A significant increase of IgG concentration of two consecutive withdrawals allows the diagnosis of current or recent infection. The LIAISON® Mycoplasma pneumoniae IgG & IgM assays are the first fully automated solution for Mycoplasmal pneumonia antibody detection, and use chemiluminescence immunoassay (CLIA) technology for the semi-quantitative (IgG) and qualitative (IgM) determination of specific IgG antibodies to Mycoplasma pneumoniae in human serum or plasma samples. The interpretation of results are based on the combination of IgG and IgM antibody detection (Table 1).

### CLINICAL DIAGNOSTICS

**Mycoplasmas** are the smallest self-replicating organisms that are capable of cell-free existence (Figure 1). Due to the lack of a cell wall, mycoplasmas do not respond to penicillins and other beta-lactams used for the treatment of bacterial pneumonia and can be considered an elusive pathogen. Infection occurs worldwide, being endemic in most areas and cyclic epidemics of the virus are observed every 3 - 7 years, usually in the early autumn. The infection has an insidious onset with malaise, myalgia, sore throat or headache and increasing chest symptoms by one to five days. Children aged 2 - 12 are infected more often than adults and infection sequelae are also influenced by age. As clinical findings are often insufficient to distinguish between Mycoplasma pneumoniae and pneumonia caused by other pathogens, correct etiologic determination depends on differential laboratory diagnosis. Culture is 100% specific but is time-consuming and relative intensive and complement fixation test does not rule out acute infection. When it does occur, the IgM response may persist for months. However, the presence of IgM is considered most significant in paediatric populations, where there have been fewer opportunities for repeated exposures. Adults who have been infected repeatedly over a period of years may not respond to mycoplasmal antigens with a brisk IgM response. In approximately two weeks before IgG antibody.

**Figure 1**

### SEROLOGY

Following initial infection, the normal immune system responds by rapidly producing antibodies that peak after three to six weeks, followed by gradual decline over months to years. As a result of the long incubation period, antibody response is often evident by the time symptoms appear. Increased Mycoplasma pneumoniae-specific IgM levels alone can often be interpreted as evidence of acute infection, since this antibody typically appears within one week of the initial infection and approximately two weeks before IgG antibody. However, the presence of IgM is considered most significant in paediatric populations, where there have been fewer opportunities for repeated exposures. Adults who have been infected repeatedly over a period of years may not respond to mycoplasmal antigens with a brisk IgM response. In these cases, reinfection leads directly to IgG response; therefore, the presence of a negative IgM over a period of years may not respond to mycoplasmal antigens with a strong IgM response. The interpretation of results are based on the combination of IgG and IgM antibody detection (Table 1).

### INTERPRETATION OF RESULTS

<table>
<thead>
<tr>
<th>IgG</th>
<th>IgM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>Negative or Positive</td>
<td>Negative or Positive</td>
</tr>
<tr>
<td>Positive</td>
<td>Positive</td>
</tr>
</tbody>
</table>

**Table 1**

The unique practical and technological advantages of the LIAISON® system have been combined to incorporate the best available choices of reagents and antigens. The LIAISON® Mycoplasma pneumoniae IgG uses a recombinant antigen against the 170- kDa p1 adhesion protein of Mycoplasma pneumoniae (Figure 3). The LIAISON® Mycoplasma pneumoniae IgM, in addition to the P1 antigen, incorporates the whole-cell lysate (Figure 4).

### METHODS AND RESULTS

A study was performed on 465 specimens (IgG) and 445 specimens (IgM) belonging to a population with signs and symptoms of atypical pneumonia, collected in different laboratories. The specimens were also tested by a reference ELISA method and consensus with additional serological data was applied to define the expected results for discrepant specimens (Table 3).

### PAIRED SERA

In addition, 49 paired samples were tested, collected at least two weeks apart from patients with recent Mycoplasma pneumoniae infection. Specimens were classified using LIAISON® Mycoplasma pneumoniae IgG and a commercially available ELA method for detection of Mycoplasma pneumoniae IgG. Diagnostic concordance on paired samples was 95.9% (47/49) - 95% confidence interval: 86.0-99.5%.

- • 14 / 49 paired samples (28.6%) concordantly graded as negative
- • 18 / 49 paired samples (36.7%) concordantly graded as current infection (range of LIAISON IgG titer ratios: from 3.3 to 210, MEHANN: 33)
- • 7 / 49 paired samples (14.3%) concordantly graded as past infection
- • 2 / 49 paired samples (4.1%) discordantly graded past infection or negative

Both assays classified the result as no current infection.

### CONCLUSION

We have developed the first fully automated solution for Mycoplasma pneumoniae antibody detection with specificity and sensitivity comparable to assays currently available on the market, for a new flexible approach to Mycoplasma pneumoniae diagnosis.