（**FOR RESEARCH USE ONLY. DO NOT USE IT IN CLINICAL DIAGNOSIS !**）

Human HCG Lateral Flow Assay Kit

Catalog No: E-HD-C076

20T/40T

Version Number:	V3.2
Replace version:	V3.1
Revision Date:	2022.07.11

This manual must be read attentively and completely before using this product.

If you have any problems, please contact our Technical Service Center for help.

Toll-free: 1-888-852-8623 Tel: 1-832-243-6086 Fax: 1-832-243-6017

Email: techsupport@elabscience.com

Website: www.vetassay-elab.com

Please kindly provide us the lot number (on the outside of the box) of the kit for more efficient service.

Test principle

This kit contains colloidal gold labeled HCG monoclonal antibody I that is wrapped in conjugate pad, HCG monoclonal antibody II that is fixed on the membrane, and quality-control line C that is coated with goat anti mouse IgG antibody, adopt the highly specific antigen-antibody reaction and colloidal gold dry type immune chromatography technology, qualitatively determine HCG levels in human serum, plasma and urine.

Kit components

Item	Specification
Test Strip	20T/40T
Manual	1 copy

Note: All reagent bottle caps must be tightened to prevent evaporation and microbial pollution.

Notes

1. The product is disposable and cannot be reused. Please use it within the validity date.
2. Please do not open the product before use. If the package is obviously damaged, please do not use it.
3. The reagent components of different batches cannot be mixed.
4. Appropriate protective measures shall be taken during the collection, disposal, storage, mixing and testing of samples.
5. There is a desiccant in the aluminum foil bag, which should not be taken orally.
6. Excessive high temperature of the experimental environment should be avoided. The cold stored test card should be opened after returning to room temperature to avoid moisture absorption.
7. Fresh samples are recommended. If there is obvious hemolysis or blood clot in the samples, it will interfere with the test and lead to wrong results.
8. All specimens, waste liquid and pipes are treated as infectious pollutants. After the test, the used test card should be discarded in the corresponding biological hazard container and treated as biological hazard.
9. If the detection reagent stored in the refrigerator, it is suggested that it should be taken out of the refrigerator and placed at room temperature before being opened for use.
10. False negative results may occur in gestational trophoblast diseases due to high HCG content in urine.
11. The presence of HCG cross-reaction substances in the urine of menopausal patients can cause false positive results.
12. If you have any questions or suggestions during use, please contact the manufacturer.

Storage and expiry date

Storage: Store at 4-30℃. With cool and dry environment.

Expiry date: expiration date is on the packing box.

Requirements of sample

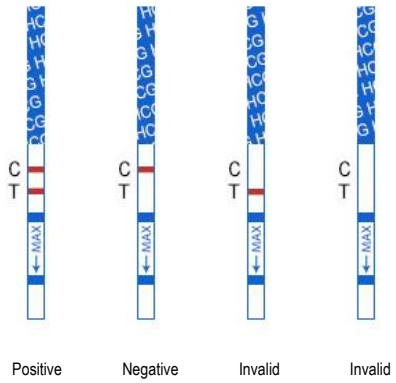
1. Chorionic gonadotropin (HCG) test kit can be performed using serum, plasma and urine.
2. Serum and plasma samples could be collected by conventional methods. After blood collection, serum and plasma should be immediately separated for analysis. EDTA or heparin sodium anticoagulant plasma could be used.
3. For serum or plasma, please determine within 4 hours after separation; If the sample cannot be tested within 4 hours, please store it at 2℃ - 8℃ for up to 5 days. The sample can be stored at -20℃ for at least 3 months. After urine samples collection, it is recommended to complete the test within 4 hours. If the test cannot be finished within 4 hours, the urine samples can be stored for 2 days at 2℃ - 8℃, and should not be frozen.
4. Bring samples to room temperature prior to testing. Frozen serum or plasma samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly.

Assay procedure

1. Before the test, the operation manual of the kit must be read completely. Before the test, the strip should be restored to room temperature (15℃-30℃). The test should be conducted at room temperature.
2. Take out the test strip from the aluminum foil packaging bag, use it within 1 hour after unsealing to prevent moisture of test card.
3. Add samples: put the end of test strip into serum, plasma or urine samples, follow as the direction of the arrow (be careful to avoid sample solution exceed the max line), and start the timer.
4. Interpretation: at 5 minutes, observe the color rendering and interpret the result qualitatively. The result is valid within 15 minutes, read results after 15 minutes is invalid.

Interpretation of results

1. Positive: two purplish red bands appear on the test line (T) and quality control line (C).
2. Negative: only one purplish red band appears on line C.
3. Invalid: no purplish red band on the quality control line (C), indicating incorrect operation or deterioration of the reagent. In this case, please read the instructions carefully again and retest with a new reagent.



NOTE: This figure is only used as a reference.

Limitations of this test method

1. This reagent is only used for the detection of human serum, plasma and urine samples. The correct results can only be obtained by careful operation in strict accordance with the operating procedures. Any modification to the operating procedures may affect the results.
2. The test result of this reagent can only be used as auxiliary tool. The test result should be combined with other data.
3. False positive results can be caused by several factors: cross-reaction of similar antibody components in the samples; some of the nonspecific components in the samples have similar antigen epitope capture labeled antibodies.
4. False negative results may be due to the following reasons: some unknown components blocked antigen epitope to prevent it from binding to the antibody; unstable antigens gradually degrade with time and temperature and cannot be recognized by antibodies. Unreasonable sample collection, transshipment and treatment resulted in too low concentration of the substance in the sample. Effective test results depend on a good kit sample storage environment.
5. Other factors can also cause test errors, including technical reasons, operational errors, and other sample factors.
6. Hemoglobin, triglyceride and bilirubin in the samples all interfere with the test results, and the maximum allowable concentrations of hemoglobin is 5g/L, triglyceride is 25g/L and bilirubin is 0.1g/L, respectively.