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

Human Monkeypox IgG/IgM Lateral Flow Assay Kit

Catalog No: E-HD-C058
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 (info in the header of each page).

Phone: 240-252-7368(USA) 240-252-7376(USA)
Email: techsupport@elabscience.com
Website: www.elabscience.com

Please refer to specific expiry date from label on the side of box.

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

Test principle

This kit applies the Sandwich-Gold Immunochromatography method for the qualitative detection of IgG and IgM specific to monkeypox virus in human whole blood, serum, or plasma.

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 antibody (IgG and IgM) in the sample binds to the colloidal gold-labeled monkeypox 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

The kit can be stored at room temperature or refrigerated (4-30℃). DO NOT FREEZE.

The test cassette is stable before the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use.

Item	Specifications
Detection Card	20T/40T
Sample Diluent	1/2 vial
Manual	1 copy

Other supplies required

Sample collection container

Centrifuge

Micropipette

Timer

Requirements of sample

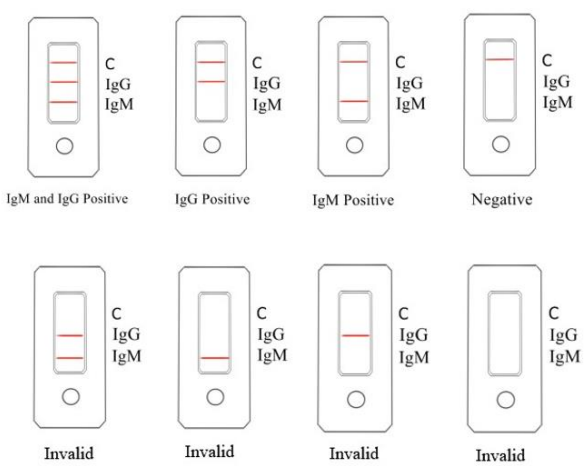
1. This kit can be performed with human whole blood, serum, or plasma.
2. **Whole blood:** Collect whole blood by using anticoagulant tube.
3. **Serum**: Use a serum separator tube (SST) and allow samples to clot for 30 minutes at room temperature before centrifugation for 15 minutes at 1000×g at 2-8℃. Collect the supernatant to carry out the assay.
4. **Plasma**: Collect plasma by using an anticoagulant tube. Centrifuge samples for 15 min at 1000×g at 2-8℃ within 30 min of collection. Collect the supernatant to carry out the assay.
5. Collect the **fingerstick whole blood** in a common way. The following steps can be the reference.
   - 5.1 Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
   - 5.2 Then 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. Wipe away the first sign of blood.
   - 5.3 Rub the hand gently from wrist to palm to finger to form a rounded drop of blood over the puncture site.
   - 5.4 Add the fingerstick whole blood to the test by using the micropipette/ dropper immediately.
6. **Note for sample**
   - 6.1 Don't use hemolysis, turbidity, hyperlipidemic or polluted samples.
   - 6.2 Serum and plasma samples should be assayed within 4 hours or 3 days when stored at room temperature or 2-8℃, otherwise samples must be stored at -20℃ for a long-term storage. Whole blood collected by venipuncture should be stored at 2-8℃ if the test is to be run within 2 days of collection. Whole blood collected by fingertip should be tested immediately. **Do not freeze whole blood samples.** Avoid repeated freeze-thaw cycles.
   - 6.3 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.
   - 6.4 If samples are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.
   - 6.5 EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for sample collection.
   - 6.6 Do not use heated inactivated samples. Heat inactivation will degrade antibodies.

Assay procedure

1. Bring the test cassette, sample, Sample Diluent, and/or controls to room temperature (15-30℃) prior to testing.
2. Take the test cassette from the sealed pouch and use it within one hour. It is recommended to run the test immediately after opening the foil pouch.
3. Place the test cassette on a clean and level surface.
   a) For Serum or Plasma Samples.
      i. Add 20 μL of sample into the test cassette, then add 1 drop of **Sample Diluent** (approximately 40 μL) to the sample well and start the timer.
   b) For Whole Blood Samples.
      i. Add 20 μL of sample into the test cassette, then add 3 drops of **Sample Diluent** (approximately 100 μL) to the sample well as soon as possible and start the timer.
   c) Note: It's recommended to add 1 more drop of **Sample Diluent** if the liquid flows too slowly.
4. Wait for the colored line(s) to appear. Incubate for 15 to 30 minutes and then judge the results immediately.

Results

1. **Positive**: Red line appears in both test line (IgG or IgM) and 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.
   Note: The intensity of the color in the IgG or IgM test line region(s) will vary depending on the concentration of monkeypox antibodies in the sample. Therefore, for any shade of color in the IgG and/or IgM test line(s) indicates detection of IgG or IgM.
2. **Negative**: Only the control line region (C) shows a line in the observation well.
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: The figure is only used as a reference for judging results.

Limitations

1. This kit should be used for the detection of monkeypox antibodies in human serum, plasma or whole blood samples only. Neither the quantitative value nor the rate of increase in monkeypox antibody concentration can be determined by this qualitative test.
2. 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.
3. Anti-monkey pox IgM or IgG antibodies in the sample may be below the level of detection of the kit. That is, antibodies may be present but undetectible by the kit. A sample collection time course may be useful to evaluate the presense or absence of IgM and IgG antibody detection over time.
4. Samples from immunosuppressed donors may not be suitable for this kit; the results may be difficult to interpret.
5. 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.
6. 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.
7. Other factors can also cause test errors, including technical reasons, operational errors, and other sample factors.

Notes

1. This product is for scientific research use only.
2. Please read the manual carefully before use. All kinds of reagents provided in this kit are only for this experiment. Do not reuse it. Please use it within the validity date.
3. Do not use expired products or products with a broken aluminum foil.
4. 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.
5. Handle all samples cautiously as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of samples. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when samples are assayed.
6. Do not eat, drink or smoke in the area where samples or kits are handled. The desiccant in the aluminum foil bag shall not be taken orally.
7. The used tests, samples and potentially contaminated should be discarded according to the local regulation.
8. Humidity and temperature could adversely affect results. 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.
9. Do not use components from different batches of kits.
10. If you have any questions or suggestions during use, please do not hesitate to contact the manufacturer.
11. Each reagent is optimized for use in the E-HD-C058. Do not substitute reagents from any other manufacturer into the test kit. Do not combine reagents from other E-HD-C058 with different lot numbers.

Storage and expiry date

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

Expiry date: expiration date is on the packing box.