CE IVD

FRENOVO

# Monkeypox IgG/IgM Rapid Test Kit

Instructions For Use

## PRODUCT NAME

FRENOVO Monkeypox IgG/IgM Rapid Test Kit

## PACKAGE SPECIFICATION

20 tests/kit

## INTENDED USE

FRENOVO Monkeypox IgG/IgM Rapid Test Kit is an in vitro qualitative immunochromatographic assay for the rapid detection of IgG and IgM antibodies to monkeypox virus in human whole blood, serum or plasma specimens simultaneously. The test results are intended to aid in the diagnosis of monkeypox infection.

## SUMMARY AND PRINCIPLES OF THE PROCEDURE

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.

FRENOVO Monkeypox IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test strip in the cassette device consists of: 1) a colored conjugate pad containing Monkeypox specific recombinant antigen conjugated with colloidal gold and a control antibody conjugated with colloidal gold; 2) a nitrocellulose membrane strip containing two test lines (G and M lines) and a control line (C line). The G line is pre-coated with mouse anti-human IgG for detection of anti-Monkeypox IgG. The M line is pre-coated with mouse anti-human IgM for detection of anti-Monkeypox IgM. The C line is pre-coated with a control antibody.

When specimen and sample diluent are dispensed into the sample and buffer wells, respectively, the specimen migrates by capillary action across the test strip. If anti-Monkeypox IgG is present in the specimen, it will bind to the Monkeypox conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse anti-human IgG forming a colored G line, indicating a Monkeypox IgG positive test result. If anti-Monkeypox IgM is present in the specimen it will bind to the Monkeypox conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse anti-human IgM forming a colored M line, indicating an Monkeypox IgM positive test result. Absence of any test lines (G or M) suggests a negative result. The test contains an internal control (C line) which should exhibit a colored line of the immunocomplex of the control antibodies, regardless of color development on the test lines (G and M). If no control line (C line) develops, the test result is invalid and the specimen must be retested with another device.

## MATERIALS PROVIDED

**Each kit contains:**

1. test cassettes: 20 pieces test cassettes individually pouched.
2. Wash Buffer Solution: 3.0 ml in dropper bottle.
3. Droppers: 20 pieces droppers of 10 ul.
4. Package insert: 1 piece attached.

## MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Specimen collection containers
- Disposable gloves and/or protective clothing
- Centrifuge(for plasma only)
- Micro-pipette
- Lancets (for fingerstick whole blood only)

## WARNINGS

1. Read the package insert completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. The kits for diagnostic use only.
3. Perform test at room temperature.

## PRECAUTIONS

1. FRENOVO Monkeypox IgG/IgM Rapid Test Kit is for professional use only.
2. The package insert instructions must be followed to ensure optimum test performance.
3. The kit is intended for in vitro diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.

### Safety Precautions

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear protective clothing such as lab coat, safety glasses and disposable gloves when handling specimens and assay reagents.
3. Wash hands thoroughly after use.
4. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

### Bio safety Precautions

Appropriate bio safety practices should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

1. Do not smoke,eat,drink,apply cosmetics or handle contact lenses in areas in which specimens are handled.
2. Dispose of all specimens, used devices and tubes as though they are capable of transmitting infection. The preferred methods of disposal are by autoclave at 121°C for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach.
3. When disposing of solution, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
5. Use a separate dropper and device for each specimen tested.

### Handling Precautions

1. Do not use if the kit safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix wash buffer solution/test cassettes from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. The result should be read immediately after the end of the 10 minutes incubation time following the addition of specimen and wash buffer solution. Do not read results beyond 15 minutes.

## STORAGE INSTRUCTIONS

1. The kit should be stored between 2-30°C and the shelf life is 24 months.
2. The kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the wash buffer solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
4. Do not freeze the kit.

## SAMPLE COLLECTION AND PREPARATION

1. Applicable samples: Whole Blood/Serum/Plasma.
2. Separate serum or plasma from whole blood as soon as possible to avoid hemolysis. Use only clear nonhemolysis specimens.
3. Testing should be performed immediately after the specimens have been collected as soon as possible. Do not leave the specimens at room temperature for prolonged periods.
4. Serum and plasma specimens may be stored at 2~8 ℃ for up to 7 days, for long term storage, serum/plasma 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.
5. Do not freeze whole blood specimens.
6. 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.
7. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.
8. EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

## QUALITY CONTROL

An internal procedural control is included in the test. a colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. 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.

