# Monkeypox Virus IgM/IgG Rapid Test Package Insert

## PRINCIPLE AND INTENDED USE

VivaDiag™ Monkeypox Virus IgM/IgG Rapid Test is for the rapid, qualitative detection of the Monkeypox antibodies in human whole blood (from venipuncture or fingerstick), serum or plasma.. The test is for in vitro diagnostic use only. For professional use only. It is intended for clinical laboratories and healthcare professional use only for point-of-care testing. Not for at-home testing.

VivaDiag™ Monkeypox Virus IgM/IgG Rapid Test is based on immunochromatography technology. Each test device has 3 pre-coated lines, "IgG" (IgG Test Line), "IgM" (IgM Test Line) and "C" (Control Line) on the surface of the membrane. When extracted specimen is added to the specimen well, it will react with the labeled antibody to form a complex, the mixture then migrates through the membrane by capillary action and interacts with the coated antibody on the line. A purple "IgG" and "IgM" lines will be visible in the result window if there are enough IgG and/or IgM antibodies to monkeypox in the sample. If IgG and/or IgM antibodies to monkeypox are not present in the sample, there is no color appearance in "IgG" and/or "IgM". The test device also contains a quality control line C which should appear red for all valid tests. If the quality control line C does not appear, the test result will be invalid even if the detection line appears.

## COMPOSITION

Each test kit contains test device, buffer, pipette and package insert..
*Materials required but may not be provided: alcohol pad or timer.*

## STORAGE AND HANDLING

- Store the test kit in a cool, dry place between 2-30°C. Keep away from light. Exposure to temperature and/or humidity outside the specified conditions may cause inaccurate results.
- Whole blood can be stored at 2-8°C (36-46.4°F) for 3 days; Serum and plasma can be stored at 2-8°C (36-46.4°F) for 7 days and -20°C (-4°F) for 6 months; When stored at -20°C (-4°F), serum and plasma should not be frozen and thawed more than twice times.
- The test device should be used within 60 minutes after removed from foil pouch.
- Do not freeze or refrigerate. Use the test kit at temperatures between 15-30°C.
- Use the test kit between 10-90% humidity.
- Do not use the test kit beyond the expiration date (printed on the foil pouch and box).

***Note:*** *All expiration dates are printed in Year-Month-Day format. 2022-06-18 indicates June18, 2022.*

## WARNINGS, PRECAUTIONS AND LIMITATIONS

- Results from Monkeypox Virus IgM/IgG testing should not be used as the sole basis to diagnose or exclude monkeypox infection or to inform infection status.
- Negative results do not rule out monkeypox infection, particularly in those who have been in contact with the virus.
- For *in vitro* diagnostic use only.
- Not for at-home testing.
- Do not open the foil pouch of the test device exposing it to the ambient environment until the test device is ready for immediate use.
- Do not use any damaged test device or material.
- Do not reuse the test device.
- Handle buffer with caution, do not contact with eyes or skin. If spilled on eyes or skin, wash thoroughly with water.
- Do not use test kit beyond the expiration date.
- Specific training or guidance is recommended if operators are not experienced with specimen collection and handling procedures.
- Only use human whole blood (from venipuncture or fingerstick), serum or plasma as specimen. Follow the package insert to obtain accurate results.
- Wear protective gears such as laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated.
- Wash hands thoroughly after handling.
- All parts of kit are considered biohazardous and can potentially transmit infectious diseases from blood borne pathogens, even after you have performed cleaning and disinfection. Follow proper precautions and all local regulations when disposing of the used test kits.

## SPECIMEN COLLECTION AND HANDLING

**1 Specimen collection**

1) 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.
- Fingerstick whole blood specimens should be used immediately.

2) Collect venous whole blood specimens.
- Collect venous whole blood into vacuum blood collection tube with the anticoagulations of EDTA, Citrate or Heparin.
- If specimens are not immediately tested, they should be refrigerated at 2-8℃ for not more than 3 days.

3) Collect serum or plasma specimens
- Collect venous whole blood into vacuum blood collection tube with serum separation gel to obtain serum.
- Separate the plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected.
- Serum and plasma specimens can be stored at 2-8℃ for 7 days. Serum specimen can be stored at -20℃ for 6 months and can be frozen and thawed twice times.

**2 Specimen handling**

Freshly collected specimens should be tested as soon as possible. It is essential that correct specimen collection and preparation methods are followed.

## TEST PROCEDURE

**Allow the Test Devices and Buffer to equilibrate to 15-30°C prior to testing.**

1. Place a Test Device on a clean and level surface.
2. Hold the pipette slantly and fill the capillary part of the dropper (not to exceed the capillary part) with Serum or Plasma or Whole Blood (approximately 20 µL), then carefully dispense the specimen into the Specimen Well (S).

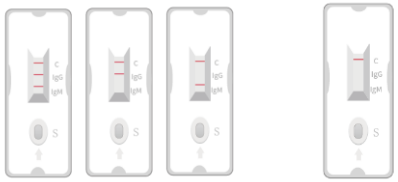

3. Add 2 drops of buffer into the specimen well of a Test Device.
4. Read the test result at 15 minutes. Don't read the result after 20 minutes.

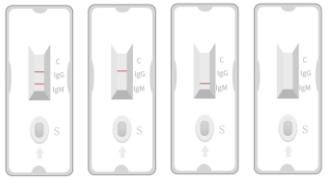
***Note:***

- *Do not interchange or mix buffer from different lots.*
- *Handle buffer with caution, do not contact with eyes or skin. If spilled on eyes or skin, wash thoroughly with water.*
- *Please follow local regulations to handle the used materials.*

## INTERPRETATION OF TEST RESULTS

**1. Negative**
The control line is the only visible line on the test device. No IgG or IgM antibodies were detected.
**2. IgM Positive**
The control line (C) and the IgM line are visible on the test device. This is positive for IgM antibodies to monkeypox virus.
**3. IgG Positive**
The control line (C) and IgG line are visible on the test device. This is positive for IgG antibodies to monkeypox virus.
**4. IgG and IgM Positive**
The control line (C), IgG and IgM lines are all visible on the test device. This is positive for both IgG and IgM antibodies.
**5. Invalid**
Quality control line C fails to appear indicating the test is invalid, no matter if the detection line appears or not. Collect a new specimen and perform another test with a new test





Invalid

## QUALITY CONTROL

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

## INDEX OF SYMBOLS

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| | Consult instructions for use | | Use by | Σ | Contains sufficient for <n> tests |
| IVD | For *in vitro* diagnostic use only | LOT | Lot number | REF | Catalog number |
| 2°C 30°C | Storage temperature limitations | | Manufacturer | | Do not reuse |
| EC REP | Authorized Representative | | | | |

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