Human Monkeypox virus Rapid Test Cassette Package Insert

REF IHMPV-C91 | **English**

A rapid test for the qualitative detection of Monkeypox Virus Antigen in pus *swab.*
For professional in vitro diagnostic use only.

【INTENDED USE】

The Human Monkeypox Virus Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of Monkeypox Virus antigen in pus swab as an aid in the diagnosis of Monkeypox Virus infections.

【SUMMARY】

Human monkeypox (HMPX), caused by the monkeypox virus (MPXV) which is a double-stranded DNA virus, a member of the orthopoxvirus genus within the Poxviridae family. It is a viral zoonotic disease, meaning that it can spread from animals to humans. It can also spread between people.

The incubation period of monkeypox can range from 5 to 21 days. The febrile stage of illness usually lasts 1 to 3 days with symptoms including fever, intense headache, lymphadenopathy (swelling of the lymph nodes), back pain, myalgia (muscle ache), and an intense asthenia (lack of energy). The febrile stage is followed by the skin eruption stage, lasting for 2 to 4 weeks. Lesions evolve from macules (lesions with a flat base) to papules (raised firm painful lesions) to vesicles (filled with clear fluid) to pustules (filled with pus), followed by scabs or crusts.

The Human Monkeypox Virus Rapid Test Cassette is a rapid test that utilizes a combination of Monkeypox Virus antigen coated colored particles for the detection Monkeypox Virus antigen in pus *swab*.

【PRINCIPLE】

The Human Monkeypox Virus Test Cassette is a qualitative membrane-based immunoassay for the detection of human monkeypox virus antigen in pus swab. In this test, antibody specific of Monkeypox Virus is separately coated on the test line regions of the test cassette. During testing, the extracted specimen reacts with the antibody of Monkeypox Virus that are coated onto particles. The mixture migrates up the membrane to react with the antibody of Monkeypox Virus on the membrane and generate one colored line in the test regions. The presence of this colored line of the test regions indicates a positive result. To serve as a procedural control, a colored line will always change from Blue to Red in the control line region, indicating that membrane wicking has occurred.

【REAGENTS】

The test cassette contains to monkeypox virus antibody conjugated gold colloid particles and monkeypox virus antibody coated on the membrane.

【PRECAUTIONS】

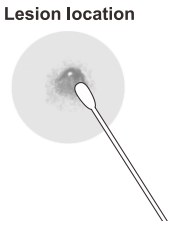
- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used tests, specimens and potentially contaminated material should be discarded according to the local regulations.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

Use the pus swab supplied in the kit. Prior to collecting the pus swab, the patient should be instructed to squeeze out the exudate from their lesion. To collect a pus swab sample, take the absorbent tip of the swab onto the pus and firmly sample the exudate by rotating the swab at least 5 times. Take approximately 10 seconds to collect the sample. Be sure to collect any pus that may be present on the swab.



【MATERIALS 】

Materials provided

Test cassettes
Sterile pus Swabs
Extraction buffer Tubes
Package insert

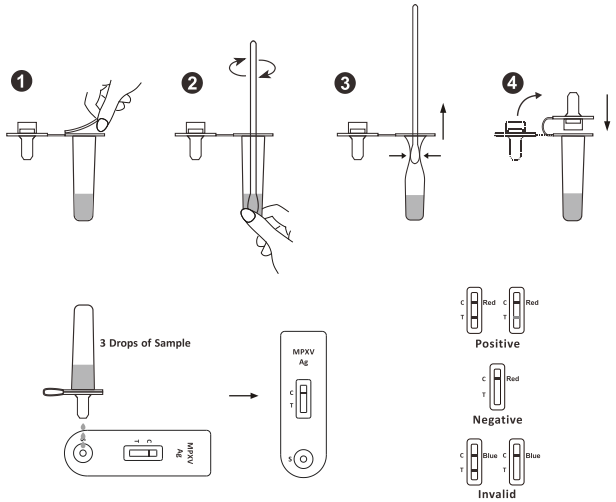
Materials required but not provided

Timer

【DIRECTIONS FOR USE】

Allow the test cassette, specimen, buffer, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening. Remove the test cassette from the sealed pouch and use it within one hour.
2. Tear the aluminum foil on the extraction buffer tube.
3. Place the swab specimen in the extraction tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.
4. Remove the swab while squeezing the swab head against the inside of the Extraction Tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.
5. Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface.
6. Add 3 drops of the solution (approx.80μL) to the sample well and then start the timer. Read the result at 10 minutes. Do not interpret the result after 20 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two lines appear. The colored line in the control line region (C) changes from **Blue to Red**, and other colored lines should appear in test line region (T).

