AccuDiag™ Mycoplasma pneumoniae IgG ELISA Kit

REF 8042-P2

IVD | See External Label | 2-8°C | 96 Tests

Mycoplasma pneumoniae IgG ELISA	
Principle	Indirect ELISA
Detection	Qualitative
Sample	10 µL serum/plasma
Incubation Time	60 minutes
Sensitivity	94.5%
Specificity	87.5%
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 *Mycoplasma pneumoniae* IgG Test System provides a means for the qualitative detection of IgG antibodies to *Mycoplasma pneumoniae* in human sera. The test may aid in the determination of the patient's serological status, or may aid in the diagnosis of disease associated with *Mycoplasma pneumoniae*. Potential cross-reactivity with *M. genitalium* has not been assessed, nor were studies performed on very young and/or elderly patients.

SIGNIFICANCE AND SUMMARY

Mycoplasma pneumoniae is the most common cause of pneumonia and febrile upper-respiratory tract infections in the general population (except for influenza A) (1 - 5). Other nonrespiratory complications may also develop with this disease in virtually any organ system, with insult ranging from mild to life-threatening (6 - 8). *Mycoplasma pneumoniae*, a prokaryote, is the smallest (10 x 200nm), and simplest self-replicating microorganism known, and more closely resembles a bacterium rather than a virus. However, because it lacks a cell-wall, a resistance to cell-wall-active antibiotics is obvious (i.e., penicillin, cephalosporins (1)). This concern for diagnostic, or at least therapeutic accuracy in the early management of community-acquired infections is particularly critical in very young or elderly patients where very little temporal margin of error exists. Until recently, the routine laboratory diagnosis of this infection has been limited to insensitive and/or non-specific assays (i.e., cold agglutinins, complement-fixation, and culture isolation). Research shows that species-specific antibodies to surface antigens exist. They are protective, and are readily detected by ELISA; even in the early stages of the disease. The diagnosis therefore, is best achieved serologically (9).

ASSAY PRINCIPLE

The DAI *M. pneumoniae* IgG test system is designed to detect IgG class antibodies to *M. pneumoniae* in human sera. Creation of the sensitized wells of the plastic microwell strips occurred using passive absorption with M. pneumoniae IgG antigen. The test procedure involves three incubation steps:

1. Test sera are diluted with the Sample Diluent provided, and then incubated in antigen coated microwells. During sample incubation, any antigen specific IgG antibody in the sample will bind to the immobilized antigen. The plate is washed to remove unbound antibody and other serum components.

2. Peroxidase Conjugated goat anti-human IgG is added to the wells and the plate is incubated. The Conjugate will react with IgG antibody immobilized on the solid phase in step 1. The wells are washed to remove unbound Conjugate.

3. The microwells containing immobilized peroxidase Conjugate are incubated with peroxidase Substrate Solution. Hydrolysis of the Substrate by peroxidase produces a color change. After a period of time the reaction is stopped and the color intensity of the solution is measured photometrically. The color intensity of the solution depends upon the antibody concentration in the original test sample.

SPECIMEN COLLECTION & PREPARATION

1. DACD recommends that the user carry out specimen collection in accordance with CLSI document M29: Protection of Laboratory Workers from Infectious Disease (Current Edition).
2. No known test method can offer complete assurance that human blood samples will not transmit infection. Therefore, consider all blood derivatives potentially infectious.
3. Use only freshly drawn and properly refrigerated sera obtained by approved aseptic venipuncture procedures in this assay (10, 11). Do not use if there are any added anticoagulants or preservatives. Avoid using hemolyzed, lipemic, or bacterially contaminated sera.
4. Store sample at room temperature for no longer than 8 hours. If testing is not performed within 8 hours, sera may be stored between 2 - 8°C, for no longer than 48 hours. If a delay in testing is anticipated, store test sera at –20°C or lower. Avoid multiple freeze/thaw cycles which may cause loss of antibody activity and give erroneous results. It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine stability criteria for its laboratory (15).

