preggo

INSTRUCTIONS FOR USE

Please read this manual carefully before operation to ensure proper use.

PRODUCT NAME

PREGGO Pregnancy Test Kit

PACKING SPECIFICATIONS

2/4/5/10 Tests per Kit

INTENDED USE

This product is used to qualitatively detect human chorionic gonadotropin (HCG) in human urine in vitro, and is mainly used for auxiliary diagnosis of early pregnancy in clinical practice.

Human chorionic gonadotropin (HCG) is a glycoprotein secreted by placental trophoblast cells, which is composed of alpha and beta dimerized glycoproteins. Modern thought that HCG is produced by trophoblast transitional cells and syncytial cells. Proliferation is rapid in the first 8 weeks of pregnancy to maintain pregnancy. After about 8 weeks of gestation, HCG gradually declines until it reaches a relatively stable level at about 20 weeks. The product is used to detect HCG in the urine of women of pregnancy age, and the result can be quickly obtained in the early stage of pregnancy, which is an effective means of auxiliary diagnosis. The double-antibody sandwich immunocolloidal gold chromatography technique is used to achieve the qualitative detection of human chorionic gonadotropin in human urine in vitro, but it cannot be used for the detection of trophoblastic tumors. This product is suitable not only for professional medical personnel to test in medical units.

The main detection methods are chemiluminescence and immunochromatography.

TEST PRINCIPLE

This product adopts the principle of immunochromatographic double antibody sandwich method. The test area (T) and the quality control area (C) on the nitrocellulose membrane were respectively coated with mouse anti-human β-HCG monoclonal antibody 2 and goat anti-mouse IgG polyclonal antibody, and the binding pad contains colloidal gold mouse anti-human β-HCG monoclonal antibody 1. During the test, the urine sample is dripped onto the test strip and chromatographed upwards due to the capillary effect. If it is positive, HCG in the specimen will be combined with the colloidal gold HCG antibody during the chromatography process, and then continue to be chromatographed upwards, subsequently the complex will be combined by the HCG antibody immobilized on the membrane, and a red band will appear in the detection line area (T). If it is negative, there will be no red band in the test line area (T). The uncombined colloidal gold HCG antibody complex will bind to goat anti-mouse IgG, and a red band will appear in the control line area (C). The red band displayed in the control line area (C) is the standard for judging whether there are enough samples and whether the chromatography process is normal, and it also serves as an internal control standard for reagents.

MAIN COMPONENT

1. Test pad, individually packaged in aluminum foil bag (1 piece/bag, 1/5/10/25/50 piece(s)/kit)
2. Instruction manual (1 copy/bag, 1 copy/kit)

Note: The components in kits of different batch numbers are non-interchangeable.

STORAGE CONDITIONS AND VALIDITY PERIOD

1. Storage conditions: The original packaging should be stored in a dry place protected from light at 2~30°C, and should not be frozen. Validity period: 18 months.
2. The test strip/card/pen should be used within 1 hour after unpacking the aluminum foil bag under the condition of 2~30°C, humidity < 65%; it is recommended to use it immediately under high temperature and humidity.
3. See label for production date and expiration date.

SAMPLE REQUIREMENTS

1. The sample types are random urine and morning urine, and fresh morning urine is recommended.
2. Usually the concentration of HCG in morning urine is the highest. Morning urine is the first urine excretion collected in the morning, before breakfast and exercise.
3. Injection or use of progesterone, estrogen and other hormone drugs will affect the sample test results.
4. Urine specimens must be collected in clean, dry plastic urine cups or other containers that do not contain any preservatives.
5. If the urine sample is turbid or has particle precipitation, it should be centrifuged, filtered or the supernatant should be collected after precipitation.
6. The sample should be tested as soon as possible after collection. If it cannot be detected in time, the urine sample should be stored at 2-8°C within 48 hours. For long-term storage, it needs to be frozen at -20 °C. Before testing, the samples should be returned to room temperature and shaken well. The samples should not be frozen and thawed repeatedly.

TEST METHOD

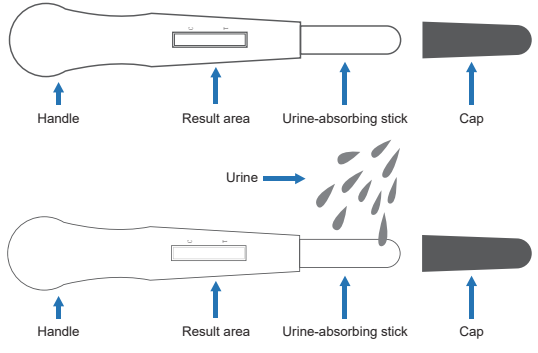
Please read the instruction manual carefully before the test, check whether the reagent is within the validity period, and check whether the kit is missing or damaged. Reagents and samples should be returned to room temperature before testing, and testing should be performed at room temperature.

1. Tear the aluminum foil bag along the incision site, take out the test strip/card/pen.

Remove the cap, and pour urine directly on the urine-absorbing stick of the test pen for 5-10 seconds when urinating. Be careful not to exceed the result area when urinating. Make sure that urine can be soaked into the urine-absorbing stick as much as possible. Wait until the urine climbs to the result display area, and lay the test pencil flat.

2. Start timing, the test results can be observed after 5 minutes, and the results displayed after 20 minutes are invalid.
3. All used consumables, test strips/cards/pens and other wastes should be put into medical waste bags and properly disposed in accordance with relevant national regulations.
4. Wash your hands or disinfect again.

