M. Pneumoniae IgM Rapid Test

Cat. No.: DTS625
Pkg. Size: 20T

Intended use

A simple and reliable rapid test for the detection of IgM antibodies against Mycoplasma pneumoniae antigen from serum or fingertip blood sample.

General Description

Mycoplasma pneumoniae is the smallest and simplest self-replicating bacteria, which completely lacks a cell wall. This bacterium is a common human pathogen causing asymptomatic, mild or, rarely, severe upper and lower respiratory tract infections. M. pneumoniae infection has been found to account for 15-20% of all cases of pneumonia. The infection with M. pneumoniae is usually endemic, however small epidemic peaks are observed at several years' intervals. M. pneumoniae is weakly contagious affecting mainly children, young adults and immunosuppressed adults.

Principle Of The Test

CD M. pneumoniae IgM test is a rapid immunochromatographic test that detects anti-Mycoplasma pneumoniae IgM antibodies from a blood sample. If the sample contains these antibodies, they will bind with the blue latex labelled antibodies and with the stationary reagent in the test line. The test also contains an integrated control system. A red control line indicates the proper function of the test.

The test requires only one drop (10μl) of blood from the fingertip, and it can be performed and evaluated in 10 minutes. A positive test result with CD M. pneumoniae IgM test is an aid for the diagnosis of acute Mycoplasma pneumoniae infection.

Reagents And Materials Provided

1. 20 Aluminium pouches containing a test cassette
2. 20 automatic lancets for obtaining a blood sample
3. 1 plastic vessel containing 20 pcs of 10 μl glass capillary
4. 20 tubes containing 0.5 ml of sample dilution buffer
5. 20 alcohol swabs
6. 1 package leaflet with instructions for use

Materials Required But Not Supplied

Timer

Storage

Store the test cassettes, buffer and accessories in room temperature at +2°C…+27°C. Avoid freezing.

The self life of the test is 18 months provided that the storage conditions are followed. The date of expiry is indicated on the aluminium pouch of the test device and on the outer carton box.

Specimen Collection And Preparation

CD M. pneumoniae IgM test is intended for use with capillary whole blood samples, but also IV (intravenous) whole blood
samples and serum samples may be used. If using the IV blood samples or serum samples, start the test from phase 6 by adding 10μl of whole blood sample or 5μl of serum sample into the tube containing the buffer. The sample dilution for whole blood samples is 1/50 and for serum samples 1/100.

IV samples should be analyzed within one working day or frozen for later studies. Blood may be collected in EDTA tubes. Diluted samples (capillary or IV) should be used within one working day.

Assay Procedure

All components required for the test should be at room temperature. Before taking the blood sample, prepare all the test components: Automatic lancet, alcohol-soaked swap and glass capillary. Open the tube containing the buffer by removing the cap.

1. Twist off the blue thin protective cap by rotating it ¼ turn and pull it straight out.
2. Gently massage the fingertip and then clean it with the alcohol-soaked swap. Wait until the finger is dry.
3. Press the automatic lancet with the round opening firmly against the cleaned fingertip and press the blue push button to activate the needle. The puncture is practically painless.
4. Press a drop of blood out of the fingertip. Open the plastic vessel and remove with caution the glass capillary. Hold the glass capillary horizontally in the drop of blood until it has completely filled.
5. Place the filled glass capillary in the tube containing buffer and close the tube firmly with the cap. Shake the tube several times until the blood from the capillary is mixed completely with the buffer.
6. Remove the cap of the buffer tube again and remove a few drops of diluted sample with the pipette. Hold the pipette containing the diluted blood sample vertically over the round application field (S) and drop 3 drops onto it. After applying the drops, do not touch and move the test card for 2 minutes.

Note that a positive result can be read as soon as the test and control lines are clearly visible, which takes place in the majority of cases in about 2-3 minutes. If the test result is unsettled or difficult to read after 5 minutes, wait for another 5 minutes and read the result once again.

Interpretation of Results

The test result is positive if a red control line appears in the control field (C) and a light to dark blue line forms in the test field (T). Figure 1.

![Positive Result]

The test result is negative if a red control line appears in the control field and no blue line forms in the test field. Figure 2.
If the control line is not formed, you have likely not followed the instruction for use or the test unit is damaged. In such a case, repeat the testing with a new test unit.

Figure 3.

Interpretation of the results

Positive
The test indicates that there are anti-Mycoplasma pneumoniae IgM antibodies in the blood sample and therefore most probably indicates an acute Mycoplasma pneumoniae infection. In primary acute infection, an IgM response may be detected already in the first serum samples.

Negative
The test indicates that there are no anti-Mycoplasma pneumoniae IgM antibodies in the blood sample. This indicates either that there is no Mycoplasma pneumoniae infection or infection is non-acute.

Sensitivity and Specificity

Sensitivity and specificity of CD M. pneumoniae IgM was studied with 50 clinical samples in correlative evaluation study.

Expected result

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<tr>
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<tbody>
<tr>
<td>CD</td>
<td>26</td>
<td>1</td>
</tr>
<tr>
<td>M. pneumoniae</td>
<td>0</td>
<td>24</td>
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CD M. pneumoniae IgM showed 100 % sensitivity and 96 % specificity against expected results.

Precautions

1. If the instruction for use is not followed in detail, outcome of the test may be false. Do not reuse tests or accessories.
2. General laboratory procedures and precautions shall be followed in the handling and disposal of samples and used materials.
3. Do not use the test if the aluminium pouch is damaged or accessories are broken.
4. Do not use the test after the expiry date.
5. After the aluminium pouch has been opened, the test should be carried out within next 10 minutes.
6. Do not mix reagents or tests from different lots.
7. The sample buffer contains 0.09 % sodium azide. Avoid contact with the skin. Do not swallow!
Limitations

1. If the sample has been obtained too early, IgM-class antibodies may not yet be detectable.
2. In reinfections IgM-class antibodies may be absent.
3. The results should be interpreted in conjunction with the clinical condition and symptoms, epidemiological situation and with further laboratory data.

REFERENCES