

β-HCG Rapid Test Kit

Instruction for use

【Product Name】β-HCG Rapid Test Kit

【REF】A10090001G, A10090001H

【Specification】50 tests/kit, 100 tests/kit

【Intended Use】

The β-HCG Rapid Test Kit is intended for vitro qualitative test of β-HCG in urine, serum, plasma or whole blood samples. This test is used as an aid in the early detection of pregnancy.

【Summary】

Beta-human chorionic gonadotropin (β-HCG) is a hormone produced by the placenta during pregnancy. It is also produced by some cancer cells, such as testicular or ovarian cancers. In pregnancy, β-HCG plays an important role in maintaining progesterone production and supporting the growth of the developing embryo. It can be detected in the blood or urine of pregnant women and is commonly used in pregnancy testing. Abnormal levels of β-HCG can indicate various conditions. High levels may indicate multiple pregnancies (twins or more), molar pregnancies, or certain types of cancers. Low levels may indicate ectopic pregnancies, threatened miscarriages, or fetal growth problems. In the context of cancer, β-HCG levels are measured to monitor the progress of treatment, as well as to detect and diagnose certain types of cancer. Elevated levels of β-HCG in men can indicate testicular cancer, while in women, it can indicate ovarian or germ cell tumors. Overall, β-HCG is an important hormone in pregnancy and a useful marker for certain medical conditions, particularly those related to pregnancy and cancer.

【Test Principle】

The test is a sandwich immunoassay of double antibodies. If there are β-HCG in the sample, it will be combined with colloidal gold labeled β-HCG antibody, form a complex. Under the action of chromatography, the complex flows on the nitrocellulose membrane. Then, the complex will combine to another β-HCG antibody (T line) coated on the nitrocellulose membrane. The control line (C line) must appear in the control area of the rod for the result to be valid. A line will appear in the test line area, indicating a positive result.

【Main Components】

Materials Provided:

Material	50 tests/kit	100 tests/kit
Test Cassette	50	100
Sample Diluent	1	1
Disposable pipettes (10 μL, for serum, plasma or whole blood sample use)	50	100
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Materials Required but Not Provided:

1. Timer
2. Urine cups
3. Tube rack for specimens
4. Any necessary personal protective equipment

【Storage Conditions and Validity】

1. This product should be stored in a dark and dry place at 2~30°C. The validity period of the kit is 24 months.
2. After unpacking the aluminum foil bag of the test cassette, it should be used in the specified environment (Temperature 2-35°C, Humidity 40%-90%) within 1 hour.
3. Please see label for the information about the date of manufacture and shelf life.

【Samples Collection Handling】

1. Urine specimens should be collected in a clean, dry container. Randomly collected specimens can be used. However, the first morning urine generally contains the highest concentration of β-HCG.

Specimens may be refrigerated (2°C - 8°C) and stored up to 72 hours prior to testing. If specimens are refrigerated, they must be brought to room temperature before testing.

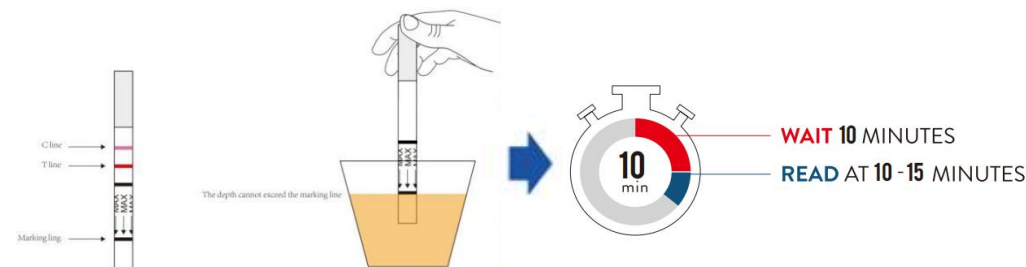
2. The plasma and whole blood samples are recommended to use EDTA, heparin or sodium citrate for anticoagulation. Other body fluids and samples may not get accurate results. After the blood samples are collected, if they cannot be tested in time, the serum/plasma should be stored at 2-8°C for 7 days. The sample can be stored for 30 days under -15°C. The whole blood samples should not be frozen and can be stored for 3 days at 2-8°C.

【Test Method】

1. Read the instructions for use completely before testing.
2. Before use, take out the reagents and specimens, place the reagent on a flat table and balance them to room temperature (18-25°C).

For urine sample

1. The operator takes the test strip out of the packaging bag.
2. Hold the test strip and vertically dip the end marked with the arrow into the container of urine until the horizontal line marked at the lower end of the arrow. When the red liquid moves in the result display area, wait for 5-10 seconds and then remove the test strip and place it on a flat surface of clean non-adsorbent material, the operators start timing and keep it react for 10 minutes.



