

Instructions for use

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

Product Name

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

Intended use

The PocRoc® Monkeypox Virus IgM/IgG Antibody Rapid Test Kit (Colloidal Gold) is intended for in vitro qualitative detection and differentiation of anti-Monkeypox Virus IgM and IgG antibodies in human serum/plasma/whole blood samples (including venous blood and fingertip blood) from patients suspected of Monkeypox Virus infection.

Summary

Monkeypox virus (MPXV) is a member of the Orthopoxvirus genus, including variola (smallpox) virus, vaccinia (the smallpox vaccine) virus, cowpox virus, camelpox virus^[1]. Monkeypox is a rare disease caused by infection with the monkeypox virus and can be spread from person to person through direct contact with the infectious rash, scabs, or body fluids. It also can be spread by respiratory secretions during prolonged, face-to-face contact, or during intimate physical contact^[2]. Endemic monkeypox is generally self-limited, with clade-dependent case fatality rates of 1-10%. The monkeypox virus typically incubates for 7-14 days before symptoms appear, symptoms include fever, headache, muscle aches, and swollen lymph nodes, followed by a rash^[3].

During the presence of an acute-phase induction against monkeypox virus, detection of both anti-orthopoxvirus IgG and IgM reactivity within the first week after rash onset was observed in both vaccinated and nonvaccinated cases. Positive IgG titers appeared as early as day 1 and day 2 after rash onset and until day 147 and day 139 in vaccinated and unvaccinated cases, respectively. Positive IgM titers were observed as early as day 2 after rash onset in both vaccinated and unvaccinated cases. Positive IgM titers were observed out to day 126 in unvaccinated cases, while vaccinated cases had detectable titers out to day 77^[4].

Test principle

The PocRoc® Monkeypox Virus IgM/IgG Antibody Rapid Test Kit (Colloidal Gold) is a lateral flow immunoassay with colloidal gold labeling. The test strip is composed of the following parts: sample pad, conjugate pad, reaction membrane, and absorbing pad. Reaction membrane contains two separated test lines which are pre-coated respectively with two mouse anti-human IgM and IgG antibodies on the nitrocellulose membrane. Conjugate pad contains colloidal gold particles conjugate with Monkeypox virus recombinant envelope protein antigen which can specifically bind to human anti-monkeypox virus antibodies (IgM and IgG). When the sample is applied to the sample well, the human anti-monkeypox virus IgM and/or IgG antibodies and the labeled monkeypox virus recombinant envelope protein antigens complexes are formed and travel along the test strip. The complexes are captured by the mouse anti-human IgM and anti-human IgG antibodies to form a colored line in the two test lines, respectively.

An internal quality control is included in the test, in the form of a colored line appearing in the control line (C), indicating that the test is functional, and proper and sufficient volume of specimen has been applied to enable migration through the test and control lines, regardless of whether there is a test line or not. If the control line (C) does not appear within the testing time, test result is invalid and the test should be repeated with a new test card and specimen.

Materials included

REF No	Package	Test strip	Sample buffer mL/ bottle*quantity	Pipette	Lancet	IFU
C3107-001	1 test / box	1	1.0*1	1	1	1
C3107-005	5 tests / box	5	1.0*1	5	5	1
C3107-010	10 tests / box	10	1.0*1	10	10	1
C3107-025	25 tests / box	25	3.5*1	25	25	1
C3107-050	50 tests / box	50	3.5*2	50	50	1

Composition of the test kit

1. Test device is composed of a plastic cassette and a test strip. The test strip is comprised of a sample pad, a conjugate pad, nitrocellulose membrane, an absorbing pad and polyvinyl chloride (PVC) backing card.
2. The extraction reagent is composed of 0.9% sodium chloride and proclin300.
3. Do not exchange components with different batch numbers.
4. Components not included in the test kit but necessary for the experiment: Timer, mask, nitrile glove, disposal bag, centrifuge tube.

Storage and stability

All components are ready to use as supplied. Unopened test kits are stable at 4-30°C for 24 months tentatively. The performance of the test kit remains unchanged under 37 °C up to 14 days. The test kit should be used within 1 hours once the pouch is opened. Do not freeze the test kit or expose it above 37°C during storage.

