FSH-CHECK-1

Quantitative determination of Follicle Stimulating Hormone (FSH) in whole blood, plasma or serum samples

Ref. 11091 (20 tests) / Ref. 11091-10T (10 tests)

FOR EASY READER® AND EASY READER+® USE ONLY -

I- PRINCIPLE

The follicle stimulating hormone (FSH) is a glycoprotein hormone produced in the anterior pituitary in response to the gonadotropin releasing hormone from the hypothalamus. It promotes the development and maintenance of gonadal tissues which synthetise and secret the steroid hormones. In females, FSH is responsible for the ovum maturation during the menstrual cycle. The level of FSH is controlled through a negative feed-back mechanism by estradiol and progesterone. The determination of FSH in conjunction with LH is useful in detecting amenorrhea or anovulatory menstrual cycles. Furthermore, FSH can be used in diagnosis of polycystic ovary syndrome, psychogenic amenorrhea, pituitary tumors and ectopic tumor production. Follow-up of patients with choriocarcinoma and hydatidiform mole. In males, FSH stimulates the production of sperm and testosterone. FSH and LH measurement in males are useful in detection of primary and secondary testicular failures. FSH values are up to 15 IU/L for adult males and 200 IU/L for post menopausal females. Menstruating females have a mid cycle peak.

The FSH-CHECK-1 is a rapid quantitative assay for the specific detection of FSH in whole blood, plasma and serum samples.

As the test sample flows through the absorbent device, the labelled antibody-dye conjugate binds to the FSH forming an antibody-antigen complex. This complex binds to the anti FSH antibody in the reaction zone (T) and produces a pink-rose coloured band. In the absence of FSH, there is no line in the reaction zone (T). The mixture continues to flow through the absorbent device past the reactive zone (T) and control zone (C). Unbound conjugate binds to the reagents in the control zone (C), producing a pink-rose coloured band, demonstrating that the reagents are functioning correctly.

II- FSH CHECK-1 KIT COMPONENTS

Each kit contains everything needed to perform 10 or 20 tests.

1- FSH CHECK-1 reaction devices :	10	20
2- Disposable plastic pipettes :	10	20
3- Diluent in a dropper bottle :	2.5mL	5mL
4- Instruction leaflet :	1	1

5- **Controls** (**Optional):**

Positive control ref. V6000 and Negative control ref. V6001: a freeze-dried preparation of a non-infectious compound in diluted human serum, tested and found negative for anti-HIV, anti-HCV and HBs antigen, containing 0.05 % sodium azide is optionally available as a positive and negative control (1x 0.25 mL). The concentration range is indicated on the vial label.

III- STORAGE AND STABILITY

1- All FSH CHECK-1 kit components, including optional control before reconstitution with distilled water, should be stored at any temperature between +4°C and +30°C in their original package.

2- **Do not freeze the test kit**.

3- FSH CHECK-1 is stable until the expiry date stated on the package label.

IV- PRECAUTIONS

1- For *in vitro* diagnostic use and for professional use only.

2- Read the instruction notice carefully before using the test.

3- Handle all specimens as if they contained infectious agents. When the assay procedure is completed, dispose of specimen carefully after autoclaving them for at least one hour. Alternatively, they can be treated with 0.5% to 1% solution of sodium hypochlorite for one hour before disposal.

4- Wear protective clothing such as laboratory coats and disposable gloves while assaying samples.

5- Do not eat, drink or smoke in the area where specimens and kit reagents are handled.

6- Avoid any contact between hands and eyes or nose during specimen collection and testing.

7- Do not use the test from a damaged protective wrapper.

8- Do not use beyond the expiry date which appears on the package label.

V- SPECIMEN COLLECTION AND PREPARATION

1- FSH-CHECK-1 is to be performed on human serum, plasma or whole blood.

2- The specimen should be collected under the standard laboratory conditions (aseptically in such a way as to avoid haemolysis).

3- If anticoagulant is needed, only citrate, EDTA or heparin (ammonium or lithium) should be used.

