



Early Detection One Step Ultra Pregnancy Test

Package Insert

REF SFHC 103-1 & 2

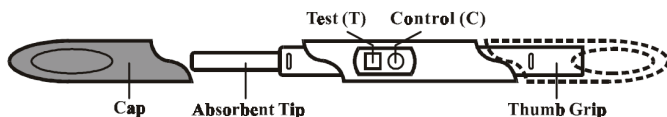
English

For Self Testing

PRINCIPLE

The Early Detection One Step Ultra Pregnancy Test is a rapid, one-step lateral flow immunoassay in midstream format for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the detection of pregnancy. The test utilizes a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG. The assay is conducted by urinating on the Absorbent Tip or immersing the Absorbent Tip in urine, and obtaining the result from the colored 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 foil pouch.
- Store in a dry place at 2-30°C or 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. Not to be taken internally.
- Do not open the test foil pouch until you are ready to start the test.

KIT CONTENTS

- Test midstream
- Package insert

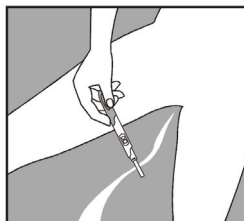
INSTRUCTIONS

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** until it is thoroughly wet. See illustration at right.

NOTE: Do not urinate on the Test and Control windows. If you prefer, you can urinate into a clean and dry container, then 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 coloured flow moving across the Test and Control windows. **Read the result at 3 minutes.** If no coloured line appears, wait one minute longer. Some positive results may be observed in 1 minute or less depending on the concentration of hCG. Do not read the result after 10 minutes.



READING THE RESULTS



PREGNANT

Two distinct coloured lines appear. One line should be in the Control Window (C) and another line should be in the Test Window (T). One line may be lighter than the other; they do not have to match. This means you are probably pregnant.



NOT PREGNANT

One coloured line appears in the Control Window (C). No line appears in the Test Window (T). This means that you are probably not pregnant.



INVALID

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 the test with a new midstream test.

LIMITATIONS

There is the possibility that this test may produce false results. Consult your physician before making any medical decisions.

1. Drugs which contain hCG (such as Pregnyl, Profasi, Pergonal and APL) can give a false positive result. Alcohol, oral contraceptives, painkillers, antibiotics or hormone therapies that do not contain hCG should not affect the test result.
2. A number of medical conditions other than pregnancy, including, ovarian cyst or ectopic pregnancy (pregnancy outside the uterus) can cause elevated levels of hCG, which can result in a false positive result.

QUESTIONS & ANSWERS

1. Q: How does the test work?

A: The Early Detection One Step Ultra Pregnancy Test detects a hormone in your urine that your body produces during pregnancy (hCG-human chorionic gonadotropin). The amount of pregnancy hormone increases as pregnancy progresses.

2. Q: How soon after I suspect that I am pregnant can I take the test?

A: You can test your urine as early as the first day you miss your period. You can perform the test anytime of the day; however, if you are pregnant, first morning urine contains the most pregnancy hormone.

3. Q: Do I have to test with first morning urine?

A: Although you can test at any time of the day, your first morning urine is usually the most concentrated of the day and would have the most hCG in it.

4. Q: How accurate is the test?

A: A clinical evaluation was conducted comparing the results obtained using the Early Detection One Step Ultra Pregnancy Test to another commercially available urine membrane hCG test. The consumer clinical trial included 70 urine specimens: both assays identified 27 positive and 43 negative results. The results demonstrated >99.0% overall accuracy of the Early Detection One Step Ultra Pregnancy Test when compared to the other urine membrane hCG test.

5. Q: How sensitive is the test?

A: The Early Detection One Step Ultra Pregnancy Test detects hCG in urine at a concentration of 10 mIU/mL or greater. The test has been standardized to the W.H.O. Third International Standard. The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 µIU/mL) to negative (0 mIU/mL hCG) and positive (10 mIU/mL hCG) specimens showed no cross-reactivity.

6. Q: What should I do if the result shows that I am pregnant?

A: It means that your urine contains hCG and you are probably pregnant. See your doctor to confirm that you are pregnant and to discuss the steps you should take.

7. Q: How do I know that the test was run properly?

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.

8. Q: What should I do if the result shows that I am not pregnant?

A: It means that no hCG has been detected in your urine and probably you are not pregnant. If you do not start your period within a week of its due date, repeat the test with a new midstream test. If you receive the same result after repeating the test and you still do not get your period, you should see your doctor.

You are encouraged to take the following steps to increase your chances for a healthy pregnancy and a healthy baby.

1. Use the Early Detection One Step Ultra Pregnancy Test to detect pregnancy when your period is late. You can begin better prenatal care as soon as you learn of your pregnancy.
2. If you get a positive result, it is advisable to visit your doctor immediately to begin your prenatal care.
3. Maintain a well-balanced diet, stop smoking, and reduce your intake of alcohol.

Index of Symbols

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



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