REAGENTS

Materials provided with the kit

Each kit contains the following components in sufficient quantities to perform the number of tests indicated on packaging label. **Note: The following reactive reagents contain sodium azide as a preservative at a concentration of <0.1% (w/v): Controls, Calibrator, and Sample Diluent.**

1. Plate: 96 wells configured in twelve 1x8-well strips coated with inactivated preparation of M. pneumoniae (strain FH) antigen. The strips are packaged in a strip holder and sealed in an envelope with desiccant.
2. Conjugate: Conjugated (horseradish peroxidase) goat anti-human IgG (Fc chain specific). Ready to use. One, 15 mL vial with a white cap.
3. Positive Control (Human Serum): One, 0.35 mL vial with a red cap.
4. Calibrator (Human Serum): One, 0.5 mL vial with a blue cap.
5. Negative Control (Human Serum): One, 0.35 mL vial with a green cap.
6. Sample Diluent: One 30 mL bottle (green cap) containing Tween-20, bovine serum albumin and phosphate-buffered-saline. **Note: The Sample Diluent will change color when combined with serum.**
7. TMB: One 15 mL amber bottle (amber cap) containing 3,3',5,5'-tetramethylbenzidine (TMB). Ready to use.
8. Stop solution: One 15 mL bottle (red cap) containing 1M H_2SO_4, 0.7M HCl. Ready to use.
9. Wash buffer concentrate (10X): Dilute 1 part concentrate + 9 parts deionized or distilled water. One 100 mL bottle (clear cap) containing a 10X concentrated phosphate-buffered-saline and Tween-20 solution (blue solution). ***NOTE: 1X solution will have a pH of 7.2 ± 0.2.***

Notes:

1. ***The following components are not kit lot number dependent and may be used interchangeably with the ELISA assays: TMB, Stop Solution, and Wash Buffer.***
2. ***Component list containing lot specific information is inside the kit box.***

Materials required but not provided

1. ELISA microwell reader capable of reading at a wavelength of 450nm. ***NOTE: Use of a single (450nm), or dual (450/620 – 650nm), wavelength reader is acceptable. Dual wavelength is preferred, as the additional reference filter has been determined to reduce potential interference from anomalies that may absorb light.***
2. Pipettes capable of accurately delivering 10 - 200µL.
3. Multichannel pipette capable of accurately delivering 50 - 200µL.
4. Reagent reservoirs for multichannel pipettes.
5. Wash bottle or microwell washing system.
6. Distilled or deionized water.
7. One-liter graduated cylinder.
8. Serological pipettes.
9. Disposable pipette tips.
10. Paper towels.
11. Laboratory timer to monitor incubation steps.
12. Disposal basin and disinfectant. (i.e.: 10% household bleach, 0.5% Sodium Hypochlorite.)

ASSAY PROCEDURE

1. Remove the individual components from storage and allow them to warm to room temperature (20-25°C).
2. Determine the number of microwells needed. Allow six Control/Calibrator determinations (one Blank, one Negative Control, three Calibrators and one Positive Control) per run. A Reagent Blank should be run on each assay. Check software and reader requirements for the correct Controls/Calibrator configurations. Return unused strips to the resealable pouch with desiccant, seal, and return to storage between 2 and 8°C.

EXAMPLE PLATE SET-UP		
	1	2
A	Blank	Patient 3
B	Neg. Control	Patient 4
C	Calibrator	Etc.
D	Calibrator	
E	Calibrator	
F	Pos. Control	
G	Patient 1	
H	Patient 2	

