



## DIAGNOSTIC AUTOMATION, INC.

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See external label

2°C  8°C



96 tests



8042-2Z

# Mycoplasma pneumoniae IgG

Test	Mycoplasma pneumoniae IgG
Method	Enzyme Linked Immunosorbent
Principle	Peroxidase – Conjugated Sandwich ELISA
Detection Range	Positive and Negative Control
Sample	10ul serum
Specificity	87.5%
Sensitivity	95%
Total Time	~ 60 min
Shelf Life	12-14 months

***For In-vitro diagnostic use only***

*Laboratory results can never be the only base of a medical report. The patient history and further tests have to be taken into account.*

## **INTENDED USE**

The Diagnostic Automation, Inc. Mycoplasma IgG ELISA 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, or were studies performed on very young and/or elderly patients.

## **SIGNIFICANCE AND BACKGROUND**

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 the 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). Species-specific antibodies to surface antigens are now known to 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).

## **PRINCIPLE OF THE ELISA ASSAY**

The Diagnostic Automation, Inc. Mycoplasma IgG ELISA test system is designed to detect IgG class antibodies to Mycoplasma IgG in human sera. Wells of plastic micro well strips are sensitized by passive absorption with Mycoplasma IgG antigen. The test procedure involves three incubation steps

- The diluted test sera are incubated in antigen coated micro wells. Any antigen specific antibody in the sample will bind to the immobilized antigen.
- After wash procedure peroxidase Conjugated goat anti-human IgG ((γ chain specific) is added to the wells and the plate is incubated. The Conjugate will react with IgG antibody immobilized on the solid.
- After wash procedure 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.

## EQUIPMENT AND MATERIALS

### MATERIALS PROVIDED

Each kit contains the following components in sufficient quantities to perform the number of tests indicated on packaging label. The following components are not kit lot number dependent and maybe used interchangeably with the ELISA assays: TMB, Stop Solution, and Wash Buffer.

Note: All reactive reagents contain sodium azide as a preservative at a concentration of 0.1% (w/v).

1. **Plate:** 96 wells configured in twelve, 1x8- well, strips coated with inactivated M. pneumonia (strain FN) 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 ( $\gamma$  chain specific). One, 15 mL, white- capped bottle. Ready to use.
3. **Positive Control (Human Serum):** One, 0.35 mL, red-capped, vial.
4. **Calibrator (Human Serum):** One, 0.5mL, blue-capped vial.
5. **Negative Control (Human Serum):** One, 0.35mL, green-capped vial.
6. **Diluent:** One, 30mL, green-capped, bottle containing Tween-20, bovine serum albumin and phosphate-buffered-saline, (pH  $7.2 \pm 0.2$ ). Ready to use. Note: The Diluent will change color when combined with serum.
7. **TMB:** One, 15 mL, amber-capped, amber bottle containing 3, 3', 5, 5' – tetramethylbenzidine (TMB). Ready to use. Contains DMSO < 15% (w).
8. **Stop Solution:** One, 15 mL, red-capped, bottle containing 1M H<sub>2</sub>SO<sub>4</sub>, 0.7M HCl. Ready to use.
9. **Wash Buffer Concentrate (10X):** Dilute 1 part concentrate + 9 parts deionized or distilled water. One, 100mL, clear-capped, bottle containing a 10X concentrated phosphate-buffered – saline and Tween-20 solution (Blue solution). Note: 1X solution will have a pH of  $7.2 \pm 0.2$ .

#### Note:

1. Component list containing lot specific information in inside the kit box.
2. Package insert will provide instruction for use.]

### MATERIALS REQUIRED BUT NOT PROVIDED

- Reagent reservoirs for multi-channel pipettes, reagent tubes for the serum dilution
- Wash bottle or micro well washing system.
- Distilled or deionized water, one liter graduated cylinder.
- Serological pipettes, disposable pipette tips, Paper towels, Laboratory timer to monitor incubation steps.
- Disposal basin and disinfectant.
- Microtiter Plate Reader (450 nm) (Cat # DAX 800), Microtiter Plate Washer (Cat # DAX 50)

### STORAGE CONDITIONS

1. Store the unopened kit between 2° and 8°C.
2. Coated micro well strips: Store between 2° and 8°C. Extra strips should be immediately resealed with desiccant and returned to proper storage. Strips are stable for 60 days after the envelope has been opened and properly resealed and the indicator strip on the desiccant pouch remains blue.
3. Conjugate: Store between 2° and 8°C. DO NOT FR EEZE.
4. Calibrator, Positive Control and Negative Control: Store between 2° and 8°C.
5. TMB: Store between 2° and 8°C.
6. Wash Buffer concentrates (10X): Store between 2° and 25°C. Diluted wash buffer (1X) is stable

at room temperature (20° to 25°C) for up to 7 days or for 30 days between 2° and 8°C.

