

iCARE One Step FSH Urine Test
Cat. No. W52 -M (Midstream)

iCARE One Step FSH Urine Test is a qualitative test used to detect the levels of FSH associated to the symptoms and stages of menopause. It can help you to determine if your hot flashes, irregular periods and other health symptoms are menopause related.

For in vitro self test use only. For external use only.

HOW DOES IT WORK?

FSH (follicle-stimulating hormone) is associated with low estrogen and the stages of menopause in women. Usually, as a woman nears menopause her FSH (follicle-stimulating hormone) levels surge and notably rise. The FSH surge is generally that of ten (10) fold (approximately 110mIU/ml, can reach as high as 500mIU/ml) compared to normal levels. The FSH level could remain constant for many years after menopause. iCARE One Step FSH urine Test midstream detects this particular hormone level in urine.

When the absorbent pad is immersed into a urine specimen, capillary action carries the specimen to migrate along the membrane. When the FSH levels are equal to or above the target cutoff, there is a visible colored band in the test region which is equal to or darker than the control band. Absence of this test colored band or the test colored band weaker than the control band suggests a negative result.

To serve as a procedure control, a colored line will appear at the Control Zone region, if the test has been performed properly.

CONTENT OF THE TEST KIT

1. One pouch containing a midstream and desiccant. The desiccant is for storage purposes only, and is not used in the test procedures.
2. Leaflet with instructions for use.

WHAT ELSE DO YOU NEED?

1. A clean, dry, plastic or glass container to collect the urine.
2. Timer (watch or clock)

PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test midstream cannot be used more than once.
3. Do not use test kit beyond expiration date.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Keep out of reach of children.

STORAGE AND STABILITY

1. Store 4°C to 30°C in the sealed pouch up to the expiration date.
2. Keep away from direct sunlight, moisture and heat.
3. **DO NOT FREEZE.**
4. Preferably open the pouch only shortly before the test.

SPECIMEN COLLECTION AND PREPARATION

WHEN TO COLLECT URINE FOR THE TEST?

The first morning urine contains the highest level of FSH and is the best for testing. Urine collected during the day will contain lower levels of FSH and may cause false negatives. Do not drink excess fluids after midnight before testing in the morning

HOW TO COLLECT URINE?

Urine specimens may be collected in any clean, dry, plastic or glass container.

WHEN TO BEGIN TESTING

Peri-menopause is the period of time between pre- and post-menopause. Symptoms of peri-menopause vary from woman to woman. The most common symptoms are hot flashes, insomnia, irregular periods, mood swings, and fatigue. During the stages of peri-menopause changes take place in the balance of hormones that regulate and control your monthly menstrual cycle. This slow change in ovary cycle can start between two to ten years before your final menstrual period.

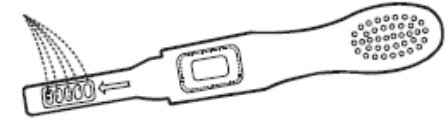
Test every 6-12 months starting at the age of 35 or when the symptoms of menopause occur discuss results with your physician.

HOW TO DO THE TEST

1. The test midstream has to be at room temperature (10°C -30°C) prior to testing.
2. To begin testing, open the sealed pouch by tearing along the notch. Remove test device—midstream from the pouch.
3. Hold the round end of cover with one hand. Use the other hand to pull out the midstream cap and expose the absorbent.
4. Point the absorbent tip downward, and place the absorbent tip in urine stream for at least 10 seconds to be thoroughly wet. **Do not urinate past the arrow mark.**

Otherwise, you can collect your urine into a clean cup (the urine has to be at room temperature (10°C -30°C) prior to testing) and dip half of the absorbent pad into the urine for at least 15 seconds.

5. Re-cap the device and wait for color bands to appear. Read the result at 5 minutes. **Do not read results after more than 10 minutes.**



HOW TO READ THE RESULTS?

