

CLEAR CHOICE

GB

INSTRUCTION

CLEAR CHOICE HCG Urine Pregnancy Test (cassette).
For Self-Testing

INTENDED USE

The Human Chorionic Gonadotropin (HCG) Test Kit is a rapid and convenient immunochromatographic in vitro assay for the detection of HCG hormone in urine to help in early diagnosis of pregnancy. The device is designed for professional and over the counter use. The test provides a visual, qualitative result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

SUMMARY AND PRINCIPLE OF THE ASSAY

HCG is a hormone produced by trophoblastic tissue and it appears around the 8-9th day after ovulation, or around the 4th day after conception. In a 28-day cycle with ovulation occurring at day 14, HCG can be detected in urine or serum in minute quantities around day 23, or 5 days before the expected menstruation. The hormone concentration doubles approximately every 2 days and peaks between 7-12 weeks after the first day of the last menstrual period. In normal females, HCG in urine provides an early indication of pregnancy. The elevated HCG levels are also associated with trophoblastic diseases and certain nontrophoblastic neoplasms. Thus, the possibility of other diseases must be eliminated before the diagnosis of pregnancy can be made.

HCG consists of two subunits, alpha and beta. Alpha subunits of these various glycoprotein hormones are structurally very similar, but beta subunits differ in amino acid sequences. These differences are responsible for their biological and immunological specificity.

HCG Test Kit is an antigen-capture immunochromatographic assay, which detects the presence of HCG in human serum or urine samples. Monoclonal antibodies specifically against HCG (beta or alpha unit) are 1) conjugated with colloidal gold and deposited on the conjugate pad, and 2) immobilized on the test line of the nitrocellulose membrane. When the urine sample is added the gold-antibody conjugate is rehydrated and the HCG, if any in samples, interacts with the gold conjugated antibodies. The antigen-antibody-gold complex will migrate toward the test window until the Test Zone (T) where it will be captured by immobilized antibodies, forming a visible pink line (Test band), indicating a positive result. If HCG is absent in the sample, no pink line will appear in the Test Zone (T), indicating a negative result.

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a pink control line in the Control Zone is an indication of an invalid result.

The detection limit for the HCG Test Kit is 10 mIU/ml. Urine samples containing HCG levels equal to or greater than the detection limit will test positive. Samples containing HCG at levels less than the detection limit may also produce a very faint positive line.

SPECIMEN PREPARATION

1. Urine specimen may be collected at any time of day. However, urine specimens collected in early morning are most desirable as the HCG concentration is the highest at that time.
2. Urine specimens may be collected in any clean and dry plastic or glass container (not provided).
3. If specimens cannot be assayed immediately, it may be stored at 2-8°C for up to 48 hours prior to testing.
4. Specimens should be equilibrated to room temperature before testing if they were refrigerated or frozen.

TEST PROCEDURES

Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a leveled surface.

Hold the sample dropper vertically and add three full drops (0.15 ml) of specimen without air bubbles into the sample well that is marked with an arrow on the testing device.

Read the result in 10 minutes. Read results as shown under interpretation of results.

NOTE: Strong positive specimens may produce positive results in as little time as 1 minute. Confirm negatives in 10-20 minutes.

DO NOT INTERPRET RESULTS AFTER 30 MINUTES.

RESULT INTERPRETATIONS

NEGATIVE

A pink colored band appears only in the control region (C), indicating a negative result for pregnancy.

POSITIVE

A clear pink control band (C) and a detectable test band (T) appear, indicating a positive result for pregnancy.

INVALID

No visible band in the control region (C). Repeat with a new test device. If the test still fails, please contact the distributor with the lot number.

QUALITY CONTROL

The HCG Test Kit has included an internal control in the test. If a test device is valid and the assay was performed properly, a pink colored band will always appear in the control region (C) regardless of positive or negative results. It is recommended that control specimens of both HCG negative and HCG positive be used with each new kit. Users, however, should follow their state and local regulations and guidelines regarding GLP requirements.

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
2. Besides from pregnancy, a number of conditions such as trophoblastic diseases, proteinuria, hematuria, choriocarcinoma, ovarian and testicular teratomas can cause elevated levels of HCG. These diagnoses should be considered if appropriate to the clinical evidence.
3. Immunologically interfering substances such as those used in antibody therapy treatments may invalidate this assay.
4. Ectopic pregnancy cannot be distinguished from normal pregnancy using HCG measurements alone.
5. Samples from patients on chemotherapy for cancer should be ruled out before running the assay.
6. Positive HCG levels may be detectable for several weeks following delivery or abortion.
7. Specimens which tested positive during the initial days after conception may be negative later due to natural termination of the pregnancy.

STORAGE AND STABILITY

1. Test device in the sealed pouch can be stored at 2-30°C up to the expiration date. Do not freeze the test device.
2. The test device should be kept away from direct sunlight, moisture and heat.

PACKAGE CONTENTS

1. Pouch (contain: test cassette, sample dropper, desiccant).
2. Test instructions.

MATERIALS REQUIRED (BUT NOT PROVIDED)

1. Clean, dry urine specimen collection container (plastic or glass).
2. Clock or timer.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not use after the expiration date shown on the pouch. Do not reuse.
3. Do not use if the pouch seal or its packaging is compromised.
4. Do not mix and interchange different specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay.
6. Wash hands thoroughly after finishing the tests.
7. Do not eat, drink or smoke in the area where the specimens or kits are being handled.
8. Clean up spills thoroughly with appropriate disinfectants.
9. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
10. Dispose of all specimens and used kits in a proper biohazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
11. Keep out of children's reach.

Manufacturer: FORANS Medical GmbH, Martener Straße 275, 44379 Dortmund, Germany
Distributor: SIA FORANS Piepilsetas, Krustkalni novads, Kekavas pagasts, LV-2111, Latvia



In vitro Diagnostic Use



Can not be reused



Consult instructions for use



Keep dry



Keep away from sunlight



Disposal of all waste material should be in accordance with local guidelines.



Store at between 2-30°C



tests per package



Use before



Manufacturer



Date of Manufacture



Batch number



0483

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