Warnings and Precautions

1. For In vitro diagnostic use only and for medical professional use only
2. Read the package leaflet carefully. All instructions must be followed carefully. The reliability of the test results cannot be guaranteed if the user does not follow the instructions in this package leaflet exactly.
3. Do not use the test kit beyond the expiration date printed on the outside of the box.
4. Different batches of sample buffers and test strips cannot be mixed.
5. The test kit is for single use only. Do not re-use under any circumstances.
6. Follow your clinical and/or laboratory safety guidelines in the collection, handling, storage and disposal of patient samples and all items exposed to patient samples.
7. The best test temperature is 20-30°C and humidity RH is 40% - 60%.
8. Ensure the test kit and specimens to equilibrate to room temperature (15-30°C) prior to testing.
9. Follow the storage recommendations listed on the product labels. Storage and handling outside of these conditions may adversely affect the performance.
10. It is not recommended to operate the test on blood samples with visible hemolysis.

Specimen collection and preparation

Treat any materials of human origin as infectious and handle them using standard biosafety procedures.

Whole blood

1. Collect whole blood by venipuncture into blood sampling tub containing EDTA, citrate or heparin.
2. Stand or centrifuge the whole blood specimens at 3000rpm for serum or plasma, store the serum or plasma at 2-8°C if not tested immediately. Specimens can be stored at 2-8°C for up to 3 days, and be frozen at -20°C for longer storage.

Note: Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity so as to avoid interference on result interpretation.

Fingertip blood

1. Preparation: disposable micropipette and Lancet, 75% alcohol wet wipe.
2. Massage: gently massage the ring finger to make the local tissue naturally congested.
3. Disinfection: wipe with 75% alcohol wet wipe and leave it dry.
4. Acupuncture: make the skin tight with left hand, hold the Lancet in the right hand and stab it from the inside of the finger end abdomen, fast in and fast out.
5. Blood collecting: squeeze the handle of micropipette to take samples to fill the part of the front thinner end.

Serum/Plasma

1. Collect blood specimens into blood sampling tube containing EDTA, citrate or heparin for plasma or blood sampling tube containing no anticoagulants for serum by venipuncture.
2. Test the specimens as soon as possible after collecting. Store specimens at 2-8°C if not tested immediately. Specimens can be stored at 2-8°C for up to 3 days, and should be frozen at -20°C for longer storage.
3. The assay is unaffected by icterus (bilirubin ≤ 0.2g/L), hemolysis (hemoglobin ≤ 5g/L), lipemia (triglyceride ≤ 10g/L).

Test Procedure

Step 1: Check whether the components of the test kit are complete, then equilibrate the specimens and test components to room temperature (15-30°C).

Step 2: When ready to test, open the pouch and remove the test strip. Place the test strip on a clean, flat surface. (The kit should be used within 1 hour) if opened.

Step 3: Label the device with specimen ID number.

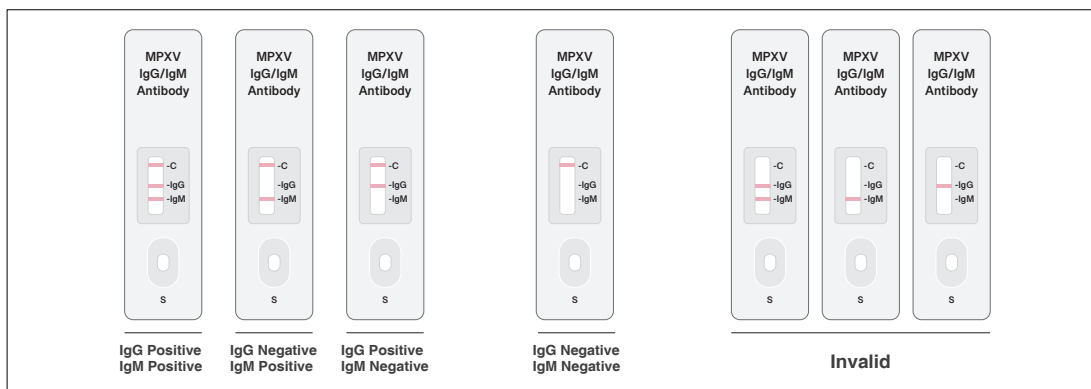
Step 4: Take 20µL whole blood (fingertip blood can be used preferably), or 10µL serum/plasma, and apply the sample into the sample well of the test strip, then add 3 drops sample buffer to the sample well, and timing.

Step 5: Read the result in 15-20 minutes. Do not read the result after 30 minutes.

Note: 1. Do not read the results in dim or too bright environment.
2. The color band in the test line (T) can show different color depths, even a very weak color should be judged as a positive result.

