CE IVD

Package insert for Monkeypox Virus Antibody Rapid Test Kit

For professional and in vitro diagnostic use only.

Intended Use

The product is a lateral flow chromatographic immunoassay for the qualitative detection of monkeypox virus antibody in human whole blood, serum or plasma.

Principle

Monkeypox Virus IgM/IgG Ab Test use colloidal gold labeled monkeypox recombinant antigen and chicken IgG,with nitrocellulose membrane fixed with two detection lines (T1 and T2) and a quality control line (C line). T1 line was fixed with chicken anti-human IgM antibody and used to detect monkeypox IgM antibody. The chicken anti-human IgG antibody was fixed on T2 line to detect monkeypox IgG antibody. Sheep anti-chicken IgG antibody was fixed in line C. When adding suitable amount of sample in the sample hole, samples will be along the strip under the capillary action to move forward, if the sample contains monkeypox IgM antibody, monkeypox IgM antibody will first with colloidal gold labeled monkeypox recombinant antigen to form a complex, this complex will be membrane on the chicken anti-human IgM antibody capture , a red strip appears on the detection line T1, Indicating monkeypox IgM antibody positive; If the sample contains monkeypox IgG antibody,monkeypox IgG antibody will first with colloidal gold labeled monkeypox recombinant antigen to form a complex, this complex will be membrane on the chicken anti-human IgG antibody capture , a red strip appears on the detection line T2, Indicating monkeypox IgG antibody positive. Neither T1 nor T2 lines appear, indicating a negative result. Whether or not Monkeypox Virus IgM/IgG antibodies are present in the sample, a red band is formed in the quality control area (C). The color of thequality control area (C) is the standard to determine whether there are enough samples and whether the chromatography process is normal, and it also serves as the internal control standard of the reagent.

Warnings and Precautions

- This cassette is only used for in vitro diagnosis.
- If there are too a few of monkeypox virus antibody, it will cause false negatives.
- The cassette is disposable.
- This cassette is for visual testing. To avoid misjudgment, please do not read it in dim light.
- Used cassettes and specimens should be properly disposed of as medical waste with a risk of biological transmission.

Material

Material Provided

- Individually packed test devices
- Droppers
- Specimens dilution tube with buffer
- Package insert

Material Required but not Provided

- Specimen collection container
- Centrifuge
- Clock, timer or stopwatch
- Disposable latex gloves

Storage and Stability

- 2~30°C dry and stored away from light, valid for 24 months.
- Production date and service life: see label, do not freeze or use after expiry date.
- The cassette should be used within 1 hour after the tear of the aluminum foil bag; If the temperature is higher than 30°C or in high humidity environment, it should be to use immediately.

Specimen Requirement

Consider any materials of human origin as infectious and handle them using standard bio- safety procedures.

Plasma:

1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively, in Vacutainer®) by venipuncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma into a new pre-labeled tube.

Serum:

1. Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2°C-8°C if not tested immediately. Specimens can be stored at 2°C -8°C for up to 5 days. The specimens should be frozen at -20°C for longer storage.
Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.
Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

Blood:

Drops of whole blood can be obtained by either finger tip puncture or venipuncture.

Whole blood specimens should be stored in refrigeration (2°C-8°C), if not tested immediately. The specimens must be tested within 24 hours of collection.

Test Procedure

Strip product inspection

1. Bring the pouched test strip to room temperature (15-30℃) prior to testing. Do not open the pouch until ready to perform the assay.
2. Remove the test strip from the sealed pouch. Lay it on a flat, clean and dry surface.
3. Use the pipette to draw and slowly add 1 drop of whole blood/serum/plasma to the sample pad of the test strip.
4. Hold the buffer bottle vertically and add 2 drops to the sample pad of the test strip. / If using a pipette, change a new one to avoid cross-contamination. Draw and transfer 3-4drops of buffer to the sample pad.
5. Wait for colored lines to appear.Read the results within 15-20 minutes.

DO NOT INTERPRET RESULT AFTER 30 MINUTES.

