Monkeypox Antigen Rapid Test Cassette Package Insert

REF: IMPV-c112 **Specimens:** whole blood/serum / plasma
REF: IMPV-8112 **Specimens:** Oropharyngeal swab
Version: Z **Effective Date:** 02.2022

For professional in vitro diagnostic use only.

INTENDED USE

Monkeypox Antigen Rapid Test Cassette is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of monkeypox virus antigen in human whole blood, serum / plasma or Oropharyngeal swab specimen. This test provides only a preliminary test result. Therefore, any reactive specimen with the Monkeypox Antigen Rapid Test Cassette must be confirmed with alternative testing method(s) and clinical findings.

PACKAGE SPECIFICATIONS

25 tests/pack

INTRODUCTION

Monkeypox is a rare disease that is caused by infection with monkeypox virus. The first human case of monkeypox was recorded in 1970 in the Democratic Republic of the Congo (DRC) during a period of intensified effort to eliminate smallpox. Since then, monkeypox has been reported in people in several other central and western African countries. In humans, the symptoms of monkeypox are similar to but milder than the symptoms of smallpox. Monkeypox begins with fever, headache, muscle aches, and exhaustion. The main difference between symptoms of smallpox and monkeypox is that monkeypox causes lymph nodes to swell (lymphadenopathy) while smallpox does not. The incubation period (time from infection to symptoms) for monkeypox is usually 7−14 days but can range from 5−21 days. Within 1 to 3 days (sometimes longer) after the appearance of fever, the patient develops a rash, often beginning on the face then spreading to other parts of the body. The illness typically lasts for 2−4 weeks. In Africa, monkeypox has been shown to cause death in as many as 1 in 10 persons who contract the disease.

PRINCIPLE

The Monkeypox Antigen Rapid Test Cassette is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect monkeypox antigen in huiman human whole blood, serum / plasma or Oropharyngeal swab specimen. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against the monkeypox virus; the reaction membrane contains the secondary antibodies for monkeypox virus. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If monkeypox virus antigen is present in the sample, a complex forms between the anti-monkeypox conjugate and the virus will be captured by the specific anti-monkeypox monoclonal antibodies coated on the test line region (T). Absence of the test line (T) suggests a negative result. To serve as a procedural control, a red line will always appear in the control line region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

REAGENTS

The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against the monkeypox virus; the reaction membrane contains the secondary antibodies for monkeypox virus.

PRECAUTIONS

1.For professional in vitro diagnostic use only. Do not use after expiration date.
2.This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test
results.
3.Do not use it if the tube/pouch is damaged or broken.
4.Test is for single use only. Do not re-use under any circumstances.
5.Handle all specimens as if they contain infectious agents.Observe established precautions against microbiological
hazards throughout testing and follow the standard procedures for proper disposal of specimens.
6.Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7.Humidity and temperature can adversely affect results.
8.Do not perform the test in a room with strong air flow, ie. electric fan or strong airconditioning.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30℃).
2. Do not freeze any of the test kit components.
3. Do not use test device and reagents after expiration date.
4. Test devices that have been outside of the sealed pouch for more than 1 hour should be discarded.
5. Close the kit box and secure its contents when not in use.

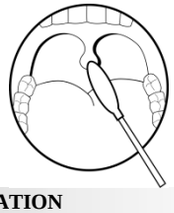
KIT COMPONENTS

Materials provide
1. 25 Test cassettes
2. 25 Sterile swabs
3. 25 Extraction tubes with buffer and tips
4. 25 Droppers/Capillary tubes
5. 1 Buffer
6. 2 Workstations
7. 1 Package insert

Materials required but not provide
Timer For timing use.

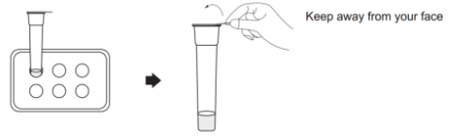
SPECIMEN COLLECTION AND PREPARTION

1. Monkeypox Antigen Rapid Test Cassette can be performed using either whole blood, serum/ plasma or Oropharyngeal swab.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
3. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8℃ for up to 3 days. For long term storage, specimens should be kept below -20℃. Whole blood collected by venipuncture should be stored at 2-8℃ if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
4. For Oropharyngeal swabbing
Deeply insert the sterilized swab into the Oropharyngeal and swab several times to collect the epidermal cells of the mucus. Caution has to be paid to avoid the swab to be contaminated with saliva.

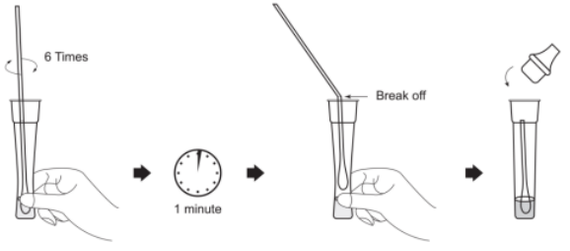


SPECIMEN PREPARATION

1. Insert the test extraction tube into the workstation provided in the kit. Make sure that the tube is standing upright and reaches the bottom of the workstation.
2. Tear off the sealing film on the extraction tube gently to avoid spilling out the liquid.
3. Insert the swab into the extraction tube which contains the extraction buffer (approximately 0.3 mL).

