

ONE STEP HCG Pregnancy Rapid Test

For detection of HCG in Human Urine Specimens.

Introduction

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. When you are pregnant, your body will produce a special pregnancy hormone known as hCG. The appearance of hCG in both the urine and serum soon after conception and its rapid rise in concentration make it an excellent marker for confirmation of pregnancy. The hormone will begin to appear in your urine. The hCG pregnancy test will detect the presence of hCG in urine as early as the first day of a missed period. The concentration of hCG continues to rise rapidly, frequently exceeding 100 mIU/ml by the first missed menses and peaking in the 30,000 ~ 100,000 mIU/ml range by 10 to 12 weeks into pregnancy.

The hCG pregnancy test is an in-vitro immunochromatographic one step assay designed for qualitative determination of hCG in urine. This test kit use specific antibodies to selectively identify hCG in urine with a high degree of sensitivity. Elevated levels of hCG as low as 25 mIU/ml and be detected within 3 minutes. It is intended for professional use. The hCG pregnancy test contains a membrane strip, which is pre-coated with goat anti-hCG capture antibody on test band region. The mouse anti-beta hCG monoclonal antibody-colloid gold conjugate and urine sample moves along the membrane chromatographically to the test region (T) and forms a visible line as the antibody-antigen-antibody gold particle complex forms. The hCG pregnancy test device has a letter of T and C as "Test Line" and "Control Line" on the surface of the case. Both the Test Line and Control Line in result window are not visible before applying any samples. The Control Line is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working.

Intended Use

OneStep HCG Urine Rapid Test is a test kit for the determination of hCG (Human Chorionic Gonadotropin) in urine specimens. There is an appearance of hCG in urine soon after conception, and its subsequent rapid rise in concentration during early gestational growth. This test is used to obtain a visual, qualitative result for the early detection of pregnancy.

Materials Included and Active Ingredients

- 1) One Step hCG pregnancy kit contains the following items to perform the assay.
 - hCG test device foil pouched with a desiccant
 - Disposable urine dropper (may not be provided for midstream format)
 - Instruction for use
- 2) Active ingredients of main components of one step hCG pregnancy rapid test strips
 - Gold Conjugates (as main component): Mouse anti-beta hCG monoclonal antibody-gold colloid,
 - Test Line (as main component): Goat anti-alpha hCG mcAb,
 - 3) Control Line (as main component): Goat anti-mouse IgG

Kit Precautions and Storage Instructions

- 1) For best results, adhere to instructions provided
- 2) All specimens should be handled as potentially infectious
- 3) The test device should be stored at room temperature
- 4) The test device is sensitive to humidity as well as heat
- 5) Do not use beyond expiration date
- 6) Do not use test kit if pouch is damaged or seal is broken
- 7) Use test device immediately after removing from the pouch
- 8) The components (test device and assay diluents) in this kit have been quality control tested as a standard batch unit. Do not mix components from different lot numbers.
- 9) Store kit at room temperature (2 -30 °C). Do not expose the kit to temperature over 30 °C.
- 10) The stability of the test under above conditions is 24 months from the date of manufacturing.

Warnings

- 1) For in vitro diagnostic use only. DO NOT RE-USE test device
- 2) The instructions must be followed to obtain accurate results. Anyone performing an assay with this product must be trained in its use and laboratory procedures.
- 3) Do not eat or smoke while handling specimens
- 4) Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
- 5) Avoid splashing or aerosol formation
- 6) Clean up spills thoroughly using an appropriate disinfectant
- 7) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
- 8) Do not mix with other specimens.

Specimen Collection, Storage and Precautions

Urine Assay

A urine specimen must be collected in a dry and clean container. The first morning urine specimen is preferred since it usually contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used.

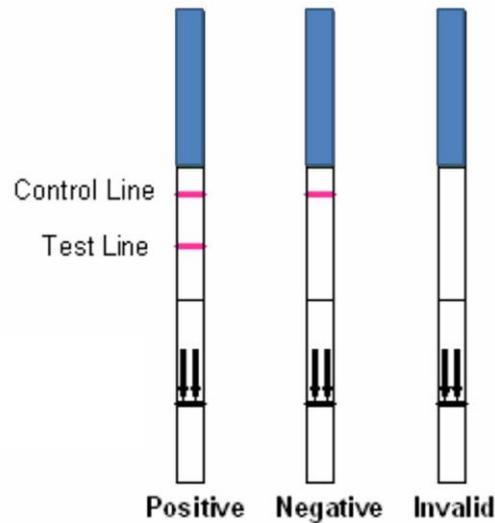
Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and stirred before testing.

Test Procedure

1. To begin testing, open the sealed pouch by tearing along the notch. Remove the test kit from the pouch and use it as soon as possible.
2. Immerse the strip into the urine sample with the arrow end pointing towards the urine.

3. Do Not immerse past the "Mark" Line. Take the strip out after 10 seconds and lay the strip flat on a clean, dry, non-absorbent surface (such as the mouth of the urine container).
4. Wait for colored bands to appear. Depending on the concentration of hCG in the test specimen, positive results may be observed in as soon as 40 seconds. However, to confirm negative results, the complete reaction time of 5 minutes is required. It is important that the background is clear before the result is read. Do not read results after more than 30 minutes.



Interpretation of Test Results (Refer to Figure)

1) Negative

The control line is the only visible line on the test device. This indicates a negative result.

2) Positive

The presence of two color lines ("T" line and "C" line) within the result window, no matter which line appears first, indicates a positive result.

3) Invalid

If the "C" line (control) is not visible within the result window after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.

Limitations of the Test

1) Although one step hCG pregnancy test is highly accurate in detecting pregnancy, a low incidence of false results (positive when no pregnancy exist or negative when pregnancy is present) can occur. Consult your physician if you get unexpected or inconsistent test results. Oral contraceptives, pain killers, antibiotics and other common drugs do not affect the result of the test.

2) A very early pregnancy containing an extremely low concentration of hCG (below 25 mIU/ml) can give a negative results. In this case, another specimen should be obtained at least 48 hours later and tested.

Internal Quality Control

The One Step hCG pregnancy rapid test device has a "Test line" and a "Control line" on the surface of the cassette. Both the Test Line and Control Line in the result window are not visible before applying any samples. The Control Line is used for procedural control. The Control line should always appear if the test procedure is performed properly and the test reagents of the control line are working.

Expected value

The One Step hCG pregnancy test is capable of detecting hCG levels of **25 mIU/ml**.

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