

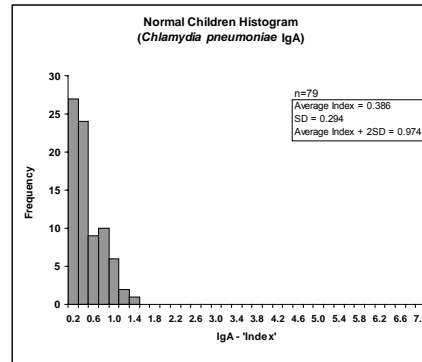
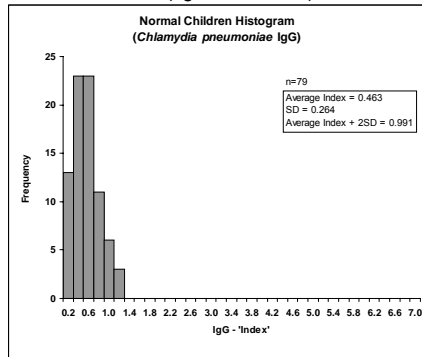
## Establishment of Normal Ranges For Bioclone *Chlamydia pneumoniae* IgG and IgA ELISAs

As part of the establishment of normal ranges and a cut-off level for positive samples, 79 normal children were tested with the *Chlamydia pneumoniae* IgG and IgA ELISAs. The average O.D. + 2SD was 0.2 for both assays. This value was then effectively set to an index of 1.0; i.e. 95% of a normal (antibody negative) population would read less than 1.0 (figs 1a & 1b).

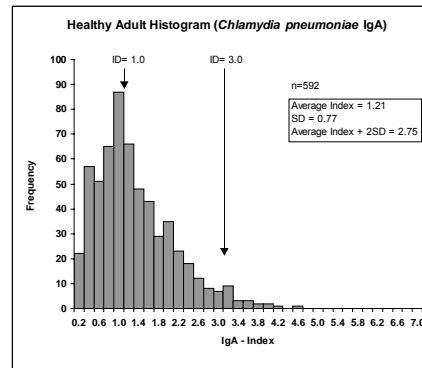
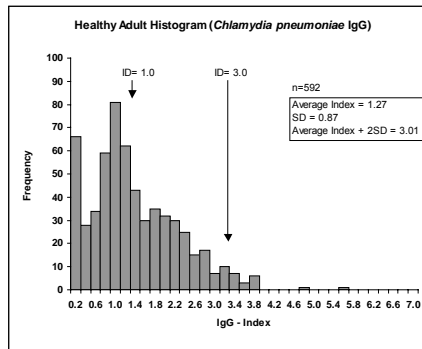
Healthy adults (n=592) were also tested in the *Chlamydia pneumoniae* IgG and IgA ELISAs. The average index for these samples was 1.27 and 1.21 respectively. The average index + 2SD was 3.01 and 2.75 respectively. This means that essentially 95% of healthy adult samples should be less than an index of 3.0 (figs 2a & 2b).

Assay results for suspected *C pneumoniae* infected adults (n=106) showed that approximately 50% of these samples were above an index of 3.0 (figs 3a & 3b). Also a comparison between the ELISA and Micro-IF methods using the same 106 samples produced a very good correlation with infection status. All samples with a Micro-IF titre of  $\geq 512$  (the measure of a current infection by Micro-IF) had an ELISA index of  $>3.0$  (figs 4a & 4b). Based on this data an index of 3.0 was set as the cut-off for a current infection. A summary of results and their interpretation is in Table 1.

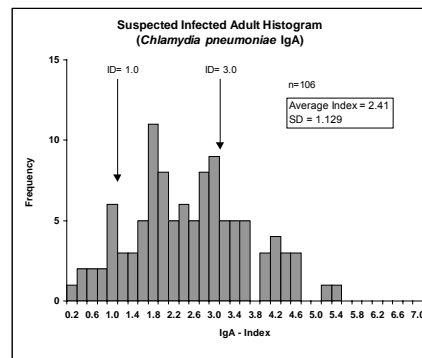
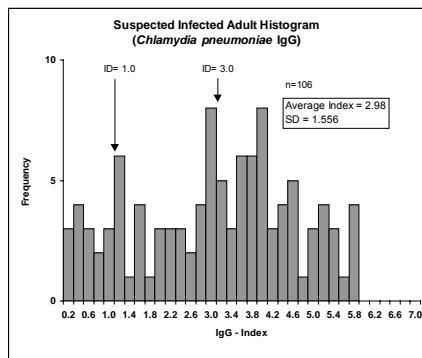
### Normal Children (figures 1a & 1b)

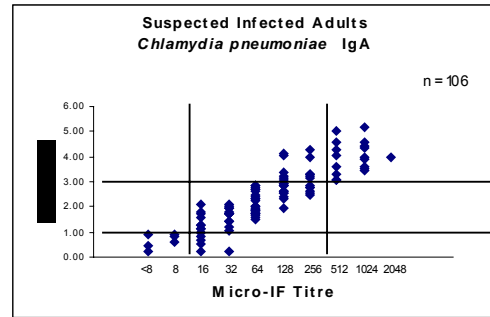
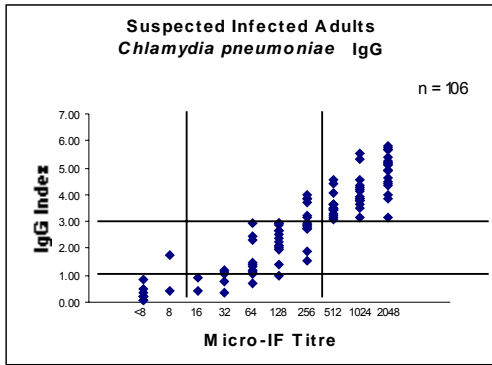


### Healthy Adults (figures 2a & 2b)



### Suspected Infected Adults (figures 3a & 3b)





**ELEGANCE Chlamydia pneumoniae: Interpretation of All Sample Results (Table 1a)**

Index	Result	
$\square \square$	Strong Positive	++
1.10 – 2.99	Positive	+
0.90 – 1.09	Equivocal	=
< 0.9	Negative	-

**ELEGANCE Chlamydia pneumoniae: Results Analysis for Suspect Adult (>16 years old) Patients (Table 1b)**

IgG	IgA	Result Explanation
++	++	Highly likely to be acute or present infection
++	=	
++	-	
+	++	
-*	++*	
+	+	Possible infection but increasing antibody levels would confirm – so retest is necessary
-*	+*	
+	-	Some slight possibility of infection – maybe past infection; retest necessary.
-	-	Little change of infection by increasing antibody levels may indicate recent infection. Retest necessary

\* IgA positive and IgG negative is very rare (<2~3% of all cases)

Notes: 1. As for any other diagnostic procedures, the values obtained by the use of the *ELEGANCE Chlamydia pneumoniae* IgG and IgA ELISAs yield data that should be used as an adjunct to other information available to the physician. It should be noted that retesting to check for rise in antibody levels should be performed for all doubtful results.

2. For children (<16 years old) positive results are suggestive of current infection. Retest is necessary to check for rise in antibody levels to confirm infection status.