

**TECO DIAGNOSTICS**  
 1268 N. Lakeview Ave.  
 Anaheim, CA 92807  
 1-800-222-9880

## MIDSTREAM PREGNANCY TEST

### PRINCIPLE

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 adding urine to the hydrophilic stick and obtaining the result from the colored lines.

### PRECAUTIONS

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

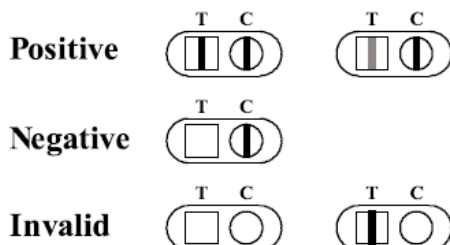
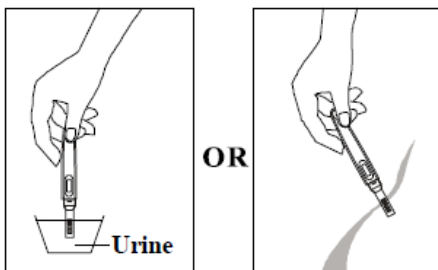
- Do not use after the expiration date printed on the foil pouch.
- Store in a dry place at 2-30°C or 35.6-86°F. Do not freeze.
- Do not use if pouch is torn or damaged.
- Keep out of the reach of children.
- For in vitro diagnostic use. Not to be taken internally.
- Do not open the test midstream foil pouch until you are ready to start the test.
- The used test midstream should be discarded according to local regulations.

### MATERIALS PROVIDED

- Midstream test
- Package insert

### INSTRUCTIONS

1. Remove the midstream test from the foil pouch and test it immediately in one hour.
2. Remove the cap of the midstream test, and place it aside for now. Urinate on the exposed part of the midstream test or place the midstream test in urine sample in a clean cup for at least 10 seconds.
3. Re-cap the midstream test, and lay it down on a clean and stable surface and start the timer immediately.
4. Read the result at 5 minutes; do not interpret the result after 10 minutes.



### READING THE RESULTS

### PREGNANT

Two distinct colored lines appear. One line should be in the control line region (C) and another line should be in the test line region (T). One line may be lighter than the other; they do not have to match. This means that you are probably pregnant.

### NOT PREGNANT

One colored line appears in the control line region (C). No line appears in the test line region (T). This means that you are probably not pregnant.

### INVALID

The result is invalid if no colored line appears in the control line region (C), even if a line appears in the test line region (T). You should repeat the test with a new midstream test.

### LIMITATIONS

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

1. Drugs which contain hCG (such as Pregnyl, Profasi, Pergonal, 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.

### EXTRA INFORMATION

#### Q. How does the test midstream work?

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.

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

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.

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

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.

#### Q. How accurate is the test?

In a laboratory testing, urine samples from 151 non-pregnant women and 55 pregnant women were correctly identified with the pregnancy test when compared with a professional pregnancy test. Overall, this test is greater 99% accurate in laboratory testing. In a home testing, 43 women between the age of 19 and 42 correctly followed the instructions, performed tests, and interpreted the results. These results are consistent with those obtained by laboratory technicians performing on the same set of samples.

#### Q. How sensitive is the test?

Pregnancy Test detects hCG in urine at a concentration of 25mIU/mL or greater. The test has been standardized to the W.H.O. International Standard. The addition of LH (500 mIU/mL), FSH (1,000 mIU/mL), and TSH (1mIU/mL) to negative (0mIU/mL hCG) and positive (25mIU/mL hCG) specimens showed no cross-reactivity.

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

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.

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

The appearance of a colored line in the control line region (C) tells you that you followed the test procedure properly and the proper amount of urine was absorbed.

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

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.

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