Diagnostic Automation/Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

AccuDiag™ Chlamydia Trachomatis IgG ELISA Kit

REF 1407-P1

IVD ⚠ See External Label 2°C–8°C ∑ 96 Tests

Chlamydia Trachomatis IgG ELISA	
Principle	Indirect ELISA
Detection	Qualitative
Sample	5 µL serum/plasma
Incubation Time	75 minutes
Sensitivity	91.1%
Specificity	98.5%
Shelf Life	12 Months from the manufacturing date

PRODUCT FEATURES

✓ Very easy to use with little training

✓ Highly specific and consistent Assay

✓ Provides accurate results quickly

✓ Reading of results both visually and as absorbance data

INTENDED USE

The DAI ELISA, Chlamydia Trachomatis IgG is intended for use in evaluating a patient's serologic status to Chlamydia Trachomatis infection. It is also used to evaluate paired sera for the presence of a significant increase in specific IgG as indicative of a recent or current Chlamydia Trachomatis infection.

SIGNIFICANCE AND SUMMARY

Chlamydia Trachomatis is one of the most common human pathogens. Of the 15 recognized serotypes, 4 (A, B, Ba, and C) have been shown to cause hyperendemic blinding trachoma, a disease which afflicts hundreds of millions of people in developing countries. Three serotypes (L-1, L-2, and L-3) are the causes of lymphogranuloma venereum (LGV), a sexually transmitted systemic disease. The other serotypes (D through K) have been associated with genital tract infections and sporadic cases of conjunctivitis in industrialized societies. These agents are the major recognized cause of nongonococcal urethritis in men, in whom they may also cause epididymitis. In women, C. trachomatis causes cervicitis and has been associated with acute salpingitis. Infants born through an infected birth canal may contract the infection and then develop inclusion conjunctivitis of the newborn and/or the characteristic chlamydial pneumonia syndrome.

High levels of anti-Chlamydia IgG antibody are of diagnostic value in chronic or systemic infections such as salpingitis, mechanical infertility, perihepatitis, epididymitis, Reiter's syndrome and pneumonitis.

DAI ELISA Chlamydia Trachomatis test employs the LGV type 2 broadly reacting antigen of Chlamydia Trachomatis. It will detect Chlamydia Trachomatis, Chlamydia Psittaci and Chlamydia Pneumoniae (TWAR) antibodies.

ASSAY PRINCIPLE

Purified Chlamydia Trachomatis antigen is coated on the surface of microwells. Diluted patient serum is added to wells, and the Chlamydia Trachomatis IgG specific antibody, if present, binds to the antigen. All unbound materials are washed away. After adding enzyme conjugate, it binds to the antibody-antigen complex. Excess enzyme conjugate is washed off, and TMB Chromogenic Substrate is added. The enzyme conjugate catalytic reaction is stopped at a specific time. The intensity of the color generated is proportional to the amount of IgG specific antibody in the sample. The results are read by a microwell reader compared in a parallel manner with calibrator and controls.

SPECIMEN COLLECTION & PREPARATION

1. Collect blood specimens and separate the serum.
2. Specimens may be refrigerated at 2 – 8°C for up to seven days or frozen for up to six months. Avoid repetitive freezing and thawing of serum sample.

MATERIALS AND COMPONENTS

Materials provided with the kit

1. Microwell strips: Chlamydia Trachomatis antigen coated wells. (12 x 8 wells)
2. Sample diluent: Blue color solution. 1 vial (22 ml)
3. Calibrator: Factor value (f) stated on label. Red Cap. 1 vial (150 µl)
4. Negative Control: Range stated on label. Natural Cap. 1 vial (150 µl)
5. Positive Control: Range stated on label. Brown Cap. 1 vial (150 µl)
6. Washing Concentrate 20x. 1 bottle (50 ml)
7. Enzyme Conjugate. 1 vial (12 ml)
8. TMB Chromogenic Substrate: Amber bottle. 1 vial (12 ml)
9. Stop Solution. 1 vial (12 ml)

REAGENT PREPARATION

1. Prepare 1x washing buffer.
   Prepare washing buffer by adding distilled or deionized water to **20x** wash concentrate to a final volume of 1 liter.
2. Bring all specimens and kit reagents to room temperature (20-25°C) and gently mix.
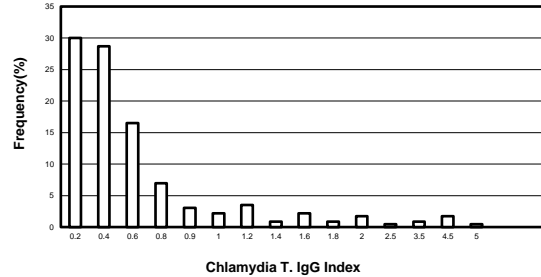
ASSAY PROCEDURE

1. Place the desired number of coated strips into the holder.

2. Prepare 1:40 dilutions by adding 5 µl of the test samples, negative control, positive control, and calibrator to 200 µl of sample diluent. Mix well.
3. Dispense 100 µl of diluted sera, calibrator, and controls into the appropriate wells. For the reagent blank, dispense 100 µl sample diluent in 1A well position. Tap the holder to remove air bubbles from the liquid and mix well. Incubate for 30 minutes at room temperature.
4. Remove liquid from all wells. Repeat washing three times with washing buffer.
5. Dispense 100 µl of enzyme conjugate to each well and incubate for 30 minutes at room temperature.
6. Remove enzyme conjugate from all wells. Repeat washing three times with washing buffer.
8. Dispense 100 µl of TMB Chromogenic Substrate to each well and incubate for 15 minutes at room temperature.
9. Add 100 µl of Stop solution to stop reaction.
   Make sure there are no air bubbles in each well before reading.
10. Read O.D. at 450 nm with a microwell reader.

