



# Bioclone Australia Pty. Limited.

## ELEGANCE *Chlamydia pneumoniae* IgM ELISA

### Intended Use

The ELEGANCE *Chlamydia pneumoniae* IgM ELISA has been designed for the *in vitro* diagnostic measurement of anti-*C pneumoniae* IgM in the screening of human serum.

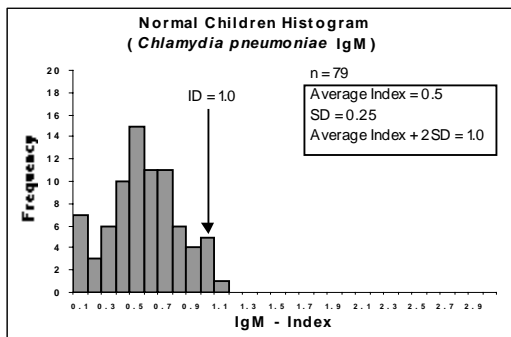
### Principles of the ELEGANCE *Chlamydia pneumoniae* IgM ELISA

The *Chlamydia pneumoniae* IgM ELISA measures anti-*Chlamydia pneumoniae* IgM in human serum by an enzyme-linked immunosorbent assay method (ELISA). Highly purified *Chlamydia pneumoniae*-specific outer membrane protein complex, bound to the microwells, reacts with the anti-*Chlamydia pneumoniae* IgM in the sample. After a wash, any bound IgM is further reacted with anti-human IgM polyclonal antibody labelled with alkaline phosphatase. A substrate solution, containing p-nitrophenol phosphate (p-NPP), reacts with alkaline phosphatase to produce colour correlating with the presence of anti-*Chlamydia pneumoniae* IgM in the sample. The result is determined by calculating an index value from optical density (OD) values relative to control material.

### Clinical Significance

Until recent years, it was thought that *Chlamydia pneumoniae* was a subspecies of *Chlamydia psittaci*, but in 1989 the existence of this third *Chlamydia* species was established.<sup>1</sup> Depending on the host, *Chlamydia pneumoniae* can bring about acute chronic upper respiratory infection, bronchitis, and pneumonia-based lung disease. Depending on the site of inflammation, these can lead to very serious complications.<sup>2,3</sup> Research results are also suggesting the involvement of *Chlamydia pneumoniae* in asthma, lung infections and other chronic diseases.

### Sample Ranges (Children)



### Intraassay / Interassay Coefficient of Variation

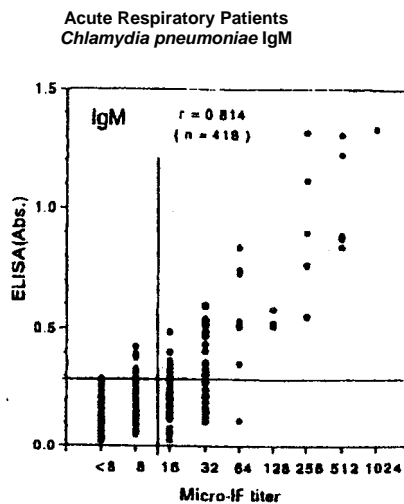
Intraassay coefficient of variation is typically <10% for the IgM ELISA.

Interassay coefficient of variation is typically <10% for the IgM ELISA.

### Interassay

Sample	1	2	3
n =	10	10	10
Average OD	0.364	0.602	1.000
SD	0.032	0.053	0.058
%CV	8.8	8.7	5.8

### Comparison to Micro-IF



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## Comparison to Micro-IF Method (Acute Respiratory Patients (n=418))

IgM		Micro-IF Method		Total
		+	-	
ELEGANCE	+	49	12	61 (14.6%)
	-	44	313	357 (85.4%)
Total		93 (22.2%)	325 (77.8%)	418 (100%)

Positive Rate: 49 / 93 = 52.7%  
 Negative Rate: 313 / 325 = 96.3%  
 Total Rate: 362 / 418 = 86.6%

## (Antigen Positive Patients (n=51))

IgM		Micro-IF Method		Total
		+	-	
ELEGANCE	+	23	1	24 (47.1%)
	-	8	19	27 (52.9%)
Total		31 (60.8%)	20 (39.2%)	51 (100%)

Positive Rate: 23 / 31 = 74.2%  
 Negative Rate: 19 / 20 = 95.0%  
 Total Rate: 42 / 51 = 82.4%

IgM	Western Blot Method (analysis of above)		
	+	-	Total
ELEGANCE + Micro-IF -	6 (50.0%)	6 (50.0%)	12
ELEGANCE - Micro-IF +	7 (15.9%)	37 (84.1%)	44

IgM	Western Blot Method (analysis of above)		
	+	-	Total
ELEGANCE + Micro-IF -	1 (100%)	0 (0.0%)	1
ELEGANCE - Micro-IF +	1 (12.5%)	7 (87.5%)	8

## REFERENCES

1. Grayston, JT, Kuo, C-C, Campbell, LA, Wang, S-P. Int. J. Sys. Bacteriol. 39: 88-90, 1989.
2. Grayston, JT, Campbell, LA, Kuo, C-C, Mordhorst, CH, Saikku, P, Thom, DH, Wang, S-P. J. Infect. Dis. 161: 618-625, 1990.
3. Kishimoto, T. J. Infect. Dis. 64: 986-992, 1990

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