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

Human cTnI Lateral Flow Assay Kit

Catalog No: E-HD-C084

20T/40T

Version Number:	V1.0
Replace version:	V1.0
Revision Date:	2023.11.02

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 adopts the sandwich method and the technical principle of colloidal gold immunochromatography. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the test cassette. cTnI if presents in the specimen, will bind to the colloidal labeled cTnI monoclonal antibody III conjugates. This marked complex is attached to the test area of pre-coated cTnI monoclonal antibody I and II and the other colloidal gold-labeled antibody are attached to the quality control area of pre-coated goat anti-mouse IgG antibody. If the C line does not show color, it indicates that the result is invalid, and this sample needs to be tested again.

Kit components

Item	Specification
Detection Card	20T/40T
Sample Diluent	20/40
Manual	1 copy

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

Notes

1. It is a disposable reagent, do not reuse it. 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. Appropriate protective measures shall be taken during the collection, disposal, storage mixing and testing of samples.
4. The desiccant in the aluminum foil bag shall not be taken orally.
5. Excessive high temperature of the experimental environment should be avoided. The cold stored test cassette should be opened after returning to room temperature to avoid moisture absorption.
6. Fresh samples are recommended. Do not use samples with obvious hemolysis or blood clots, for which may interfere with the test and lead to false results.
7. 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.
8. 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. This Kit can be performed with serum, plasma and whole blood
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. The whole blood samples could be collected by conventional methods and the test should be performed immediately after sample collection.
4. It is recommended to use serum or plasma as the priority sample types for testing, and whole blood samples can be used in urgent or special cases.
5. 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℃ (valid for up to 5 days) or at -20℃ (valid for at least 3 months).
6. For whole blood, please determine within 4 hours after collection; If the sample cannot be tested within 4 hours, please store it at 2℃ -8℃ (valid for 3 days). Do not freeze whole blood samples.
7. Bring samples to room temperature prior to testing. Frozen serum or plasma samples must be completely thawed and mixed well prior to testing. Do not freeze and thaw samples repeatedly.

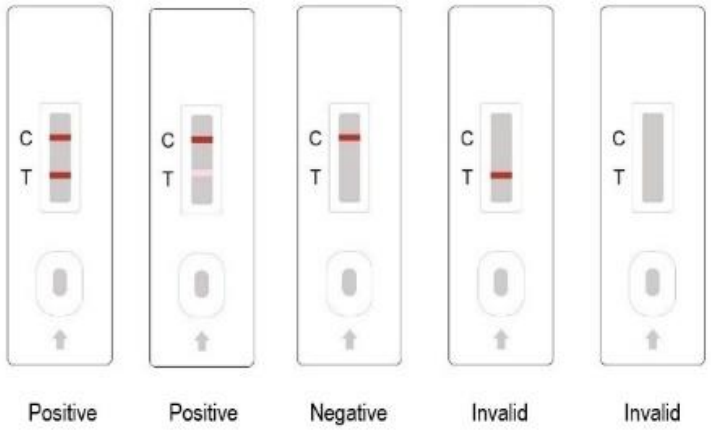
Assay procedure

Before the test, the operation manual and applicable instrument instructions must be read completely, and the reagent should be restored to room temperature (15℃ -30℃). The test should be conducted at room temperature.

1. Take out the test cassette from the aluminum foil packaging bag, place it on a horizontal, dry plane, and use it within 1 hour after unsealing to prevent moisture of the test cassette.
2. For serum/plasma test: accurately add 80 μL serum or plasma samples into the sample well (S) of the test cassette, and start the timer.
3. For whole blood test: accurately add 80 μL of whole blood samples into the sample well (S) of the test cassette, then add 1 drop of whole blood buffer as soon as possible and start the timer.
4. Interpretation: Observe the result after 15 minutes. The result is only valid within 30 minutes. (Each laboratory can set appropriate quality control procedures and quality control cycle according to its own situation.)

Interpretation of results

1. Positive: in addition to one purplish red line in the control line (C) region, an apparent colored line will also appear in the test line (T) region.
2. Negative: only one purplish red line appears in the control line (C) region. No line appears in the test line (T) region.
3. Invalid: no line appears in the control line (C) region. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette.



Note: this figure is only used as a reference.

Limitations of this test method

1. The test results of this reagent can only be used as an auxiliary tool, and the test results should be combined with other data.
2. Test results for the same sample using reagents from different manufacturers may differ due to methodological or antibody specificity reasons.
3. The test results may be affected by the personal cleanliness of the subject, drinking and eating.
4. The measured values by other methods are not directly comparable with the results determined by this reagent.
5. This reagent is only used for the detection of human serum, plasma and whole blood 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.
6. The test result of this reagent can only be used as auxiliary tool. The test result should be combined with other data.
7. 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.
8. 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.
9. Other factors can also cause test errors, including technical reasons, operational errors, and other sample factors.

10. Hemoglobin, triglyceride and bilirubin in the samples all interfere with the test results, and the maximum allowable concentrations of hemoglobin is 5 g/L, triglyceride is 25 g/L and bilirubin is 0.1 g/L, respectively.