SeroMP™ Recombinant

NEW SeroMP™ Recombinant ELISA kit for improved identification of pneumoniae infections

The SeroMP™ Recombinant kit is Savyon Diagnostics new assay for the semi-quantitative determination of antibodies to M. pneumoniae recombinant antigens in the IgG and IgA ELISA and a mixture of recombinant and native antigen in the IgM ELISA.
The kit is semi quantitative utilizing three ready to use calibrators.

Current Diagnosis

Mycoplasma pneumoniae culture is successful in as few as forty percent of cases, requires two to three weeks to grow and requires sampling of respiratory secretions. PCR does not distinguish carriers from acute infection, since the organism can be excreted from the respiratory tract for several weeks after the acute infection. Therefore, routine laboratory methods for diagnosis of Mycoplasma pneumoniae infection are based primarily on serology. Some ELISA tests offer high sensitivity but poor specificity due to high positives rate. Current identification of the pathogen enables physicians to choose the most effective course of treatment efficiently. In addition, excessive, unnecessary antibiotic treatment is expensive and contributes to the emergence of drug resistant bacteria. Therefore improved discrimination between positive and negative results in both sick and healthy populations is vital.

Why a recombinant ELISA?

The SeroMP™ Recombinant presents improved performance parameters in different aspects, which bring to a net result of increasing the difference between sick and healthy populations and between positive and negative results. The assay has reduced dependence upon growing bacteria, therefore reducing variation between batches of ELISA that may derive from this reason. The kit enables a differential determination of specific IgG, IgA and IgM antibodies, as well as the possibility to adapt the assay for automation.

The added value of using recombinant antigen:

- Specificity increased due to substantial reduction of prevalence in healthy population
- Borderline results are clarified to either positive or negative values
- Sensitivity is maintained or increased in parallel with increasing specificity

Ordering information

Kit name	No. Tests/Kit	Catalog No.
SeroMP™ Recombinant IgG	96 Tests	A1261-01M
SeroMP™ Recombinant IgG	192 Tests	B1261-01M
SeroMP™ Recombinant IgM	96 Tests	A1262-01M
SeroMP™ Recombinant IgM	192 Tests	B1262-01M
SeroMP™ Recombinant IgA	96 Tests	A1263-01M
SeroMP™ Recombinant IgA	192 Tests	B1263-01M

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Savyon's SeroMP™ Recombinant represents a new generation of tests

The effect of recombinant based - compared to native based- antigen in IgG, IgA and IgM in pneumonia patients *

	Group	Native Antigen %	Recombinant Antigen %
IgG N=91	Positive	35	45
	Border line	12	0
	Negative	53	55
IgA N=91	Positive	44	58
	Border line	16	0
	Negative	40	42
IgM N=91	Positive	63	65
	Border line	2	2
	Negative	35	33

The effect of recombinant based- compared to native based- antigen in IgG, IgA and IgM in a healthy population *

	Group	Native Antigen %	Recombinant Antigen %
IgG N=91	Positive	27	10
	Border line	30	0
	Negative	43	90
IgA N=91	Positive	7	4
	Border line	13	0
	Negative	80	96
IgM N=91	Positive	3	1
	Border line	0	0
	Negative	97	99

- In the pneumonia patients - rate of positive is higher and border line samples are eliminated in the recombinant test (in IgM border line is not significant)
- In the healthy population – rate of positive is lower and border line samples are eliminated in the recombinant test

Comparison between Savyon and competitor MP Recombinant kits *

	Group (N)	SeroMP Recombinant % POS.	Commercial MP % POS.
IgG	Healthy Population (30)	20	40
	Pneumonia Patients (61)	32.8	36.1
IgA	Healthy Population (30)	6.6	3.3, 6.6 (BL)
	Pneumonia Patients (61)	55.7	42.6
IgM	Healthy Population (30)	6.6	3.3
	Pneumonia Patients (56)	64.2	44.6, 18 (BL)

- Higher sensitivity of the SeroMP recombinant in pneumonia patients experiencing acute or current infections, as represented by IgM and IgA results
- The prevalence within the healthy population is lower in Savyon SeroMP recombinant assay
- The discrimination between sick patients and healthy population in cases of acute and current infections will be greater in the SeroMP recombinant

* In house study

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