



## HOME PREGNANCY TEST STRIP

### INTENDED USE

This Home Pregnancy Strip test is a rapid immunoassay for the qualitative detection of Human Chorionic Gonadotropin (hCG) in urine as an aid in the early detection of pregnancy.

For self-testing at home.

For *in-vitro* diagnostic use only, not for internal use.

Do not reuse.

### INTRODUCTION

Human Chorionic Gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after implantation. From the onset of pregnancy, the hCG concentration in a woman's serum and urine increases rapidly, making the hormone a good marker for pregnancy testing.

### PRINCIPLE

The test strip detects Human Chorionic Gonadotropin (hCG) through visual interpretation of colour development on the strip. The strip is dipped into a urine sample and the hCG, if present in the sample, interacts with reagents on the membrane. If there is sufficient hCG in the urine sample, a second coloured band will form in the result window. The presence of a second coloured band in the result window of the strip indicates a positive result, whilst the absence of any colour in the result window indicates a negative result. The first coloured band that appears in the result window of the strip serves only as an indication that sufficient volume of the urine sample has been used.

### REAGENTS

The test contains anti-hCG particles and anti-hCG antibodies coated on the membrane.

### MATERIALS

#### **Materials provided:**

Test strip packed in a foil pouch

Instructions for use

#### **Materials required but not provided:**

Sample collection container

Timer

### WARNINGS / PRECAUTIONS

Do not open the foil pouch until you are ready to do the test.

Do not use after the expiry date, as printed on the carton.

Do not use the strip if the foil pouch has been damaged or opened.

For single use only – do not reuse.

Discard the strip after use.

### CONDITIONS FOR COLLECTION OF SAMPLE

For detection of an early pregnancy, it is recommended that the first morning urine specimen is used.

### PERFORMANCE AND ACCURACY

Depending on the hCG concentration in the sample, a positive result may be observed within 30 seconds. However, to confirm a negative result, the complete reaction time of 3 minutes must be observed.

For the detection of an early pregnancy, it is recommended that the first morning urine is used.

The sensitivity of this test is 25mIU/ml.

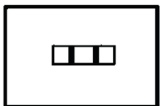
100% correlation with commercially available pregnancy tests.

## DIRECTIONS FOR USE



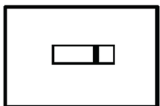
1. Collect the urine sample in a clean, dry container.
2. Open the sealed pouch and remove the strip from the pouch.
3. Dip the strip (arrows pointing down) into the urine sample for 6 seconds. Do not dip over the max level on the strip.
4. Place the strip test on a flat surface.
5. Read the result after 3 to 5 minutes. (Do not wait longer than 10 minutes to read the test as the results may no longer be accurate due to the composition of the test.)

## INTERPRETATION OF RESULTS



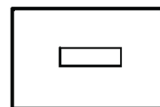
### POSITIVE / PREGNANT

The presence of two red lines in the result window indicates conception has occurred and that it is highly likely that you are pregnant. (One line may be lighter than the other; they do not have to match.)



### NEGATIVE / NOT PREGNANT

The presence of only one red line in the result window indicates conception has possibly not occurred or that the hCG level of the sample is below the detection sensitivity of the test. It is likely that you are not pregnant.



### INVALID RESULT

If no red line appears in the result window after 3 minutes, the result is invalid. Proper procedures may not have been followed in performing the test, or the test may have deteriorated. The test should be repeated with a fresh strip.

## STORAGE AND STABILITY

Store as packaged, in the foil pouch, at room temperature (4 – 30 °C). When stored in the foil pouch, the strip is stable until the expiry date printed on the carton.

The foil pouch should be kept away from direct sunlight, moisture and heat.

Do not freeze.

## LIMITATIONS

- hCG levels vary from person to person during early pregnancy and a low concentration of hCG can give a negative result. In this case, another test should be done 48 hours later.
- A high percentage of pregnancies end in a chemical pregnancy. It should therefore be noted that a positive pregnancy test recorded before, on or a day or two after expected menses should not be interpreted as a “false” positive result should menses commence a few days afterwards.
- 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.
- Fertility treatments, based on hCG, may cause false results. Consult your physician.
- hCG levels may remain detectable for several weeks after normal delivery, delivery by caesarean section, spontaneous abortion or therapeutic abortion.
- Elevated levels of hCG can be caused by a few conditions other than pregnancy. Therefore, the presence of hCG in urine sample should not be used to diagnose pregnancy unless these conditions have been ruled out.
- This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of HCG.
- Unclean sample or interfering substances in the urine may cause false results.
- For the test to work properly, it is essential that instructions are followed as set out.
- As with all diagnostic tests, a confirmed pregnancy diagnosis should only be made by a physician after evaluating all clinical and laboratory findings.

For various reasons, as a very small percentage of tests may give a false-positive result, Transatlantic Medical Supplies accepts no responsibility for any consequential damages associated with such results.

## PACKAGING

These tests are available in three pack sizes:

PREGTEST CLIN PACK STRIP (25) TMS

PREGTEST CLIN PACK STRIP(50) TMS

PREGTEST CLIN PACK STRIP(100) TMS

### Manufactured by:

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### Marketed and Distributed by:

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