hCG Pregnancy Urine/Serum Combo Test

For professional in vitro diagnostic use only.

INTENDED USE

The HCG Rapid Test Device (Urine/Serum) is a rapid visual immunoassay for the qualitative, presumptive detection of human chorionic gonadotropin in human urine specimens. This kit is intended for use as an aid in the early detection of pregnancy.

INTRODUCTION

Human chorionic gonadotropin (hCG), a glycoprotein hormone secreted by viable placental tissue during pregnancy, is excreted in urine approximately 20 days after the last menstrual period. hCG levels rise rapidly, reaching peak levels after 60-80 days. The appearance of hCG in urine soon after conception and its rapid rise in concentration makes it an ideal marker for the early detection and confirmation of pregnancy. However, elevated hCG levels are frequently associated with trophoblastic and non-trophoblastic neoplasms and hence these conditions should be considered before a diagnosis of pregnancy can be made.

PRINCIPLE

The HCG Rapid Test Device (Urine/Serum) detects hCG through visual interpretation of color development. Anti-hCG antibodies are immobilized on the test region (T) of the membrane and anti-mouse antibodies on the control region (C). During testing, hCG, if present in the specimen, will bind to anti-hCG antibodies conjugated to colored particles and precoated onto the sample pad. As the specimen migrates along the strip by capillary action and interacts with reagents on the membrane, the complex will be captured by anti-hCG antibodies at the test region. Excess colored particles are captured at the internal control region.

The presence of a red band in the test region (T) indicates a positive result for the particular antigens, while its absence indicates a negative result. A red band at the control region (C) serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking is working.

MATERIALS

Materials Provided

- Individually packed test devices
- Disposable pipettes
- Package insert

Materials Required but Not provided

- Specimen collection container
- Centrifuge
- Timer

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

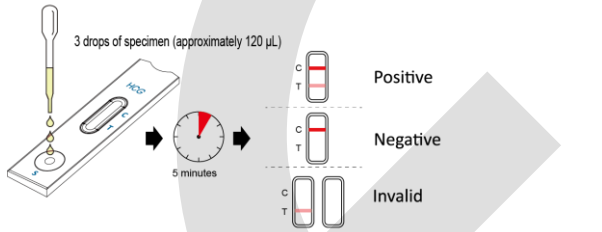
SPECIMEN COLLECTION AND STORAGE

- The HCG Rapid Test Device (Urine/Serum) is intended for use with human urine or serum specimens only.
- Although urine specimens from any time of day can be used, first morning urine specimens are preferred as they contain the highest concentration of hCG.
- Only clear specimens are recommended for use with this test. Serum should be separated as soon as possible to avoid hemolysis.
- Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- Collected urine/serum specimens must be put in clean, dry containers.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 48 hours. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.

PROCEDURE

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results the assay should be performed within one hour.
2. Add 3 drops of specimen (approximately 120 µL) directly into the specimen well (S) and start the timer. As the test begins to work, color will migrate across the result area in the center of the device.
   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.
3. Wait for the colored band(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

NOTE: Low hCG concentrations may produce very weak T lines after a prolonged period of time. Therefore, do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears, in the control region (C). No colored band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. The appearance of a colored band in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The HCG Rapid Test Device (Urine/Serum) is for professional *in vitro* diagnostic use, and should only be used for the qualitative detection of hCG.
2. Very dilute urine specimens, exhibiting low specific gravity, may not contain representative levels of hCG. If pregnancy is suspected after a negative result, a first morning urine sample should be obtained 48~72 hours later and tested.
3. Very low levels of hCG (less than 50 mIU/mL) are present in urine or serum shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be interpreted in conjunction with other clinical and laboratory data.
4. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer and lung cancer, cause elevated levels of hCG (>10 mIU/mL). Therefore, the presence of hCG in urine as determined by using the HCG Rapid Test Device (Urine/Serum) should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. When hCG levels are below the minimum detection level of the test, a false negative result may be obtained. If pregnancy is suspected after a negative result, a first morning urine specimen should be collected 48-72 hours later and tested. If pregnancy is suspected and the test continues to produce negative results, see a physician for further diagnosis.
6. As with all diagnostic tests, a confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

hCG concentration in pregnant women rises very rapidly after implantation, reaching a peak concentration in excess of 200 mIU/mL about 2~3 months after the last menstrual period. The HCG Rapid Test Device (Urine/Serum) has a sensitivity of 20 mIU/mL for urine/serum and is capable of detecting pregnancy as early as 1 day after the first missed menses.
Reportedly, a level of 25 mIU/mL or more, is present 7-10 days after conception or 4-5 days prior to the first missed menses. Test results which appear as very light bands in the test region are not definitive for the diagnosis of pregnancy. It is strongly recommended that an additional urine/serum specimen be obtained after 48~72 hours and tested again. Patients suspected to be pregnant but showing negative test results should be re-tested with first morning specimens obtained 48~72 hours later.

PERFORMANCE CHARACTERISTICS

Table: HCG Rapid Test Device vs. EIA (Urine)

Relative Sensitivity: >99.9% (97.2%-100.0%)*
Relative Specificity: >99.9% (98.0%-100.0%)*
Overall Agreement: >99.9% (98.8%-100.0%)*
***95% Confidence Interval**

		hCG Rapid Test +	hCG Rapid Test -	Total
EIA	+	130	0	130
	-	0	178	178
		130	178	308

Table: HCG Rapid Test Device vs. EIA (Serum)

Relative Sensitivity: >99.9% (97.8%-100.0%)*
Relative Specificity: >99.9% (98.5%-100.0%)*
Overall Agreement: >99.9% (99.1%-100.0%)*
***95% Confidence Interval**

		hCG Rapid Test +	hCG Rapid Test -	Total
EIA	+	169	0	169
	-	0	250	250
		169	250	419

SPECIFICITY

The specificity of the HCG Rapid Test Device (Urine/serum) was determined in cross reactivity studies with known amounts of Luteinizing Hormone (hLH), Follicle Stimulating Hormone (hFSH) and Thyroid Stimulating Hormone (hTSH). 300 mIU/mL hLH, 1000 mIU/mL hFSH and 1000 µIU/mL hTSH all gave negative results.

LITERATURE REFERENCES

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GLOSSARY OF SYMBOLS

	Catalog number		Temperature limitation
	Consult instructions for use		Batch code
	In vitro diagnostic medical device		Use by
	Manufacturer		Contains sufficient for <n> tests
	Do not reuse		Authorized representative in the European Community
	CE marking according to IVD Medical Devices Directive 98/79/EC		

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