Monkeypox Virus (MPV) Antigen Test Kit

Catalog Number: AU2038

For Research Use Only. Not for use in Diagnostic Procedures.

1. Intended Use

Monkeypox Virus Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of monkeypox virus antigen in human rash exudates and blood samples.

2. Introduction

Monkeypox is a viral zoonosis. Its pathogen monkeypox virus is a DNA virus, belonging to the genus orthopoxvirus of poxviridae, which is "close relative" to smallpox virus. Rodents are most likely to be natural hosts, and animals such as squirrels, Gambian rats and different kinds of monkeys may be infected. It is mainly prevalent in Western and Central Africa. Most of the cases reported so far are distributed in African countries such as the Democratic Republic of The Congo, the Central African Republic, and Nigeria. The first human infection was found in the Democratic Republic of The Congo in 1970, and the first epidemic outside the African continent occurred in the United States in 2003. Since 2018, Israel, Britain, Singapore and other countries have found infected people among passengers from Nigeria, Direct contact with the blood, body fluid, skin or mucous membrane of infected animals, eating improperly cooked infected animals is risk factor. Interpersonal transmission refers to close contact with the infected person and may be infected, including close contact with the respiratory secretions, skin damage parts or contaminated articles of the infected person; Prolonged face-to-face contact may cause respiratory droplet transmission; Mother to child transmission may occur through placenta or close contact during childbirth.

The incubation period is usually 6 to 13 days and may be as long as 21 days; Early symptoms include fever, headache, enlarged lymph nodes, muscle soreness, severe fatigue and so on; Then it develops into a large-scale rash on the face and body, which may lead to secondary infection, bronchopneumonia, sepsis, etc; Most patients recover within a few weeks. Severe cases are common in children or people with immune deficiency. They are also related to the basic health status of infected people, the degree of exposure to virus and the severity of complications; The mortality rate of the epidemic varies greatly, about 3% to 6% in recent years.

3. Principle

Monkeypox Virus Antigen Test uses double antibody sandwich method. During the test, a specimen is dropped into the hole, and then the specimen is superimposed under the capillary effect. If the specimen contains monkeypox virus antigen, A color band appears in the test area (T) indicating a positive result for monkeypox virus antigen. If the specimen does not contain the corresponding substance to be tested,

there will be no color bands in the test area (T), and the result will be negative. A color band appears in the quality control area (C) regardless of whether the corresponding substance to be tested is present in the specimen. The color band in the quality control area (C) is the standard to determine whether there are enough specimens and whether the chromatographic process is normal, and also serves as the internal control standard of the test.

4. Kit Contents

Contents	Total Tests provided
Cassette Device	10 devices (each sealed foil pouch contains: 1 device, 1 desiccant)
Sample Diluent	10 tubes with an integrated dropper
Collection Swabs	10 sterile single use specimen cotton collection swabs
Instruction Manual	1 each

5. Storage and Stability

- The kit should be stored at 2~30°C, valid for 12months.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Care should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

6. Precautions

- Read this IFU carefully before use.
- Do not spill solution into the reaction zone.
- Do not use test if pouch is damaged.
- Do not use test kit after expiration date.
- Do not mix Sample Diluent Solution and Transfer Tubes from different lots.
- Do not open the Test Cassette foil pouch until ready to perform the test.
- Do not spill solution into the reaction zone.
- For professional use only.
- Do not touch the reaction zone of the device to avoid contamination.

- Avoid cross-contamination of samples by using a new specimen collection container and specimen collection tube for each sample.
- All patient samples should be treated as if capable of transmitting disease. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Do not use more than the required amount of liquid.
- Bring all reagents to room temperature (15~30°C) before use.
- Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when testing.
- Evaluate the test result after 20 minutes and not beyond 30 minutes.
- Store and transport the test device always at 2~30°C.

7. Sample Collection and Storage

Consider any materials of human origin as infectious and handle them using standard bio- safety procedures.

Rash Exudate swab:

