CE IVD

Package insert for Monkeypox Virus Antigen Rapid Test Kit

For professional and in vitro diagnostic use only.

Intended Use

The product is a lateral flow chromatographic immunoassay for the qualitative detection of monkeypox virus antigen in human whole blood, serum, plasma， rash exudate or nasal swab.

Principle

This product use 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, A color band appears in the test area (T) indicate a positive result for monkeypox virus. 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.

Warnings and Precautions

- This cassette is only used for in vitro diagnosis.
- If there are too few viral antigens, it will cause false negatives.
- The cassette is disposable.
- This cassette is for visual testing. To avoid misjudgment, please do not read it in dim light.
- Used cassettes and specimens should be properly disposed of as medical waste with a risk of biological transmission.

Material

Material Provided

- Individually packed test devices
- Specimens dilution tube/extraction tube with buffer
- Droppers/Swab
- Package insert

Material Required but not Provided

- Specimen collection container
- Clock, timer or stopwatch
- Centrifuge
- Disposable latex gloves

Storage and Stability

- 2~30°C dry and stored away from light, valid for 24 months.
- Production date and service life: see label, do not freeze or use after expiry date.
- The cassette should be used within 1 hour after the tear of the aluminum foil bag; If the temperature is higher than 30°C or in high humidity environment, it should be to use immediately.

Specimen Requirement

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

Plasma:

1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively, in Vacutainer®) by venipuncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma into a new pre-labeled tube.

Serum:

1. Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2°C-8°C if not tested immediately. Specimens can be stored at 2°C -8°C for up to 5 days. The specimens should be frozen at -20°C for longer storage.
Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.
Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

Blood:

Drops of whole blood can be obtained by either finger tip puncture or venipuncture.

Whole blood specimens should be stored in refrigeration (2°C-8°C), if not tested immediately. The specimens must be tested within 24 hours of collection.

Rash Exudate:

1. Wipe the rash exudate with a sterile swab;
2. Insert the swab into the extraction tube with buffer;
3. Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.
4. Leave the swab in the extraction tube for 1 minute.
5. Squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab. The extracted solution will be used as test sample.

Nasal swab:

1.Insert the entire absorbent tip of the swab into your nostril, but do not insert the swab more than ¾ of an inch (1.5 cm) into your nose.
2. Slowly rotate the swab in a circular path against the inside of your nostril at least 4 times for a total of 15 seconds.
3. Using the same swab, repeat this process for the other nostril to ensure that adequate sample is collected.
4. Insert the swab into the extraction tube with buffer;
5. Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.
6. Leave the swab in the extraction tube for 1 minute.
7. Squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab. The extracted solution will be used as test sample.

Test Procedure

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

For Plasma/Serum/Whole Blood:

1. Bring the specimen and test components to room temperature if refrigerated or frozen. Once thawed, mix the specimen well prior to performing the assay.
2. When ready to test, open the pouch at the notch and remove the device. Place the test device on a clean, flat surface.
3. Fill the plastic dropper with the specimen. Holding the dropper vertically, dispense 1 drop of serum/plasma (about 30-45 μL) or 1 drop of whole blood (about 40-50 μL) into the sample well, making sure there are no air bubbles.
4. Immediately add 1 drop (about 35-50 μL) of sample diluent with the bottle positioned vertically.
5. Wait for colored line(s) to appear. Interpret the test results in 15 minutes. Do not read results after 20 minutes.

For Rash Exudate/Nasal swab:

1. Remove test Cassette from the sealed pouch just prior to the testing and lay flat on workbench.
2. Insert a nozzle with filter into the sample extraction tube tightly.
3. Reverse the sample extraction tube, and add 3 drops sample by squeezing the extracted solution tube into the sample window.
4. Wait for colored line(s) to appear. Interpret the test results in 15 minutes. Do not read results after 20 minutes.

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 quality control area (C), no color band appears in test area (T). Negative results indicated that no substance under test could be tested in the specimen.
Invalid: no color stripe appears in the quality control area (C), the result is considered invalid. Some causes of invalid results are because of 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 with your local supplier.

Positive　Negative　Invalid　Invalid

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 supplied 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 proper test performance.

Limitations

- The positive results of this cassette cannot exclude the infection of other pathogens other than Monkeypox Virus.
- This cassette can only qualitatively detect Monkeypox Virus in the specimen, and cannot indicate the content 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

Positive Coincidence Rate

Testing the positive enterprise references, the positive coincidence rate should be 100%.

Negative Coincidence Rate

Testing the negative enterprise references, the negative coincidence rate should be 100%.

Precision

Testing the precision enterprise references and repeat for 10 times (n = 10), the results shall be consistent, and the apparent chromaticity shall be uniform without difference.

INTERPRETATION OF SYMBOLS

	Consult instructions for use		Tests per kit		Authorized Representative
	For *in vitro* diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Requirement on IVD
	Manufacturer		Keep away from sunshine		Keep away from moisture

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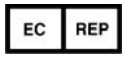

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