FAMKA
FAST • EASY • ACCURATE

hCG Pregnancy Test Midstream (Urine)

Intended Use

The hCG Pregancy Test Midstream is a rapid one step assay designed for qualitative detection of human chorionic gonadotropin (hCG) in urine for early detection of pregnancy.
For in vitro diagnostic use only.

Principle

Because the amount of a hormone called human chorionic gonadotropin (hCu) in your body increases rapidly during the first two weeks of pregnancy, the test midstream will detect the presence of this hormone in your urine as early as the first day of a missed period. The test midstream can accurately detect pregnancy when the level of hCG is between lOm lU/ml 10 500,000mlU/ml.
The test reagent is exposed to urine, allowing urine 10 migrate through the absorben1 test midstream. The labeled antibody-dye conjugate binds to the hCG in the specimen forming an antibody-antigen complex. This complex binds to the anti-hCG antibody in the test region (T) and produces a red line when hCG concentration is equal to or greater than lOmlU/ml In the absence of hCG. there is no line in the test region (T). The reaction mixture continues flowing through the absorbent device past the test region (T) and control region (C). Unbound conjugate binds to the reagents 10 the control region (C), producing a red line, demonstrating that the test midstream is functioning correctly.

Warnings and Precautions

For in vitro diagnostic use only.

- Please read all the information in this leaflet before performing the test.
- Do not use the kit beyond the labeled expiry date.
- Do not open the sealed foil pouch until you are ready to start the test.
- Do not touch the membrane located within the Result Window.
- As with all diagnostic tests, a final clinical diagnosis should not be based on the results of a single test, but should only be made by a physician after all clinical and lab findings have been evaluated.
- Do not reuse the test midstream. Discard it in the dustbin after single use.
- All urine specimens and used midstream should be considered potentially infectious and avoided contact with skin.

Composition

The test midstream consists of colloidal gold-monoclonal antibody against hCG coaled on polyester membrane, and monoclonal antibody against hCG and goat-anti-mouse lgG coated on nitrocellulose membrane.
Each pouch contains one lest midstream and one desiccant. Each box contains one pouch and one instruction for use.

Storage and Stability

- Store as packaged in the sealed pouch at room temperature (4-30 'C or 39.2-861'). The kit is stable within the expiry date printed on the labeling.
- Once open the pouch, the test midstream should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.

Additional Special Equipment

- Timer

Specimen

First morning urine usually contains the highest concentration of hCG and is therefore the best specimen when performing the urine test. However, urine collected at any time of day may be used.

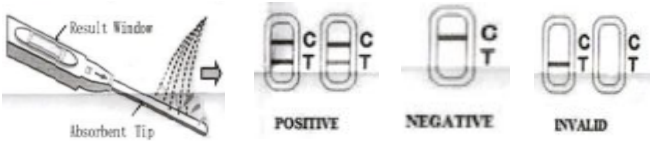
Test Procedure

- Read the entire procedure carefully before performing any tests.
- Remove the test midstream from the scaled pouch.
- Remove the Cap and hold the midstream with the exposed Absorbent Tip pointing downward directly into your urine stream for at least 10 seconds until it is thoroughly wet.

NOTE: If you prefer, you can urinate into a clean and dry container, then dip only the Absorbent Tip of the midstream into the urine for at least 10 seconds.

- After removing the midstream from your urine, immediately replace the Cap over the Absorbent Tip, lay the midstream on a flat surface with the Result Window facing, and then begin timing.
- Wait for colored lines to appear. Interpret the test results at 3-5 minutes.

NOTE: Do not read results after 5 minutes.



Interpretation of Results

Positive: Two distinct red lines will appear, one in the test region (T) and another in the control region (C). You can assume that you are pregnant.

Negative: Only one red line appears in the control region (C). No apparent line in the test region (T). You can assume that you are not pregnant.

Invalid: The result is invalid if no red Jim, appears in the control region (C), even if a line appears in the test region ("T'). In any event, repeat the test. If the problem persists, discontinue using the lot immediately and contact your local distributor.

NOTE: Clear background in the Result Window can be seen as a basis for effective testing. If the test line is weak, it is recommended that the test be repeated with the first morning specimen obtained 48-72 hours later. No matter how the test results, It is recommended to consult your physician.

Performance Characteristics

The hCG Pregnancy Test Midstream will detect hCG concentrations between 10m!U/ml to 500,000m!U/ml. The addition of Luteinizing Hormone (LH, 500mJU/ml). Follicle Stimulating Hormone (FSH, 1000m!U/ml) and Thyroid Stimulating Hormone (TSH, 1000 µ JU/ml) to negative specimens (0m!U/ml hCG) showed that these hormones do not impact the pregnancy test results.

Limitations and Possible Errors

- False-negative readings can occur when testing is done too early. In order to get the most accurate results, it is a good idea to wait for about a week after your period is due before testing. This allows more hCG to build up in your urine, which will allow for a more accurate test.
- When hCG levels are below the minimum detection level of the test, a false negative result may be obtained. If pregnancy is suspected after a negative result, a first morning urine specimen should be collected 48-72 hours later and tested. If pregnancy is suspected and the test continues lo produce negative results, see a physician for further diagnosis.
- Certain fertility medications which contain hCG (such as Pregnyl, Profasi, Novarel) can give a false-positive result. Alcohol, oral contraceptives, birth control pills, analgesics (pain killers), antibiotics or hormone therapies that do not contain hCG should not affect the test result.
- A number of medical conditions other than pregnancy, including ovarian cyst, choriocarcinoma or ectopic pregnancy (pregnancy outside the uterus) can cause elevated levels ofhCG.
- Using the test midstream within 8 weeks of giving birth or having a miscarriage may also cause a positive result. You should ask your doctor for help in interpreting your test result if you have had the experience of described above recent!

Version No.: 1.0
Effective Date: 2019-04-30