

## CORRELATION BETWEEN KIT REAGENTS AND MICRO-IF METHODS

### The Correlation Between Micro-IF and Efficient Clinical Testing

Using 418 serum samples from patients showing symptoms of respiratory infection, which indicates the possibility of *Chlamydia pneumoniae* infection, IgG was measured with the kit reagents and the standard Micro-IF antibody method. Results are shown on the table below:

IgG		Micro-IF Method		Total
		+	-	
Kit Reagents	+	147	9	156 (37.3%)
	-	58	204	262 (62.7%)
Total		205 (49.0%)	213 (51.0%)	<u>418</u> (100%)

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

The IgG reagents for this set of data were manufactured by Hitachi Chemical Co. Ltd.

As the two methods provided some differences in results (67 in total), the Western Blot test was used as a confirmation method. For the kit reagents, the results for positive correlation were 100% (9/9), negative correlation 58.6% (34/58) and thus total correlation was 64.2% (43/67).

### Clinical Trials

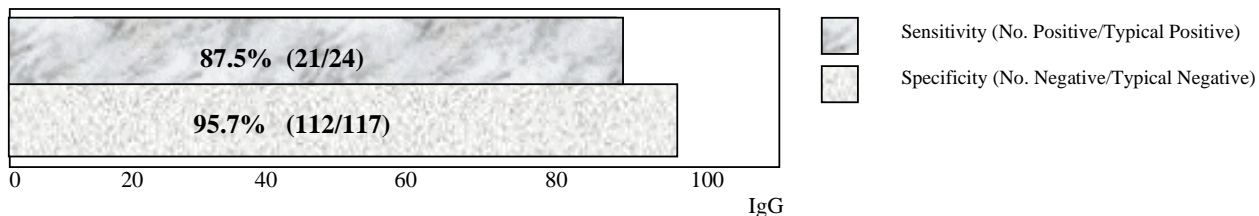
At the time of initial medical consultation, 255 samples were taken, and tested for sensitivity (using IgG kit reagents and Micro-IF methods), and for specificity (using IgG kit reagents and Micro-IF methods). From the table below, the sensitivity and specificity can be determined. There were 24 positive samples, of which 21 (87.5%) were detected by the IgG kit reagents. For negative samples, the IgG kit reagents detected 112 of 117 samples (95.7%).

Kit Comparison		Micro-IF Methods*		Total
		+	-	
Kit Reagents	+	21	5	26
	-	3	112	115
Total		24	117	<u>141</u>

\* Sample results from both Antigen and Antibody Micro-IF methods

The IgG reagents for this set of data were manufactured by Hitachi Chemical Co. Ltd.

### Comparative Sensitivity from the above IgG data



### Comments on Crossreactivity

- In some conditions, the kit may show some crossreactivity (i.e. false positives) with *C. psittaci*. Note there is a low prevalence of *C. psittaci* in the general population.
- Where high levels of *C. trachomatis* are present in a sample, there is only a low probability of crossreactivity with the kit reagents.

Bioclone's Quality Management System certified to ISO 9001, ISO 13485, GMP and CE Mark

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