7. Sample Diluent: Store between 2° and 8°C.
8. Stop Solution: Store between 2° and 25°C.

## SPECIMEN COLLECTION

1. It is recommended that specimen collection be carried out in accordance with NCCLS document M29: Protection of Laboratory Workers from Infectious Disease.
2. No known test method can offer complete assurance that human blood samples will not transmit infection. Therefore, all blood derivatives should be considered potentially infectious.
3. Only freshly drawn and properly refrigerated sera obtained by approved aseptic venipuncture procedures should be used in this assay (10, 11). No anticoagulants or preservatives should be added. 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° and 8°C for no longer than 48 hours. If delay in testing is anticipated, store test sera at -20°C or lower. Avoid multiple freeze/thaw cycles that may cause loss of antibody activity and give erroneous results.

## 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. NOTE: Shake Well before Use) of the Negative Control, Calibrator, Positive Control, and each patient serum. The Sample Diluent will undergo a color change confirming that the specimen has been combined with the diluent.
4. To individual wells, add 100µL of each diluted control, calibrator and 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 micro well strips 5X.

**A. Manual Wash Procedure:**

- a. Vigorously shake out the liquid from the wells.
- b. Fill each microwell with Wash Buffer. Make sure no air bubbles are trapped in the wells.
- c. Repeat steps a. and b. for a total of 5 washes.
- d. 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 0.5% sodium hypochlorite (bleach) at the end of the days 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 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 micro well 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.

**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:

	<u>OD Range</u>
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 NCCLS document C24: Statistical Quality Control for Quantitative Measurements for guidance on appropriate QC practices.

**INTERPRETATION OF RESULTS**

**A. Calculations:**

### 1. Correction Factor

A cutoff OD value for positive samples has been determined by the manufacturer and correlated to the Calibrator. The correction factor (CF) will allow you to determine the cutoff value for positive samples and to correct for slight day-to-day variations in test results. The correction factor is determined for each lot of kit components and is printed on the Component List located in the kit box.

### 2. Cutoff OD Value

To obtain the cutoff OD value, multiply the CF by the mean OD of the Calibrator determined above.  
( $CF \times \text{mean OD of Calibrator} = \text{cutoff OD value}$ )

### 3. Index Values or OD Ratios

Calculate the Index Value or OD Ratio for each specimen by dividing its OD value by the cutoff OD from step 2.

#### Example:

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

## B. Interpretations:

### **Negative $\leq 0.90$**

*NO detectable IgG antibody to Mycoplasma by the ELISA test. Suggests to current immunological exposure to Mycoplasma pneumoniae; result does not rule out recent exposure and collection of test sample prior to development of IgG. Culture is recommended for determining current infection.*

### **Equivocal 0.91-1.09**

*Samples should be retested. Immunological exposure cannot be assessed. Samples that remain equivocal after repeat testing should be retested by an alternate method, e.g., immunofluorescence assay (IFA). If results remain equivocal upon further testing, an additional sample should be taken.*

### **Positive $> 1.10$**

*Significant level of detectable IgG antibody to Mycoplasma. Indicative of current or recent infection.*

1. An OD ratio  $\leq 0.90$  indicates no detectable IgG antibodies to *M. pneumoniae*. A non-reactive result indicates no current or previous infection with *M. pneumoniae*.
2. An OD ratio  $\geq 1.10$  is reactive for IgG antibodies to *M. pneumoniae*. A reactive test result indicates a past or recent infection with *M. pneumoniae*.
3. Specimens with OD ratio values in the equivocal range (0.91 - 1.09) should be retested in duplicate. Any two of the three results which agree should be reported. Specimens that remain equivocal after repeat testing should be tested by an alternate serologic procedure such as the Zeus Scientific, Inc. indirect fluorescent antibody (IFA) test procedure.

**NOTE:** Performance of this assay has not been tested with specimens known to be positive for antibodies to organisms which are known to be associated with lower respiratory illness ( i.e., Influenza A & B, CMV, *C. pneumoniae*, parainfluenza), and closely related Mycoplasma serovars known to cross-react with *M. pneumoniae*. **Cross-reactivity studies with such**

organisms have not been performed with this test system.