Warning: If the result is read after 30 minutes, the result may be invalid.

Interpretation of Results



Positive results:

IgG and IgM Positive: The control line, IgG line and IgM line are visible in the result window. The test is positive for IgG and IgM antibodies.

IgG Positive: The control line, IgG line is visible in the result window. The test is positive for IgG antibodies.

IgM Positive: The control line, IgM line is visible in the result window. The test is positive for IgM antibodies.

Negative results:

The control line is the only line visible in the result window. No IgG or IgM antibodies have been detected.

Invalid results:

If the control line does not appear in the result window, whether there is a IgM line /IgG line or not, it is regarded as an invalid result.

Quality Control

1. A red line appearing in the control line is considered as an internal procedural control. It confirms sufficient specimen volume and correct operation procedural.

Limitation

1. This test kit is for in vitro diagnostics only.
2. This test kit is only used to detect human animal whole blood samples, fingertip blood, serum and plasma, and the results of other sample tests may be incorrect.
3. This test kit is only used for qualitative testing and does not show the concentration of the Monkeypox Virus (MPXV) antibody in the sample.
4. This test kit is only a clinical auxiliary diagnostic tool. The test results of this test kit 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 combined with their symptoms, signs, medical history, other laboratory examinations, treatment response and epidemiology.
5. If the results are positive, it is recommended to use other methods for further examination and to follow the doctor's diagnosis.
6. If the result is negative, the infection of monkeypox virus (MPXV) cannot be excluded. It is possible that the concentration of monkeypox virus antibody is lower than the sensitivity of the test kit.

Performance

1. Coincidence rate of positive reference materials: No negative reaction was found in 5 samples of positive reference materials.
2. Coincidence rate of negative reference materials: No positive reaction was found in 10 samples of negative reference materials.
3. Limit of Detection (LoD) : 500pg/mL of human monkeypox virus specific IgG.
4. The PocRoc® Monkeypox Virus IgM/IgG Antibody Rapid test kit (Colloidal Gold) was tested for cross-reactivity study using serum samples which contained antibodies to the pathogens as follow, the final results show that the kit does not cross react with the antibodies to the pathogens: COVID-19, Influenza A, Influenza B, Adenovirus, Rhinovirus, Human metapneumovirus Mycoplasma pneumoniae, Chlamydia pneumoniae, HCV Haemophilus influenza, HBV, Bacterial pneumonia.
5. Endogenous Interference Substances Studies:
some substances were added into the samples for endogenous substances interference study of The PocRoc® Monkeypox Virus IgM/IgG Antibody Rapid test kit (Colloidal Gold) , there was no interference between the test kits and the interference substances: 20mg/dL Ascorbic acid, 1000mg/mL Hemoglobin, 10mg/mL Bilirubin, 2000mg/mL Albumin.

References

1. Moss B. Poxviridae. In: Knipe DM, Howley PM, editor. Fields virology, Vol. 2. 6th ed. Philadelphia: Lippincott Williams & Wilkins; 2013. p. 2129–2159.
2. Durski KN, McCollum AM, Nakazawa Y, et al. Emergence of monkeypox—West and Central Africa, 1970–2017. MMWR Morb Mortal Wkly Rep 2018;67:306–310.
3. Thornhill, J. P. et al. N. Engl. J. Med. <https://doi.org/10.1056/NEJMoa2207323> (2022).
4. Yinka-Ogunleye A, Aruna O, Dalhat M, et al. Outbreak of human monkeypox in Nigeria in 2017–18: a clinical and epidemiological report. Lancet Infect Dis. 2019 Aug;19(8): 872–879.
5. Characterization of Acute-Phase Humoral Immunity to Monkeypox: Use of Immunoglobulin M Enzyme-Linked Immunosorbent Assay for Detection of Monkeypox Infection during the 2003 North American Outbreak. CLINICAL AND DIAGNOSTIC LABORATORY IMMUNOLOGY, July 2005, p. 867–872.

Glossary:

	Consult Instructions for Use		Bach code
	Do not reuse		Manufacturer
	In-vitro diagnostic device		Date of manufacture
	Temperature limitation		Expiry date
	European Representative		Do not use if package damaged
	Caution, consult accompanying documents		Contains sufficient for <n> tests
	European conformity		Biological risks
	Set up		Catalogue number
	Fragile. Handle with care		Protect from moisture



Manufacturer

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