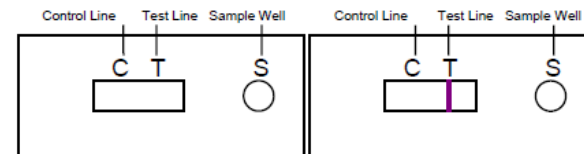
Negative:

If only the C line appears, the FSH concentration of the specimen is not detectable.



Invalid:

If no C line develops within 5 minutes, the result is invalid. In this case, do not report test results. Repeat the assay with a new test. If the result is still invalid, stop using the test and contact the manufacturer.



QUALITY CONTROL

- **Built-in Control Features**
This test contains built-in control feature, the C line. The presence of the C line indicates that an adequate sample volume was used and that the reagents migrated properly. If a C line does not form, the result is invalid. Review the procedure and repeat with a new test.
- **External Quality Control**
Good Laboratory Practice recommends using external controls, positive and negative, to ensure the proper performance of the assay.

LIMITATIONS OF PROCEDURE

- This kit is not intended for any use other than an aid in the diagnosis and treatment of pituitary and gonadal disorders.
- In certain cases of infertility, treatment with human gonadotropin poses a potential problem for the accurate measurement of FSH. The FSH administered can cause the individual to produce antibodies to FSH, which will interfere with the assay results.
- Positive results must be evaluated with other data by a physician before diagnosis.

EXPECTED VALUES

This test is designed to detect FSH at the level as low as 40 mIU/mL (WHO 2nd IRP 78/549) in urine.



PERFORMANCE CHARACTERISTICS

Sensitivity

This test is capable of detecting FSH at the level as low as 40 mIU/mL in urine, standardized to the WHO 2nd IRP 78/549.

Specificity

The α subunit of hTSH, hLH, and hCG is similar to that of FSH, which may cause cross reactivity between those hormones (4). High physiological concentrations of hTSH (up to 1,000 μ IU/mL), hLH (up to 300 mIU/mL), and hCG (up to 300 mIU/mL) spiked in FSH positive (spiked to 40 mIU/mL) and negative specimens were tested, separately, in the FSH Cassette Test, and did not affect the expected results in that study.

Interfering Substances

The following analytes spiked in urine pools containing 0, or 40 mIU/mL FSH (WHO 2nd IRP 78/549) were tested, separately, in the FSH Cassette Test, and did not affect the expected results in that study.

Chemical Analytes

Compound	Concentration
Acetoacetic acid	2,000 mg/dL
Acetaminophen	20 mg/dL
Acetylsalicylic acid	20 mg/dL
Ascorbic acid	20 mg/dL
Benzoyllecgonine	10 mg/dL
Caffeine	20 mg/dL
Cannabinol	10 mg/dL
DMSO	5%
EDTA	80 mg/dL
Ephedrine	20 mg/dL
Ethanol	1%
Gentisic acid	20 mg/dL
Methadone	10 mg/dL
Methanol	10%
Phenothiazine	20 mg/dL
Phenylpropanolamine	20 mg/dL
Salicylic acid	20 mg/dL

β -Hydroxybutyrate	2,000 mg/dL
Uric acid	20 mg/dL

Biological Analytes

Compound	Concentration
Albumin (serum)	2,000 mg/dL
Bilirubin	1,000 μ g/dl
Hemoglobin	1,000 μ g/dL
Glucose	2,000 mg/dL

Positive and negative urine pools were tested at various pH levels. pH ranges from pH 5 to pH 9 did not affect the expected results in the study.

Bacteria

Bacteria	Concentration
<i>E. coli</i>	10^8 CFU/mL
Group B streptococcus	2.5×10^8 CFU/mL
<i>Chlamydia trachomatis</i>	10^4 IFU/mL

REFERENCES

1. Pierce JG, Parsons TF. Glycoprotein hormones: structure and function. Annu Rev Biochem. 1981;50:465-95.
2. Daughaday WH. Adenohypophysis. In: Williams RH, editor. Williams Textbook of Endocrinology. 2nd ed. Philadelphia: W.B. Saunders Co.;1981.
3. Shome B, Parlow AF. Human follicle stimulating hormone (hFSH): first proposal for the amino acid sequence of the alpha-subunit (hFSHa) and first demonstration of its identity with the alpha-subunit of human luteinizing hormone (hLHa). J Clin Endocrinol Metab. 1974 Jul;39(1):199-202.
4. Reame N, Sauder SE, Kelch RP, Marshall JC. Pulsatile gonadotropin secretion during the human menstrual cycle: evidence for altered frequency of gonadotropin-releasing hormone secretion. J Clin Endocrinol Metab. 1984 Aug;59(2):328-37.

MANUFACTURER AND BRAND DETAILS

ISO 13485:2016



Diagnostic Automation/Cortez Diagnostics, Inc.
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Date Adopted	2024-01
Brand Name	RapiCard™ InstaTest
REF 198220	OneStep FSH Urine RapiCard™ InstaTest
PIC	ID198220YQ1
EU REP	AR Experts BV, Boeingavenue 209, 1119 PD Schiphol-Rijk, The Netherlands info@ar-experts.eu
Revision Date: 2011-08-16	