## PRECAUTIONS

1. For *In Vitro* Diagnostic Use.
2. Normal precautions exercised in handling laboratory reagents should be followed. 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, the strips should be considered **POTENTIALLY BIOHAZARDOUS MATERIALS** and handled accordingly.
4. The human serum 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, these products should be handled 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 (12).
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, wash buffer, and conjugate 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 on hammering. To prevent, rinse sink thoroughly with water after disposing of solution containing sodium azide.
8. The Stop Solution is TOXIC. Causes burns. Toxic by inhalation, in contact with skin and if swallowed. In case of accident or if you feel unwell, seek medical advice immediately.
9. The TMB Solution is HARMFUL. Irritating to eyes, respiratory system and skin.
10. The Wash Buffer concentrate is an IRRITANT. Irritating to eyes, respiratory system and skin.
11. Wipe bottom of 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. Reagents from other sources or manufacturers should not be used.
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 micro well strips and holder to equilibrate to room temperature prior to opening the protective envelope will protect the wells from condensation.
22. Wash solution should be collected in a disposal basin. Treat the waste solution with 10% household bleach (0.5% sodium hypochlorite). Avoid exposure of reagents to bleach fumes.
23. Caution: Liquid waste at acid pH should be neutralized before adding to 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 kit.

## **LIMITATIONS OF THE ASSAY**

1. A diagnosis should not be made on the basis of anti-Mycoplasma results alone. Test results for anti-Mycoplasma should be interpreted in conjunction with the clinical evaluation and the 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 fourteen days later.
3. The use of hemolytic, lipemic, bacterially contaminated or heat inactivated specimens should be avoided. Erroneous results may occur.
4. Assay performance characteristics have not been established 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 4-6 weeks.
7. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.
8. Testing should not be performed 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. Testing should only be done when clinical evidence suggests the diagnosis of M. pneumoniae associated disease.
9. The performance of this device has not been established on neonates and immunocompromised patients.

## **EXPECTED RESULTS**

Symptomatic infections attributable to this organism most commonly occur in children and young adults (ages 2-19 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 own expected results based upon the population type typically evaluated. The clinical study for this product included 205 random specimens which sent to a reference laboratory in the Northeastern United States for routine Mycoplasma serological analysis. With respect to this population, 92/205 (45%) were negative, 21/205 (10%) were equivocal, and 92/205 (45%) were reactive.



# PERFORMANCE CHARACTERISTICS

## Comparative Study:

A comparative study was performed to demonstrate the equivalence of the DAI Mycoplasma IgG ELISA test system to the DAI IgG IFA test system.

The performance of the DAI Mycoplasma IgG ELISA test system was evaluated in 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 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 to Mycoplasma IgG antibody, and were found to be positive. All specimens were frozen and maintained according to the guidelines indicated under the Specimen Collection section of this insert.

Specimens were tested on the ELISA test system at the clinical sites, and were then tested in-house by IFA. Table 1 below 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**

### DAI IFA Test System

	$\geq 1:64$ Positive	$<1:32$ Negative	1:32 Equivocal	Totals
+	69	12	17	98
-	4	84	0	88
$\pm$	2	6	0	8
Total	75	102	17	194

## DAI Mycoplasma IgG ELISA Results

Relative Sensitivity =  $69/73 = 94.5\%$  (95% Confidence Interval\* = 89.3 to 99.7%)

Relative Specificity =  $84/96 = 87.5\%$  (95% Confidence Interval\* = 80.9 to 94.1%)

Relative Agreement =  $153/169 = 90.5\%$  (95% Confidence Interval\* = 86.1 to 94.9%)

\* 95% confidence intervals calculated using the exact method.

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.

## 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 tested, two relatively strong positive specimens, two specimens near the cut-off, and two which were clearly negative. Additionally, the kit's Negative Control and Positive Control were included as additional panel members, for a total of eight specimens. On each day of testing, each of the eight 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 twenty 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	High	0.682	1.016	20	80	16.75
	2	6.124	Positive	0.349	0.683	20	80	11.15
M-2	1	3.084	High	0.220	0.449	20	80	14.55
	2	3.295	Positive	0.185	0.397	20	80	12.04
M-3	1	1.089	Near	0.117	0.127	20	80	11.678
	2	0.896	Cut-off	0.087	0.124	20	80	13.83
M-4	1	0.881	Near	0.056	0.073	20	80	8.32
	2	0.611	Cut-off	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
Positive Control	1	3.611	Positive	0.210	0.275	20	80	7.61
	2	3.680		0.257	0.311	20	80	8.44
Negative Control	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.

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