

Summary of Safety and Effectiveness Information  
Chlamydia IgG ELISA Test Kit

K962558

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II. Description of Device

The Chlamydia IgG ELISA kit is an Enzyme-Linked Immunosorbent Assay (ELISA) for qualitative detection of IgG antibodies in human serum to *Chlamydia* for the determination of immunological experience.

The Chlamydia IgG ELISA test is an enzyme linked immunosorbent assay to detect IgG antibodies to Chlamydia. Purified Chlamydia antigen (strain LGV II) is attached to a solid phase microtiter well. Diluted test sera is added to each well. If the antibodies are present that recognize the antigen, they will bind to the antigen in the well. After incubation the wells are washed to remove unbound antibody. An enzyme labeled anti-human IgG is added to each well. If antibody is present it will bind to the antibody attached to the antigen on the well. After incubation the wells are washed to remove unbound conjugate. A substrate solution is added to each well. If enzyme is present the substrate will undergo a color change. After an incubation period the reaction is stopped and the color intensity is measured photometrically, producing an indirect measurement of specific antibody in the patient specimen.

III. Predicate Device

The Chlamydia IgG ELISA test is substantially equivalent to IFA. Equivalence is demonstrated by the following comparative results:

## Performance Characteristics

**1. Relative sensitivity and specificity.** Two different sites compared the Wampole Chlamydia IgG ELISA test relative to a commercial IFA kit. The two sites were R&D laboratories at commercial companies located in Maryland and New York and affiliated with the manufacturing of the kit. The sera were from normal individuals of various ages, gender, and geographical areas. The results of the studies are compiled and summarized in Table 1. None of the performance characteristics were established with specimens from patients having documented chlamydia infections.

**Table 1**  
**Comparison of Chlamydia IgG ELISA and IFA**

	Wampole Chlamydia IgG ELISA			Total	
	+	eq	-		
Chlamydia IFA	+ >1:8	81	7	7	95
	- <1:8	5	9	246	260
	<b>Total</b>	86	16	253	355

Relative Sensitivity =  $81/88 = 92.1\%$       95% Confidence interval = 86.3% - 97.8%

Relative Specificity =  $246/251 = 98.0\%$       95% Confidence interval = 96.2% - 99.8%

Relative Agreement =  $327/339 = 96.5\%$       95% Confidence interval = 94.5% - 98.5%

Equivocals were not included in the above calculations.

The 95% confidence intervals were calculated using the normal method.

Please be advised that 'relative' refers to the comparison of this assay's results to that of a similar assay. There was not an attempt to correlate the assay's results with disease presence or absence. No judgment can be made on the comparison assay's accuracy to predict disease.

**2. Precision.** Seven sera were assayed ten times each on three different assays at two different sites. Both sites were affiliated with the manufacturing of the kit. The inter and intra assay precision for each site is presented in Tables 2 and 3 and the intersite precision is shown in Table 4. With appropriate technique the user should obtain precision of <15% CV.

**Table 2 Chlamydia IgG ELISA Intra and Inter Assay Precision Study 1**

Assay(n=30) Sera#	Assay 1 (n=10)			Assay 2 (n=10)			Assay 3 (n=10)			Inter-		
	X	SD	CV	X	SD	CV	X	SD	CV	X	SD	CV
1	2.86	0.152	5.32%	2.97	0.076	2.57%	3.13	0.115	3.69%	2.99	0.162	5.42%
2	1.71	0.101	5.91%	1.88	0.098	5.20%	1.90	0.092	4.89%	1.83	0.129	7.05%
3	1.74	0.107	6.15%	1.87	0.071	3.78%	1.95	0.072	3.67%	1.85	0.121	6.50%
4	1.78	0.126	7.07%	1.92	0.053	2.77%	2.03	0.075	3.72%	1.91	0.135	7.06%
5	1.06	0.051	4.83%	1.12	0.034	3.00%	1.16	0.049	4.24%	1.11	0.060	5.42%
6	0.34	0.032	9.59%	0.32	0.042	13.06%	0.37	0.052	14.25%	0.34	0.046	13.55%
7	0.30	0.061	19.95%	0.29	0.056	19.43%	0.33	0.043	12.81%	0.31	0.054	17.75%

**Table 3 Chlamydia IgG ELISA Intra and Inter Assay Precision Study 2**

Sera#	Assay 1 (n=10)			Assay 2 (n=10)			Assay 3 (n=10)			Inter-Assay(n=30)		
	X	SD	CV	X	SD	CV	X	SD	CV	X	SD	CV
1	3.08	0.052	1.69%	3.11	0.106	3.40%	3.00	0.117	3.91%	3.06	0.104	3.41%
2	1.77	0.085	4.80%	1.78	0.073	4.10%	1.75	0.094	5.38%	1.77	0.084	4.75%
3	1.86	0.062	3.35%	1.85	0.086	4.63%	1.86	0.083	4.46%	1.86	0.076	4.08%
4	1.81	0.060	3.30%	1.84	0.112	6.12%	1.84	0.102	5.52%	1.83	0.091	4.98%
5	0.93	0.051	5.46%	0.93	0.071	7.69%	0.94	0.053	5.61%	0.93	0.058	6.19%
6	0.04	0.014	31.17%	0.03	0.018	53.59%	0.06	0.024	39.50%	0.05	0.022	46.90%
7	0.05	0.016	35.60%	0.05	0.015	32.60%	0.07	0.032	47.62%	0.05	0.024	45.41%

**Table 4 Chlamydia IgG ELISA Inter Site Precision Study**

Inter-Site (n=60)			
Sera #	X	SD	CV
1.	3.03	0.140	4.63%
2.	1.80	0.112	6.24%
3.	1.86	0.100	5.37%
4.	1.87	0.121	6.46%
5.	1.02	0.110	10.73%
6.	0.19	0.153	78.91%
7.	0.18	0.137	75.20%

X = Mean

SD = standard deviation

CV = coefficient of variation =  $SD/X \times 100$

Refer to NCCLS EP5 for guidance for appropriate precision determination.

**3. CF Paired Serum Analysis.** Nine serum pairs showing a greater than 4 fold increase in CF titer or seroconversions by CF were assayed on the Chlamydia IgG ELISA assay. Each serum pair was evaluated to determine an seroconversion in antibody (acute negative and convalescent positive). Four pairs demonstrated a seroconversion by ELISA. Therefore the assay showed a sensitivity of 44% (4/9) in demonstrating a seroconversion when the CF showed a 4 fold increase or a seroconversion.

**4. Reproducibility Study.** Fifty different sera with various levels of activity were assayed at three different sites. Two sites were R&D laboratories at commercial companies located in Maryland and New York. The third site was a large clinical laboratory located in Pennsylvania. The data from the three sites show good correlation with ISR values with product moment correlation coefficients of  $>0.989$  between the sites. Excluding equivocal (n = 13) four determinations varied from its expected result (negative results for a positive specimen) giving a %agreement of expected results between the three sites of 97.1% (133/137). The expected results were derived from previous Wampole ELISA testing of the samples.