English

Monkeypox Virus (MPV) Antigen Rapid Test Kit

A test for the qualitative detection of Monkeypox Virus (MPV) sIgA in secretions of human mucous membrane,such as saliva, tears, nasal and bronchial secretions, gastroenteric fluid, urine, sweat, etc.

Intended Use

Monkeypox Virus (MPV) Antigen Rapid Test Kit is intended for the In Vitro qualitative detection Monkeypox Virus (MPV) sIgA in secretions of human mucous membrane,such as saliva, tears, nasal and bronchial secretions, gastroenteric fluid, urine, sweat, etc. It is only used as an auxiliary detection indicator for Monkeypox Virus (MPXV) infection. This product can be used in a clinical setting / health-care setting / laboratory setting.

Specifications

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50 Tests 25 Tests 20 Tests 5 Tests 1 Tests

Summary and Explanation

Monkeypox is a viral zoonosis (a virus transmitted to humans from animals) with symptoms very similar to those seen in the past in smallpox patients, although it is clinically less severe. With the eradication of smallpox in 1980 and subsequent cessation of smallpox vaccination, monkeypox has emerged as the most important orthopoxvirus for public health. Monkeypox primarily occurs in Central and West Africa, often in proximity to tropical rainforests and has been increasingly appearing in urban areas. Animal hosts include a range of rodents and non-human primates.

Monkeypox virus is an enveloped double-stranded DNA virus that belongs to the Orthopoxvirus genus of the Poxviridae family.

Secretory immunoglobulin A (SIgA) mainly exists in exudates such as respiratory tract fluid, gastroenteric fluid and breast milk. SIgA is the first immune barrier against the invasion of pathogens and harmful substances in respiratory tract, digestive tract and urogenital tract. It is the most important antibody of mucosal immunity.

Principles of the Procedure

Monkeypox Virus (MPV) Antigen Rapid Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of MPXV SIgA in human saliva samples.

If the specimen contains MPXV SIgA, it will bind with the colloidal gold labelled MPXV antigen to form a sandwich complex. As the anti-human SIgA antibody is coated on the test line (T1 line), colloidal gold will accumulate and precipitate here and appear red.

To serve as a procedural control, a colored line will always appear in the control line (C line) region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Materials Supplied

- Test Device

Additional Materials Required

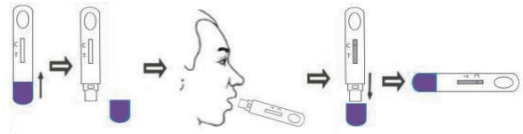
- Timer
- Biohazard container

Storage Instructions

1. Store as packaged in the hermetically-sealed bag at the temperature 2-30℃ and avoid direct sunshine and moisture. The kit is stable within the expiration date printed on the labeling. Do not use if package is damaged.
2. Once the sealed bag is opened, the test should be used immediately. Prolonged exposure to hot and humid environments will cause product deterioration.
3. The lot number and the expiration date are printed on each sealed bag.

TEST PROCEDURE

Allow the test device and specimens to equilibrate to room temperature (15-30℃ or 59-86℉) prior to testing.



1. Put the tampon of the test card into the mouth, gently bite the end of the plastic card housing, and hold the test card down at a 15-30 degree Angle, and wait for 2-5minutes (sometimes saliva is sticky and takes longer)until the wet liquid reaches the top of the observation window,
2. When the wet liquid arrives at the top of the observation window, remove the test card and close the cover. Place it flat on the desktop and wait for 15min.

Interpretation of Test Results

- POSITIVE (+): Two distinct colored line appears. One line in the control line region and the other line in the test line region. The shade of color may vary，but it should be considered positive whenever there is even a faint line.
- NEGATIVE (-): Only one colored line appears in the control line region, and no colored line appears in the test line region. The negative result indicates that there are no MPXV SIgA in the specimen.
- INVALID: The Control line (C line) fails to appear. The test is invalid even if a colored line appears in the test line region. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device. If the problem persists, discontinue using the product immediately and contact your local distributor.

Positive Negative Invalid

Limitations

- The result of the product for reference only and cannot be used as the only evidence of diagnosis.
- This product is only for the qualitative detection of MPXV SIgA in human saliva, nasal and bronchial secretions specimens but not for quantitative detection.
- Subject to the limitations of the assay methodology, when the result is negative, cannot exclude the presence of antibodies. It is recommended verified with other test methodology.
- False negative results may result from wrong specimen collection.

Performance Characteristics

1. Sensitivity

Detection of manufacturer’s sensitivity reference materials, the results are as follows: S1 and S2 should be positive, S3 should be negative.

2. Negative coincidence rate

Detection of manufacturer’s negative reference materials, the results are as follows: Negative coincidence rate (-/-) is no less than 24/25;

3. Positive coincidence rate

Detection of manufacturer’s positive reference materials, the results are as follows: Positive coincidence rate (+/+) is no less than 10/10;

4. Repeatability

Detection of manufacturer’s repeatability reference material in parallel for 10 times. The intensity of the test lines should be consistent in color.

5. High dose hook effect

Test the high dose specimen, the result should be positive.

Warnings and Precautionsimitations

- This product is only for in vitro diagnosis, not for any other purposes.
- Do not use after the expiration date.
- Perform test at room temperature 15 to 30°C.
- Ensure foil pouch containing test device is not damaged before opening for use.
- Wear gloves when taking the samples, avoid touching the reagent membrane and sample window.
- All samples and used accessories should be treated as infectious and discarded according to local regulations.
- This product requires proper visual inspection in a well-lit room, please do not interpret the results in a dim light environment. Practitioner with color blindness and color weakness may give incorrect test results

Technical Assistance

For technical assistance, contact your National Distributor.

Key to Symbols Used

REF	Catalog Number		Expiration Date
IVD	For *In Vitro* Diagnostic Use	LOT	Lot Number
2°C–30°C	Store at 2-30°C		Consult Instruction for Use
	Manufacturer	EC REP	Authorized Representative in European Union
CE	EC Declaration of Conformity	Σ	Contains Sufficient for < *n* > Tests
			Chemical Risk Warning

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