Monkeypox Virus Antibody Rapid Test (Whole Blood/Serum/Plasma) Package Insert

CE IVD

REF IMXB-402	English

A rapid test for the qualitative detection of antibodies to Monkeypox Virus in human whole blood, serum or plasma.

For professional in vitro diagnostic use only.

【INTENDED USE】

The Monkeypox Virus Antibody Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies to Monkeypox Virus in whole blood, serum or plasma to aid in the diagnosis of Monkeypox Virus infection.

【SUMMARY】

Monkeypox is a zoonotic orthopoxvirus that incidentally causes disease in humans similar to smallpox, although with notably lower mortality. This virus is clinically relevant because it is endemic to western and central Africa, with outbreaks in the Western Hemisphere related to the exotic pet trade and international travel.

Transmission can occur through contact with bodily fluids, skin lesions, or respiratory droplets of infected animals directly or indirectly via contaminated fomites. Although human-to-human transmission has previously been limited, mathematical modeling in the context of decreasing herd immunity to orthopoxviruses reflects an increasing threat of disease spread between humans. The Centers for Disease Control and Prevention (CDC) recommends isolation in a negative pressure room and standard, contact, and droplet precautions in the healthcare setting with escalation to airborne precautions if possible.

Following viral entry from any route (oropharynx, nasopharynx, or intradermal), the monkeypox virus replicates at the inoculation site then spreads to local lymph nodes. Next, an initial viremia leads to viral spread and seeding of other organs. This represents the incubation period and typically lasts 7 to 14 days with an upper limit of 21 days.[1]

【PRINCIPLE】

The Monkeypox Virus Antibody Rapid Test (Whole Blood/Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of antibodies to Monkeypox Virus in whole blood, serum or plasma specimens. In this test, mouse anti-human IgG and mouse anti-human IgM are coated in the test line regions of the test respectively. During testing, the antibodies to monkeypox virus in whole blood, serum or plasma specimen reacts with Monkeypox Virus recombinant protein coated particles in the test strip, then the antibody-antigen complex will be captured with mouse anti-human IgG and/or mouse anti-human IgM in the membrane when migration. The presence of a colored line in the test line region indicates a positive result for Monkeypox Virus infection, while its absence indicates a negative result for that infection.

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

【REAGENTS】

The test contain mouse anti-human IgG, mouse anti-human IgM as the capture reagent, and monkeypox virus recombinant protein as the detection reagent. A goat anti-mouse IgG and mouse IgG are employed in the control line system.

【PRECAUTIONS】

1. For *in vitro diagnostic* use only. Do not use after the expiration date.
2. Do not smoke, drink, or eat in areas where specimens or kits reagents are handled.
3. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
4. Humidity and temperature can adversely affect results.
5. The used test should be discarded according to local regulations.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The Monkeypox Virus Antibody Rapid Test (Whole Blood/Serum/Plasma) can be performed using whole blood.
- Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.
- To collect **Fingerstick Whole Blood specimens:**
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using **a Dropper.**
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 3 days of collection.
- For long term storage, specimens should be kept below -20°C. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly for more than three times.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.
- EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as the anticoagulant tube for collecting the blood specimen.

【MATERIALS 】

Materials provided

- Test cassettes
- Droppers
- Package insert
- Buffer

Materials required but not provided

- Specimen collection containers
- Centrifuge
- Timer
- Lancet
- Alcohol pad

【DIRECTIONS FOR USE】

Allow the test, specimen and buffer to reach room temperature (15-30°C) prior to testing.

1. Remove the test from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Place the test on a clean and level surface.
3. Add Specimen and Buffer to the test cassette and read results according to illustrations below.

Note: The specimen and buffer only can be added into the specific well with "S" remark. Do not use the buffer beyond 6 months after opening the vial.

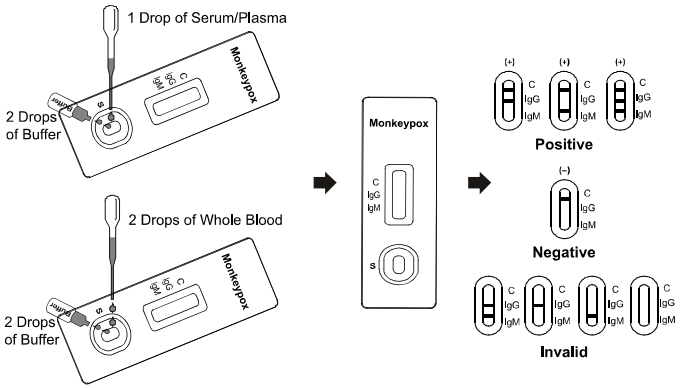
For Serum or Plasma specimen:

- Use a dropper: Hold the dropper vertically and **transfer 1 full drop of serum or plasma** (approximately **10 µL**) to the specimen well(S), then **add 2 drops of buffer** (approximately 80 µL), and start the timer.
- To use a pipette: To **transfer 10 µL of serum or plasma** to the specimen well(S), then **add 2 drops of buffer** (approximately 80 µL), and start the timer.

