

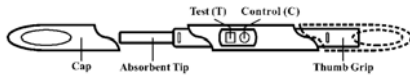


SURESIGN One Step Menopause Test
Package Insert
REF SFFS-103-2 English
For Self Testing

PRINCIPLE

Menopause is the permanent cessation of menstruation but is usually not scientifically diagnosed until one full year after a woman's menstrual periods have stopped. The period leading up to menopause, and the 12 months following, is known as perimenopause. Many women experience symptoms during this time including hot flashes, irregular menstrual cycles, sleep disorders, vaginal dryness, hair loss, anxiety and mood swings, short-term memory loss and fatigue. The onset of perimenopause is caused by changes in the levels of hormones in the female body that regulate the menstrual cycle. As the body produces less and less estrogen, it increases its production of Follicle-Stimulating Hormone (FSH), which normally regulates the development of a female's eggs. Therefore, testing for FSH can help determine whether a woman is in the perimenopause stage. If a woman knows she is perimenopausal, she can take the appropriate steps to keep her body healthy and avoid the health risks associated with menopause, which include osteoporosis, increased blood pressure and cholesterol, and increased risk of heart disease. The Easy Detection One Step Menopause Test is a rapid, one-step lateral flow immunoassay for the qualitative detection of FSH in urine to aid in the detection of menopause. The test utilizes a combination of antibodies including a monoclonal FSH antibody to selectively detect elevated levels of FSH. The assay is conducted by urinating on the Absorbent Tip or immersing the Absorbent Tip in urine, and obtaining the result from the coloured lines.

PRECAUTIONS



Please read all the information in this package insert before performing the test.

- Do not use after the expiration date printed on the back of the foil pouch.
- The test should remain in the sealed pouch until use.
- Store in a dry place at 2-30°C (36-86°F). Do not freeze.
- Do not use if pouch is torn or damaged.
- Keep out of the reach of children.
- For *in vitro* diagnostic use only. Not to be taken internally.
- Do not open the foil pouch until you are ready to start the test.
- The used test should be discarded according to local regulations.

KIT CONTENTS

- Tests midstream
- Package insert

INSTRUCTIONS

WHEN TO TEST

- If you are still having monthly periods, take the first test during the first week of your cycle (days 2-7, with day 1 being the first day of menstruation). If the result is negative but symptoms persist, repeat with the second test one week later.
- If you are no longer having regular periods, take the test at any time during the month and repeat with the second test 1 week later.

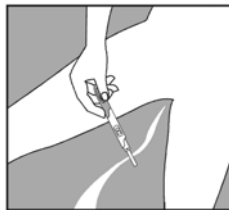
DIRECTIONS FOR USE

1. Remove the midstream test from the foil pouch and familiarize yourself with the product.
2. Remove the Cap and place it over the Thumb Grip. See illustration above.
3. Hold the midstream test by the capped Thumb Grip with the **exposed Absorbent Tip pointing downward directly into your urine stream for at least 10 seconds.**

Note: Do not urinate on the Test and Control Windows. If you prefer, you can urinate into a clean dry container. Dip only the Absorbent Tip of the midstream test into the urine for at least 10 seconds.

4. After removing the midstream test from your urine, immediately replace the Cap over the Absorbent Tip, lay the midstream test on a flat surface with the Test and Control Windows facing upwards, and then begin timing.

5. As the test begins to work, you may notice a light pink colour flowing through the Test and Control Windows. **Read results at 3 minutes.** If no coloured line appears, wait one minute longer. Do not read the result after 10 minutes.



READING THE RESULTS



POSITIVE

Two distinct coloured lines are visible, and the line in the Test Window (T) is the same as or darker than the line in the Control Window (C). This indicates that your FSH level is higher than normal and you may be experiencing perimenopause.



NEGATIVE

Two coloured lines are visible, but the line in the Test Window (T) is lighter than the line in the Control Window (C), OR there is no line in the Test Window (T). This indicates that you are probably not experiencing perimenopause in this cycle.



INVALID

Control line fails to appear. The result is invalid if no coloured line appears in the Control Window (C), even if a line appears in the Test Window (T). You should repeat with a new test.

INTERPRETATION OF RESULTS

For women experiencing menopausal symptoms who have had **no menstrual cycle** for the past 12 months:

1st Test	Interpretation
Positive	Menopause has most likely occurred. You may want to repeat the test, but discuss the results with your doctor to confirm them and discuss therapies to promote good health after menopause.

For women experiencing perimenopausal symptoms plus **irregular menstrual cycles**:

1st Test	2nd	Test Interpretation
Positive	Positive	Most likely in perimenopause. Discuss results with doctor. Do not discontinue contraception.
Positive	Negative	May be in early stages of perimenopause. Discuss results with doctor. Do not discontinue contraception.
Negative	Positive	
Negative	Negative	Most likely not experiencing perimenopause this cycle. If symptoms persist, repeat testing in the following month or see your doctor about other possible causes for your symptoms.

LIMITATIONS

There is the possibility that this test may produce false positive or false negative results. Consult your physician before making any medical decisions. Invalid results are most likely caused by not following the instructions properly. Review the instructions and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUESTIONS AND ANSWERS

1. Q: How does the test work?

A: As your body ages and produces less estrogen, FSH levels increase as the hormone tries to stimulate the ovaries to produce a healthy egg. This test measures FSH and can tell you whether your body is producing excess FSH as a result of low estrogen levels, signalling that your body is in the perimenopause stage.

2. Q: When can I use the test?

A: We recommend performing the test using first morning urine as it contains the most hormone and will give the most accurate result. If you are still menstruating, we recommend testing during the first week of your cycle (see WHEN TO TEST) and then retesting one week later.

3. Q: How will I know the test worked?

A: The appearance of a coloured line in the Control Window (C) tells you that you followed the test procedure properly and the proper amount of urine was absorbed. If you do not see a line in the Control Window (C), you should review the procedure and repeat with a new midstream test. The test is not reusable. If you still experience problems, contact your distributor.

4. Q: I received a positive result. Can I stop using contraception?

A: No, this test cannot determine fertility. Continue using contraception until your test results have been confirmed by your doctor.

5. Q: I am not sure that I held the test in my urine stream long enough. Will I still get an accurate result?

A: In order to receive an accurate result, you should hold the Absorbent Tip of the test in your urine stream for at least 10 seconds and wait 3 minutes to read the result. If the line in the Control Window (C) fails to develop, you should repeat with a new midstream test.

6. Q: How accurate is the test?

A: A clinical evaluation was conducted comparing the results obtained using the Easy Detection One Step Menopause Test to another commercially available urine membrane FSH test. The clinical trial included 200 urine specimens: both assays identified 92 positive and 108 negative results. The results demonstrated >99.0% overall accuracy of the Easy Detection One Step Menopause Test when compared to the other urine membrane FSH test.

7. Q: How sensitive is the test?

A: The Easy Detection One Step Menopause Test detects follicle-stimulating hormone (FSH) in urine at concentrations of 25 mIU/mL or higher. The addition of LH (1,000 mIU/mL), hCG (100 IU/mL), and TSH (1,000 µIU/mL) to negative (0 mIU/mL FSH) and positive (25 mIU/mL FSH) specimens showed no cross-reactivity.

8. Q: Do alcohol or common medications affect the test?

A: No, but you should consult your physician if you are taking any hormonal medication. Also, recent oral contraceptive use, breastfeeding, or pregnancy could affect the test results.

Index of Symbols

	Attention see instructions for use		Store between 2-30°C		Use by		Lot Number
	For <i>in vitro</i> use only		Tests per Kit		Do not reuse		Catalogue #

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