Reference No: CT070
Version: 01/2024

IVD

# Monkeypox Virus Antigen Rapid Test Instruction for Use

For professional and in vitro diagnostic use only.

## PRODUCT NAME

Monkeypox Virus Antigen Rapid Test

## PACKING SPECIFICATION

25Tests/box

## INTENDED USE

The product is a lateral flow immunoassay for the qualitative detection of monkeypox virus antigen in human nasopharyngeal swabs, throat swabs or skin lesion samples (including swabs of rash surfaces and/or exudates; vesicular fluid). It is indicated for use as an aid in the diagnosis of Monkeypox Virus infection.

## SUMMARY

Monkeypox virus is a member of the Orthopoxvirus genus, which also includes variola virus (the causative agent of smallpox) and vaccinia virus. It causes monkeypox, a zoonotic disease primarily found in Central and West Africa. The virus can be transmitted to humans through direct contact with infected animals, particularly rodents and primates, or through consumption of their meat. Human-to-human transmission can also occur, primarily through respiratory droplets or contact with infected bodily fluids and skin lesions.

Clinically, monkeypox manifests similarly to smallpox but is generally milder. It begins with flu-like symptoms such as fever, headache, muscle aches, and exhaustion, followed by the development of a rash characterized by papules, pustules, and scabs. Monkeypox can vary in severity from a mild illness to a potentially fatal disease, especially in immunocompromised individuals.

## PRINCIPLE

This product uses the double antibody sandwich method. The membrane is pre-coated with monkeypox virus antibodies, and the labeled pad is pre-coated with monkeypox virus antibodies conjugated to colored microspheres. During the test, if the specimen contains monkeypox virus antigens, they will bind to the monkeypox-specific antibodies on the labeled pad, forming a monkeypox antigen-antibody complex. This complex will then continue to migrate upward by capillary action, where it is captured by the monkeypox antibodies pre-coated at the test area (T), forming a monkeypox antibody-antigen-antibody complex, which will result in a color band appearing at the test area (T), indicating a positive result for monkeypox virus. If the specimen does not contain monkeypox virus antigens, 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 being 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.

## MATERIALS

**Materials provided**

☐ Test Cassette ☐ Extraction Buffer ☐ Swab ☐ Tube holder
☐ Instruction for Use

**Materials required but not provided**

☐ Timer

## REAGENTS

The Monkeypox Virus Antigen Rapid Test contains anti-Monkeypox Virus antibodies conjugated to red latex microspheres and anti-Monkeypox Virus antibodies coated on the membrane.

## STORAGE

Pack in sealed bag and lay at temperature (2-30°C). Do not freeze. After opening the pouch, the test should be used within one hour. Prolonged contact with hot and humid environment will cause the product to deteriorate. The Test Kit is stable within the expiration date printed on the label.

## SPECIMEN COLLECTION

**For Nasopharyngeal swabs specimen**

1. Carefully insert the swab into the nostril of the patient, reaching the surface of posterior nasopharynx, that presents the most secretion under visual inspection.
2. Swab over the surface of the posterior nasopharynx. Rotate the swab several times.
3. With draw the swab from the nasal cavity.

Note: Use the same cotton swab to collect sample from both nostrils.

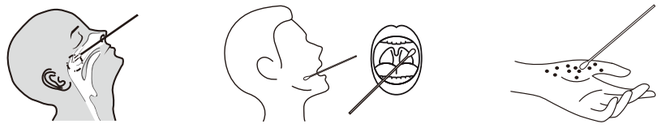


**For throat specimen**

1.Prepare the oral swab and other components of the test kit (such as the buffer solution), and ensure that the test kit is at room temperature.
2.Have the patient sit in a comfortable position, open their mouth, use one hand to stabilize their head, and hold the swab with the other hand.
3.Gently insert the tip of the swab into the patient's oropharyngeal area, avoiding contact with other parts of the mouth.
4.Use the swab to gently rub the throat and tonsil areas, ensuring adequate sample collection for 5-10 seconds.
5.Carefully remove the swab from the oropharyngeal area after sampling, avoiding contact with other parts of the mouth.

**For skin lesion specimen**

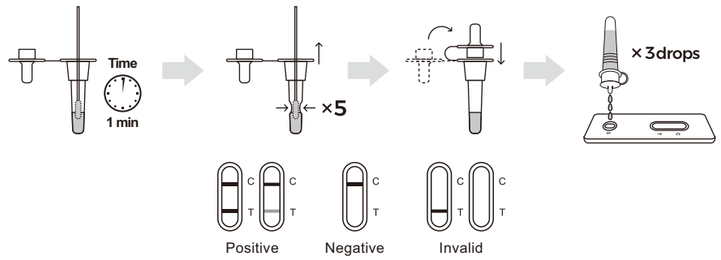
1.Ensure that the test kit and its components (such as swabs, buffer solution, etc.) are prepared and that the test kit is at room temperature.
2.Make sure the skin lesion area is clean and free of any interfering substances (such as dirt or skincare products).
3.Verify that the lesion area meets the sampling requirements and select a prominent or representative site for sampling.
4.Gently press the skin around the lesion area to avoid applying excessive pressure.
5.Lightly touch the tip of the swab to the lesion area, ensuring the swab adequately contacts the lesion.
6.Rotate or rub the swab gently on the lesion area for 10-15 seconds to ensure adequate sample collection.



