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

Instructions For Use

Format: Strip
Specimen: Serum/Urine
Catalog Number: A01-01-213

* Please carefully read the instructions before use

INTENDED USE

The Human Chorionic Gonadotropin Serum/Urine (HCG S/U) Combo Test Kit is a rapid and convenient immunochromatographic *in vitro* assay. It is used for the detection of HCG hormone in urine for early diagnosis of pregnancy. The test provides a visual, qualitative result, and all positive specimens are advised to be confirmed with other qualified assays.

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 subjects, 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.

The HCG S/U Test Kit is based on the principle of immunochromatography. Each test device contains monoclonal anti-beta-HCG antibody/colloidal gold conjugate pre-dried on a pad. Monoclonal anti-alpha-HCG antibody (at the test region) and goat anti mouse IgG (at the control region) are coated on the membrane. When the absorbent pad is soaked with urine, the urine will migrate via capillary action toward the result window. If HCG is present in the urine, it reacts with anti-beta-HCG antibody/colloidal gold conjugate to form a complex which will move and be captured by anti-alpha-HCG antibodies to form a colored line in the test region. The control line is not influenced by the presence or absence of HCG in sample, and it should be present in all reactions. Absence of a colored control line in the control region is an indication of an invalid result. The detection limit for the HCG S/U Test Kit is 20 mIU/ml HCG. Urine samples equal to or greater than 20 mIU/ml will induce a positive test. Samples containing less than 20 mIU/ml HCG may also produce a very faint positive line.

PACKAGE CONTENTS

- Pouch contents: Test strip, desiccant
- Test instructions

MATERIALS REQUIRED BUT NOT PROVIDED

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

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not reuse.
- Test device should remain sealed until use.
- Do not use after the expiration date shown on the pouch.
- Dispose all specimens and used devices in a proper biohazard container
- Keep out of children's reach.

SPECIMEN PREPARATION

Urine

- Any urine specimen is appropriate for HCG testing. However, the first morning urine specimen is the most optimal because 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, it may be stored at 2-8°C for up to 48 hours prior to testing.
- Specimens should be equilibrated to room temperature before testing if they were refrigerated or frozen.

Serum

- 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 prolonged periods.

TEST PROCEDURES

1

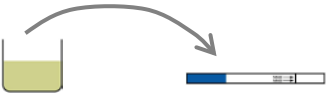
Remove the testing device from the foil pouch by tearing at the notch. Hold the strip by the colored end.

2

Immerse the strip into the urine with the arrow end pointing towards the specimen. Do not immerse past the MAX line.

3

Take the strip out after a minimum of 10 seconds. Lay the strip (MAX side facing up) flat on a clean, dry, non-absorbent surface.

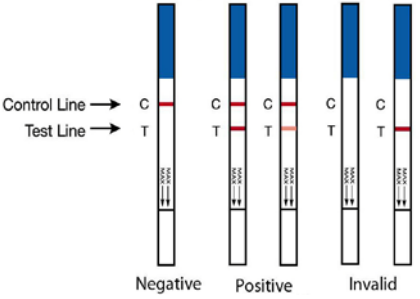


4

Read the result in 15 minutes. Ensure that the background of the test area is white before interpreting the results.

DO NOT INTERPRET RESULTS AFTER 30 MINUTES

RESULT INTERPRETATIONS



Negative
A pink colored band appears only at the control region.

Positive
A clear pink control band and a detectable test band appear. This indicates pregnancy.

Invalid
No visible band at the control region. Repeat with a new test device. If test still fails, please contact the distributor with the lot number.

QUALITY CONTROL

The HCG S/U Test Kit includes a process control in the test. If a test device is valid and the assay was performed properly, a red colored band will always appear in the control region (C) regardless of positive or negative results. It is recommended that both negative urine HCG and positive urine HCG control specimens be used with each new kit. Users, however, should 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, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
- A number of disease conditions other than pregnancy 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.
- Immunologically interfering substances such as those used in antibody therapy treatments may invalidate this assay.
- Ectopic pregnancy cannot be distinguished from normal pregnancy from 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 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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