

Biocard *Chlamydia Pneumoniae* IgM

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

REF 3-034-000

Carefully read the instructions for use before testing. To perform a Biocard *Chlamydia pneumoniae* IgM test you will also need a timer. Perform the test in a well illuminated place.

PRINCIPLE OF THE TEST

Chlamydia pneumoniae belong to the chlamydiae, which are obligate intracellular bacterium pathogens. The bacteria form intracellular inclusion bodies and replicate within the host cell cytoplasm (1,2).

C. pneumoniae is a primary respiratory pathogen causing 10-20 % of community acquired pneumonia in the lower respiratory track among adults and children, and 10-20 % of acute bronchitis in adults (3,4,5). It also causes sinusitis, primary pharyngitis, and there is evidence associating *C. pneumoniae* infection with the onset of asthma (6,7). Furthermore, *C. pneumoniae* infections are linked to the development of atherosclerosis (8,9,10).

Most of the diagnosis of *C. pneumoniae* is done serologically and modified microimmunofluorescence (MIF) methods are commonly used (2,11). Other methods used are e.g. Enzyme immunoassays (EIA) and PCR methods (2). All of these methods require trained personnel and a skilled interpreter.

Biocard™ *Chlamydia pneumoniae* IgM test is a rapid immunochromatographic test that detects anti-*Chlamydia pneumoniae* IgM antibodies from a blood sample. If the sample contains these antibodies, they will bind with the gold labelled antibodies and with the stationary reagent in the test line. The test also contains an integrated control system and a red control line indicates the proper function of the test.

The test requires only one drop (10 µl) of blood from the fingertip, and it can be performed and evaluated in 5 to 10 minutes. A positive test result with Biocard™ *Chlamydia pneumoniae* IgM stick test is an aid for the diagnosis of acute *Chlamydia pneumoniae* infection.

CONTENTS

3-034-000:

- 10 Aluminium pouches containing a test cassette
- 10 automatic lancets for obtaining a blood sample
- 1 plastic vessel containing 10 pcs of 10 µl glass capillary
- 10 tubes containing 1.2 ml of sample dilution buffer
- 10 alcohol swabs
- 1 package leaflet with instructions for use

SAMPLES

Biocard *Chlamydia 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 10 µl of whole blood sample or 5 µl of serum sample into the tube containing the buffer. The sample dilution for whole blood samples is 1/120 and for serum samples 1/240.

IV samples should be analyzed within one working day or frozen for later studies. Blood may be collected

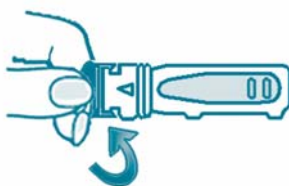
in EDTA tubes. Diluted samples (capillary or IV) should be used within one working day.

TEST PROCEDURE

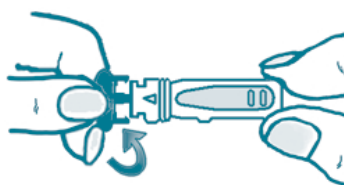
All components required for the test should be at room temperature.

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 grey cap by rotating it until it bounces up.



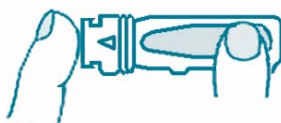
2. After that rotate it for at least 2 full turns.



2X

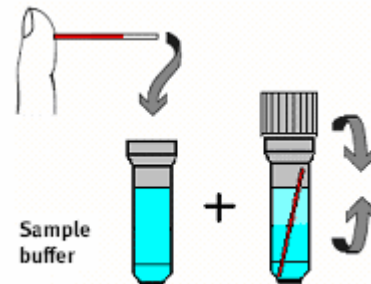
3. Gently massage the fingertip and then clean it with the alcohol-soaked swap. Wait until the finger is dry.

4. Press the automatic lancet with the round opening firmly against the cleaned fingertip and activate with the button. The puncture is practically painless.



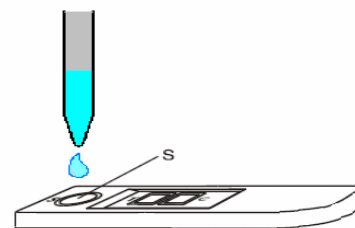
5. Press a drop of blood out of the fingertip. Open the plastic vessel and remove with caution one glass capillary. Hold the glass capillary horizontally in the drop of blood until it has completely filled.

6. 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 completely mixed with the buffer.



7. Open the cap and place the tube on the rack in the test kit package.

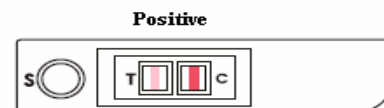
8. Remove a few drops of diluted sample with the pipette. Hold the pipette containing the diluted blood sample vertically over the round application field (S) and drop 3 drops onto it. After applying the drops, do not touch or move the test card for 2 minutes.



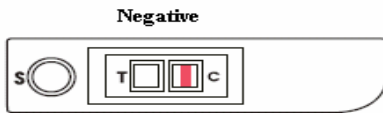
Note that a positive result can be read as soon as the test and control lines are clearly visible, which takes place in the majority of cases in about 5 minutes. If the test result is unsettled or difficult to read after 5 minutes, wait for another 5 minutes and read the result once again. Do not read the test after more than 15 minutes.

INTERPRETATION OF THE RESULTS

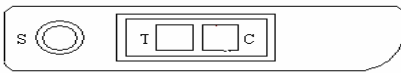
The test result is **positive** if a red control line appears in the control field (C) and a light to dark red line forms in the test field (T).



The test result is **negative** if a red control line appears in the control field and no red line forms in the test field.



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.



Interpretation of the results

Positive

The test indicates that there are anti-*Chlamydia pneumoniae* IgM antibodies in the blood sample and therefore most probably indicates an acute *Chlamydia 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-*Chlamydia pneumoniae* IgM antibodies in the blood sample. This indicates either that there is no *Chlamydia pneumoniae* infection or infection is non-acute. A negative result may be obtained also with stable or decreasing anti-*Chlamydia pneumoniae* IgG and/or IgA antibodies indicating past infection, recent infection, cured condition, or persistent infection.

LIMITATIONS OF THE PROCEDURE

- If the sample has been obtained too early, IgM-class antibodies may not yet be detectable (11,12).
- In reinfections IgM-class antibodies may be absent (11,12).
- In some rare occasions, "tail" IgM-class antibodies may be detectable in asymptomatic subjects and may persist as long as 3 years (13)
- The results should be interpreted in conjunction with the clinical condition and symptoms, epidemiological situation and with further laboratory data.

PRECAUTIONS OF THE PROCEDURE

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

STORAGE

Store the test sticks, 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.

SENSITIVITY AND SPECIFICITY

Sensitivity of Biocard™ *Chlamydia pneumoniae* IgM Test was studied with 42 clinical samples and the results were compared to Ani Labsystems MIFA test results.

	MIFA	
	+	-
Biocard™	+ 28	4
	- 0	10

Biocard™ *Chlamydia pneumoniae* IgM Test showed 100% sensitivity and 87,5% specificity.

Test has also been found to be negative with following serum samples:

Chlamydia trachomatis IgM
Chlamydia trachomatis IgG
Chlamydia trachomatis IgA
Bordetella pertussis IgM
 Eppstein-Barr virus IgM
 Cytomegalovirus IgM
Mycoplasma pneumoniae IgM
 Herpes simplex virus IgM
 Rubella IgM
Toxoplasma gondii IgM

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