IVD

SYNTHGENE

CE

Monkeypox Virus Antibody Rapid Test Kit

【Product name】
Monkeypox Virus Antibody Rapid Test Kit

【Packaging specification】
1 test/bag, 1/5/10/25/50 test(s)/kit

【Intended use】
This product is used for in vitro qualitative detection of monkeypox virus IgG/IgM antibodies in human serum, plasma and whole blood samples.
Human monkeypox virus is a rare, sporadic, smallpox-like virus of animal origin. The first case of monkeypox virus infection in humans was reported in Congo in 1970. Humans are infected with monkeypox mainly through the bite of the infected animal, or direct contact with the blood, body fluids, or monkeypox lesions of the infected animal; usually transmitted from animals to humans, human-to-human transmission of monkeypox can also occur occasionally. It is generally believed that it is transmitted through a large number of toxic respiratory droplets during direct, prolonged face-to-face contact. Additionally, monkeypox can also be spread through direct contact with the infected person's body fluids or virus-contaminated items, such as clothing and bedding. The clinical features of monkeypox are very similar to those of common smallpox, except that monkeypox may have more symptoms of swollen lymph nodes, and about 12 days after infection, the patient will have fever, head pain, myalgia, back pain, swollen lymph nodes, general malaise and fatigue. After 1-3 days (sometimes longer) the patients develop papuliform pustular lesions, usually first on the face and sometimes on other parts of the body. The rash generally scabs and falls off after several stages. The typical course of monkeypox is 2-4 weeks, with a very rapid recovery period.

【Testing principle】
This product adopts the principle of indirect method and colloidal gold immunochromatography. Using colloidal gold-labeled MPV recombinant antigen and chicken IgY as indicator markers, the detection area (M, G) and quality control area (C) on the nitrocellulose membrane are coated with anti-human IgM antibody, anti-human IgG antibody and goat anti-chicken IgY, respectively. During detection, the sample is chromatographed under capillary effect. If the tested sample contains anti-MPV IgG antibody, the colloidal gold-labeled MPV recombinant antigen combines with MPV IgG antibody to form a complex, which combines with the anti-human IgG antibody coated at the detection area (G) during the chromatography process to form "Au-MPV recombinant antigen-MPV IgG antibody-anti-human IgG antibody" sandwich, so that a purple-red band appears in the detection area (G). If the tested sample contains anti-MPV IgM antibody, the colloidal gold-labeled MPV recombinant antigen combines with MPV IgM antibody to form a complex, which combines with the anti-human IgM antibody coated on the detection area (M) during the chromatography process to form "Au-MPV recombinant antigen-MPV IgM antibody-anti-human IgM antibody" sandwich, so that a purple-red band appears in the detection area (M). On the contrary, no purple-red band appears in the detection area (G, M). Regardless of the presence or absence of monkeypox virus antibodies in the tested sample, the complex will continue to be chromatographed up to the quality control area (C), react with goat anti-chicken IgY, and a purple-red band will appear. The purple-red band displayed by the quality control area (C) is the standard for judging whether the chromatography process is normal, and also serves as the internal control standard of the reagent.

【Main components】
1. Test pad, individually packaged in aluminum foil bag (1 piece/bag, 1/5/10/25/50 piece(s)/kit)
2. Sample diluent (1 piece/bag, 1/5/10/25/50 piece(s)/kit)
3. Disposable plastic straw (1 piece/bag, 1/5/10/25/50 piece(s)/kit)
4. Instruction manual (1copy/bag, 1copy/kit)

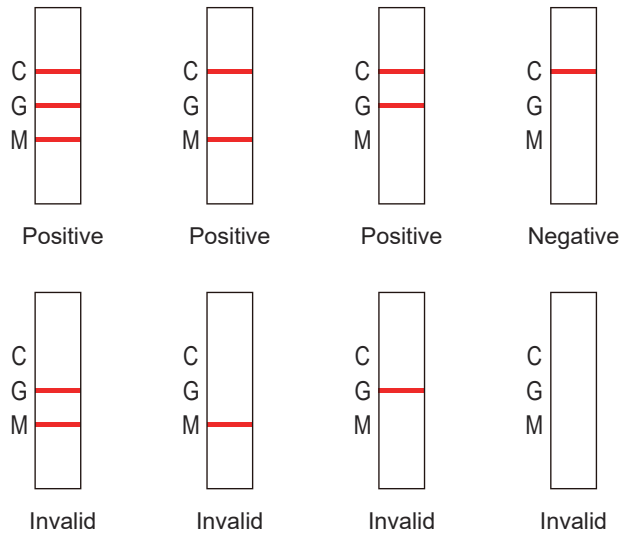
【Optional components】
□ Medical waste bag (1 piece/bag, 1/5/10/25/50 piece(s)/kit)
□ Alcohol cotton pad (1 piece/bag, 1/5/10/25/50 piece(s)/kit)
□ Blood collection needle (1 piece/bag, 1/5/10/25/50 piece(s)/kit)
Note: The components in different batch kits are not interchangeable.

【Storage conditions and validity】
Storage conditions: The product should be stored in a dry place at 2-30°C protected from light, and do not freeze.
Validity period: 24 months.
The reagent should be used as soon as possible within 1 hour after the aluminum foil bag is opened; it is recommended to use it immediately after opening under high temperature and high humidity conditions.

