Monkeypox Virus (MPV) Rapid Test

Catalog Number: AU2031

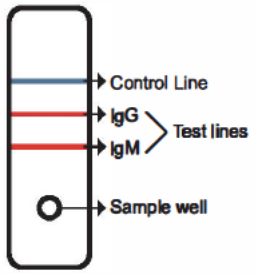
For Research Use Only. Not for use in Diagnostic Procedures.

1. Intended Use

This product is intended for the qualitative detection of Monkeypox Virus antibodies (IgM and IgG). It provides an aid in the determination of Monkeypox Virus exposure. A rapid test for the qualitative detection of Monkeypox Virus (MPV) IgG/IgM in human serum, plasma, or whole blood.

For professional medical institutions use only, not for self-testing.

2. Introduction



Monkeypox virus (MPV) is a rare viral infectious disease similar to human smallpox caused by monkeypox virus, and it is also a zoonotic disease. Mainly found in the tropical rain forests of central and western Africa. The main route of transmission is animal-to-human transmission. People are infected with the disease by being bitten by infected animals or by direct contact with the blood and body fluids of infected animals. The Monkeypox virus is a high fatality rate virus, so the early screening test is very important to control the Monkeypox virus spread.

The test strip in this kit includes two test lines (M and G), and one control line. The M line is coated with anti-human IgM antibody, and the G line is coated with antihuman IgG antibody. When a test sample is loaded into the sample loading hole on the cassette, the sample moves on the strip under capillary effect. If MPV IgM antibody is present in the test sample, it will combine with the MPV conjugate to form an immune complex. The complex will be detected by antibody coated on the M line and visualized as a purple red band. Similarly, if MPV IgG antibody is present in the test sample, it will be visualized as a purple red band at the G line. If neither M line nor G line appears, the antibody test result is negative. As a product quality control, the C line should always appear at the control region indicating that proper volume of specimen has been added and the membrane wicking effect has occurred.

3. Kit Contents

Contents	Quantity
Cassette device (1 device per pouch)	10 devices
Disposable pipette	10 pipettes
Sample Diluent	10 bottles

4. Storage and Stability

- Store the product at temperature 2°C - 30°C or 38°F - 86°F
- Avoid direct exposure to sunlight.
- The kit is stable within 2 years after production. Please refer to the expiration date printed on the label.
- Once an aluminum foil pouch is opened, the test card inside should be used within one hour. Prolonged exposure to hot and humid environment may cause inaccurate results.
- The lot number and the expiration date are printed on the labeling.

5. Required Materials Not Supplied

- Specimen collection container - For specimen collection use
- Timer - For timing use
- Centrifuge - For preparation of clear specimens

6. Precautions

- For Research Use Only (RUO).
- For professional use only.
- Use the test device only once.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.

- Do not use test kit after expiration date.
- Do not mix Sample Collection Tubes from different lots.
- Do not open the Test Cassette foil pouch until you are ready to perform the test.
- Do not spill solution into the reaction zone.
- Do not touch the reaction zone of the device to avoid contamination.
- Avoid cross-contamination of samples by using a new specimen collection container and specimen collection tube for each sample.
- All samples should be treated as if capable of transmitting disease. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Do not use more than the required amount of liquid.
- Bring all reagents to room temperature (15°C - 30°C) before use.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Evaluate the test result after 10 minutes and not beyond 20 minutes.
- Store and transport the test device always at 2°C - 30°C (36°- 86°F).

7. Specimen Collection and Storage

- The Monkeypox Virus IgG/IgM Combo Rapid Test can be performed using whole blood (from venipuncture or finger stick), serum, plasma or cell culture media.
- To collect finger, stick whole blood specimens:
- Wash the hand then allow to dry. Massage the hand without touching the puncture. 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 Finger stick Whole Blood specimen to the test device by using a capillary tube or hanging drops. NOTE: Finger sticks can typically be purchased at local stores that carry glucose meters.
- 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. Serum and plasma specimens may be stored at 2°C -8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Whole

blood collected by venipuncture should be stored at 2°C - 8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.

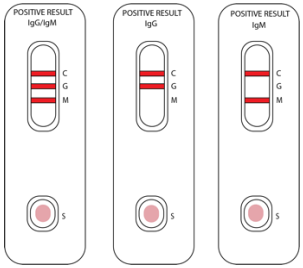
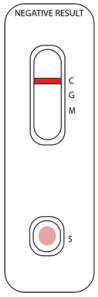
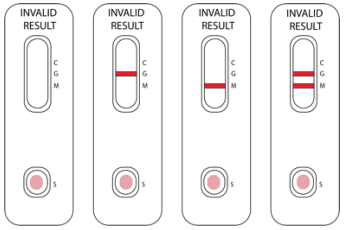
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

8. Procedure

Allow the test device and specimens to restore to room temperature (15°C - 30°C or 59°F - 80°F) prior to testing.

