Diagnostic Kit for detection of Anti-Measles Virus (MV) IgM Antibody (Colloidal Gold)

INTENDED USE

The test kit is used to detect qualitatively MV IgM antibody in human serum in vitro.

PRINCIPLE

According to the principle of indirect immunoassay, the test utilizes colloidal gold as a mark tracer and is based on Gold Immunofiltration Assay (GIFA) principle to detect MV IgM in human serum.

MAIN COMPONENTS

Test Device, Colloidal Gold Conjugate, Wash Buffer, Package Insert.

SAMPLE REQUIREMENTS

1.All samples must be centrifuged well immediately prior to using and take the clear serum for detection.

2.The sample to be detected can be placed for 3 days at 2 - 8 ℃, or for 3 months at -20 ℃.

STORAGE AND EXPIRY

1. Store at 2 - 8 ℃, be valid within 10 months.

2. Take protective measures in winter and summer to avoid freeze-thawing or high temperature for a long term.

TEST METHODS

Instruction for Use must be read carefully before taking the test. Allow the required test device to come to room temperature for 30 minutes before use (20 - 30 ℃). Do not open the inner packaging (pouch) until ready.

Test Procedure:

1. Remove the test device from the pouch and place on a clean and level surface.
2. Add 2 drops of Wash Buffer into the test window, waiting for the liquid to wet the membrane.
3. Add 50 μL of serum into the test window, waiting for the liquid to be absorbed completely.
4. Add 2 drops of Wash Buffer into the test window, waiting for the liquid to be absorbed completely.
5. Add 3 drops of Colloidal Gold Conjugate into the test window, waiting for the liquid to be absorbed completely.
6. Add 3 drops of Wash Buffer into the test window, and interpret the result within 3 minutes immediately after the liquid is absorbed adequately.

LIMITATIONS

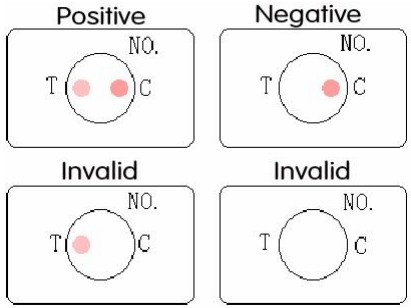
1. The test kit cannot determine the accurate content of MV IgM antibody.
2. This assay is a qualitative screening test reagent. The results are only for clinical reference, which are not the only basis for clinical diagnosis and treatment.

INTERPRETATION OF RESULTS

Negative: Only the quality control area(C) shows a red dot.

Positive: Both the quality control area(C) and the test area (T) show red dots.

Invalid: That a red dot does not present in the quality control area(C) indicates operation faults or reagents invalidation.



ATTENTIONS

1.The test kit should be transported under temperature of 2 - 8 ℃.

2.This reagent is designed for in vitro diagnosis only, please use within the validity period if opened. Different products and different batches of one product can not be cross-used.

3.There must not be time intervals between steps of experiment; The liquid during one step should be added at one time quickly and adsorbed completely.

4. The result observed beyond stated time is invalid.

5. The depth of the dot color in quality control area(C) does not indicate the quality of reagents. Reagents are valid as long as the dot is clear to identify.

6. If the speed of filtration is very slow or even no filtration occurs, please retreat the sample and test again.

7. Serum, including the healthy human serum, is a potential biological hazard substances and the operator should wear gloves; After testing, items where exposure to serum should be disinfected and then discarded.

8. The liquid bottle cover should be tightened immediately after using to avoid contact with air.

9. Severe chylaemia samples may block the hole of the nitrocellulose membrane, it is recommended not to be used. Severe chylaemia samples will result in forming red background and affect result interpretation.