Human Chorionic Gonadotropin (HCG) Serum/Urine Combo Test Kit

Instructions For Use

Format: Strip
Specimen: Serum/Plasma/Urine

Catalog Number: A01-01-213

CE

* Please read the instructions carefully before use

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 serum/plasma or urine to help in early diagnosis of pregnancy. The test provides a visual, qualitative result. Clinical expertise and professional judgment should be sought to further evaluate the results of the test.

SUMMARY AND PRINCIPLE OF THE ASSAY

HCG is a hormone produced by the trophoblastic tissue and it appears at 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 small quantities in urine or serum/plasma of pregnant women at 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 healthy females, HCG in urine or serum/plasma provides an early indication of pregnancy. The elevated HCG levels are also associated with trophoblastic diseases and certain non-trophoblastic 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. The 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.

Artron One-Step HCG Test Kit is an antigen-capture immunochromatographic assay that detects the presence of HCG in human serum/plasma 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 sample is added, the gold-antibody conjugate is rehydrated and the HCG, if present in the sample, interacts with the gold-conjugated antibodies. The antigen-antibody-gold complex then migrates towards the test window until the Test Zone (T) where it gets captured by immobilized antibodies, forming a visible pink line (Test band), indicating a positive result. If HCG is absent from the sample, no pink line will be visible 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 indicates an invalid result.

The detection limit is 20 mIU/ml HCG. Urine and serum/plasma samples containing HCG levels equal to or greater than the detection limit will test positive. Samples containing HCG at levels smaller than the detection limit may also produce a very faint positive line.

PACKAGE CONTENTS

- Pouches (contain: test strip, desiccant).
- Test instructions.

MATERIALS REQUIRED (BUT NOT PROVIDED)

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

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use after the expiration date shown on the pouch. Do not re-use.
- Do not use if the pouch seal or its packaging is compromised.
- Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay.
- Wash hands thoroughly after finishing the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are being handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contained infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.

- Dispose of all specimens and used kits in a proper biohazard container. The handling and disposal of hazardous materials should follow local, national or regional regulations.
- Keep out of the reach of children.

SPECIMEN PREPARATION

Urine

- Any urine specimen is appropriate for HCG testing. However, urine specimens collected early in the morning are mostly recommended as the HCG concentration is the highest at that time.
- Urine specimens may be collected in any clean and dry plastic or glass container (not provided).
- If specimens cannot be assayed immediately, they may be stored at 2-8°C for up to 48 hours prior to testing.
- If refrigerating of freezing specimens please allow them to equilibrate to room temperature before testing.

Serum/Plasma

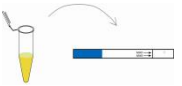
- For serum samples, collect blood in a tube without anticoagulant and allow it to clot.
- For plasma samples, collect the blood in a tube containing anticoagulant.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for long periods of time.

TEST PROCEDURES

1. Remove the testing device from the foil pouch by tearing at the notch. Hold the strip from the colored end. (Do not touch the arrow end; Do not touch test window (the middle part of the strip).

2. Holding the strip vertically, immerse the end of the strip marked with arrows into the specimen. Do not immerse past the MAX line.

3. Take the strip out when the sample migrates to the test window (about 10 seconds). Lay the strip (MAX side facing up) flat on a clean, dry, non- absorbent surface.

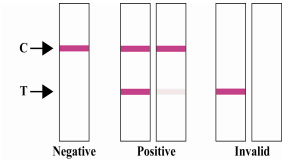


4. Read the results after 10 minutes, following instructions under the “Results Interpretation” section.

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

DO NOT INTERPRET RESULTS AFTER 30 MINUTES

RESULTS INTERPRETATION



Negative
A pink colored band is visible 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) are observed, 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 includes an internal control within 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 nature are used with each new kit. Users should always follow their state and local regulations and guidelines regarding GLP requirements.

STORAGE AND STABILITY

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

LIMITATIONS

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

MANUFACTURER CONTACT INFORMATION

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