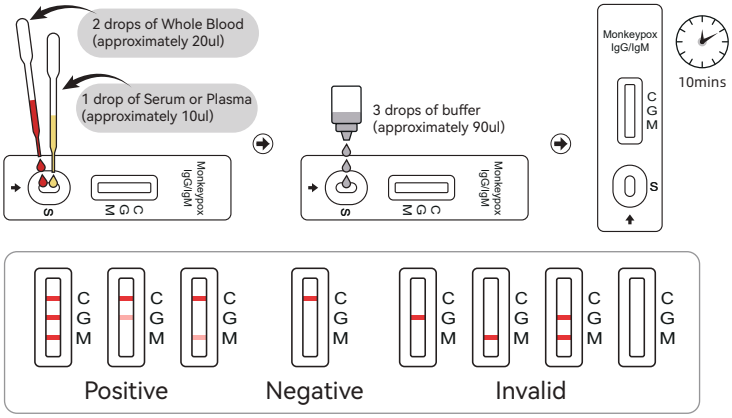
## TEST PROCEDURE

**Allow the test cassette, specimen, buffer solution to equilibrate to room temperature (15-30°C) prior to testing.**

1. Remove the test cassette from the sealed pouch and use it within one hour. Place the test cassette on a clean and level surface.
2. For Serum or Plasma Specimens
   **To use a dropper:** Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (one drop/approximately 10ul), then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.
   **To use a micro-pipette:** Pipette and dispense 10ul of specimen to the sample well of the test

cassette, then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) to the sample well and start the timer.
For Whole Blood Specimens
**To use a dropper:** Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (two drops/approximately 20ul), then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.
**To use a micro-pipette:** Pipette and dispense 20ul of specimen to the sample well of the test cassette, then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) to the sample well and start the timer.

3. Wait for the colored line(s)to appear. The test result should be read at 10 minutes. Do not interpret the result after 15 minutes.




## INTERPRETATION OF RESULTS

**IgG and IgM POSITIVE:** Three lines appear. One colored line should be in the control line region(C), and two colored lines should appear in IgG test line region and IgM test line region. The color intensities of the lines do not have to match.

**IgG POSITIVE:** Two lines appear. One colored line should be in the control line region(C), and a colored line appears in IgG test line region.

**IgM POSITIVE:** Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgM test line region.

**NOTE:** The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of Monkey antibodies in the specimen. Therefore, any shade of color in the IgG and/or IgM test line region(s)should be considered positive.

**NEGATIVE:** One colored line should be in the control line region (C). No line appears in IgG and IgM test line region(s).

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

## LIMITATIONS

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. A negative result for an individual subject indicates absence of detectable anti-Monkeypox antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with Monkeypox, particularly for patients who have been in contact with known infected persons or in areas with high prevalence of active infection. Follow-up testing with a molecular diagnostic test is necessary to rule out infection in these individuals.
4. A negative result can occur if the quantity of the anti-Monkeypox antibodies present in the specimen is below the detection limits of the assay, or the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody utilized in the test, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. False positive results may occur due to cross-reacting antibodies from previous infections, such as other coronaviruses, or from other causes.
7. Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made.
8. If symptoms persist and the result from the Monkeypox IgG/IgM Rapid Test is negative, it is recommended to resample the patient a few days later or test with an alternative test device.
9. Results from antibody 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

**Interference Substances**
The following potential interfering substances have been tested using The kit and no interference was observed:

| Substance | Tested Concentration |
|---|---|
| Ascorbic Acid | 20mg/dL |
| Hemoglobin | 1000mg/dL |
| Bilirubin | 10mg/dL |
| Albumin | 2000mg/dL |
| Triglyceride | 500mg/dL |

**Cross Reaction**
Cross-reactivity of the Monkeypox IgG/IgM Rapid Test was evaluated using serum samples which contain antibodies to the pathogens listed below. No false positivity or false negativity was found with the following:

| | |
|---|---|
| COVID-19 IgG | COVID-19 IgM |
| Influenza A virus IgG | Influenza A virus IgM |
| Influenza B virus IgG | Influenza B virus IgM |
| Respiratory syncytial virus IgG | Respiratory syncytial virus IgM |
| Adenovirus IgG | Adenovirus IgM |
| Rhinovirus IgG | Rhinovirus IgM |
| Human metapneumovirus IgG | Human metapneumovirus IgM |
| Mycoplasma pneumoniae IgG | Mycoplasma pneumoniae IgM |
| Chlamydia pneumoniae IgG | Chlamydia pneumoniae IgM |
| HCV IgG | HCV IgM |
| Haemophilus influenza IgG | Haemophilus influenza IgM |
| HBV core antibody IgG | HBV core antibody IgM |
| Bacterial pneumonia | ANA |

## INDEX OF SYBOML

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|---|---|---|---|
| IVD | In vitro diagnostic medical device | | single-use, Please don't reuse it |
| | Use-by date | | Consult instructions for use |
| | Cautions | | Manufacturer |
| 2°C 30°C | Temperature limit | LOT | Batch code |
| | Date of manufacture | | Keep Dry |
| | Avoid overexposure to the sun | | Don't use the product when the package is damaged |
| | Biological risks | CE | CE mark |

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## INSTRUCTION APPROVAL AND REVISION DATE

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