BioAssay+
Making Rapid Tests Smarter
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M. Pneumonia IgM rapid test -cassette form

Early detection of *M. pneumonia* IgM in serum or plasma for *in vitro* diagnostic use

Introduction

Mycoplasma pneumonia is the causative agent of atypical pneumonia and is also responsible for other respiratory tract infections such as tracheobronchitis, croup, and less severe upper respiratory tract infection in older children and young adult. It has been estimated that 10 to 20% of X-ray-proven pneumonia cases that occur in the endemic period and that up to 50% of all cases that occur in the epidemic period are caused by *M. pneumonia*.

Diagnosis of *Mycoplasma pneumonia* infections is complicated by the delayed onset of symptoms due to the similarity of symptoms to other pulmonary conditions. Cold agglutinin test is most often used now for serological diagnosis of *M. pneumonia* infection. But cold agglutinin test can be detected only 50 to 60% cases after 10 days infection, it is not considered a specific index as well, many other infections such as Epstein-Bar, cytomegalovirus, Klebsitella pneumonia, lymphoma, and some autoimmune disease are associated with the increased cold agglutinins, now the cutoff point for diagnosis of *M. pneumonia* infection by cold agglutinin method is 1:40 to 1:60.

Lateral flow immunoassay to test *M. pneumonia* IgM is a new tool to diagnose *M. pneumonia* infection with low cost, short test time and convenience easely accepted by clinical practice.

M. pneumonia IgM is a specific antibody to *M. pneumonia* infection, it forms earlier within 3 to 5 days after the infection, compared to cold agglutinin method, it is a specific diagnostic index with earlier detection and without interference by other diseases. Our current cutoff point to detect *M. pneumonia* IgM is equivalent to 1:80 tested by cold agglutinin method.

Assay principle

Serum or plasma sample is used for the test. After a specimen is loaded to the test device, the specific IgM antibodies to *M. pneumonia* in specimen binds to colloid gold - conjugated anti-human IgM. As *M. pneumonia* IgM-anti-human IgM conjugated gold complex migrates along nitrocellulose membrane, the recombinant *M. pneumonia* antigens coated over membrane captures the immune-complex forming a deep pink band at test line. The intensity of the band is varible depending on the amount of antibody present in the blood sample. A red control line should always develop on the test strip indicating the proper performance.

Kit Components

Each test kit contains:
1. A pouch
2. Pouch contains one casette
3. One 30 ul plastic pipette
4. One 5 ml dropper bottle with assay buffer

Stability and Storage Conditions

Assayplus *M. Pneumonia* IgM test kit is stable at room temperature between 8-28^{o}C for one and half year when in the unopened pouches.

DO NOT FREEZE the kit or expose to temperature extremes.

General Precautions

- The test is for In Vitro Diagnostic Use only.
- Appropriate infection control and handling procedures should be followed – do not smoke, eat or drink in the area where the test is to be performed. Use suitable clothing and gloves when handling samples and when performing the test.
- Do not pipette any samples or reagents by mouth.
- All materials should be considered as potentially infectious. To disinfect, either autoclave materials at 121.5'C for 1 hour or treat with Sodium hyprochlorite (1 percent solution).
- Do not use test beyond the expiration date indicated.

Sample Collection

Serum or plasma is used for this device. The test works best on fresh samples. If testing cannot be done immediately, they should be stored at 2-8^{o}C after collection for up to 3 days. If test cannot be done within 3 days, serum can be stored frozen at –20'C for later use.

Test Procedure

1. Remove test cards from the pouches as needed. Lay on a clean flat surface.

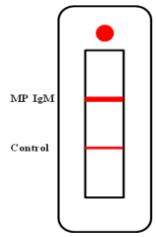
2. Add 25 to 35ul microliter of serum or plasma sample to the well of the test card using an included pipette.

3. Follow sample, add 2 drops assay buffer from the dropper bottle.

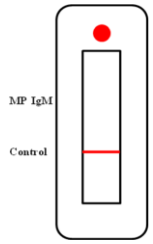
4. Results are then read up to 25 to 30 minutes, make sure negative control line is always positive.

Reading the Test Results

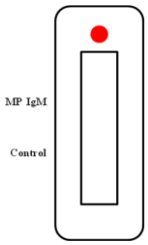
1: *M. Pneumonia* IgM positive



2: *M. Pneumonia* IgM negative



3: Invalid or Indeterminate



Control line should appear always If test line is positive but without control line, It is then recommended that a fresh device be used and the test repeated carefully following the directions in this insert.

Quality Control

A known positive and negative control should be run to insure proper performance. All control tests should be handled in the same manner as patient samples.