Note: Please interpret the results within the specified time, and reading less or more than this time may lead to wrong results.



POSITIVE JUDGMENT VALUE

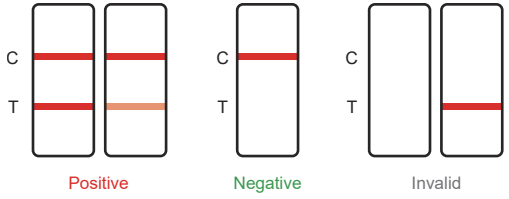
This reagent tests samples with a HCG concentration of not less than 25 mIU/ml, and the test result should be positive.

INTERPRETATION OF TEST RESULTS

Positive: Red bands appear in both the test area (T) and the control area (C). The results indicate for pregnancy.

Negative: No red band appears in the test area (T), and a red band appears in the control area (C). The results indicate for no pregnancy.

Invalid: There is no red band in the control area (C), no matter whether there is a red band in the detection area (T), the test strip/card/pen is judged to be invalid, and retesting is recommended.



Note: Do not read in dim light.

It is recommended not to make any medically related decisions without first consulting a healthcare provider.

LIMITATIONS OF TEST METHODS

1. This reagent is only for in vitro qualitative diagnosis.
2. The test results of this reagent are for reference only and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be comprehensively considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment response.
3. Limited by the methodology of the testing reagents, the testing personnel should pay more attention to the negative results and make a comprehensive judgment based on other testing results. It is suggested that other methods can be used to review the negative results in doubt.
4. Prompt the case of weakly positive test results, and suggest using other methodologies for testing.
5. People with uterine tumor, hydatidiform mole or menopause may have a positive result due to the high content of HCG in urine.
6. Ectopic pregnancy will produce very low levels of HCG, and a negative result does not rule out ectopic pregnancy. If still in doubt, a quantitative kit is recommended for testing.

PERFORMANCE CHARACTERISTICS

1. Detection limit

Should be no higher than 25 mIU/mL.

2. Specificity

2.1 Negative specificity

500 mIU/mL human luteinizing hormone (hLH), 1000 mIU/mL human follicle stimulating hormone (hFSH) and 1000 μIU/mL human thyrotropin (hTSH) solution without human chorionic gonadotropin (HCG) are used for testing, respectively, the results should be negative.

2.2 Positive specificity

25mIU/mL HCG solution containing 500mIU/mL hLH, 1000mIU/mL hFSH and 1000μIU/mL hTSH are used for detection, respectively, the results should all be positive.

3. Repeatability

10 HCG test strips of the same batch number are taken for detection with HCG solution at a concentration of 25 mIU/mL. The reaction results should all be positive and the color development should be uniform.

4. Batch-to-batch difference

Three batches of HCG test papers are taken for detection with HCG solution at a concentration of 25 mIU/mL. The results of the three batches of test papers should all be positive and the color development should be uniform.

PRECAUTIONS

1. This product is only used for in vitro qualitative diagnosis, please use it within the validity period.
2. Please read the instruction manual carefully before use, and carry out the test operation in strict accordance with the kit instructions.
3. The product is for one-time use. If the aluminum foil bag is found to be damaged, please do not use it.
4. If the test reagents are stored in the refrigerator, it is recommended that they should be taken out of the refrigerator before the test and placed at room temperature before use, otherwise the test results will be affected.
5. This reagent contains animal-derived materials and has potential infectious risks, so try to avoid direct contact with the test strip.
6. Gestational trophoblastic diseases may lead to false negative results due to high levels of HCG in urine.
7. There are HCG cross-reactive substances in the urine of menopausal patients, which can cause false positive results.
8. It should be clear that the depth of the test strip inserted into the urine should not exceed the marking line, and the immersion time should be specified. That the test strip should be placed flat after taking it out to avoid inhaling excessive urine, causing excess HCG antigen and causing false negative results.
9. If the urine test result is negative and the possibility of gestation is still suspected (urine is too thin or in the early stage of pregnancy), the morning urine can be re-collected after 48 to 72 hours for retesting; if the result is positive, please use other methods in time to do further examination and the doctor's diagnosis shall prevail.
10. The product cannot be used for the detection of trophoblastic tumors.
11. Inconsistent or erroneous results may be caused by improper technical or procedural operations, contaminated samples, or the presence of drugs that interfere with the assay.
12. There is a desiccant in the aluminum foil bag, which should not be taken orally.
13. It is recommended not to make any medically related decisions without consulting a healthcare provider.

Approval and modification date of the specification

2022.9.22

SYMBOLOGY INFORMATION

Abbreviation	Explanation	Abbreviation	Explanation
IVD	In vitro diagnostic medical device	LOT	Batch code
Σ	Contains sufficient for<n>tests		Date of manufacture
	Manufacturer		Use-by date
EC REP	Authorized representative in the European Community	30℃ 2℃	Temperature limit: 2~30℃
CE	CE Marking		Keep dry
	Do not use if package damaged		Keep away from sunlight
	Consult instructions for use		Do not re-use
REF	Catalogue number		Biological risks

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REP

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GUARANTEE AND TECHNICAL SUPPORT

If you get repeated invalid test results, or need technical support, please contact Preggo customer support.

Service Email: info@getpreggo.com