【Sample requirements】
1. This reagent is suitable for whole blood (venous or fingertip blood), serum or plasma samples.
2. Whole blood and plasma samples have no requirements for commonly used clinical anticoagulants (such as EDTA, heparin sodium, sodium citrate, etc.).
3. Whole blood samples should avoid hemolysis.
4. If a blood collection needle is used to collect fingertip blood, the first drop of blood may contain too much body fluid, which will affect the test result, so please use a sterile cotton swab to wipe off the first drop of blood.
5. If the serum or plasma sample is tested within 7 days after collection, the sample must be stored at 2-8°C, if it is longer than 7 days, it must be frozen (-20°C). It is recommended that whole blood samples should be tested within 3 days, and the samples should be stored at 2-8°C and should not be frozen.
6. The refrigerated samples must be returned to room temperature before the test. The frozen samples must be completely thawed, rewarmed, and mixed well before use. Avoid repeated freezing and thawing.

【Test method】
1. Before testing, the unopened reagent should be placed at room temperature to allow the temperature of the reagent to reach equilibrium.
2. Tear the aluminum foil bag along the incision site, take out the test pad and lay it flat on a clean surface.
3. Use a disposable plastic straw to vertically drop 1 drop of fingertip blood sample or serum, plasma, whole blood sample (about 25 μL) into the sample well, and then drop 2 drops of sample diluent to start timing.
4. Read the result at 10 minutes, and the result is valid within 20 minutes.

【Interpretation of test results】



1. Negative: Only one red quality control line (C line) is visible to the naked eye
2. IgM, IgG positive: Three clear red lines are visible to the naked eye, one is the quality control line (C line), one is the M detection line, and the other is the G detection line.

3. IgM positive, IgG negative: Two clear red lines are visible to naked eyes, one is the quality control line (C line) and the other is the M detection line.
4. IgM negative, IgG positive: Two clear red lines are visible to the naked eye, one is the quality control line (C line) and the other is the G detection line.
5. Invalid: If there is no visible red line or only the detection line (M, G line) without the quality control line (C line), it indicates that the sample is tested incorrectly or the test result is invalid, and the sample should be re-tested.

【Limitations of test methods】

1. This product is only used for in vitro qualitative testing. The test results are for clinical reference only and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptoms, signs, medical history, other laboratory tests, treatment response, and epidemiological information. It is recommended to retest suspicious samples at intervals.
2. This product only provides qualitative detection of monkeypox virus IgG/IgM antibodies in samples, and cannot be used for quantification. If you need to detect the specific content of a certain index, please use relevant professional instruments.
3. The accuracy of the test is affected by the sample collection process. Improper sample collection and storage process will affect the test results. Avoid high temperature and direct sunlight.
4. This product is used for preliminary screening. Due to the limitations of detection methodology, the possibility of monkeypox virus infection cannot be ruled out for negative results. It is necessary to combine other test results and comprehensive clinical judgments to make an accurate diagnosis.

【Performance characteristics】

Use this product to detect the enterprise negative reference product, positive reference product, minimum detection limit reference product and repeatability reference product, and the results all meet the requirements.

【Precautions】

1. Please read the instruction manual carefully before use. Professionally trained inspectors are required to operate it, and the test operation should be carried out in strict accordance with the kit instructions.
2. This product is a one-time use in vitro diagnostic product, please use it within the validity period.
3. If the aluminum foil bag is found to be damaged, do not use it. Use the kit as soon as possible after opening the foil bag.
4. If the test result is negative and clinical symptoms are present, other clinical methods may be recommended for testing. A negative result does not rule out infection with monkeypox virus.
5. The temperature has a great influence on the test results.

【References】

[1] Ren Jiao, Ye Fei, Zhao Li, Guan Qianqian, Zhao Ying, Song Jingdong, Tian Houwen, Tan Wenjie. Establishment of an ELISA method for the detection of serum antibodies in monkeypox virus infection [J]. Journal of Experimental and Clinical Virology, 2018, 32(06): 636-639.
[2] Guan Qianqian, Tian Houwen. Research progress of monkeypox virus detection [J]. Chinese Journal of Experimental and Clinical Virology, 2017, 31(03): 273-276.
[3] Guan Qianqian. Preparation and identification of monkeypox virus-specific monoclonal antibodies [D]. Chinese Center for Disease Control and Prevention, 2017.

【Approval and modification date of the specification】

2022.6.8

【Production date and expiration date】

See label

LABEL INTRODUCE FOR USER

Abbreviation	Explanation	Abbreviation	Explanation
IVD	In vitro diagnostic medical device	LOT	Batch code
Σ	Contains sufficient for<n>tests		Date of manufacture
	Manufacturer		Use-by date
EC REP	Authorized representative in the European Community	2℃ 30℃	Temperature limit: 2~30℃
CE	CE Marking		Keep away from sunlight
REF	Catalogue number		Keep dry
	Consult instructions for use		Do not re-use
	Biological risks		Do not use if package is damaged

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GUARANTEE AND TECHNICAL SUPPORT
If invalid message repeats or need technical support,please contact Synthgene Medical Technology Co., Ltd. Customer Service and Support Center.

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