3. Prepare a 1:21 dilution (e.g.: 10µL of serum + 200µL of Sample Diluent) of the Negative Control, Calibrator, Positive Control, and each patient serum.
4. To individual wells, add 100µL of each diluted control, calibrator and patient sample. Ensure that the samples are properly mixed. Use a different pipette tip for each sample.
5. Add 100µL of Sample Diluent to well A1 as a reagent blank. Check software and reader requirements for the correct reagent blank well configuration.
6. Incubate the plate at room temperature (20-25°C) for 25 ± 5 minutes.
7. Wash the microwell strips 5X.
   a. **Manual Wash Procedure:**
      1. Vigorously shake out the liquid from the wells.
      2. Fill each microwell with Wash Buffer. Make sure no air bubbles are trapped in the wells.
      3. Repeat steps a. and b. for a total of 5 washes.
      4. Shake out the wash solution from all the wells. Invert the plate over a paper towel and tap firmly to remove any residual wash solution from the wells. Visually inspect the plate to ensure that no residual wash solution remains. Collect wash solution in a disposable basin and treat with disinfectant at the end of the day's run.
   b. **Automated Wash Procedure:**
      If using an automated microwell wash system, set the dispensing volume to 300-350µL/well. Set the wash cycle for 5 washes with no delay between washes. If necessary, the microwell plate may be removed from the washer, inverted over a paper towel and tapped firmly to remove any residual wash solution from the microwells.
8. Add 100µL of the Conjugate to each well, including the reagent blank well, at the same rate and in the same order as the specimens were added.
9. Incubate the plate at room temperature (20-25°C) for 25 + 5 minutes.
10. Wash the microwells by following the procedure as described in step 7.
11. Add 100µL of TMB to each well, including reagent blank well, at the same rate and in the same order as the specimens were added.
12. Incubate the plate at room temperature (20-25°C) for 10 to 15 minutes.
13. Stop the reaction by adding 50µL of Stop Solution to each well, including reagent blank well, at the same rate and in the same order as the TMB was added. Positive samples will turn from blue to yellow. After adding the Stop
    Solution, tap the plate several times to ensure that the samples are thoroughly mixed.

14. Set the microwell reader to read at a wavelength of 450nm and measure the optical density (OD) of each well against the reagent blank. The plate should be read within 30 minutes after the addition of the Stop Solution.

ABBREVIATED TEST PROCEDURE

1. Dilute Serum 1:21.
2. Add diluted sample to microwell – 100µL/well.
3. → *Incubate 25 ± 5 minutes.*
4. Wash.
5. Add Conjugate – 100µL/well.
6. → *Incubate 25 ± 5 minutes.*
7. Wash.
8. Add TMB – 100µL/well.
9. → *Incubate 10 - 15 minutes.*
10. Add Stop Solution – 50µl/well – Mix.
11. READ within 30 minutes.

RESULTS

1. **Calculations:**
   a. *Correction Factor:* The manufacturer determined a Cutoff OD Value for positive samples and correlated it to the Calibrator. The Correction Factor (CF) allows for the determination of the Cutoff Value for positive samples. It will also correct for slight day-to-day variations in test results. The Correction Factor is determined for each lot of components and is printed on the Component Label located in the Test System box.
   b. *Cutoff OD Value:* To obtain the Cutoff OD Value, multiply the CF by the mean OD of the Calibrator determined above. (CF x Mean OD of Calibrator = Cutoff OD Value)
   c. *Index Values/OD Ratios:* Calculate the Index Value/OD Ratio for each specimen by dividing its OD Value by the Cutoff OD from step b.

Example:	
Mean OD of Calibrator	0.793
Correction Factor (CF)	0.25
Cut off OD	0.793 x 0.25 = 0.198
Unknown Specimen OD	0.432
Specimen Index Value or OD Ratio	0.432 / 0.198 = 2.18

2. **Interpretations:** Index Values or OD ratios are interpreted as follows:

	Index Value/OD Ratio
Negative Specimens	≤0.90
Equivocal Specimens	0.91 to 1.09
Positive Specimens	≥1.10

   a. An OD ratio ≤0.90 indicates no significant amount of antibodies to M. pneumoniae detected. A non-reactive result indicates no current/previous infection.
   b. An OD ratio ≥1.10 indicates that IgG antibodies specific to M. pneumoniae were detected. A reactive test result indicates a past/recent infection.
   c. Specimens with OD ratio values in the equivocal range (0.91 - 1.09) should be retested in duplicate. Report any two of the three results which agree. Evaluate repeatedly equivocal using an alternate serological method and/or re-evaluate by drawing another sample one to three weeks later.