For Venipuncture Whole Blood specimen or Fingerstick Whole Blood specimens:

- Use a dropper: Hold the dropper vertically, **transfer 2 full drops of whole blood** (approximately 20 µL) to the specimen well(S), then **add 2 drops of buffer** (approximately 80 µL), and start the timer.
- Use a pipette: To **transfer 20 µL of whole blood** to the specimen well(S), then **add 2 drops of buffer** (approximately 80 µL), and start the timer.

4. Wait for the colored line(s) to appear. **Read results at 10 minutes**. Do not interpret the result after 20 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two colored lines or three lines appear. One colored line should always appear in the control line region (C) and another one or two colored line(s) should be in the test line region (IgG/IgM).

***NOTE:** The intensity of the color in the test line regions may vary depending on the concentration of Monkeypox Virus antibodies present in the specimen. Therefore, any shade of color in the test line region (IgG/IgM) should be considered positive.

NEGATIVE: **One colored line appears in the control line region (C)**. No colored line appears in the test line regions.

INVALID: **Control line fails to appear**. Insufficient specimen volume or incorrect procedural techniques are the 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.

【QUALITY CONTROL】

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

External Controls 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 Monkeypox Virus Antibody Rapid Test (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for detection of antibodies to Monkeypox Virus in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of antibodies to Monkeypox Virus can be determined by this qualitative test.
2. The Monkeypox Virus Antibody Rapid Test (Whole Blood/Serum/Plasma) will only indicate the presence of antibodies to Monkeypox Virus in the specimen and should not be used as the sole criteria for the diagnosis of Monkeypox Virus infections.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Monkeypox Virus infection.
5. The hematocrit of the whole blood should be between 25% and 65%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The Monkeypox Virus Antibody Rapid Test (Whole Blood/Serum/Plasma) was compared with Monkeypox Virus PCR kit. The results were tabulated as below.

Method			PCR		Total Results
	Results		Positive	Negative	
Monkeypox Virus Antibody Rapid Test (Whole Blood/Serum/Plasma)	Positive	IgM	1	2	11
		IgG+IgM	5		
		IgG	3		
	IgG+IgM Negative		1	198	199
	Total Results		10	200	210

Relative Sensitivity: 90.0% (95%CI*: 55.5%-99.75%)
Relative Specificity: 99.0% (95%CI*: 96.43%-99.88%)
Accuracy: 98.57% (95%CI*: 95.88%-99.70%)
*Confidence Interval

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of two specimens: a negative and a IgG/IgM Duo positive. The negative and IgG/IgM Duo positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same two specimens: a negative and a IgG/IgM Duo positive. Three different lots of the Monkeypox Virus Antibody Rapid Test (Whole Blood/Serum/Plasma) have been tested over a 3-days period using a negative and a IgG/IgM Duo positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The Monkeypox Virus Antibody Rapid Test (Whole Blood/Serum/Plasma) has been tested for anti-HAV IgG, HBsAg, HBsAb, anti-HCV, anti-HIV, anti-RF, HAMA, anti-Syphilis TP, anti-*H. pylori,* anti-Toxoplasma IgG, anti-Toxoplasma IgM, anti-Rubella IgG, anti-Rubella IgM, anti-CMV IgG, anti-CMV IgM, anti-SARS-CoV-2 positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have also been tested using the Monkeypox Virus Antibody Rapid Test (Whole Blood/Serum/Plasma) and no interference was observed.

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL	EDTA: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL	Ethanol: 10%
Ascorbic Acid: 2 g/dL	Phenylpropanolamine: 20 mg/dL	Glucose: 20 mg/dL
Bilirubin: 1000 mg/dL	Salicylic Acid: 20 mg/dL	Phenothiazine: 20 mg/dL

【BIBLIOGRAPHY】

1. Moore M, Zahra F. Monkeypox. 2022 May 22. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan–. PMID: 34662033.

Index of symbols

	Caution		Tests per kit		Do not reuse
IVD	For *in vitro* diagnostic use only		Use by	REF	Catalog #
	Store between 2-30°C	LOT	Lot number		Consult instructions for use
	Do not use if package is damaged		Manufacturer	EC REP	Authorized representative in EU

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