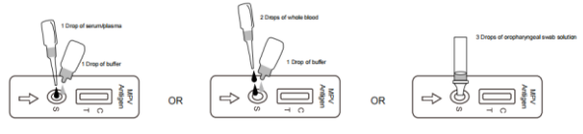


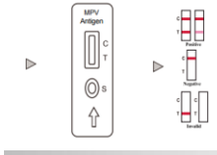
4. Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.
5. Leave the swab in the extraction tube for 1 minute.
6. Insert the swab into the tube until the breakpoint is level with the tube opening. Bend the swab shaft at a 180 degrees angle to break it off at the breaking point
7. Insert the tip into the extraction tube tightly.



DIRECTIONS FOR USE

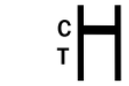
Allow the test cassette, extraction reagent to equilibrate to room temperature (15-30℃) prior to testing.
1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface.
For Serum or Plasma Specimens:
Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 30 µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
For Whole Blood Specimen:
Hold the dropper vertically and transfer 2 drops of whole blood (approximately 60µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
For Oropharyngeal Swab Specimen:
Hold the extraction tube vertically and add 3 drops (approximately 80 µL) of test sample solution tube into the sample well.
3.Start the timer.
4. Read the results at 15 minutes. Do not interpret the result after 20 minutes.





INTERPRET ATION OF RESULTS

NEGATIVE RESULT:

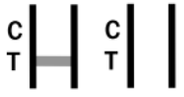


One colored line appears in the control line region (C). No line appears in the test region(T). A negative result indicates that Monkeypox antigen is not present in the specimen, or is present below the detectable level of the test.

POSITIVE RESULT:

Two lines appear.one colored line should be in the control region (C) and another apparent colored line should be in the test region (T). A positive result indicates that Monkeypox was detected in the specimen.

INVALID RESULT:



Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE:

The intensity of the color in test line region (T) will vary depending on the concentration of Monkeypox Antigen present in the specimen. Therefore, any shade of color in the test line region(T) should be considered positive.

QUALITY CONTROL

- A procedural control is included in the test. A colored line appearing in the control region(C) is considered an internal procedural control. It confirms adequate membrane winking.
- Control standards are supplied with this kit. 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 OF THE TEST

1. Use fresh samples whenever possible. Frozen and thawed samples (especially repeatedly) contain particles that can block the membrane. This slows the flow of reagents and can lead to high background color, making the interpretation of results difficult.
2. Optimal assay performance requires strict adherence to the assay procedure described in this insert sheet. Deviations may lead to aberrant results.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time rule out the presence of Monkeypox virus antigens in specimen, as they may be present below the minimum detection level of the test or if the sample was collected or transported improperly.
4. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
5. Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made.
6. If symptoms persist and the result from the Monkeypox Antigen Rapid Test is negative, it is recommended to re-sample the patient a few days later or test with an alternative test device
7. Results from antigen testing should not be used as the sole basis to diagnose or exclude Monkeypox infection. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of three specimens: one negative, one low titer positive and one high titer positive. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 5 independent assays four times: 6 negative, 1 low titer positive and 3 high titer positive. Three different lots of Monkeypox Antigen Rapid Test have been tested using these specimens. The specimens were correctly identified >99% of the time.

Interfering Substances

Low titer Monkeypox antibody positive serum samples and Monkeypox antibody negative serum samples were spiked
with one of the following substances to specified concentrations and tested in multiple replicates. No false positivity or false negativity was found with the following:

Interfering substance	Cone.
Ascorbic Acid	20mg/dL
Hemoglobin	1000mg/dL
Bilirubin	10mg/dL
Albumin	2000mg/dL
Triglyceride	500mg/dL

IBIBLIOGRAPHY

1. Responding to an Outbreak of Monkeypox Using the One Health Approach — Nigeria, 2017–2018
2. Emergence of Monkeypox — West and Central Africa, 1970–2017.
3. The detection of monkeypox in humans in the Western Hemisphere.
4.Evaluation of human-to-human transmission of monkeypox from infected patients to health care workers.

Index of Symbols

	Consult Instruction for use	Σ	Tests per kit		Do not use if package is damaged
IVD	For in vitro diagnostic use only		Use by date		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalogue number
	Keep away from sunlight		Keep dry		Manufacturer
	Caution		Date of manufacture	EC REP	Authorized Representative

Hangzhou Sejoy Electronics & Instruments Co.,Ltd.
Area C, Building 2, No.365, Wuzhou Road,Yuhang Economic Development Zone,311100 Hangzhou City,Zhejiang,China
Tel: +86-0571-81957782
Fax: +86-571-81957750
email - poct@sejoy.com

EC REP

CMC Medical Devices & Drugs S.L
C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054
Fax: +34952330100
email - info@cmcmedicaldevices.com

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