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

Anti-CCP/RF Lateral Flow Assay Kit

Catalog No: E-HD-C074

20T/40T

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 uses the technical principle of colloidal gold immunoassay. The detection of RF adopts the sandwich method; during the test, the sample is dropped into the sample well of the reagent, and chromatography is performed under the capillary effect. The RF in the sample is combined with colloidal gold labeled RF antibody I (human IgM antibody, referred to as Anti-IgM) and diffused to the test area. It is captured by another coated RF antibody II (denatured IgG), to form a complex, and gather in the test area; the quality control line C is coated with goat anti-mouse IgG antibody. The highly specific antigen antibody reaction and colloidal gold immunoassay are used for clinical qualitative diagnosis of RF in human serum, plasma and whole blood. The detection of Anti-CCP adopts the indirect method; Anti-CCP in the sample binds to the colloidal gold labeled human IgG antibody (anti-IgG) which is coated on conjugated pad. As the complex diffuses to the test area, it is captured by the coated CCP antigen, and forms a complex to aggregate in the test area. The quality control line C is coated with goat anti-mouse IgG antibody. The highly specific antigen antibody reaction and colloidal gold immunoassay are used for clinical qualitative diagnosis of anti-CCP in human serum, plasma and whole blood.

Kit components

Item	Specification
Detection card	20/40 T
Sample diluent	20/40 Vials
Manual	1 copy

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

Notes

1. Please read the manual carefully before use, changes of operation may result in unreliable results.
2. Do not use product out of date or in a broken aluminum foil, it is disposable and cannot be used repeatedly.
3. The detection card should be brought to room temperature before opening after take it out from the refrigerator. The opening detection card should be used as soon as possible.
4. Please do not use but not limited to the following liquids for negative control: Water, PBS.
5. The tested sample should be fresh and clear. Avoid of using samples of turbidity, polluted, high hemolysis or abnormal viscous.
6. Avoid of touching the chromatography membrane of the sample well and test well.
7. The waste of experiment should be considered as contaminant, and must be properly handled according to the local regulations.
8. The test environment should be kept at a fixed temperature to avoid testing at high temperatures.
9. Each reagent is optimized for use in the **E-HD-C074**. Do not substitute reagents from any other manufacturer into the test kit. Do not combine reagents from other **E-HD-C074** with different lot numbers.

Storage and expiry date

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

Expiry date: expiration date is on the packing box.

Sample preparation

1. Anti-CCP/RF Test Kit (Colloidal gold Assay) 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 could be used for anticoagulant plasma.
3. The whole blood samples could be collected by conventional methods and the test should be performed immediately after sample collection.
4. 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 -20℃ (valid for at least 3 months).
5. 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.
6. 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

Allow all kit components and sample to reach room temperature (25℃) prior to testing.

1. Before the test, read the operation manual completely and equilibrate the test reagent to room temperature (15℃ -30℃). The test should be conducted at room temperature.

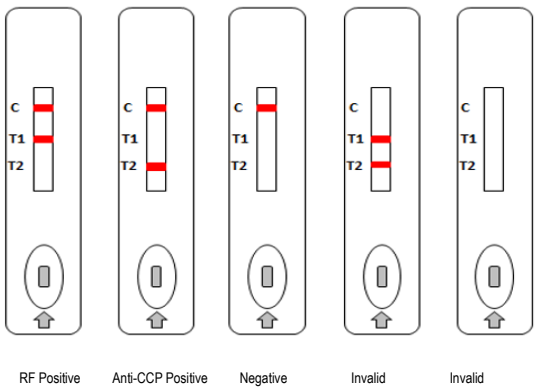
2. Take out the test cassette from the aluminum foil packaging bag, and use it within 1 hour after unsealing to prevent moisture of test card.

3. Add samples: accurately add 40 μL of serum, plasma or whole blood into a tube of sample diluent, mix well. Draw 100 μL of the mixed solution and add it vertically to the sample well of the test card, and start timing.

4. Interpretation: at 10 minutes, observe the color rendering and interpret the result qualitatively. The result is only valid within 30 minutes.

Judgment of result

1. **Positive:** Both the test line (T line) and the quality control line (C line) appear colors.
2. **Negative:** The test line (T line) does not appear color, only the quality control line (C line) appears color.
3. **Invalid:** The quality control line (C line) does not appear color, which means that the test is invalid and the test should be repeated.



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 whole blood 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 a doctor or other diagnostic auxiliary tool. The test result should be combined with other clinical and laboratory data. If the test result is inconsistent with the clinical evaluation, further examination is needed.
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.

6. 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.