RESULTS

1. To obtain Cut off OD value: Multiply the OD of Calibrator by Factor (f) printed on label of Calibrator.
2. Calculate the Chlamydia IgG Index of each determination by dividing the OD values of each sample by obtained OD value of Cut off.

For example:

If Factor (f) value on label = 0.4

This factor (f) is a variable. It is specific for a lot manufactured and printed on label of Calibrator.

Obtained Calibrator O.D. = 1.100
Cut-off O.D. = 1.100 x 0.4 = 0.44 (By definition IgG Index = 1)

Patient sample O.D. = 0.580
Chlamydia IgG Index = 0.580 / 0.44 = 1.32 (Positive result)
Patient sample O.D. = 0.320

Chlamydia IgG Index = 0.320 / 0.44 = 0.73 (Negative result)

INTERPRETATION

Negative: IgG Index of 0.90 or less are seronegative for IgG antibody.
Equivocal: IgG Index of 0.91 - 0.99 are equivocal. Sample should be retested.
Positive: IgG Index of 1.00 or greater.

Expected Values: 230 random samples were determined with DAI ELISA Chlamydia Trachomatis IgG. The test results were computed as IgG Index using a chosen reference serum (cut off) as IgG index 1. The distribution of frequency versus IgG Index is presented as the following: 29 were found to be positive (12.6%), and 196 were found to be negative (85.2%).

Histogram of Chlamydia T. IgG Index   Total samples n=230

QUALITY CONTROL

The test run may be considered valid provided the following criteria are met:
1. The O.D. value of the reagent blank against air from a microwell reader should be less than 0.150.
2. If the O.D. value of the Calibrator is lower than 0.250, the test is not valid and must be repeated.
3. The IgG Index for Negative and Positive Control should be in the range stated on the labels.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

Sensitivity, specificity and accuracy were evaluated using a commercial available ELISA kit on 104 specimens. The correlation results are summarized in the following table:

		Reference ELISA		
		N	P	Total
DAI ELISA	N	69(D)	3 (B)	72
	P	1(C)	31 (A)	32
	Total	70	34	104

Sensitivity = A / (A+B) = 31 / (31+3) = 91.1%
Specificity = 69 / (69+1) = 98.5%
Accuracy (Overall agreement) = (A+D) / (A+B+C+D) = 100 / 104 = 96.1%

Precision

The precision of the assay was evaluated by testing three different sera eight replicates on 3 days. The intra-assay and inter-assay C.V. are summarized below:

N = 8	Negative	Low Positive	Positive
Intra-assay	10.9%	10.5%	8.9%
Inter-assay	12.3%	11.1%	10.5%

Cross-reactivity:

A study was performed to determine the cross-reactivity of the test to the following antibodies:
1. IgG of EBV, Mumps, Measle, and VZV.
2. IgG and IgM of Rubella, Toxo, CMV, HSV 1, and HSV 2.
3. IgM of RF.
4. IgG of ANA, anti- ds DNA.
All positive samples tested give negative results.

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LIMITATIONS OF THE ASSAY

1. A single serum sample cannot be used to determine recent infection.
2. A serum specimen taken in an early stage during acute phase of infection may contain low levels of IgG antibody and render an IgG Index result negative.
3. As with other serological assays, the results of these assays should be used in conjunction with information available from clinical evaluation and other diagnostic procedures.

STORAGE CONDITIONS

1. Store the kit at 2 – 8°C.
2. Always keep microwells tightly sealed in pouch with desiccants. We recommend you use up all wells within 4 weeks after initial opening of the pouch.
3. The reagents are stable until expiration of the kit.
4. Do not expose test reagents to heat, sun or strong light during storage or usage.

PRECAUTIONS

Potential biohazardous materials:

The calibrator and controls contain human source components which have been tested and found nonreactive for hepatitis B surface antigen as well as HIV antibody with FDA licensed reagents. However, as there is no test method that can offer complete assurance that HIV, Hepatitis B virus or other infectious agents are absent, these reagents should be handled at the Biosafety Level 2, as recommended in the Centers for Disease Control/National Institutes of Health manual, "Biosafety in Microbiological and Biomedical Laboratories." 1984.

1. Do not pipette by mouth. Do not smoke, eat, or drink in the areas in which specimens or kit reagents are handled.
2. The components in this kit are intended for use as an integral unit. The components of different lots should not be mixed.
3. This product contains components preserved with sodium azide. Sodium azide may react with lead and copper plumbing to form explosive metal azide. On disposal, flush with a large volume of water.

REFERENCES

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MANUFACTURER AND BRAND DETAILS

ISO 13485:2016

bsi — ISO 13485 Quality Management for Medical Devices CERTIFIED

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