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"See Now" hCG CassetteTest

CE

Urine

For in vitro Diagnosis Use
Product Code: SN 1.2

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 urine and early diagnosis of pregnancy

.PRINCIPLE

The hCG is a hormone produced by trophoblastic tissue and it appears around the 4th day after conception. hCG in urine provides an early indication of pregnancy.

The principle of "See Now" hCG test device is a double-antibodies, sandwiched immunochromatography in vitro assay. HCG antibodies are conjugated to colloidal gold particles and immobilized onto nitrocellulose membrane. If hCG is present in the sample, a visible red line will appear at the Test Zone (T), otherwise, no red line will appear. A red line will always present at the Control Zone (C) as an internal control. Absence of a colored control line at C zone is an indication of an invalid result.

MATERIALS SUPPLIED

- Test Device, 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 15-25ºC up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

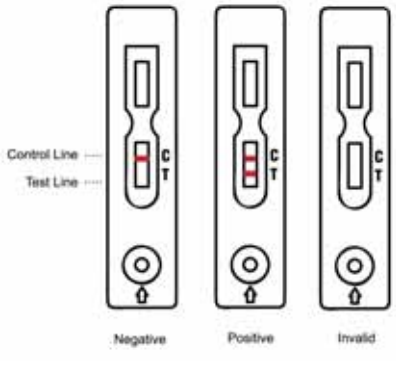
PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not reuse.
- Test device should remain sealed until use.
- Do not used after the expiration date shown on the pouch.
- Keep out of children's reach.

TEST PROCEDURE

- Remove the test device from pouch when ready to perform the test .Label the test device with patient or control identification
- Remove the test device from the sealed pouch by tearing at the notch. Then place the testing device on a level surface
- Holding the sample dropper vertically, add 5 drops (0.2 ml) of specimen without air bubbles into the sample well that is make with an arrow on the testing device
- Wait for colored bands to appear and read results. Positive results can be read as soon as it appears. Negative results may be confirmed in 5 to 10 minutes. Ensure that the background of the test area is white before interpreting the results.
- Read the result after 10 minutes.

INTERPRETATION OF RESULTS



Negative

Only one pink colored band appears at the control region.

Positive

Distinct pink colored bands appear at the control and test line regions.

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.

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 Urinary Pregnancy Test Device has been evaluated.

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 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 Urinary Pregnancy Test Device was validated by the following experiment. 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 Urinary Pregnancy Test Device is 20 mIU/ml hCG. Urine 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%

Biological Analytes

1. Albumin 2,000 mg/dl
2. Glucose 2,000 mg/dl
3. Bilirubin 1,000 μg/dl
4. Hemoglobin 1,000 μg/dl

Urinary Test pH

1) pH 9
2) pH 8
3) pH 6
4) pH 5