Monkeypox Virus IgG/IgM Rapid Test Kit (Colloidal Gold)

Instructions for Use (IFU)

【PRODUCT NAME】

Monkeypox Virus IgG/IgM Rapid Test Kit (Colloidal Gold)

【PACKAGE AND SPECIFICATION】

1Test/box (1Test/pouch ×1 pouch), 5Tests/box (1Test/pouch ×5 pouches),10 Tests/box (1Test/pouch ×10 pouches) ,12 Tests/box (1Test/pouch ×12pouches) ,15 Tests/box (1Test/pouch ×15 pouches) ,20 Tests/box (1Test/pouch ×20 pouches),25 Tests/box (1Test/pouch ×25 pouches), 40 Tests/box (1Test/pouch ×40 pouches)

【INTENDED USE】

For in vitro qualitative determination of the content of Monkeypox Virus IgG/IgM antibody in human serum, plasma and whole blood. This test is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing.

A positive test result requires further confirmation, and a negative test result cannot rule out the possibility of infection. The test results of this kit are only for clinical reference. It is recommended to conduct a comprehensive analysis of the patient's condition in combination with clinical manifestations and other laboratory tests.

The Monkeypox virus is a kind of orthopoxvirus in poxviridae. People get infected through direct contact with the blood, body fluids, skin or mucous membrane damage of infected animals. Interpersonal transmission is caused by close contact with infected respiratory secretions, skin damage of infected persons, or articles recently contaminated by patient's body fluids or pathological materials. Transmission is mainly through face-to-face contact with respiratory droplets for a long time. The incubation period of monkeypox is usually 6 to 16 days. Infection can be divided into two stages:

Onset (0-5 days): fever, severe headache, lymphadenopathy (lymphadenopathy), back pain, myalgia (muscle pain), severe fatigue and weakness (low spirits);

Rash stage (within 1-3 days after fever): rash in different stages often starts from the face and then spreads to other parts of the body. The most common skin rashes were on the face (95% of cases), palms and soles of feet (75%). The rash changes from maculopapular (flat lesions at the bottom) to small blisters (small blisters filled with liquid) and pustules. The scab will form after about 10 days and disappear after about three weeks.

For in vitro diagnostic use only. For professional use only

【TEST PRINCIPLE】

In this kit, IgG antibody and IgM antibody of monkeypox were detected by immunocapture method. Mouse anti-human IgM antibody, mouse anti-human IgG antibody and goat anti- chicken IgY antibody were coated with cellulose nitrate membrane. Recombinant monkeypox virus antigen and chicken IgY antibody labeled by colloidal gold are as tracers.

Add the sample to the sample well of test strip; and the sample flows through the blood filter film (filter red blood cells).If the sample contains the monkeypox virus IgM antibody, it can combine with colloidal gold labeled monkeypox virus antigen to form a complex, which is captured by the mouse anti-human IgM antibody coated with colored band (M line).If the sample contains the monkeypox virus IgG antibody, it can combine with colloidal gold labeled monkeypox virus antigen to form a complex, which is captured by the mouse anti-human IgG antibody coated with colored band (G line). The colloidal gold labeled chicken IgY antibody is bound to the goat anti- chicken IgY antibody coated with a colored band (C line), which acts as a control line.

【COMPONENT】

COMPONENT	1 Test/ Box	5 Tests/ Box	10 Tests/ Box	12 Tests/ Box	15 Tests/ Box	20 Tests/ Box	25 Tests/ Box	40 Tests/ Box	Main components

