First Romanian rapid tests manufacturer !

rev1

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"See Now" hCG combo Strip Test

CE

Serum / Urine

For in vitro Diagnosis Use
Product Code: SN 1.1'

INTENDED USE

The *"See Now"* human Chorionic Gonadotropin (hCG) test is a rapid and convenient immunochromatographic *in vitro* assay. It is used for the detection of hCG hormone in serum or urine and early diagnosis of pregnancy. The test provides a visual, qualitative result. All positive specimens must be confirmed with other qualified assays.

.PRINCIPLE

The 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.

"See Now" hCG combo rapid test 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.

MATERIALS SUPPLIED

- Test Strip, desiccant
- Test instruction

MATERIALS REQUIRED BUT NOT SUPPLIED

- Specimen collection container, Timer

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.

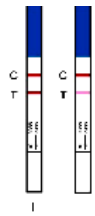
PRECAUTIONS

- For *in vitro* diagnostic use only.
- Test device should remain sealed until use.
- Do not use after the expiration date shown on the test.

TEST PROCEDURE

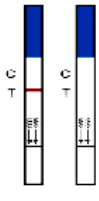
- Remove the test device from pouch when ready to perform the test .Label the test device with patient or control identification
- Immerse the strip into the serum or urine specimen with the arrow end pointing towards the urine. Let it stay immersed until you see liquid traveling up past the MAX word.
- 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
- Read the result after 10 minutes. Ensure that the background of the test area is white before interpreting the results.

INTERPRETATION OF RESULTS



Positive: Two colored lines should be observed. The line in the test region (T) is the probe line; the line in the control region (C) is the control line, which is used to indicate proper performance of the device. **The color intensity of the test line may be weaker or stronger than that of the control line.**

Negative: The control line appears in the test, but the test line is not visible.



Invalid: No line appears in the control region. Under no circumstances should a positive sample be identified until the control line forms in the viewing area. If the control line does not form, the test result is inconclusive and the assay should be repeated.

LIMITATION OF PROCEDURE

- 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 testing positive during the initial days after conception may be negative later due to natural termination of the pregnancy.

PERFORMANCE CHARACTERISTICS

Accuracy

Accuracy of the "*See Now*" hCG Serum/Urinary Pregnancy Test Device has been evaluated by a comparison study with a currently marketed hCG pregnancy test device and was conducted at external clinical sites. Out of 120 patients who visited walk-in and ob-gyn clinics, 54 were tested positive and 64 were tested negative for both devices. The two assays gave a 98.3% agreement.

Specificity

Specificity of the "*See Now*" hCG Serum/Urinary Pregnancy Test Device was determined from testing urine samples spiked with stuctrually similar hormones: 500mIU/ml human lutenizing hormone (hLH), 1000mIU/ml human follicle stimulating hormone (hFSH), and 1000 µIU/ml human thyroid stimulating hormone (hTSH). Specimens containing these hormones at the tested levels were found not to significantly cross-react with hCG antibodies, as to yield false positive or false negative results.

Sensitivity

Sensitivity of the "*See Now*" hCG Serum/Urinary Pregnancy rapid test was validated by the following experiment. Serum and urine specimens from 40 healthy non-pregnant individuals were collected and spiked with hCG concentrations of 0, 10, 15, 20, 25, 50, and 100 mIU/ml. The specimens were ran on "*See Now*" hCG test strips. Results are tabulated below.

hCG mIU/ml	0	10	15	20	25	50	100
(+)	0	24	36	40	40	40	40
(-)	40	16	4	0	0	0	0

The detection limit for the "*See Now*" hCG Pregnancy Test Device is 20 mIU/ml hCG. Specimen samples equal to or greater than 20 mIU/ml will be tested positive. Samples containing less than 20 mIU/ml hCG may also produce a very faint positive line.

Interference Testing

The chemicals commonly found in OTC, prescription, or abuse drugs were spiked into both hCG negative and 20 mIU hCG/ml urine specimens. The spiked samples against following substances or pH at the indicated concentrations were tested. There was no interference observed.

List of potentially interfering chemical analytes or pH's and concentrations tested:

1. Acetaminophen 20 mg/dl
2. Acetylsalicylic acid 20 mg/dl
3. Ascorbic acid 20 mg/dl
4. Caffeine 20 mg/dl
5. Gentesic acid 20 mg/dl
6. Phenylpropanolamine 20 mg/dl
7. Salicylic acid 20 mg/dl
8. EDTA 80 mg/dl
9. Acetylsalicylic acid 20 mg/dl
10. Benzoylecgonine 10 mg/dl
11. Atropine 20 mg/dl
12. Cannabinol 10 mg/dl
13. Ethanol 1%
14. Methanol 1%