1. Take out a test card from an aluminum foil pouch.
2. Disinfect the patient's fingertip with a piece of 70% alcohol wipe.
3. Open the blood sampling needle. Press the needle firmly on the fingertip until you hear a click sound. Discard the needle properly.
4. Hold the dropper vertically, transfer 1 drop of sample (about 30-35μL) into the antibody loading hole on the test card.
5. Add 3 drops of buffer into the antibody loading hole immediately.
6. Read the result in 15 minutes. The result is considered inaccurate and invalid after 20 minutes.

9. Interpretation of Results

	**IgG and IgM Positive:** Red bands appear in the control area (C) and test area (M or G), corresponding to positive test items. If a red band appears at: G line, IgG antibody positive. M line, IgM antibody positive.
	C line appears while no test line appears (M or G) in 15 minutes after sample loading.
	**Control line (C) fails to appear.** As long as the C line does not appear, it indicates that the test result is invalid, and should retest with another test card. If the problem persists, discontinue using the test kit immediately and contact Attogene at 512-333-1330.

10. Note

The intensity of the color in test regions (G and M) may vary depending on the concentration of IgG/IgM present in the sample. The IgG/IgM level cannot be determined by this qualitative test. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

11. Quality Control

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

2. External controls are not supplied with this kit. 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.

12. Limitations of the Test

1. This product is intended for assisting in the determination of viral infections only. A final clinical diagnosis should also consider factors like symptoms, results of other tests as well.
2. A negative result indicates that the antibody level in tested sample is below the limit of detection of this product. It cannot completely exclude the possibility of viral infection of patient.
3. A positive result indicates that the tested sample has antibody level higher than the limit of detection of this product. However, the color intensity of test line may not correlate with the severity of infection or disease progression of the patient.

13. Notice

1. This product is used for Research Use Only.

2. Must strictly follow the instructions for operation and interpretation of the results.

3. The product is qualitatively tested, and the result cannot be used as a quantitative basis should be tested using reagents within the validity period.

4. The reagent, and device is for one sample, one-time use and cannot be reused.

5. Because the sample titer is different, the red lines of the test line will show different shades of color. The depth of the test line color cannot be used as the basis for determining the antibody titer in the sample.

6. The samples stored at low temperature should be balanced to room temperature and fully mixed before testing.

7. Samples and waste must be treated as a potential source of infection and the desiccant in the foil bag is not edible.

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14. Product Performance

Sensitivity, Specificity, & Total Accuracy

- The product performance was evaluated with clinical specimens, using clinical diagnosis as the standard reference.

IgG	Standard Reference		
	Positive	Negative	Total
Positive	42	1	43
Negative	3	300	303
Total	45	301	346
Relative Sensitivity: 90.91%(95%CI:88.19%-92.63%); Relative Specificity:99.67%(95%CI:99.01%-100%); Overall agreement: 98.55%(95%CI:97.94%-99.17%)			

IgM	Standard Reference		
	Positive	Negative	Total
Positive	40	1	41
Negative	4	300	304
Total	44	301	345
Relative Sensitivity: 90.91%(95%CI:88.19%-92.63%); Relative Specificity:99.67%(95%CI:99.01%-100%);			

Overall agreement: 98.55%(95%CI:97.94%-99.17%)

Interference Test

1. No interference observed with endogenous substances tested below.

Substance	Test Level
Hemoglobin	20 mg/mL
Human serum albumin	20 mg/mL
Triglyceride	40 mg/mL
Oxalic acid	0.5 mg/mL
Bilirubin	0.5 mg/mL
Vitamin C	0.2 mg/mL

2. No interference observed with exogenous substances tested below.

Substance	Test Level
Acetaminophen	0.2 mg/mL
Acetoacetic Acid	0.2 mg/mL
Acetylsalicylic Acid	0.2 mg/mL
Benzoylecgonine	0.1 mg/mL
Caffeine	0.2 mg/mL
EDTA	0.8 mg/mL

Ethanol	1.0%
Gentisic Acid	0.2 mg/mL
β-Hydroxybutyrate	20 mg/mL
Methanol	1.0%
Phenothiazine	0.2 mg/mL
Phenylpropanolamine	0.2 mg/mL
Salicylic Acid	0.2 mg/mL

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