Test Kit	1Test/box (1Test/pouch ×1 pouch)	5Tests/box (1Test/Pouch×5 pouches)	10 Tests/box (1Test/pouch ×10 pouches)	12 Tests/box (1Test/pouch ×12 pouches)	15 Tests/box (1Test/pouch ×15 pouches)	20Tests/box (1Test/pouch×20 pouches)	25Tests/box (1Test/pouch×25 pouches)	40Tests/box (1Test/pouch×40 pouches)	The detection lines were coated with mouse anti-human IgM antibody and mouse anti-human IgG antibody, the control line was coated with goat anti-chicken antibody, Recombinant monkeypox virus antigen and chicken IgY antibody labeled by colloidal gold are as tracers.
Desiccant	1 pouch	5pouches	10pouches	12pouches	15pouches	20pouches	25pouches	40pouches	Silica Gel
Sample Diluent	1 bottle(200 μL/bottle)	5 bottles(200μL/bottle)	10 bottles(200μL/bottle)	12 bottles(200μL/bottle)	15 bottles(200μL/bottle)	20 bottles(200μL/bottle)	25 bottles(200μL/bottle)	40 bottle(200 μL/bottle)	Solution of trimethylaminomethane hydrochloride(0.02M Tris - HCl)
Dropper	1 branch	5 branches	10 branches	12 branches	15 branches	20 branches	25 branches	40 branches	Disposable dropper
Alcohol Prep pad	1 pad	5 pads	10 pads	12 pads	15 pads	20 pads	25 pads	40 pads	70% Isopropyl Alcohol
Blood taking needle	1 branch	5 branches	10 branches	12 branches	15 branches	20 branches	25 branches	40 branches	Disposable sterile needle

【STORAGE AND STABILITY】

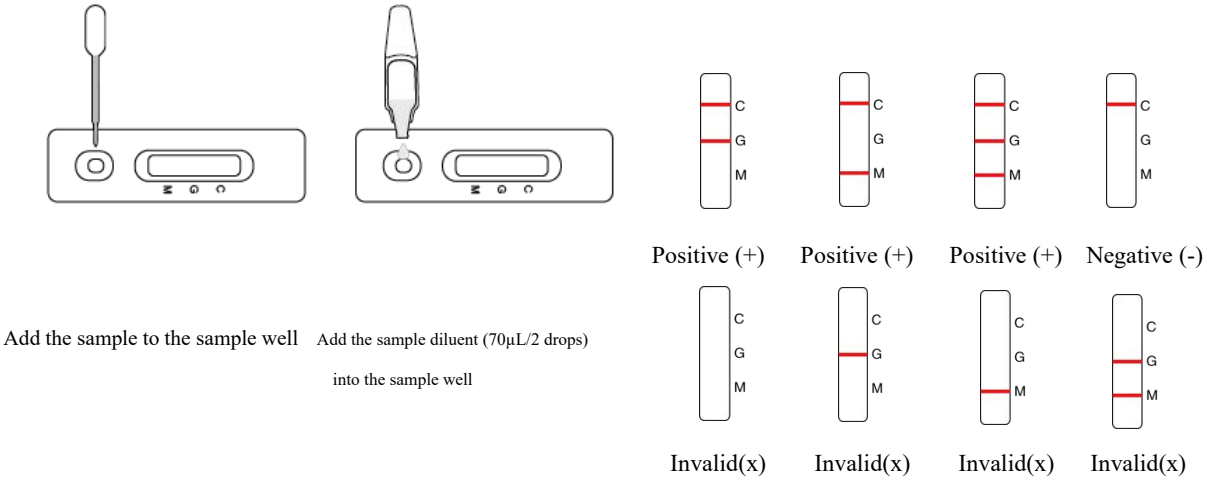
1. Store at 2~30ºC in the sealed pouch up to the expiration date, and the validity is tentatively 24 months. Do not freeze.
2. The test cassette should be used within 1 hour after taking out from the aluminum foil bag. Sample diluent should be re-capped in time after use.
3. Keep away from sunlight, moisture and heat.

【SPECIMEN COLLECTION AND PREPARATION】

1. The recommended samples for this kit are serum, plasma, whole blood. Plasma and whole blood can be collected by blood collection tube or centrifuge tube with EDTA-2K or heparin sodium anticoagulant.
2. The samples collected with the correct medical technology should be returned to room temperature before testing. Jaundice, hemolysis, lipemia, and cloudy samples cannot be used. Severe hemolytic or heat-inactivated specimens are not recommended.
3. Samples should be tested as soon as possible. If the test cannot be completed within 8 hours, the samples can be stored at low temperature. Serum and plasma can be stored for 7 days at 2-8℃ or for 6 months at -20℃, and whole blood can be stored for 3 days at 2-8℃. Do not freeze and thaw samples repeatedly.