*NOTE: The intensity of the color in the test line region will vary depending on the concentration of Monkeypox Virus Antigen in the specimen. Therefore, any shade of color in the test line region should be considered positive.

NEGATIVE: The colored line in the control line region (C) changes from **Blue to Red**. No line appears in test line region (T).

INVALID: Control line (C) is still completely or partially blue, and fails to completely change from **Blue to Red**. 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.

【QUALITY CONTROL】

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. Control standards are not supplied with this kit; however, 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.

【LIMITATIONS】

1. The Human Monkeypox Virus Rapid Test Cassette is for use only by individuals who have been given appropriate training for in vitro diagnostic use. Neither the quantitative value nor the rate of increase in Monkeypox virus concentration can be determined by this qualitative test.
2. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
3. The Monkeypox Virus Rapid Test Cassette will only indicate the presence of Monkeypox Virus antigen in the specimen from both viable and non-viable Monkeypox Virus strains.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. A negative result obtained from this kit should be confirmed by PCR, and/or should be interpreted and followed up in line with national/regional guidance. A negative result may be obtained if the concentration of the Monkeypox virus present in the swab is not adequate or is below the detectable level of the test.
6. A positive result for Monkeypox Virus does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.
7. 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.
8. Positive results may be due to past or present infection with other Orthopoxvirus.
9. Results from antigen testing should not be used as the sole basis to diagnose or exclude Monkeypox Virus infection or to inform infection status.
10. The extraction reagent has the ability to kill the virus, but it cannot inactivate 100% of the virus. The method of inactivating the virus should be referred to as recommended by WHO/CDC, or according to local regulations.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

A clinical evaluation was conducted comparing the results obtained using the Human Monkeypox Virus Rapid Test Cassette to clinical performance.The study included 10 positive specimens and 50 negative specimens.

Item		Clinical performance		Total Result
Human Monkeypox Virus Rapid Test Cassette	Result	Positive	Negative	
	Positive	10	0	10
	Negative	0	50	50
Total Result		10	50	60

Relative sensitivity: 10/10=100%(95%*CI: 74.1%~100.0%);
Relative Specificity: 50/50=100%(95%*CI: 94.2%~100.0%);
Accuracy:60/60=100%(95%*CI: 95.1%~100.0%);
*CI means confidence interval.

Cross-reactivity

The Human Monkeypox Virus Rapid Test Cassette has been tested for Influenza A virus, Influenza B virus, Staphylococcus aureus, Candida albicans, Staphylococcus epidermis, Streptococcus pyogenes positive specimens. The results showed no cross-reactivity.

【BIBLIOGRAPHY】

1. World Health Organization (WHO). Laboratory testing for the monkeypox virus; 23 May 2022.
2. Harapan, H, Setiawan, A. M, et al. Confidence in managing human monkeypox cases in Asia: A cross-sectional survey among general practitioners in Indonesia. Acta Tropica, 206 (2020), 105450.
3. Ihekweazu, C, Yinka-Ogunleye, A, et al. Importance of epidemiological research of Monkeypox: is incidence increasing? Expert Review of Anti-infective Therapy (2020); 1478-7210.

Index of Symbols

	Consult Instruction for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by	2	Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

Manufacturer
Hangzhou Biotest Biotech Co., Ltd.
17#, Futai Road, Zhongtai Street,
Yuhang District, Hangzhou, P. R. China

EC REP
Riomavix S.L.
Calle de Almansa 55, 1D,
Madrid 28039 Spain

Number: RP5474500
Effective date: 2022-08-29