Cassette product inspection

1.Bring the pouched test cassette to room temperature(15-30℃)prior to testing.Do not open pouch until ready to perform the assay.
2.Remove the test cassette from the sealed pouch.Lay it on a flat,clean and dry surface.
3.Use the pipette to draw and slowly add 1 drop of whole blood/serum/plasma to the sample well.
4.Hold the buffer bottle vertically and add 2 drops to the sample well./If using a pipette,change a new one to avoid cross-contamination.Draw and transfer 3-4 drops of buffer to the sample well.
6. Wait for colored lines to appear.Read the results within 15-20 minutes.

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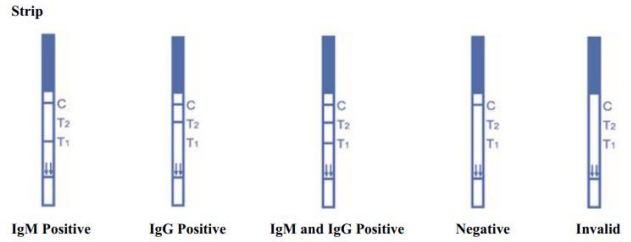
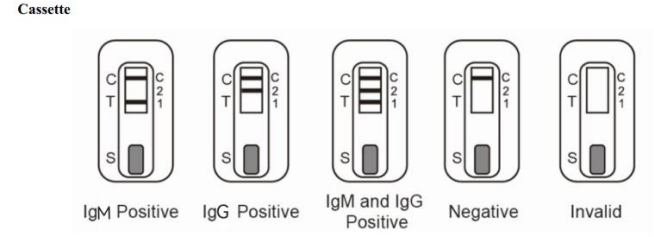
Interpretation of Results



IgM Positive: The control line and lgM line (T1)are visible in the result window. The test is positive for IgM antibodies.
lgG Positive: The control line and lgG line (T2)are visible in the result window. The test is positive for IgG antibodies.
IgM and lgG Positive: The control line, IgM line(T1) and IgG line (T2) lines are visible in the result window. The test is positive for lgM and lgG antibodies.
Negative: The control line is the only line visible in the result window. No lgG or lgM antibodies have been detected.
Invalid: If the control line does not appear in the result window,the test results are INVALID regardless of the presence or absence of the test line.
NOTE: Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for the control line failure. Review the procedure and repeat the test with a new cassette. If problem persists, please contact your local distributor.



IgM Positive: The control line and lgM line (T1)are visible in the result window. The test is positive for IgM antibodies.
lgG Positive: The control line and lgG line (T2)are visible in the result window. The test is positive for IgG antibodies.
IgM and lgG Positive: The control line, IgM line(T1) and IgG line (T2) lines are visible in the result window. The test is positive for lgM and lgG antibodies.
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presence or absence of the test line.
NOTE: Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for the control line failure. Review the procedure and repeat the test with a new cassette. If problem persists, please contact your local distributor.

Quality Control

A procedural control is included in the test. The line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
Control standards are not supplied with this kit. However, 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.

Limitations

1. This test is only used for testing human serum, plasma and whole blood samples. The results of testing with other samples or solutions may be wrong.
2. This test is qualitative and cannot determine the level of Monkeypox Virus IgM/IgG Ab in the sample.
3. This test is suitable for primary screening, and the test results cannot be used as the sole basis for diagnosis of 5 monkeypox virus infection. Confirmation should be combined with a physician's clinical diagnosis or further laboratory tests.
4. Improper sample collection or handling may result in false negative results. The test results are for reference only and shall not be used as the sole basis for clinical diagnosis and treatment. Positive results need to be further confirmed by other methods, which are limited by the detection sensitivity. Negative results may be caused by the concentration of monkeypox virus antibody lower than the sensitivity of the product analysis.

Performance Characteristics

Positive Coincidence Rate

Testing the positive enterprise references, the positive coincidence rate should be 100%.

Negative Coincidence Rate

Testing the negative enterprise references, the negative coincidence rate should be 100%.

Precision

Testing the precision enterprise references and repeat for 10 times (n = 10), the results shall be consistent, and the apparent chromaticity shall be uniform without difference.

INTERPRETATION OF SYMBOLS

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	CE	Requirement on IVD
	Manufacturer		Keep away from sunshine		Keep away from moisture

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