QUALITY CONTROL

1. Each time the assay is run, the Calibrator must be run in triplicate. A reagent blank, Negative Control, and Positive Control must also be included in each assay.
2. Calculate the mean of the three Calibrator wells. If any of the three values differ by more than 15% from the mean, discard that value and calculate the mean using the remaining two wells.
3. The mean OD value for the Calibrator and the OD values for the Positive and Negative Controls should fall within the following ranges:

	OD Range
Negative Control	≤0.250
Calibrator	≥0.300
Positive Control	≥0.500

   a. The OD of the Negative Control divided by the mean OD of the Calibrator should be ≤0.9.
   b. The OD of the Positive Control divided by the mean OD of the Calibrator
   Should be ≥1.25.
   c. If the above conditions are not met the test should be considered invalid and should be repeated.

4. The Positive Control and Negative Control are intended to monitor for substantial reagent failure and will not ensure precision at the assay cut-off.
5. Additional controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations.
6. Refer to CLSI document C24: Statistical Quality Control for Quantitative Measurements for guidance on appropriate QC practices.

EXPECTED RANGES OF VALUES

Symptomatic infections attributable to this organism most commonly occur in children and young adults (ages two-19 years (12)). One report demonstrated that 97-98% of sera from a healthy adult population were non-reactive for *M. pneumoniae* antibody by CF and IFA (13). Each laboratory should establish their own expected results based upon the population type typically evaluated. The clinical study for this product included 2015 random specimens that were sent to a reference laboratory in the northeastern United States for routine Mycoplasma serological analysis. With respect to this population, 92/2015 (45%) were negative, 21/205 (10%) were equivocal, and 92/2015 (45%) were reactive.

PERFORMANCE CHARACTERISTICS

1. **Comparative Study**

A comparative study was performed to demonstrate the equivalence of the DAI *M. pneumoniae* IgG ELISA test system to a commercially available IFA IgG test system.

Evaluation of the performance of the *M. pneumoniae* IgG ELISA test system occured during a two-site clinical investigation. There were a total of 194 specimens tested; 109 at Site One, and 85 at Site Two. Most of the specimens (192/194) were obtained from a reference laboratory in the northeastern United States. These specimens were sent to the lab for routine Mycoplasma serological analysis. The remaining two specimens were repository specimens which had been previously tested for Mycoplasma IgG antibodies, and were

found to be positive. All specimens were frozen and maintained according to the guidelines indicated under the Specimen Collection section of this package insert. Specimens were tested on the DAI Mycoplasma IgG ELISA test system at the clinical sites, and were then tested in-house by IFA. Table 1 shows the results of this comparative study. These results represent those from single patient samples and not from multiple draws from the same patient.

Table 1: Calculation of Relative Sensitivity, Specificity, and Agreement

		Commercial IFA test results			
		≥1:64 Positive	<1:32 Negative	1:32 Equivocal	Total
DAI *M. pneumoniae* IgG ELISA Test System Results	Positive	69	12	17	98
	Negative	4	84	0	88
	Equivocal	2	6	0	8
	Total	75	102	17	194

Relative sensitivity = 69/73 = 94.5% (95% CI* = 89.3 to 99.7%)
Relative specificity = 84/96 = 87.5% (95% CI* = 80.9 to 94.1%)
Relative agreement = 153/169 = 90.5% (95% CI* = 86.1 to 94.9%)
*95% Confidence Intervals calculated using the exact method.

In addition to the two-site clinical study described above, the DAI *M. pneumoniae* IgG ELISA test system was used to evaluate 35 pairs of acute and convalescent specimens which were previously characterized by complement fixation (CF). Of the 35 pairs, 29 pairs demonstrated a four-fold or greater increase in the CF endpoint titer. Of the 29 pairs, 16 pairs were ELISA negative at the acute stage, and positive at the convalescent stage; 8 pairs were positive at both the acute and convalescent stage; and 5 pairs were negative at both the acute and convalescent stage. ***NOTE: 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 and Reproducibility**

