hCG Pregnancy Rapid Test Kit

Cat No. S100-01

In vitro Diagnostics

INTENDED USE

Sensit hCG Pregnancy Rapid Test is an in-vitro immunoassay for the qualitative detection of human Chronic Gonadotropin (hCG) in urine to aid in the early detection of pregnancy. This test is intended to provide a visual and qualitative result for self-testing use.

SUMMARY & TEST DESCRIPTION

The hormone human chorionic gonadotropin (hCG) is produced during pregnancy. It is made by cells that form the placenta, which nourishes the egg after it has been fertilized and becomes attached to the uterine wall. Levels can first be detected by a blood test about 11 days after conception and about 12 - 14 days after conception by a urine test. In general the hCG levels will double every 72 hours. The level will reach its peak in the first 8 - 11 weeks of pregnancy and then will decline and level off for the remainder of the pregnancy. Sensit hCG Pregnancy Rapid Test Kit qualitatively detects the presence of hCG in urine/serum specimen at 10mIU/ml. The test uses two monoclonal antibodies to detect the elevated levels of hCG in urine/serum.

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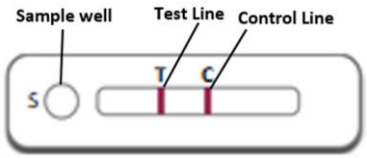
TEST DESCRIPTION & PRINCIPLE

Sensit hCG Pregnancy Rapid Test works on chromatographic immunoassay. Basic components of test strip includes: a) Conjugate pad, which contains detection molecule, colloidal gold conjugated; b) a nitrocellulose membrane strip containing two lines T: anti-hCG Ab and C: Goat Anti-Mouse antibody.



Test sample that is added to the sample well, with adequate amount of buffer migrates from the sample pad along the conjugate pad where hCG present in the sample will bind to the colloidal gold conjugate to form a complex. The sample then continues to migrate across the membrane until it reaches the capture zone where the complex will bind to the immobilized anti hCG Ab (on test line) producing a visible line on the membrane. If the hCG is not present in the sample, no reaction occurs in the capture zone and no test line is formed. The sample then migrates further along the strip until it reaches the control zone, where it produces another visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended.

MATERIALS PROVIDED

1. Each test pouch contains:
   a. One test card and dropper
   b. Desiccant
2. Instruction Leaflet

STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

PRECAUTION & WARNING

1) Use within 10 minutes after opening pouch.
2) Do not touch result window.
3) Do not reuse test kit.
4) Do not use test kit beyond expiry date.
5) Use only for in-vitro diagnostic purpose.

SAMPLE COLLECTION

Specimen: **Urine**

- Collect the urine at any time in a clean, dry container either plastic or glass.

First morning urine specimen is preferred since it generally contains the highest concentration of hCG.

Note:

- *If the specimen is not used for testing immediately, they should be refrigerated at 2~8°C.*
- *For storage period longer than 5 days, freezing is recommended. Store at -20^{0}C*
- *The specimen should be brought to room temperature prior to use.*

Treat the specimen as infectious and handle with standard biosafety measures.

TEST PROCEDURE

1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 3 drops of the specimen to the Sample well “S”
3. Wait for 10 minutes and interpret the result. The result is considered invalid after 15 minutes.

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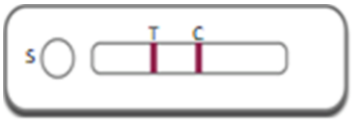
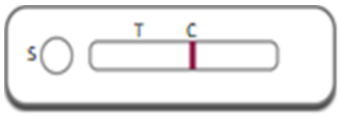
INTERPRETATION OF TEST RESULT

Positive: A clear pink control band ("C") and a detectable test band ("T") appear, indicating the presence of hCG in the sample.

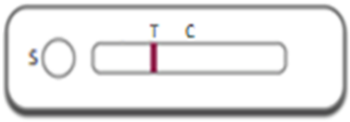


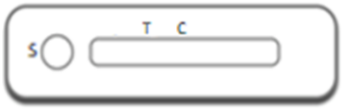
**Note: The intensity of the red color in the test region (T) will vary depending on the concentration of hCG present in the sample.*

Negative: A pink colored band appears only at control region ("C") indicating the absence of hCG in the sample.



Invalid: If the control line fails to appear within the result window, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be retested.





LIMITATIONS

1. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
2. False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
3. Very low levels of hCG (less than 50 mIU/mL) are present in urine specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons,5 a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later
4. A number of conditions other than pregnancy, including trophoblastic disease and certain nontrophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG. Therefore, the presence of hCG in urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.

References

1. Lenton EA, LM Neal, R Sulaiman "Plasma concentration of human chorionic gonadotropin from the time of implantation until the second week of pregnancy", Fertil. Steril. 1982; 37(6): 773-778
2. Dawood MY, BB Saxena, R Landesman "Human chorionic gonadotropin and its subunits in hydatidiform mole and choriocarcinoma", Obstet. Gynecol. 1977; 50(2): 172-181

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in hCG Pregnancy Rapid Test for single-step detection of hCG are the most common signs appearing on medical devices and their packaging. They are explained in more detail in the European Standards EN 980: 2008 and INTERNATIONAL Standard ISO 15223-1:2016

Key to symbols used			
	Manufacturer		Expiration/use by date
	Do not reuse		Date of manufacture
	Consult IFU [Instructions For Use]	LOT	Batch code
	Temperature limitation 2-30°C	IVD	In Vitro diagnostic medical device
Σ X	Contains sufficient for 'X ' kits		Do not use if package is damaged
REF	Catalogue No		Keep dry

Please read the user manual carefully before operating to ensure proper use

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ubio Biotechnology Systems Pvt Ltd
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