

ELEGANCE *Chlamydia pneumoniae* IgG & IgA ELISAs

Intended Use

The ELEGANCE *Chlamydia pneumoniae* IgG and IgA ELISAs have been designed for the *in vitro* diagnostic measurement of anti-*C pneumoniae* IgG and IgA in the screening of human serum.

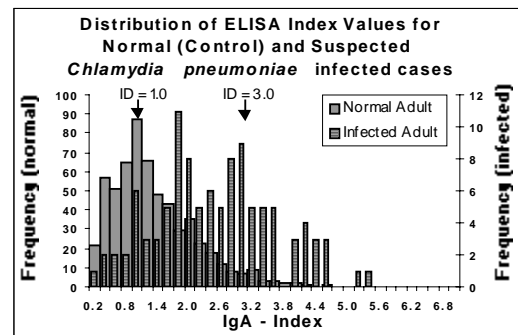
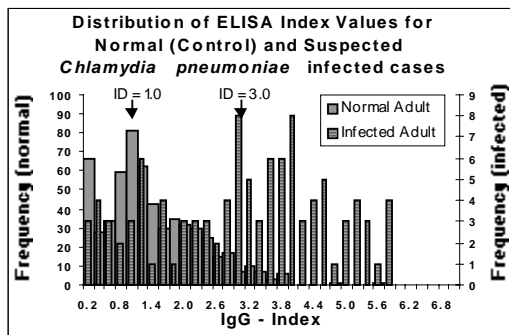
Principles of the ELEGANCE *Chlamydia pneumoniae* IgG and IgA ELISAs

The *Chlamydia pneumoniae* IgG and IgA ELISAs measure anti-*Chlamydia pneumoniae* IgG and IgA 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* IgG or IgA in the sample. After a wash, any bound IgG or IgA is further reacted with anti-human IgG or IgA polyclonal antibodies 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* IgG or IgA in the sample. The result is determined by calculating an index value from optical density (OD) values relative to control material.

Clinical Significance

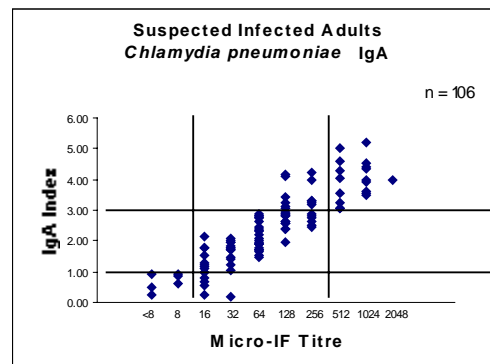
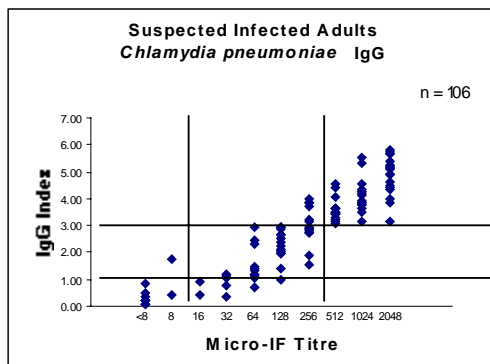
Until recent years, it was thought that *Chlamydia pneumoniae* was a subspecies of *Chlamydia psittaci*, but in 1989 the existence of this third *Chlamydia* species was established.¹ Depending on the host, *Chlamydia pneumoniae* can bring about acute chronic upper respiratory infection, bronchitis, and pneumonia-based lung disease. Depending on the site of inflammation, these can lead to very serious complications^{2,3,4}. Research results are also suggesting the involvement of *Chlamydia pneumoniae* in asthma, lung infections and other chronic diseases.

Sample Ranges (Adults; >16 years old)



Note: 1. For Normal Adults n=592; for Suspected Infected Adults n=106.
2. Adult Sample Indices >3.0 are deemed highly likely to be current infections.

Comparison to Micro-IF



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

IgG		Micro-IF Method		Total
		+	-	
ELEGANCE	+	147	9	156 (37.3%)
	-	58	204	262 (62.7%)
Total		205 (49.0%)	213 (51.0%)	418 (100%)

Positive Rate: 147 / 205 = 71.7%
 Negative Rate: 204 / 213 = 95.8%
 Total Rate: 351 / 418 = 84.0%

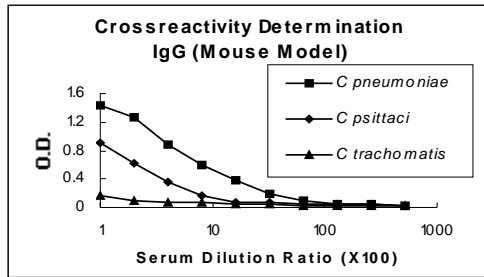
IgA		Micro-IF Method		Total
		+	-	
ELEGANCE	+	122	18	146 (33.5%)
	-	43	235	278 (66.5%)
Total		165 (39.5%)	253 (60.5%)	418 (100%)

Positive Rate: 122 / 165 = 73.9%
 Negative Rate: 235 / 253 = 92.9%
 Total Rate: 357 / 418 = 85.4%

IgG	Western Blot Method (analysis of above)		
	+	-	Total
ELEGANCE + Micro-IF -	9 (100%)	0 (0.00%)	9
ELEGANCE - Micro-IF +	24 (41.4%)	34 (58.6%)	58

IgA	Western Blot Method (analysis of above)		
	+	-	Total
ELEGANCE + Micro-IF -	15 (83.7%)	3 (16.7%)	18
ELEGANCE - Micro-IF +	17 (39.5%)	26 (60.5%)	43

Crossreactivity (IgG)



Crossreactivity Data

C psittaci 25%
C trachomatis 3%

Intraassay / Interassay Coefficient of Variation

Intraassay and interassay coefficient of variation is typically <10% for both the IgG and IgA ELISAs.

REFERENCES

1. Grayston, JT, Kuo, C-C, Campbell, LA, Wang, S-P. Int. J. Sys. Bacteriol. 39: 88-90, 1989.
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3. Grayston, JT. Dis. 15: 757-763, 1992.
4. Kishimoto, H. J. Infect. Dis. 64: 986-992, 1990

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