thyme
your time

MIDSTREAM PREGNANCY TESTS

INTENDED USE

Thyme Home Pregnancy Midstream 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 device detects Human Chorionic Gonadotropin (hCG) through visual interpretation of colour development in the internal strip. Urine is added to the test by holding the absorbent tip downward and directly into your urine stream. 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 antibodies coated on the membrane.

MATERIALS

Materials provided:

Midstream test device and a desiccant packed in a foil pouch. The desiccant is for storage purposes only and is not used in the test procedure.
Instructions for use.

Materials required but not provided:
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 device if the foil pouch has been damaged or opened.
For single use only – do not reuse.
Discard the test 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

1. Remove the test from the sealed pouch when you are ready to do the test, not before.
2. Hold the test device in one hand. Pull off the cap and expose the absorbent tip.
3. Place the absorbent tip downward into your urine stream and hold, for at least 10 seconds, to be thoroughly wet. (If you prefer, you can urinate into a clean, dry container and perform the test by dipping the absorbent tip of the test into the urine for at least 3 seconds.)
4. Re-cap the device and lay the stick down flat with the results window facing up.
5. Wait for the colour lines to appear. The control line (C) indicates that the test is working and the test line (T) indicates a positive result.
6. Depending on the hCG concentration, a positive result may be observed within a minute. However, to confirm negative results, the complete reaction time of 5 minutes is required.
7. Do not read the test results after more than 10 minutes as it may no longer be accurate due to the composition of the test.

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. It is however recommended to repeat the test, within 48 hours, if the test line is very faint.

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.

IF THE RESULT IS POSITIVE (TWO LINES)

Consult your physician. He/she should confirm your pregnancy after evaluating all clinical and laboratory findings. In certain conditions a home pregnancy test may give a false positive result.

IF THE RESULT IS NEGATIVE (ONE LINE)

If you have reason to believe that you are pregnant (e.g. no menstrual bleeding), you can repeat the test 48 hours later. If the test is still negative, consult your physician.

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 specimen 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 specimen 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.

STORAGE AND STABILITY

Store as packaged, in the foil pouch, at room temperature (4 – 30 ºC). When stored in the foil pouch, the test 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.

Manufactured by:

Atlas Link Technology Co., Ltd
Gu’an South Industry Zone, 065500 Langfang City,
Hebei Province, the People's Republic of China

Marketed and Distributed by:

Transatlantic Medical Supplies
c/o Oude Pont and Oude Brug, Wellington Industrial,
7654, Western Cape, South Africa.
Tel: +27 (0)21 864 1281

www.transatlanticmed.co.za

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