【TEST METHOD】

1. Remove test kit, specimen to room temperature. Tear off the foil pouch, take out the test strip/cassette and place the test kit on a clean and level surface.
2. Add 20μL whole blood or 10μL serum (or plasma) into sample well using a calibrated pipet. Then add 70 μL (2 drops) of the Sample Diluent. For each individual's specimen, use a separate tip and Cassette.
3. Read the test results between 15 and 20 minutes. Do not read the results after 20 minutes.



Add the sample to the sample well Add the sample diluent (70μL/2 drops) into the sample well

(The picture is for reference only)

【INTERPRETATION OF TEST RESULTS】

1. **IgG POSITIVE:** Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgG test line region. The result is positive for monkeypox virus specific-IgG and is probably indicative of secondary monkeypox virus infection.
2. **IgM POSITIVE:** Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for monkeypox virus specific-IgM antibodies and is indicative of primary monkeypox virus infection.
3. **IgG and IgM POSITIVE:** Three lines appear. One colored line should be in the control line region (C), and two colored lines should appear in IgG test line region and IgM test line region. The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies and is indicative of secondary monkeypox virus infection.

NOTE: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of monkeypox virus antibodies in the specimen. Therefore, any shade of color in the IgG and/or IgM test line region(s) should be considered positive.

4. **NEGATIVE:** One colored line should be in the control line region (C). No line appears in IgG and IgM test line region(s).
5. **INVALID:** Control line fails to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.
6. **Result determination time:** The result should be judged within 15~20 minutes after the sample is added into the sample loading well, and the result displayed after 20 minutes is invalid.

【LIMITATIONS OF TEST METHOD】

1. This product is only suitable for qualitative test and auxiliary diagnosis.
2. The test results are only for clinical reference and should not be the only basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptom, physical signs, medical history, other laboratory tests, therapeutic reaction, and epidemiological information.
3. The hemolytic, lipemia, jaundice, and contaminated samples may affect the test results. Such samples should be avoided.
4. During early infection, when IgG/IgM isn't formed or the concentration is very low, it will cause a negative result. If there is a suspected infection, it's recommended to retest in 5-8 days. Test the second sample simultaneously with the first sample under the same conditions to determine whether exist seroconversion in first infection or an elevation in antibody titer.
5. We do not test all types of collection tubes that may be used for this kit; therefore, for blood sample collection tubes from different manufacturers, different results may be obtained due to different raw materials and additives. Each laboratory shall make its own judgment on the suitability of the blood collection tubes.

【PRECAUTIONS】

1. This product is only used for in vitro diagnosis, not for other purposes; do not use expired reagents.
2. All reagent components, samples and various wastes should be treated as infectious agents. At the same time, this product is a one-time use product, and it should be destroyed centrally in accordance with the local infectious disposal law or laboratory regulation.

3. Proper specimen collection, storage and transport are critical to the performance of this test.
4. Testing should be applied by professionally trained staff working in certified laboratories or clinics at which the sample(s) is taken by qualified medical personnel.
5. Please read the instructions carefully before operation, and follow the instructions. During use, all laboratory reagent handling precautions must be followed.
6. Please use fresh samples as much as possible, and avoid using samples contaminated with bacteria, hemolysis, jaundice, or excessive blood lipid.
7. The results of this kit are invalid after 20 minutes.

【WARNINGS】

1. Negative results do not rule out Monkeypox Virus infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
2. Results from antibody testing should not be used as the sole basis to diagnose or exclude Monkeypox Virus infection or to inform infection status.
3. Not for the screening of donated blood .
4. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
5. Dispose of all specimens and materials used to perform the test as biohazardous waste.
6. Handle the negative and positive controls in the same manner as patient specimens for operator protection.
7. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

【REFERENCES】

1.《China biological product code》
2.《Guidelines for preparation of in vitro diagnostic reagent specifications》

【EXPLANATION OF LABELS】

IVD	In Vitro Diagnostic Use		See Instruction for Use	REF	Catalog #
LOT	Batch Number		Expiry Date		Manufacturing Date
	Do not reuse	30°C 2°C	Store between 2～30ºC		Keep away from Sunlight
	Keep Dry		Manufacturer	EC REP	EU Authorized Representative
CE	CE Mark		Biological risks		Warning, please refer to the instruction in the annex

【DATE OF APPROVALAND AMENDMENT OF IFU 】

Approval Date:

Revision Date:

Date of Issue:

【BASIC INFORMATION】

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