



Pregnancy Test Cassette (Urine)

INTENDED USE

Forsure Pregnancy Test Cassette is a rapid chromatographic immunoassay for the quality detection of human chorionic gonadotropin (hCG) in urine, as an aid for the early detection of pregnancy.

SUMMARY

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in both serum and urine as early as 7 to 10 days after conception. hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/ml by the first missed menstrual period and peaking in the 100-200 mIU/ml range about 10-12 weeks into pregnancy. The appearance of hCG in both the urine and serum soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy.

Forsure Pregnancy Test Cassette is a rapid urine test to qualitatively detect the presence of hCG in urine specimens at the sensitivity of 25 mIU/ml. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, the Forsure Pregnancy Test Cassette shows no cross reactivity interference from the structurally related glycoprotein hormones hFSH, jLH and hTSH at physiological levels.

PRINCIPLE

Forsure Pregnancy Test Cassette is a qualitative, solid phase, two-site sandwich immunoassay for the detection of human chorionic gonadotropin (hCG) in urine. The membrane is pre-coated with anti-hCG antibodies on the test band region and anti-mouse antibodies on the control band region. During testing, the urine sample reacts with the colored conjugate (mouse-anti-hCG antibody colloidal gold conjugate) which has been pre-coated on the test Cassette. The mixture then migrates upward on the membrane chromatographically by capillary action to react with anti-hCG antibodies on the membrane and generate a red band. Presence of the red band indicates a positive result, while its absence indicates a negative result. Regardless of the presence of hCG, as the mixture continues to migrate across the membrane to the immobilized goat anti-mouse region, a red band at the control band region will always appear. The presence of this red band

serves as a verification for sufficient sample volume and proper flow and as a control for the reagents.

REAGENTS

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

PRECAUTIONS

- For in-vitro use only.
- Do not use after expiration date.
- The test cassette should remain in the sealed pouch until use.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature 4-30°C. The test cassette is stable within the expiration date printed on the labelling. Do not freeze or use beyond the expiration date.

MATERIALS PROVIDED

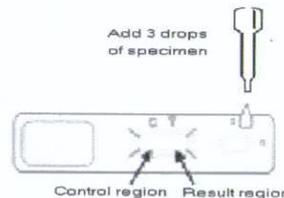
- Forsure Pregnancy Test Cassette
- Dropper
- Dessicant

SPECIMEN COLLECTION

The urine specimen must be collected in a clean, dry plastic or glass container. The first morning urine is preferred since it generally contains the highest concentration of hCG. However, urine collected at any time of day maybe used.

TEST PROCEDURE

Allow test cassette and urine samples to equilibrate to room temperature (15-30°C) prior to testing.



1. Remove the Forsure Pregnancy Test Cassette from foil pouch (bring to room temperature before opening the pouch). Use cassette as soon as possible but within 1 hour after removal from pouch specifically if the room temperature is more than 30C and in high humidity environment.

2. Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine to the specimen well (S) of the test cassette and wait.
3. Wait for the red bands to appear. The test should be read in approximately 3-5 minutes for urine. It is significant that the background is clear before reading the test, specially when samples have low hCG concentration and only a weak line appears in the test band region (T). Do not interpret result after 10 minutes.

QUALITY CONTROL

A procedural control is included in the test. A red band appearing in the control region (C) is considered an internal positive procedural control.

INTERPRETATION OF RESULT

Positive
Two distinct red bands will appear, one in the test region (T) and one in the control region (C).

Negative
Only a single red band appears in the control region (C). No apparent red or pink line appears in the test region (T).

Invalid Result
Control band fails to appear which means improper testing procedures or deterioration of reagents probably occurred.

Note : The shade of red color in the test band region (T) will vary depending on the concentration of hCG present. However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.