Reproducibility was evaluated as outlined in document number EP5: Evaluation of Precision Performance of Clinical Chemistry Devices, Current Edition, as published by the National Committee for Clinical Laboratory Standards (NCCLS), Villanova, PA. Reproducibility studies were conducted at both clinical sites using the same specimens. Briefly, six specimens were assayed in duplicate. Also, on each day of testing, the assay was performed twice, once in the morning and once in the afternoon, for a total of four replicates for each specimen daily. The clinical sites conducted this reproducibility study for a 20 day period, for a total of 80 observations for each of the eight panel members. A summary of this investigation appears in Table 2 below:

Table 2: Summary of Precision Testing Conducted at Clinical Sites 1 and 2

Specimen	Site	Mean Ratio	Result	SWR*	ST**	Days	Total observations	Overall % CV
M-1	1	6.056	Positive	0.682	1.016	20	80	16.75
	2	6.124		0.349	0.683	20	80	11.15
M-2	1	3.084	Positive	0.220	0.449	20	80	14.55
	2	3.295		0.185	0.397	20	80	12.04
M-3	1	1.089	Near Cut-off	0.117	0.127	20	80	11.68
	2	0.896		0.087	0.124	20	80	13.83
M-4	1	0.881	Near Cut-off	0.056	0.073	20	80	8.32
	2	0.611		0.056	0.094	20	80	15.30
M-5	1	0.475	Negative	0.024	0.076	20	80	16.03
	2	0.093		0.045	0.077	20	80	83.35
M-6	1	0.443	Negative	0.026	0.072	20	80	16.24
	2	0.049		0.051	0.067	20	80	137.6
+ Ctrl	1	3.611	Positive	0.210	0.275	20	80	7.61
	2	3.680		0.257	0.311	20	80	8.44
- Ctrl	1	0.415	Negative	0.013	0.068	20	80	16.42
	2	0.111		0.062	0.119	20	80	107.6

*Point estimate of within run precision standard deviation.
**Point estimate of total precision standard deviation.

NOTE: The reproducibility results depicted in Table 2 are presented only as an example of those results obtained during the clinical study, using ideal conditions of environment, equipment, and technique. Reproducibility should be evaluated at each laboratory, and may vary, depending upon the conditions at the laboratory.

LIMITATIONS OF THE ASSAY

1. Do not make a diagnosis based on ELISA *M. pneumoniae* IgG Test System results alone but in conjunction with clinical evaluation and results of other diagnostic procedures.
2. If testing a particular specimen occurs early during the primary infection, no detectable IgG may be evident. If a Mycoplasma infection is suspected, a second sample should be taken at least 14 days.
3. Avoid the use of hemolytic, lipemic, bacterially contaminated, or heat-inactivated specimens. Erroneous results may occur.
4. Assay performance characteristics have not been determined for matrices other than serum.
5. A single positive result only indicates previous immunologic exposure. The level of antibody response or class of antibody response may both be required to determine active infection or disease stage.
6. Negative results do not rule out the diagnosis of *M. pneumoniae*-associated disease. The specimen may have been drawn before the appearance of detectable antibodies. Negative results in suspected early disease should be repeated in four to six weeks.
7. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.
8. Do not use test as a screening procedure for the general population. The predictive value of a positive or negative serologic result depends on the pretest likelihood of *M. pneumoniae* being present. Test only when clinical evidence suggests the diagnosis of *M. pneumoniae* associated disease.
9. The performance of DAI Mycoplasma IgG ELISA kit has not been tested on neonates and immunocompromised patients.

STORAGE CONDITIONS

8°C / 2°C	Coated Microwell Strips: Immediately reseal extra strips with desiccant and return to proper storage. After opening - strips are stable for 60 days, as long as the indicator strips on the desiccant pouch remains blue.
	Conjugate – DO NOT FREEZE.
	Unopened Test System, Calibrator, Positive Control, Negative Control, TMB, Sample Diluent
25°C / 2°C	Stop Solution: 2 - 25°C Wash Buffer (1X): 20 - 25°C for up to 7 days, 2 - 8°C for 30 days. Wash Buffer (10X): 2 - 25°C

PRECAUTIONS

1. For *In Vitro* diagnostic use.
2. Follow normal precautions exercised in handling laboratory reagents. In case of contact with eyes, rinse immediately with plenty of water and

seek medical advice. Wear suitable protective clothing, gloves, and eye/face protection. Do not breathe vapor. Dispose of waste observing all local, state, and federal laws.

