

Pregnancy (HCG) Strip Test

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A Visual, Rapid and Reliable Test for the Early Diagnosis of Pregnancy.

Intended Use

The **PREGNANCY HCG Strip Test** is used for the qualitative early diagnosis of pregnancy and is intended for professional and home use.

Summary and Explanation

When a fertilized ovum is implanted into the chorionic tissue, the glycoprotein, human chorionic gonadotrophin (HCG) is released. HCG is composed of two sub-units. Antibodies have been developed which provide high specificity and sensitivity for the detection of HCG.

Principles of the Test

The test strip consists of two immobilized lines printed onto nitrocellulose. The first line is the capture or test line, consisting of monoclonal anti -alpha antibody. The control line is composed of rabbit anti-mouse IgG. The antibody is conjugated to a homogenous gold colloid. During the test, capillary action draws the sample through the conjugate pad where it binds to the immobilized capture antibody. The development of a pink line indicates presence of HCG and thus is suggestive of pregnancy, while only a control line demonstrates that the test procedure was completed successfully.

Reagents and Materials Supplied

1. Test strip
2. Package insert

Precautions

1. Do not use tests past their expiration date.

Collection and Storage of Specimens

Use a clean, dry container. Although early morning urine is often considered best because of greater concentration of HCG in the urine, samples from any other time in the 24-hour cycle may be used. Urine specimens may be stored at 2-8°C for 72 hours prior to use.

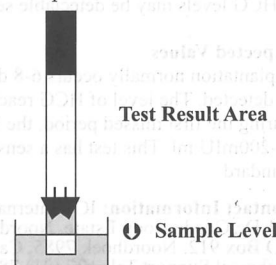
Test Procedure

1. Remove strip from its protective packaging prior to use.
2. Dip the strip into the sample collection container so that only the white block below the blue block is submerged.

Wait until observing a pink progression up the strip.

Place on a flat surface.

3. Read the results after 5 minutes. Do not read results after 10 minutes.



Dip only the lower white block into the sample.

Interpretation of Results

Control Line

Test Line



POS



NEG



INV

- POS:** A positive result is shown by the appearance of 2 pink lines, (test and control) and shows the presence of HCG in the sample. These can appear after only 20 seconds, but are best read after 5 minutes.
- NEG:** A negative result is shown by a pink control line only, demonstrating that the test has run correctly, but that no HCG was detected.
- INV:** An invalid result is shown by no lines and suggests that the procedure was not followed correctly or that a reagent is not functioning correctly. The test should be repeated with a new strip.

Quality Control

The strip contains an internal procedural control that confirms that the test was carried out correctly.

Limitations of the test

1. It is possible that the concentration of the HCG in the sample is too low to be detected. If pregnancy continues to be suspected, the test should be repeated 48 hours later.
2. HCG levels may be detectable several weeks after spontaneous abortion..

Expected Values

Implantation normally occurs 6-8 days post conception, after which very low levels of HCG can be detected. The level of HCG reaches about 30mIU/ml at about 10 days following fertilization. During the first missed period, the level is generally between 50-250mIU/ml and peaks between 20-200mIU/ml. This test has a sensitivity of <25mIU/ml as defined by the WHO Reference Standard

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