4- Each specimen should be treated as if potentially infectious.

5- Whole blood samples should be tested immediately (< 4 hours). Finger prick samples should be assayed just after collection.

6- If the test is to be run within 48 hours after collection the specimen should be stored in the refrigerator (+2°C to +8°C). If testing is delayed more than 48 hours, the specimen should be frozen. The frozen specimen must be completely thawed, thoroughly mixed and brought to room temperature prior to testing. Avoid repeated freezing and thawing.

7- In case of cloudiness, high viscosity or presence of particulate matter into the serum specimen, it should be diluted with equal volume (V/V) of diluting buffer (not provided but available upon request) before testing.

VI- ASSAY PROCEDURE

IMPORTANT: Switch the reader on and allow it to warm up for at least 30 minutes before performing any measurements.

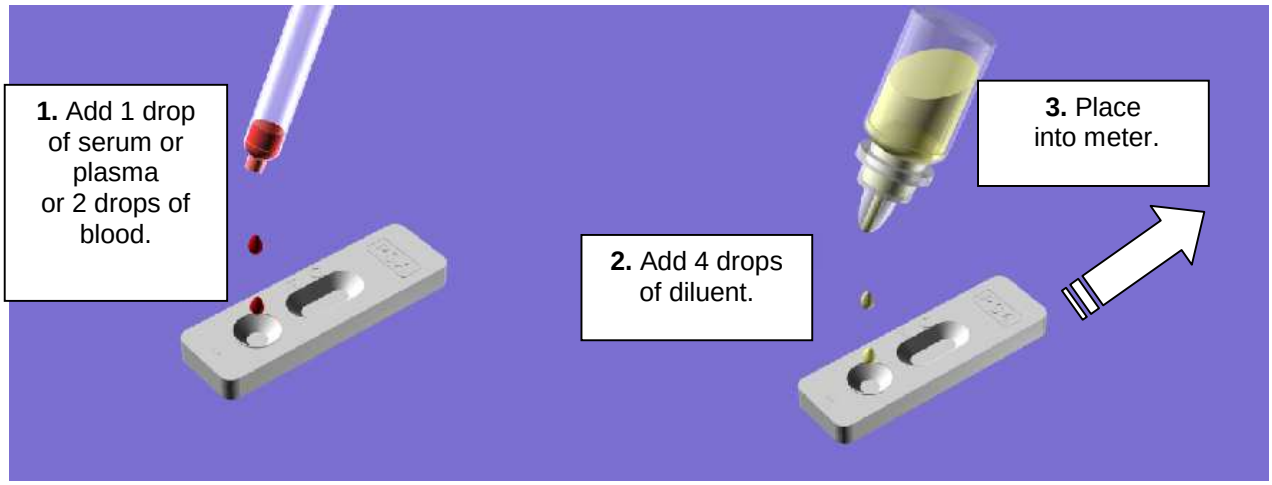
a) Controls testing

- Wait for 15 minutes after the freeze-dried control has dissolved.
- Add the requested volume (25µL) with **lab pipette (disposable tips)** into the sample well of the cassette and proceed in the same way as for a patient's sample.
- The expected concentration level (**in IU/L**) is indicated on the vial label and obtained result must match the indicated value. The concentration level can change slightly depending on lot number.
- **The reconstituted vial should be kept at +2°C to +8°C and should be used within 7 days after reconstitution**.

b) Samples testing

Follow the below instructions or refer to the picture n°1

1– Allow samples and FSH CHECK-1 test devices to come to room temperature prior to testing.
2– Remove the reaction device from its protective wrapper by tearing along the split.
3– Label device with the patient's name or control number.
4– Fill the plastic pipette with specimen (serum, plasma or whole blood) and by holding it vertically, dispense one drop (25 µL) into sample well if serum or plasma is used. If whole blood is used, dispense 2 drops (50 µL) into the well (▷) and **wait for the blood sample to be completely absorbed before adding diluent**.
5– Add exactly 4 drops of diluent (150 µL) in the sample well (▷).
6– Read the result **(in IU/L)** after 10 minutes either using the immediate or countdown reading mode (see corresponding leaflet).
For general instructions describing how to use the VEDALAB's rapid test readers, refer to the corresponding leaflet .