3. The wells of the ELISA plate do not contain viable organisms. However, consider the strips **potentially biohazardous materials** and handle accordingly.
4. The Controls are **potentially biohazardous materials**. Source materials from which these products were derived were found negative for HIV-1 antigen, HBsAg and for antibodies against HCV and HIV by approved test methods. However, since no test method can offer complete assurance that infectious agents are absent, handle these products at the Biosafety Level 2 as recommended for any potentially infectious human serum or blood specimen in the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories": Current Edition; and OSHA's Standard for Bloodborne Pathogens (14).
5. Adherence to the specified time and temperature of incubations is essential for accurate results. **All reagents must be allowed to reach room temperature (20 - 25°C) before starting the assay**. Return unused reagents to refrigerated temperature immediately after use.
6. Improper washing could cause false positive or false negative results. Be sure to minimize the amount of any residual wash solution; (e.g., by blotting or aspiration) before adding Conjugate or Substrate. Do not allow the wells to dry out between incubations.
7. The Sample Diluent, Controls, and Calibrator contain Sodium Azide at a concentration of <0.1% (w/v). Sodium Azide has been reported to form lead or copper azides in laboratory plumbing which may cause explosions upon hammering. To prevent, rinse sink thoroughly with water after disposing of solution containing Sodium Azide.
8. The Stop Solution is TOXIC if inhaled, has contact with skin or if swallowed. It can cause burns. In case of accident or ill feelings, seek medical advice immediately.
9. The TMB Solution is HARMFUL. It is irritating to eyes, respiratory system and skin.
10. The Wash Buffer concentrate is an IRRITANT. It is irritating to eyes, respiratory system and skin.
11. Wipe the bottom of the plate free of residual liquid and/or fingerprints that can alter optical density (OD) readings.
12. Dilution or adulteration of these reagents may generate erroneous results.
13. Do not use reagents from other sources or manufacturers.
14. TMB Solution should be colorless, very pale yellow, very pale green, or very pale blue when used. Contamination of the TMB with Conjugate or other oxidants will cause the solution to change color prematurely. Do not use the TMB if it is noticeably blue in color.
15. Never pipette by mouth. Avoid contact of reagents and patient specimens with skin and mucous membranes.
16. Avoid microbial contamination of reagents. Incorrect results may occur.
17. Cross contamination of reagents and/or samples could cause erroneous results.
18. Reusable glassware must be washed and thoroughly rinsed free of all detergents.
19. Avoid splashing or generation of aerosols.
20. Do not expose reagents to strong light during storage or incubation.
21. Allowing the microwell strips and holder to equilibrate to room temperature prior to opening the protective envelope will protect the wells from condensation.
22. Collect the wash solution in a disposal basin. Treat the waste solution with disinfectant (i.e.: 10% household bleach - 0.5% Sodium Hypochlorite). Avoid exposure of reagents to bleach fumes.
23. Caution: Neutralize any liquid waste at an acidic pH before adding to a bleach solution.
24. Do not use ELISA plate if the indicator strip on the desiccant pouch has turned from blue to pink.
25. Do not allow the Conjugate to come in contact with containers or instruments that may have previously contained a solution utilizing Sodium Azide as a preservative. Residual amounts of Sodium Azide may destroy the Conjugate's enzymatic activity.
26. Do not expose any of the reactive reagents to bleach-containing solutions or to any strong odors from bleach-containing solutions. Trace amounts of bleach (sodium hypochlorite) may destroy the biological activity of many of the reactive reagents within this Test System.

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MANUFACTURER AND BRAND DETAILS

ISO 13485:2016

ISO 13485 Quality Management for Medical Devices CERTIFIED

Diagnostic Automation/Cortez Diagnostics, Inc.
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Date Adopted	2023-11
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REF 8042-P2	AccuDiag™ - Mycoplasma pneumoniae IgG ELISA
EC REP	CEpartner4U, Esdoornlaan 13, 3951 DB Maarn, The Netherlands www.cepartner4u.eu
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