For serum, plasma or whole blood sample

1. Collect and process blood samples according to standard operating procedures to obtain serum, plasma or venous whole blood samples.
2. The operator uses a disposable pipette (10 μL, for serum, plasma or whole blood sample use) to absorb 1 drop (10 μL) of the serum, plasma or whole blood sample, add it to the reagent loading site. Immediately add 2 drops of sample diluent to the reagent loading site. After finish adding sample, the operators start timing and keep it react for 10 minutes.



【Interpretation of Test Results】

Positive test:

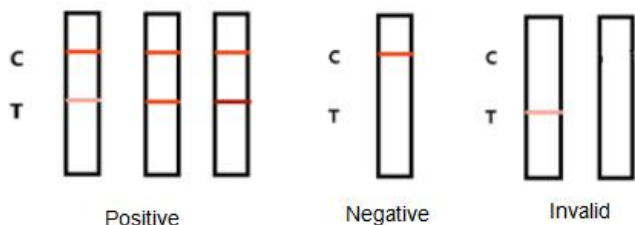
PREGNANT: The presence of two red lines in both the Test Line Region (T) and Control Line Region (C) means you are probably pregnant. One line may be lighter than the other, they do not have to match.

Negative test:

NOT PREGNANT: The presence of one red line in the Control Line Region (C) means you are probably not pregnant.

Invalid:

INVALID RESULT: The result is invalid if no red line appears in the Control Line Region (C), even if a line appears in the Test Line Region (T). You should repeat the test with a new midstream test.



【Limitation of The Test】

1. The β -HCG Rapid Test Kit is designed for in vitro diagnostic use only.
2. a. Elevated levels of β -HCG may be produced in rare conditions other than pregnancy (such as trophoblastic disease and certain nontrophoblastic neoplasms).
b. A normal pregnancy cannot be distinguished from an ectopic pregnancy based on β -HCG levels alone.
c. A spontaneous miscarriage may cause confusion in interpreting the test results.
d. Test results may vary between different individuals. If you obtain unexpected or inconsistent results, please consult with your physician.
3. As with all pre screening devices, a definitive diagnosis should not be based on the results of a single test, and should always be confirmed with a qualified specialist.

【Performance Characteristics】

1. Sensitivity and Specificity

25 mIU/mL β -HCG detection limit.

> 99% correlation was determined from cross reaction studies with known amounts of Luteinizing Hormone (300 mIU hLH/mL), Follicle Stimulating Hormone (1,000 mIU hFSH/mL), and Thyroid Stimulating Hormone (1,000 mIU hTSH/mL).

2. Cross-reactivity

None of the substances at concentration tested interfered in the assay.

Acetaminophen 20 mg/mL
Acetylsalicylic acid 20 mg/mL
Ascorbic acid 20 mg/mL
Atropine 20 mg/mL
Caffeine 20 mg/mL
Gentamic acid 20 mg/mL
Glucose 2 g/dL
Haemoglobin 1 mg/dL

【Precautions】

1. Keep away from children and prolonged exposure to extreme storage conditions.
2. This test is designed for single in vitro diagnostic use only.
3. Do not use test kit beyond expiry date printed on package.
4. Tests results may vary for different individuals.
5. Confirm all test results with a qualified specialist.

【Bibliography】

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3. Braunstein, G.D., Rasor, J., Adler, D., Danzer, H., Wade, M.E. Serum human chorionic gonadotropin levels throughout normal pregnancy. Am. J. Obstet. Gynecol., Vol.126, 678, 1976.
4. Lenton, E.A., Neal, L.M., Sulaiman R.: Plasma concentrations of human chorionic gonadotropin from the time of implantation until the second week of pregnancy. Fertility and Sterility, Vol.37, 773, 1982.
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6. Dawood, M.Y., et al.: Human chorionic gonadotropin and its subunits in hydatidiform mole and choriocarcinoma. Ob. Gyn. 50: 172-181, 1977.
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8. Uotila, M., Ruoslahti, E. and Engvall.: Two Site Sandwich Enzyme Immunoassay with Monoclonal antibodies to Human Alpha Fetoprotein E.J. Immunol. Methods, Vol. 42, 11, 1981.

【Index of Symbols】

	In vitro diagnostic medical device		Do not re-use
	Authorized representative in the European Union		Consult instructions for use or consult electronic instructions for use
	Caution		Manufacturer
	Temperature limit		Batch code
	Use-by date		Keep dry
	Keep away from sunlight		Catalog number
	Date of manufacture		Contains sufficient for <n> tests
	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		Do not use if package is damaged and consult instructions for use

【Basic Information】



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Instructions For Use Version: Rev V1.2

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