



# Bioclone Australia Pty. Limited.

## .....*ELEGANCE Chlamydia pneumoniae* IgG & IgA ELISAs

### Method Comparison

#### Introduction

The *ELEGANCE Chlamydia pneumoniae* IgG and IgA ELISAs were compared to several other methods using 47 samples. The other methods were the Sero-CP ELISA, the Micro-IF method and the Western Blot method. For the Micro-IF and Western Blot methods the samples were tested for both *C pneumoniae* and *C trachomatis*. The Sero-CP IgG and IgA ELISAs were manufactured by Savyon Diagnostics Ltd. (Israel), Catalogue #s A191-01M and A193-01E respectively, and were carried out according to the kit insert instructions. The Micro-IF test was carried out 'in-house' by Hitachi Chemical Co. Ltd. (Japan) using antigen derived from EBs, supplied by the Japanese Government Central Laboratories to most *Chlamydia* MIF testing sites in Japan. The Western Blot tests were carried out using the same antigen as for Micro-IF by Hitachi Chemical Co. Ltd. (Japan).

See *C pneumoniae* IgG and IgA data overleaf

#### Interpretation of Data

##### 1. *Chlamydia pneumoniae* Antibody Method Comparison (July 1998) - Comments

- 1.1 Samples of the appropriate type and titre are generally difficult to obtain. However, there is enough data in this study (July 1998) to draw some conclusions. Overall the study is favourable to the *ELEGANCE* kit - the key point being in respect of *C trachomatis* crossreactivity.
- 1.2 Note that "equivocal" in the commentary below is deemed to be an Index of between 0.9 - 1.1.
- 1.3 Note that "128<sub>±</sub>" in the data actually means a titre "greater than or equal to 128".
- 1.4 Shaded (or bold/underlined) data have indices greater than 1 (for *ELEGANCE* - kit by Bioclone; Sero-CP - kit by Savyon); or are positive for Micro-IF or Western Blot methods.

##### 2. In relation to the *Chlamydia pneumoniae* IgG ELISA data:

- 2.1 **Samples # 1-8; 16** were highly *Chlamydia trachomatis* (*Ct*) positive and *Chlamydia pneumoniae* (*Cpn*) negative according to Micro-IF and Western Blot. *ELEGANCE* correctly showed samples also to be *Cpn* negative. However, Sero-CP (Savyon) data produced mainly positive *Cpn* indices (3 were equivocal ; 1 was negative). Note that it is considered by Hitachi co-workers that the few borderline values of some of the associated Micro-IF data may indeed be an artefact caused by subjective assessment - that is, high fluorescence of the *Ct* spot in these wells can cloud an absolute *Cpn* determination. Further to this, the Micro-IF method used, employed fixed EBs, which, as is known, also contain common antigenic epitopes to the *Chlamydia* genus.
- 2.2 **Samples # 9-12**, with elevated *Ct* only by Micro-IF, properly showed *ELEGANCE* *Cpn* negative indices (1 equivocal). However, Sero-CP incorrectly indexed these as positive *Cpn* (1 equivocal).
- 2.3 **Samples # 13-15; 18-19; 31; 33-35** were negative all round.
- 2.4 **Sample # 17** with a high Micro-IF *Ct* strangely produced an equivocal Sero-CP value.
- 2.5 **Samples #20-30**, being highly positive for both *Cpn* and *Ct*, accordingly were positive for all kits.
- 2.6 **Samples # 32; 36-47** were positive *Cpn* (Micro-IF and Western Blot) and in *ELEGANCE* and Sero-CP.

##### 3. In relation to the *Chlamydia pneumoniae* IgA ELISA data:

- 3.1 Generally the pattern is less clear than for IgG - more samples may need to be tested here.
- 3.2 There are samples (**Sample # 9, 20**) that appear to have discrepant Sero-CP data.
- 3.3 There is some equivocal data in both kits (**Sample # 1, 38**, for Sero-CP; and **Sample # 28** for *ELEGANCE* - **Sample #28** for Sero-CP was negative). Note that **Sample # 18; 21, 22, 23, 46, 47** are dependent on validity of Micro-IF or Western Blot differential results).
- 3.4 **Sample # 19** is positive for *ELEGANCE* and equivocal for Sero-CP with negative reference tests.

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