Rapid Response™

Human Monkeypox Virus Antigen Rapid Test
(Lesion exudate/Oropharyngeal)

REF HMPV-19C25 Product Insert

A rapid test for the qualitative detection of Monkeypox Virus Antigen in lesion exudate/oropharyngeal swab.

For professional *in vitro* diagnostic use only.

Intended Use

The Rapid Response™ Human Monkeypox Virus Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of Monkeypox Virus antigen in lesion exudate/ oropharyngeal 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 Rapid Response™ Human Monkeypox Virus Antigen Rapid Test is a rapid test that utilizes a combination of Monkeypox Virus antigen coated colored particles for the detection Monkeypox Virus antigen in lesion exudate/ oropharyngeal swab.

Principle

The Rapid Response™ Human Monkeypox Virus Antigen Rapid Test is a qualitative membrane-based immunoassay for the detection of human monkeypox virus antigen in lesion exudate/ oropharyngeal 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 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.

Materials

Materials provided

- Test cassettes
- Sterile swabs
- Workstation
- Extraction buffer tubes
- Product insert

Materials required but not provided

- Timer

Storage and Stability

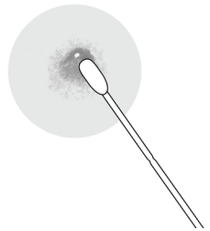
The kit can be stored at room temperature or refrigerated (35.6-86°F; 2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

Collection and Storage of Specimens

To collect lesion exudate swab Specimen:

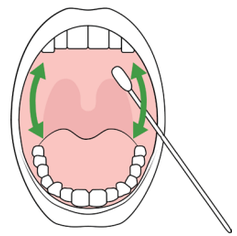
- Use the lesion exudate swab supplied in the kit. Prior to collecting the lesion exudate swab, the patient should be instructed to squeeze out the exudate from their lesion. To collect a lesion exudate swab sample, take the absorbent tip of the swab onto the lesion exudate and firmly sample the exudate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

Lesion location



To collect Oropharyngeal swab Specimen:

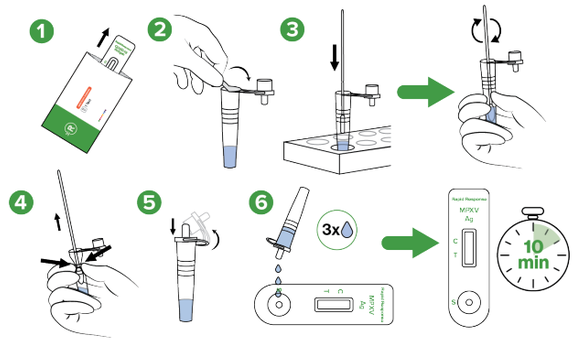
- Insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.



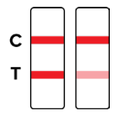
Test Procedure

Allow the test cassette, specimen, buffer, and/or controls to reach room temperature (59-86°F; 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.

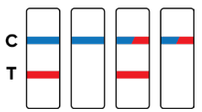


Results Interpretation



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 Rapid Response™ Human Monkeypox Virus Antigen Rapid Test 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 Rapid Response™ Human Monkeypox Virus Antigen Rapid Test 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 Rapid Response™ Human Monkeypox Virus Antigen Rapid Test to clinical performance. The study included 10 positive specimens and 50 negative specimens.

Item		Clinical performance		Total Result
Rapid Response™ Human Monkeypox Virus Antigen Rapid Test	Result	Positive	Negative	
	Positive	10	0	10
	Negative	0	50	50
Total Result		10	50	50

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 Rapid Response™ Human Monkeypox Virus Antigen Rapid Test 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.

Glossary of Symbols


Consult instructions for use


Test per Kit


Do Not Reuse


Store between 35.6˚F to 86˚F


Use by


Catalogue #


Lot Number


For in vitro diagnostic use only

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