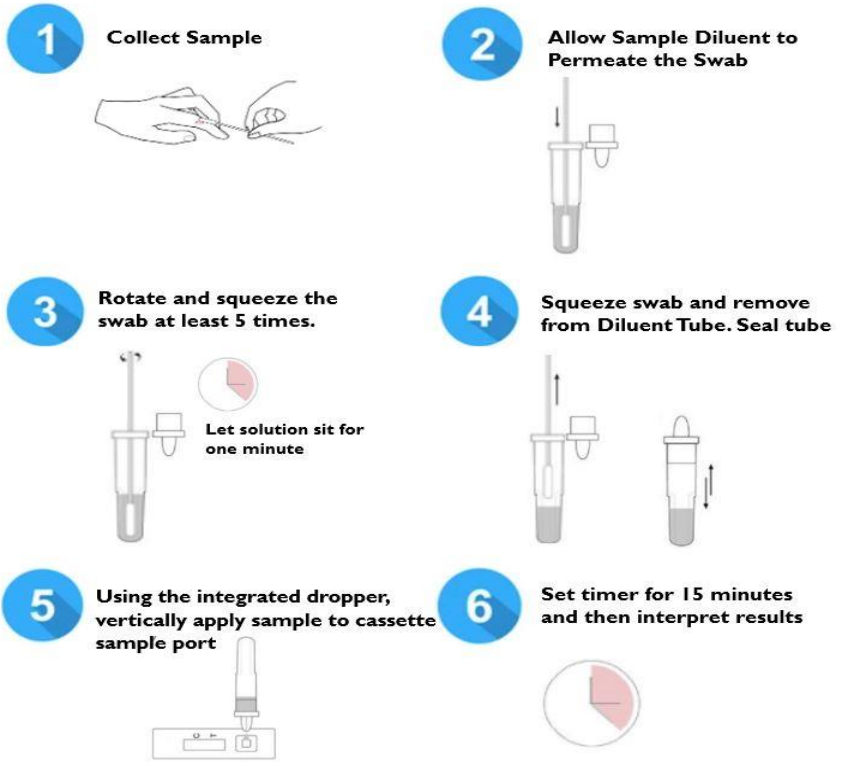
1. Wipe one of the areas above with a sterile swab.
2. After the sample has been collected, dip the swab into the Sample Diluent Solution Tube. Make sure the solution fully permeates the swab.
3. Rotate and squeeze the swab at least 5 times.
    1. Leave the swab in the extraction tube for 1 minute.
4. Squeeze the swab several times to remove excess liquid, close the tube with the attached dropper lid, and take the remaining liquid as the sample to be tested.

8. Test Procedure

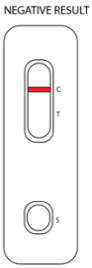
Read the instructions thoroughly before testing and bring the device and specimen to room temperature.

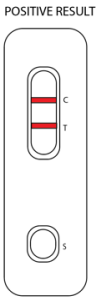
5. Using the integrated dropper function of the Sample Diluent Tube, apply the treated Sample Diluent solution vertically into the sample port of the test cassette. Take extra caution and ensure accuracy in your application of the sample to reduce the risk of potential antigen transmission.
6. Wait for colored line(s) to appear. Interpret the test results in 15 minutes. Do not read results after 20 minutes.

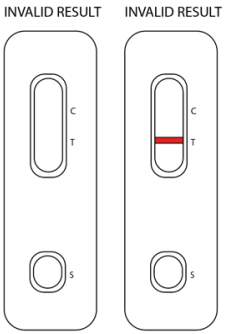
Attogene Quick Reference Guide



8. Interpretation of Results

Negative Results	
	If only the C band is present, the absence of any burgundy color in test band (T) indicates that no Mpox antigen was detected. The result is negative or non-reactive.

Positive Result	
	**Positive:** The colored line in the control line region (C) appears and a colored line appears in test line region (T). The result is positive for Mpox antigen.

Invalid Result	
	**Control line (C) 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 device. If the problem persists, discontinue using the test kit immediately and contact Attogene at 512-333-1330.

9. Note

The intensity of the color in test regions may vary depending on the concentration of antigen present in the sample. The antigen level cannot be determined by this qualitative test. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

10. Quality Control

Internal Control:

This test contains a built-in control feature, the (C) band. The (C) line develops after adding specimen and sample diluent. Otherwise, review the whole procedure and repeat test with a new device.

External Control:

External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performing of the assay, in particularly, under the following circumstances:

- New operator uses the kit, prior to performing testing of specimens.
- A new lot of test kit is used.
- A new shipment of kits is used.
- The temperature used during storage of the kit fall outside of 2°C -30°C.
- The temperature of the test area falls outside of 15°C -30°C.

11. Limitations of the Test

The positive results of Monkeypox Virus Ag Test cannot exclude the infection of other pathogens other than Monkeypox Virus.

• Monkeypox Virus Ag Test can only qualitatively detect Monkeypox Virus in the specimen, and cannot indicate the content of virus in the specimen.

• Monkeypox Virus Ag Test is only used for preliminary screening. If it is necessary to confirm the diagnosis, clinical symptoms or further laboratory tests should be performed.

12. Notice

1. Must strictly follow the instructions for operation and interpretation of the results.
2. The product is qualitatively tested, and the result cannot be used as a quantitative basis.
should be tested using reagents within the validity period.
3. The reagent and swab if for one-time use and cannot be reused.
4. Because the sample titer is different, the red lines of the test line will show different shades of color, all of which indicate positive results. The depth of the test line color cannot be used as the basis for determining the antigen in the sample.
5. The samples stored at low temperature should be balanced to room temperature and fully mixed before testing.
6. Samples and waste must be treated as a potential source of infection and the desiccant in the foil bag is not edible.

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