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

Monkeypox IgG/IgM Lateral Flow Assay Kit

Catalog No: E-HD-C058

20T/40T

Version Number:	V1.5
Replace version:	V1.5
Revision Date:	2022.08.24

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 antigen sandwich method and the technical principle of colloidal gold immunochromatography. During the test, the sample is dropped into the sample well of the reagent, and the chromatography is performed under the capillary effect. The human monkeypox abtibody (IgG and IgM) in the sample binds to the colloidal gold-labeled monkeypox monoclonal antigen, diffuses to the test area, and is captured by coated monkeypox monoclonal antibody II (anti-humam IgG and anti-human IgM), forming a complex to aggregate in the test area (test line IgG and test line IgM); the quality control area is coated with goat anti-mouse IgG antibody, which captures the colloidal gold-labeled antibody to form a complex and aggregate in the quality control area. The highly specific antigen-antibody reaction and colloidal gold immunochromatography technology are combined to qualitatively detect the content of IgG and IgM antibodies to monkeypox virus in serum, plasma or whole blood. Test principle: the combination of the analyte with the capture antibody on the membrane and the colloidal gold labeled antibody produces a color change, and the color intensity change has a correlation with the concentration of the analyte.

Kit components

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

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

Notes

1. It is a disposable diagnostic reagent. Do not reuse it. Please use it within the validity date.
2. Please do not unpack the sealed pouch until you're ready to perform the test. 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. The desiccant in the aluminum foil bag shall not be taken orally.
6. Excessive high temperature of the experimental environment should be avoided. The reagent card stored at low temperature should be restored to room temperature before unsealing to avoid moisture absorption.
7. 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.
8. The test results of this reagent are for clinical reference only. The clinical diagnosis and treatment of patients should be comprehensively considered in combination with their symptoms, signs, medical history, other laboratory tests and treatment response.

9. All specimens, waste liquid and pipes are treated as infectious pollutants. After the test, the used test card should be discarded in the corresponding biohazard container and treated as a biohazard.
10. If you have any questions or suggestions during use, please do not hesitate to 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

Monkeypox IgG/IgM Kit can be performed with serum, plasma and whole blood.

To collect finger prick whole blood samples.

1. Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
2. Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger. Puncture the skin with a sterile lancet.
3. Rub the hand gently from wrist to palm to finger to form a rounded drop of blood over the puncture site.
4. Transfer the finger blood sample to the cassette by using the micropipette/ dropper immediately.

Preparation of venous serum, plasma, and whole blood

1. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed samples.
2. Test should be performed immediately after sample collection.
3. Serum and plasma samples may be stored at 2-8℃ for up to 3 days. For long-term storage, samples should be kept below -20℃. Whole blood collected by venipuncture should be stored at 2-8℃ if the test is to be run within 2 days of collection. Do not freeze whole blood samples. Whole blood collected by fingertip should be tested immediately.
4. Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly.

Assay procedure

Keep the test cassette, sample, buffer to room temperature (15-30℃) prior to testing.

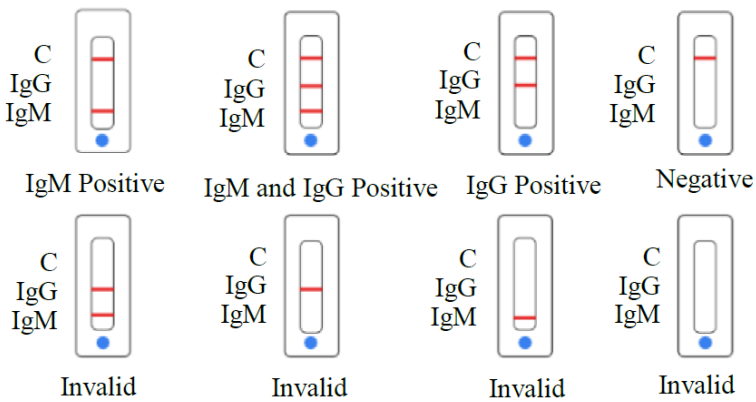
1. Bring the pouch to room temperature before opening. Take the test cassette from the sealed pouch and use it within one hour.
2. Place the test cassette on a clean and flat surface.
3. **For Serum or Plasma samples:** add 20 μL of sample into sample well, then add 1 drop of buffer and start the timer. Avoid trapping air bubbles into the sample well.

4. **For Whole Blood samples:** add 20 μL of sample into sample well, then add 3 drops of buffer as soon as possible and start the timer. Avoid trapping air bubbles into the sample well. Note: It's recommended to add 1 more drop of buffer if the liquid flows too slowly.
5. Wait for the colored line(s) to appear. The result shall be read at 15 minutes. The result is valid within 30 minutes.

   Note: 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.

Interpretation of results

1. Positive: a purplish red band appears on both the test line (T) and quality control line (C). The purplish red band on the IgG line indicates that IgG is detected; the purplish red band on the IgM line indicates that IgM is detected.
2. Negative: a purplish red band only appears on the quality control line (C).
3. Invalid: no purplish red band appears on the quality control line (C), indicating incorrect operation or deterioration of the reagent. In this case, please read the operation manual 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 or whole blood samples. 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 blood; certain non-specific components in blood with similar epitopes capture labeled antibodies; cross contamination of samples during transportation and treatment; the consumables and equipment used during the test are contaminated.

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.