Evaluation of Liaison *M. pneumoniae* IgM and IgG assay on CAP/LRTI patients

P1753

K. Loens*, H. Goossens, M. Ieven
University of Antwerp, Antwerp, Belgium

OBJECTIVES

Serological diagnosis of *M. pneumoniae* infection is mostly based on microtiter based enzyme immune assays (EIA) with variable performances. A new automated chemiluminescent immunoassay (CLIA) for *M. pneumoniae* IgG and IgM detection was developed for the LIAISON random access analyser by DiaSorin (Saluggia, Italy). The aim of this study was to evaluate the performance of this assay in sera from patients with CAP/LRTI, some of these with proven *M. pneumoniae* infection.

MATERIALS & METHODS

72 paired sera from 36 patients with CAP/LRTI and 14 single sera from 14 patients with CAP/LRTI were available. All sera were previously analysed by 4 different IgM and IgG assays. PCR and NASBA were applied to the respiratory specimens of the same patient. The DiaSorin Liaison MP IgM and IgG tests were performed according to the instructions of the manufacturer. To calculate the sensitivity and specificity of the new test an Expanded Gold Standard (EGS) was used: a sample was considered positive if 1) positive by PCR and NASBA or 2) positive by 1 amplification test and at least one serological test (either IgM or a seroconversion or significant rise of IgG antibodies), or 3) a significant rise of IgG antibodies in at least two different EIA's.

Correspondence:
Katherine Loens
Katherine.loens@uza.be
University Hospital Antwerp, Wilrijkstraat 10, B-2650 Edegem, Belgium

RESULTS

- Based on the EGS, 31 patients were positive for *M. pneumoniae*.
- The sensitivity of the *M. pneumoniae* CLIA IgM assay was 16.1% and 37.5% in the acute and convalescent sera, respectively (Table 1 and 2).
- The sensitivity of IgG significant rise in titre was 77.3% (Table 3).
- A 100% specificity was obtained for IgM in both the acute and convalescent phase serum, whereas it was 94.0% for an IgG significant rise in titre.
- 4/17 (23.5%) and 9/17 (52.9%) patients with a significant rise in the CLIA IgG were also positive for IgM in the acute and convalescent phase serum, respectively.
- Only 5/29 (17.2%) of NAAT-positive patients were also IgM positive in the acute phase, whereas no IgM positives were NAAT negative.
- All NAAT positive patients were also positive by a significant rise in IgG.

Table 1. IgM acute phase sera

	EGS+	EGS-	
IgM+	5	0	5
IgM-	26	53	79
	31	53	84

- Sensitivity: 16,1%
- Specificity: 100%

CONCLUSIONS

- The performance of the kits Liaison IgG and IgM are comparable to other EIAs, while showing lower sensitivity in the early stages of LRTI infection compared to the NAATs.
- Therefore serology and NAAT together can ensure the detection of most cases of *M. pneumoniae*.
- According to the evaluation, the Liaison *M. pneumoniae* IgM and IgG assays appear to be a valid alternative for the detection of antibodies to *M. pneumoniae* on a fully automated, random access instrument system.

Table 2. IgM convalescent phase sera

	EGS+	EGS-	
IgM+	9	0	9
IgM-	15	50	65
	24	50	74

- Sensitivity: 37.5%
- Specificity: 100%

Table 3. IgG seroconversion/significant rise

	EGS+	EGS-	
IgG+	17	3	20
IgG-	5	47	52
	22	50	72

- Sensitivity: 77.3%
- Specificity: 94.0%