

One Step FSH Urine Test

Cat. No. W52-S (Strip) (2.5 mm, 3.5mm, 5.0mm)

LABSTIX DIAGNOSTICS

LABSTIX 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. Wondfo One Step FSH Urine Test strip detects this particular hormone level in urine.

When the strip 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 strip 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 strip 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. DON 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.

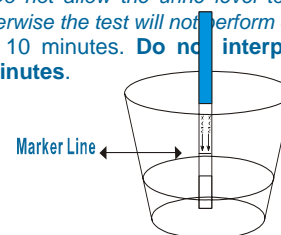
WHEN TO BEGIN TESTING

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 strip and urine have to be at room temperature (10°C ~30°C) prior to testing.
2. Remove the test strip from the sealed pouch.
3. Immerse the strip into the urine with the arrow pointing towards the urine. Take the strip out after 5 seconds and lay the strip flat on a clean, dry, non-absorbent surface (such as the mouth of the urine container).
IMPORTANT: Do not allow the urine level to exceed the MAX (marker line), otherwise the test will not perform correctly.
4. Read results at 10 minutes. **Do not interpret results after more than 15 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 in the urine 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 invalid result. If the test strip is not in contact with the lot.

