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

Human IGFBP-1 Lateral Flow Assay Kit

Catalog No: E-HD-C081

20T/40T

Version Number:	V1.1.1
Replace version:	V1.1
Revision Date:	2022.04.19

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 product adopts the double antibody sandwich method. The test strip contains colloidal gold labeled IGFBP-1 monoclonal antibody I that is wrapped in conjugate pad, IGFBP-1 monoclonal antibody II that is fixed on the membrane, and quality-control line C that is coated with goat anti-mouse IgG antibody. By highly specific antigen-antibody reaction and colloidal gold immunochromatography technology, it qualitatively determines IGFBP-1 levels in vaginal secretions of pregnant women.

Kit components

Item	Specification
Test Card	20T/40T
Sample Diluent	20/40 vials
Vaginal Swab	20/40 pieces
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 reagent is stored in the refrigerator, it is recommended to take it out and equilibrate to room temperature before opening for use.
10. If you have any questions or suggestions during the use of this reagent, 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

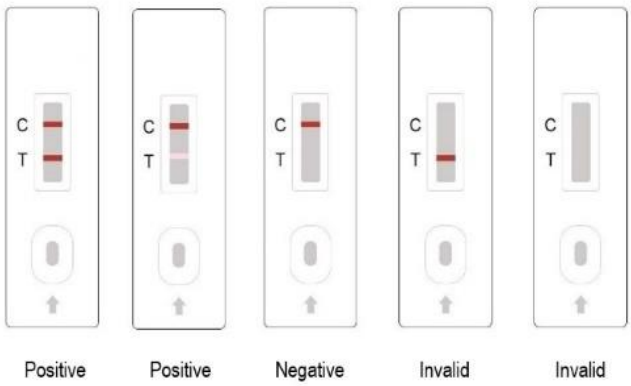
1. The sample type is vaginal discharge. The collected samples should be tested within 1 day, but the test effect will be the best within 1 hour. If the sample is contaminated with blood, etc., the test result will be disturbed.
2. Sampling method: use the vaginal swab to expand the vagina for sampling, or slowly extend it into the vagina 5-7 cm, gently rotate for 30 seconds, and take as much secretion as possible.
3. Remove the swab, insert the swab head into the test tube containing the sample diluent, and mix well for 10-15 seconds. Roll the swab as far as possible on the inside of the tube to ensure that as much of the sample is dissolved in the diluent as possible.

Assay procedure

1. Before the test, read the operation manual completely, and restore the reagent card to room temperature (20℃-30℃). The test should be conducted at room temperature.
2. Take out the test cassette from the aluminum foil packaging bag, and use it within 1 hour after unsealing to prevent moisture of test card.
3. Place the reagent card flat on the table, draw enough mixed sample with a dropper, and add 2-3 drops (80-100μL) to the sample well of the test cassette.
4. Wait for the appearance of the purple band, the test result should be interpreted at 10 minutes, and the result will be invalid after 20 minutes.

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 vaginal secretions samples. The correct results can only be obtained by careful operation in strictly 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 sample storage environment.
5. Other factors can also cause test errors, including technical reasons, operational errors, and other sample factors.