For nasopharyngeal swabs specimen | For throat specimen | For skin lesion specimen

## TEST PROCEDURE

Allow the test cassette, test sample and buffer to equilibrate to room temperature (15-30°C) prior to testing.
1.Remove the test cassette from the sealed foil pouch and use it as soon as possible and use it within one hour. Place the test cassette on a clean and level surface. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2.Insert the swab into the extraction buffer tube. While squeezing the buffer tube, press the swab against the wall of the tube and stir the swab at least 5 times. Allow the swab to stand in the extraction buffer tube for 1 minute.
3.Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Press the nozzle cap tightly onto the tube.
4.Add 3 drops of the solution to the specimen well (S) and then start the timer. Read the result at 15 minutes. Do not interpret the result after 20 minutes.
CAUTION: Do not read the result beforehand, even if a line has already appeared at control region C.




## INTERPRETATION OF RESULTS

**POSITIVE:** * A color band in the quality control area (C) and a color band in the T area.
* Note: The color bands in the test area (T) may appear in different shades of color. However, within the specified observation time, no matter the color of the color band is dark or light, even if there is only a very weak color band, it should be judged as a positive result.
**NEGATIVE:** Only one color band appears in the quality control area (C), and no color band appears in the test area (T). Negative results indicate that no target substance was detected in the specimen.
**INVALID:** No color band appears in the quality control area (C); the result is considered invalid. Some causes of invalid results include not following the directions correctly or the test may have deteriorated beyond the expiration date. In any case, it should be retested. If the problem persists, stop using this lot number immediately and contact your local supplier.

## QUALITY CONTROL

A procedural control is included in the test. The line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking, and correct procedural technique. Control standards are not provided with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify the proper test performance.

## LIMITATIONS

The positive results of this cassette cannot exclude the infection of other pathogens besides Monkeypox Virus. This cassette can only qualitatively detect Monkeypox Virus in a specimen and cannot indicate the amount of virus in the specimen. This cassette is only used for preliminary screening. If it is necessary to confirm the diagnosis, clinical symptoms or further laboratory tests should be performed.



## PERFORMANCE CHARACTERISTICS

**1. Sensitivity**
Testing the positive enterprise references, the positive coincidence rate should be 100%.
**2. Specificity**
Using the Monkeypox Virus Antigen Rapid Test by professional was compared to the RT-PCR kit. A specificity of 97.44% (152/156 known confirmed Negatives) was determined for the Monkeypox Virus Antigen Rapid Test.
**3. Cross-Reactivity**
The Monkeypox Virus Antigen Rapid Test shows no cross-reactivity with the substances listed in the table below.

| Virus or organisms | | |
|---|---|---|
| SARS-CoV-2 | Adenovirus 5 | Legionella pneumophila |
| Human coronavirus NL63 | Adenovirus 7 | Mycobacterium tuberculosis |
| Human coronavirus HKU1 | Adenovirus 55 | Mycoplasma pneumoniae |
| Human coronavirus Oc43 | Haemophilus influenzae | Pneumocystis jiroveci |
| Human coronavirus 229E | Enterovirus EV70 | Streptococcus pneumoniae |
| MERS | Bordetella pertussis | Staphylococcus aureus |
| Respiratory syncytial virus Type A | Chlamydia pneumoniae | Rhinovirus A2 |
| Respiratory syncytial virus Type B | Coxsackie virus CA16e | Rhinovirus B52 |
| Parainfluenza virus 1 | Coxsackie virus B5 | Seasonal influenza A H1N1 virus |
| Parainfluenza virus 2 | Coxsackie virus A24 | Influenza A H3N2 virus |
| Parainfluenza virus 3 | Candida albicans | Influenza B Yamagata |
| Parainfluenza virus 4 | Human Metapneumovirus A2 | Influenza B Victoria |

**5.Interfering-Reactivity**
The Monkeypox Virus Antigen Rapid Test shows no interference with the substances listed in the table below.

| Virus or organisms | | |
|---|---|---|
| Mucin | Oxymetazoline hydrochloride spray | Ceftriaxone |
| Human blood (EDTA anticoagulated) | Phenylephrine Hydrochloride | Histamine hydrochloride |
| Bedomethasone | Arbidol | Alpha interferon |
| dipropionate nasal aerosol | Zanamivir | Azithromycin |
| physiological seawater nasal spray | Ribavirin | Oseltamivir phosphate |
| Triamcinolone acetonide nasal spray | Peramivir | Meropenem |
| Mometasone furoate nasal spray | Lopinavir | Tobramycin |
| Fluticasone propionate nasal spray | Ritonavir | Hexadecadrol |
| Budesonide nasal spray | Levofloxacin | Flunisolide |

## INDEX OF SYMBOLS

| | | | | | |
|---|---|---|---|---|---|
| Σ | Contains sufficient for <n> tests | | Use-by date | | Manufacturer |
| | Consult instructions for use or consult electronic instructions for use | | Temperature limit | | Do not use if package is damaged and consult instructions for use |
| | | | Do not re-use | | |
| IVD | In vitro diagnostic medical device | CE | Conformity of European | EC REP | Authorized Representative in the European Community |
| LOT | Batch code | | Keep dry | | Keep away from sunlight |

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