A rapid test for the qualitative detection of human chorionic gonadotropin (hCG) in urine, serum, or plasma. For use in vitro diagnostic tests.

**INTENDED USE**

The HCG Pregnancy Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine or plasma to aid in the early detection of pregnancy.

**SPECIFICITY**

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. It can be detected in both urine and serum or plasma as early as 7 to 10 days after conception.1,2,3,4

**Sensitivity**

The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG. The level of hCG in the test line region (T) is one line may be lighter than the other; they do not have to match. This means that you are probably pregnant.

**INTERPRETATION OF RESULTS**

(Refer to the illustration above)

**POSITIVE:** Two colored lines appear. One line should be in the control line region (C) and another colored line also appears in the test line region (T). This means that you are pregnant.

**NEGATIVE:** One colored line appears. No line appears in the test line region (T). This means that you probably are not pregnant.

**INVALID:** If no colored line appears in the control line region (C), even if a line appears in the test line region (T). You should repeat the test with a new test cassette.

**QUALITY CONTROL**

A procedural control is included in the test. A colored line appearing in the control line region (C) confirms correct procedural technique. A clear background is an internal negative procedural control. If a background color appears in the result window and interferes with the ability to read the test result, the test result may be invalid. It is recommended that a positive hCG control (containing 25-250 mIU/mL hCG) and a negative hCG control (containing “0” mIU/mL hCG) be evaluated to validate the efficacy with new shipment of tests is received.

**LIMITATIONS**

1. The HCG Pregnancy Rapid Test Cassette is a qualitative pregnancy test, therefore, the quantity of hCG is not determined.
2. The rate of increase in hCG can be determined by the HPLC method.
3. The assay is conducted by adding urine or serum or plasma specimen to the cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. See贮存 and Stability.
4. The test results are confirmed by using a confirmed pregnancy test kit.
5. The test results do not indicate the sex of the baby.
6. A low hCG level can be present at the time of a missed abortion.
7. Cross-reactivity of antigens.

**DIRECTIONS FOR USE**

1. Bring the pouch to room temperature (15-30°C) before opening it. Remove the cassette from the sealed pouch and use it within one hour.
2. Place the cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine or plasma (50 μL) to the specimen well of the cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
3. Wait for the colored line(s) to appear. Read the result at 3 minutes when testing a urine specimen, or at 5 minutes when testing a serum or plasma specimen.

**REFERENCE METHOD (Urine)**

Pregnancy Test Cassette (Urine/serum/plasma) 50 μL of the specimen, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.

**REFERENCE METHOD (Serum/Plasma)**

HCG Pregnancy Rapid Test Cassette (Serum/Plasma/Urime)

**INTRODUCTION**

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