Picture n°1

VII- PERFORMANCES CHARACTERISTICS

a) Linearity

The measuring range is 5-400 IU/L.
For FSH concentration below 5 IU/L, the result will be given as "< 5 IU/L ".
For FSH concentration over 400 IU/L, the result will be given as "> 400 IU/L ".
For samples whose concentration is higher than 400 IU/L, dilute with saline and repeat the assay as per instructions of Part. VI.

b) Accuracy

A study has been performed using serum samples obtained from dilutions of FSH international reference material WHO (98/704) covering a range of 5 to 400 IU/L. Optical densities expressed as a function of FSH concentrations are described by following linear curve:
$Y = 16.94 + 1.94\ x - 2.398.10^{-3}\ x^2$ (r = 0.981) .

The results show a good correlation (r > 0.98) of the values obtained with FSH-CHECK-1 on VEDALAB's readers.

Another study performed using the most recent FSH standard (W.H.O. 2nd international standard n°08/282) showed an even greater correlation of obtained values (> 0.99).

c) Sensitivity

Concentrations close to 2 IU/L are detected by FSH-CHECK-1 test. In these cases, results will be rendered as "< 5 IU/L".

Expected FSH concentration in male (adults) and female (follicular and luteal phases) are below 15 IU/L. For mid-cycle and postmenopausal females, the FSH concentration is in the range of 6-30 IU/L and 20-200 IU/L respectively.

d) Precision
A correlation study was performed on 23 known serum samples preassayed using the ROCHE COBAS analyser. The overall correlation is 97% between VEDALAB FSH-CHECK-1 and ROCHE COBAS analyser.

e) Interferences
There was no interferences observed for LH (1,000 mIU/mL), TSH (200 µIU/mL) and hCG (10 K mIU/mL) hormones at respective concentrations.

f) Intra-assay reproducibility
Within run reproducibility was evaluated using 20 replicates of three sera containing 25, 100 and 200 IU/L of FSH. The obtained CVs (coefficient of variation) are 14.8%, 14.4% and 14.4% respectively.

g) Inter-assay reproducibility
Inter lot reproducibility was evaluated using the three same sera on 3 lots of FSH-CHECK-1. The obtained CVs (coefficient of variation) are 19.8%, 6.8% and 16.7% respectively.

h) Hook effect
There was no observed hook effect up to a FSH concentration of 3,000 IU/L.

VIII- LIMITATIONS

1- As for any diagnostic procedure, the physician should confirm the data obtained using this test by other clinical methods.
2-Whole blood samples should be tested immediately (< 4 hours). Finger prick samples should be assayed just after collection.
3- Some serum specimens with high rheumatoid factor concentration (RF) may yield non specific positive results during testing. Such cases should be considered before testing.
4- The test is designed to eliminate the potential interference of human antibodies to murine IgG (HAMA). However high level of HAMA could give falsely positive results.
5- This format of test is to be only used with VEDALAB rapid test readers (EASY READER® or EASY READER+®)
6- If the reading time (10 minutes) is not strictly respected, wrong results will be obtained.
7- This format of test should not be used for visual reading.
8- As it is true for any diagnostic method or for any measurements through analysers, there is a variability of the obtained result. Therefore, a confidence range of +/- 25% should be considered for the final value and for the clinical significance of the result.
9- Do not use the reader for measurements before at least 30 minutes warm-up after having switched on.

IX- BIBLIOGRAPHY

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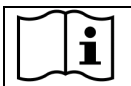
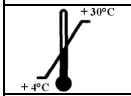
	Read the instructions before use		For *in vitro* diagnostic use
	Temperature limitations		Do not reuse
	Manufacturer		

Manufactured by VEDALAB - France