Positive (+)

If two color bands are visible and the test (T) band is equal to or darker than the control (C) band, the result is positive. That indicates the FSH concentration in the urine sample is equal to or above 25mIU/ml. If you get a positive test result, you should retest because the level of FSH may change during your menstrual cycle. Testing should be repeated after 5 to 7 days.

Two positive test results indicate that you may be in a stage of menopause and should consult with your doctor.

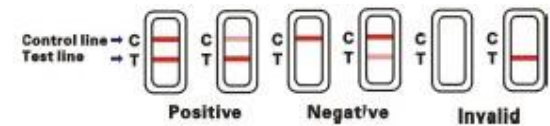
Negative (-)

If only one colored band appears on the control (C) region, or two colored bands appear, but the test (T) band is lighter than the control band, the result is negative. That indicates the FSH concentration of the sample is below 25mIU/ml.

If you get a negative test result and are experiencing menopausal symptoms consult with your doctor.

Invalid

No visible band appears on the control (C) region at all. This is an indication of procedure error and/or that test reagent deterioration has occurred. Repeat test with a new test kit. If test still fails, please contact the distributor or the store where you bought the product, with the lot number.



LIMITATIONS

1. Taking the pill (oral contraceptives), using the patch contraceptive, hormone replacement therapy (HRT), estrogen supplements, or

other forms of hormones may affect this test and cause a false negative reading. Ovarian and pituitary tumors may cause false results. Although the test is very accurate in detecting FSH concentrations in urine at or above the cutoff point of the test, a very low incidence of false results can occur.

2. Results of this test are not to be used to determine fertility or lack of fertility. This test is for FSH use only and is not to be used as a pregnancy or ovulation test. Decisions about contraception should not be made on the results of this test.
3. The device does not contain any viable infectious agents however all urine samples must be considered as being possibly infectious. Clean spills thoroughly using an appropriate disinfectant. Clean/dispose of specimen and all potentially contaminated materials.
4. A definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated and studied.
5. Discuss positive one step FSH urine Test results and questions concerning menopause and the treatment for menopausal symptoms with your doctor.

QUESTIONS & ANSWERS

1. *How does iCARE one step FSH urine Test work?* Usually, as a woman nears menopause her FSH (follicle-stimulating hormone) levels surge and notably rise. The FSH surge is generally that of ten (10) fold (approximately 110mIU/ml, can reach as high as 500mIU/ml) compared to normal levels. The FSH level could remain constant for many years after menopause. one step FSH urine Test detects this particular hormone level in urine.
2. *What should I do if I'm unsure about the test result?* If it is hard to compare the color intensity between the test line and the control line, repeat the test in 5 to 7 days after the first test.
3. *What does it mean if the test is positive?* Positive results show that the FSH level in your body is at or above 25mIU/ml. It indicates that the levels of sex hormones such as estradiol, progesterone and testosterone, etc. have declined and you are in the stage of the perimenopause. Discuss your test results and symptoms with your doctor.
4. *My test is negative. Does that mean I'm not in menopause?* No. While a negative test result means that you are probably not in menopause, if you are experiencing some of the common symptoms associated with menopause you should consult with your doctor.

5. *I'm close to the age of menopause. My test reads positive but I still have regular periods. Why is this?* A positive FSH test only tells you that FSH levels in your urine specimen are at or greater than 25mIU/ml (elevated) and you may be in the transition of menopause. Menopause by definition is having gone 12 months without a menstrual cycle. A positive FSH test does not tell you exactly when you will reach menopause. Menopause usually occurs in women in their late forties to late fifties. The transition period lasts for most women about four (4) years in which the FSH levels remain constantly high. It is not contradictory to have a positive FSH test and still have regular periods.
6. *Can the pill or patch contraceptives affect the results of this test?* Yes. After using the pill or patch your cycle may be irregular and may take some time to become regular again. You may wish to wait until you have two normal periods before using one step FSH urine Test.
7. *Can I use the test as a form of birth control?* No. Contraceptives and birth control should never be discontinued based on the results of this test.

MEANING OF SYMBOLS ON PACKAGE



Product of
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