TRANSATLANTIC
medical supplies

PREGNANCY TEST DEVICE (CASSETTE)

INTENDED USE

These Pregnancy Devices are unbranded and packed for use in a clinic or busy practice. The 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 use by a medical practitioner.
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 device detects Human Chorionic Gonadotropin (hCG) through visual interpretation of colour development in the internal strip. Urine is added to the sample well of the test device using the dropper provided. The sample migrates through the reaction pads where the hCG, if present, interacts with reagents on the membrane. If there is sufficient hCG in the urine specimen, a coloured band will form in the test (T) region of the membrane.
The presence of a coloured band in the test (T) region of the device indicates a positive result, whilst the absence of any colour in the test (T) region indicates a negative result. The coloured band that appears in the control (C) region of the device serves only as an indication that sufficient volume of the urine sample has been added.

REAGENTS

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

MATERIALS

Materials provided:

Test device packed in a foil pouch

Dropper

Instructions for use

Materials required but not provided:

Specimen 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 test if the foil pouch has been damaged or opened.

For single use only – do not reuse.

Discard the device after use.

CONDITIONS FOR COLLECTION OF SPECIMEN

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 specimen, 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.

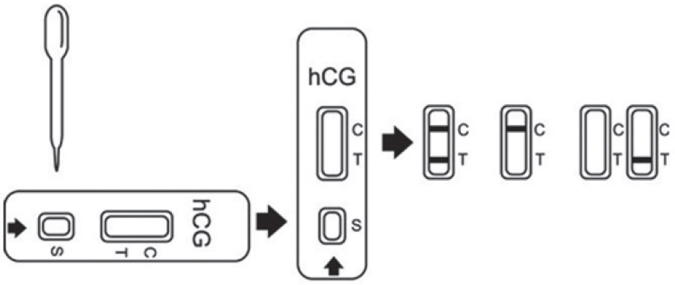
For the detection of an early pregnancy, it is recommended that the first morning urine is used.

The sensitivity of this test is 25mIU/ml.

100% correlation with commercially available pregnancy tests.

DIRECTIONS FOR USE

STEP 1: SAMPLE COLLECTION

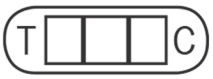


First morning urine usually contains the highest concentration of hCG and is therefore preferred for testing. However, specimens obtained at any time may be used. Collect the specimen in a clean, dry container.

STEP 2: TEST PROCEDURE

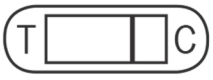
Open the foil pouch and remove the test device. Place the device on a flat, dry surface.
Holding the urine dropper above the test device, add 2 – 3 drops of urine into the urine well.
As the test begins to work, you will see a colour bar move across the result window in the centre of the device. Read the result after 3 – 5 minutes, after adding the urine sample to the urine well. 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.

STEP 3: INTERPRETATION OF RESULTS



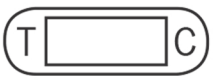
POSITIVE / PREGNANT

Two pink-rose bands are visible in the result window. Please note that if a second line is visible, even if it is faint, it indicates a positive result.



NEGATIVE / NOT PREGNANT

Only one pink-rose band is visible in the result window.



INVALID RESULT

If there are no visible colour bands in the result window, the test is invalid. Proper procedures may not have been followed when performing the test. The test should be repeated with a new device.

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.
- hCG levels may remain detectable for several weeks after normal delivery, delivery by caesarean section, spontaneous abortion or therapeutic abortion.
- As with all diagnostic tests, a diagnosis should not be based on the result of a single test, but should only be made by your doctor in conjunction with other chemical evidence.

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.

STORAGE AND STABILITY

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

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

Do not freeze.

PACKAGING

These tests are available in three pack sizes:

PREGTEST CLIN PACK DEVICE (25) TMS
PREGTEST CLIN PACK DEVICE (50) TMS
PREGTEST CLIN PACK DEVICE (100) TMS

Manufactured by:

Atlas Link (Beijing) Technology Co. Ltd.
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