

## CLIA CATEGORIZATION: WAIVED

Dealmed HCG Pregnancy Test Cassette is a rapid pregnancy test which you can easily carry out yourself. It detects the presence of human chorionic gonadotropin ("HCG") which appears in urine very early during pregnancy.

It is intended for over-the-counter and for prescription use. For *in vitro* diagnostic use.

## HOW DOES IT WORK?

Human chorionic gonadotropin (hCG) is a hormone produced by the developing placenta shortly after the conception and secreted into the urine. The pregnancy test contains antibodies which specifically react with this hormone.

When specimen is dropped into cassette, capillary action carries the specimen to migrate along the membrane. When hCG in the specimen reaches the Test Zone (T) region of the membrane, it will form a color band. Absence of this color band suggests a negative result.

To serve as a procedure control, a color band will appear at the Control Zone (C) region, if the test has been performed properly.

## CONTENT OF THE TEST KIT

1. 25 HCG Pregnancy Test Cassettes. One pouch containing a cassette, a disposable pipette and a desiccant. The desiccant is for storage purposes only and is not used in the test procedures.
2. 1 Package Insert

## WHAT ELSE DO YOU NEED?

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

## PRECAUTIONS

1. The test 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 the test kit beyond expiration date.
4. Do not use the test kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.

## STORAGE AND STABILITY

- Store at 39°F-86°F (4°C-30°C) in the sealed pouch up to the expiration date.

- Keep away from direct sunlight, moisture and heat.
- DO NOT FREEZE.
- Preferably open the pouch only shortly before the test.

## SPECIMEN COLLECTION AND PREPARATION

### WHEN TO COLLECT URINE FOR THE TEST?

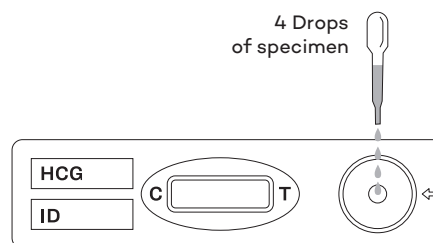
Any urine specimen is appropriate for Pregnancy Testing but the first morning urine specimen is optimal because of its highest concentration of HCG.

### HOW TO COLLECT URINE?

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

### HOW TO DO THE TEST?

1. Remove the cassette from the foil pouch from the foil pouch by tearing at the notch and place it on a level surface.
2. Holding a disposable pipette vertically, add exactly four drops of the urine specimen to the sample well (with an arrow marked).
3. Read results in 3-5 minutes. Do not read results after 5 minutes.



### HOW TO READ THE RESULTS?

#### Negative (Not Pregnant):

Only one colored band appears in the Control Zone (C). No apparent band in the Test Zone (T). This indicates that no pregnancy has been detected.

#### Positive (Pregnant):

Distinct colored bands appear in the Control and Test Zones. It indicates that you are pregnant. The color intensity of the test bands may vary since there are different concentrations of hCG hormone in different stages of pregnancy.

#### Invalid:

There is a visible band only in the Test Zone (T) or no visible bands in both zones. Repeat with a new test kit. If test still fails, please

contact the distributor or the store where you purchased the product and provide the lot number and expiration date.



**NOTE:** If the color in the Test Zone (T) is weak, it is recommended that the test should be repeated in 48 hours.

## WHAT TO DO WHEN YOU KNOW THE RESULT

### IF THE RESULT IS POSITIVE (TWO LINES)

Consult your physician who should confirm your pregnancy after evaluating all clinical and laboratory findings. Indeed, in certain conditions, the test may give a false positive result. Your physician will also give you further information and advice on your pregnancy.

Also see "Limitations".

### IF THE RESULT IS NEGATIVE (ONE LINE)

If you have reasons to believe that you are pregnant (e.g. no menstrual bleeding), you can repeat the test a few days later. If the test is still negative, consult your physician.

Also see "Limitations".

## LIMITATIONS

1. As it is with any diagnostic procedure, a confirmed pregnancy diagnosis should only be made by a physician after evaluating all clinical and laboratory findings.
2. If a urine sample is too dilute (ie, low specific gravity), it may not contain the representative level of hCG. If pregnancy is still suspected, another urine specimen should be collected 48 hours later and tested.
3. Low concentration of hCG in a very early pregnancy can give a negative result. In this case, another specimen should be obtained at least 48 hours later and tested.
4. Elevated levels of hCG can be caused by a few conditions other than pregnancy. Therefore, the presence of hCG in urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. A normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG levels alone. Also, spontaneous miscarriage may cause confusion in interpreting test results.
6. Sterility treatments, based on hCG, may cause false results. Consult your physician.

## EXPECTED RESULTS

Negative results are expected in healthy non-pregnant women and healthy men. Although the hCG levels in normal early pregnant women are variable, Dealmed HCG Pregnancy Test Cassette is capable of detecting pregnancy as early as 1 day after the first missed menses.

## QUESTIONS & ANSWERS

1. If there is a difference between the color or intensity of control lines between two tests. Is this a concern?  
No. Variations in the color of the control band will not affect the test result.
2. Can test results be interpreted after more than five minutes?  
No. Test results must be read in 3-5 minutes. Though a positive result should not change for several days, a negative result may change to a false positive within minutes after the end of the testing period, which would not be an accurate reading. It is always best to read the results in 3-5 minutes testing period and then discard the test to avoid confusion.
3. A pink background color and vertical streaking appeared in the result area during the testing period. Is this a concern?  
No. Each urine sample will vary in its chemical makeup, as will the humidity of the air in testing chamber (room). Such variations in physical conditions can cause the vertical streaking and/or the pink-rose background color but will not affect the test results. As long as the control band appears within five minutes, the test is working properly.

## ASSISTANCE

If you have any question regarding to the use of this product, please call our Toll Free Number 1-800-569-0570.

## MEANING OF SYMBOLS ON PACKAGE

|  |                                   |  |                 |
|--|-----------------------------------|--|-----------------|
|  | Store at 39°F - 86°F (4°C - 30°C) |  | Tests per Kit   |
|  | Do Not Reuse                      |  | Batch Number    |
|  | For In Vitro Diagnostic Use       |  | Expiration Date |
|  | Read Instructions                 |  |                 |

## MANUFACTURED FOR:

Dealmed  
Brooklyn, NY 11234  
www.dealmed.com

P-4326

**MADE IN CHINA**

Rev. A1  
Rel.: 2021/01/14