Diamedix®
A Subsidiary of ERBA Diagnostics, Inc.

Mycoplasma pneumoniae IgG

Enzyme Immunoassay Test Kit
For *In Vitro* Diagnostic Use
Catalog No. 720-850 – 96 Tests

SUMMARY OF PROCEDURE

1. Prepare 1: 101 dilutions of samples in Sample Diluent. Mix well.
2. Add 100 µl of diluted samples into the antigen wells. Reserve one well for reagent blank (100 µl of Sample Diluent).
3. Incubate at room temperature (18 - 30°C) for 30 ± 5 min.
4. Discard contents of the wells. Wash the wells 3 times with Wash Solution.
5. Add 100 µl of Conjugate to each well.
6. Incubate at room temperature for 30 ± 5 min.
7. Wash the wells as in #4 above.
8. Add 100 µl Substrate Solution to each well.
9. Incubate at room temperature for 30 ± 5 min.
10. Add 100 µl Stop Solution to each well.
11. Read the absorbance at 450 nm (reference at 600 - 630 nm) against the reagent blank.

INTENDED USE

For the qualitative detection of IgG antibodies to *Mycoplasma pneumoniae* in human serum by indirect enzyme immunoassay. This test can aid in the assessment of the patient's immunological status, or may aid in the diagnosis of *M. pneumoniae*-associated disease.

SUMMARY AND EXPLANATION

Mycoplasmas are members of the *Mollicutes* class of bacteria and are the smallest self-replicating organisms. These bacteria lack a cell wall making them resistant to many antibiotics. The primary human pathogen is *Mycoplasma pneumoniae,* which is known to cause a wide range of clinical symptoms, ranging from mild respiratory infections ("walking pneumonia"), to tracheobronchitis and severe atypical pneumonia (1). Unlike other respiratory infections, *M. pneumoniae* infections tend not to be seasonal. In large populations, disease is endemic year-round with periodic increases in incidence, whereas in smaller populations, outbreaks appear as epidemics (2,3). The elderly and children are at elevated risk of infection.

Diagnostic tests for *M. pneumoniae* infections include cold agglutinins, complement fixation, and culturing. Detecting the cold agglutinins is fast, simple to perform, and relatively inexpensive, but these are found in only 30 to 50% of *M. pneumoniae* infections (1,5). Complement fixation (CF) assays, though widely performed, detect predominantly "early" IgM antibodies and only to a minor extent IgG antibodies. The diagnostic value of the CF test may be limited to the initial *M. pneumoniae* infection. Another disadvantage of the CF assay is the antigen used is a crude extract, which is not specific for *M. pneumoniae.* Similar antigens (glycolipids) are found in human tissues and streptococci extracts, which may lead to false positive results (4). *M. pneumoniae* culturing is difficult due to the slow growth rate. The use of enzyme immunoassays offers several advantages over the other assay methods. Increased specificity is obtained by using purified detergent-treated *M. pneumoniae* extracts as antigens, which minimize the glycolipid cross-reactivity(4). Isotype-specific enzyme conjugates provide antibody information and the assay can be optimized for high sensitivity.

The Diamedix *immuno*simplicity® *Mycoplasma pneumoniae* IgG Test Kit is an EIA procedure intended for the qualitative detection of IgG antibodies to *M. pneumoniae* antigen.

PRINCIPLE OF THE PROCEDURE

Purified *Mycoplasma pneumoniae* antigen is bound to microwells. Diluted patient sera, Cut-Off Calibrator, and controls are placed in the microwells and incubated. Anti-*M. pneumoniae* IgG antibodies, if present, will bind to the antigen forming antigen-antibody complexes. Residual sample is eliminated by aspirating and washing. Conjugate (horseradish peroxidase-labeled anti-human IgG) is added and will bind to these complexes. Unbound conjugate is removed by aspirating and washing. Substrate is then added and incubated. In the presence of bound enzyme, the substrate is converted to an end product. The absorbance of this end product can be read spectrophotometrically at 450 nm (reference 600-630 nm) and is directly proportional to the concentration of IgG antibodies to *M. pneumoniae* present in the sample.

REAGENTS

Each Is-Mycoplasma pneumoniae IgG Test Kit contains reagents for 96 tests.

Antigen Wells	Twelve, 8-well microwell breakapart strips, color-coded dark green and coated with purified *M. pneumoniae* antigen (strain FH).
Cut-Off Calibrator	One vial with blue cap containing 0.5 ml of human serum or defibrinated plasma, weakly reactive for *M. pneumoniae* IgG antibodies, 0.1% sodium azide. The Cut-Off Calibrator is used to determine the cut-off of the assay.
Negative Control	One vial with black cap containing 0.25 ml of non-reactive human serum or defibrinated plasma, 0.1% sodium azide. Assigned range printed on the label. The Negative Control is used to control the negative range of the assay.
Low Positive Control	One vial with white cap containing 0.25 ml of reactive human serum or defibrinated plasma, 0.1% sodium azide. Assigned range printed on the label. The Positive Control is used to control the low range of the assay.
Sample **A** Diluent	One bottle with blue cap containing 60 ml Phosphate buffer with protein stabilizers. Contains 0.2% sodium azide, Proclin® 300, 90 ppm active ingredient. Color-coded blue.
Wash **T** Concentrate (20X)	Two bottles with clear caps containing 50 ml of Tris buffer with detergent and Proclin® 300, 15 ppm active ingredient. Each bottle is sufficient to make 1050 ml of wash solution.
Conjugate	One bottle with red cap containing 25 ml goat anti-human immunoglobulin G labeled with horseradish peroxidase. Also includes protein stabilizers and Proclin® 300, 30 ppm active ingredient. Color coded pink.
Substrate **HRP**	One amber bottle with brown cap containing 25 ml buffered TMB solution (3,3',5,5' tetramethylbenzi-dine).
Stop **N** Solution	One bottle with white cap containing 30 ml of 1N Sulfuric Acid. **CAUTION:** Acids are corrosive. Avoid contact with skin or eyes. If contact is made, flush area with copious amounts of water.

Store these reagents at 2 to 8° C.

OTHER MATERIALS REQUIRED

Manual Users:

Wash bottle or automated microplate washer.

Pipettors capable of dispensing appropriate volumes.

Timer.

One liter graduated cylinder.

One liter wash solution reservoir.

Deionized or distilled water.

Absorbent toweling.

Tubes or microwell plate for sample dilution.

Reader capable of reading absorbance at 450 nm, reference at 600-630 nm.

Automated EIA Processor Users:

One liter graduated cylinder.

Deionized or distilled water.

Pre-dilution cups, strips or plates.

ProbeClean™ Concentrate, or tip washing detergent solution, if applicable.

PRECAUTIONS

1. Handle samples, Calibrator, controls and the materials that contact them as potential biohazards. Each donor unit in the Calibrator and controls has been found negative for Hepatitis B surface antigen, Hepatitis C and HIV-1 &2 antibodies by FDA-approved third generation tests. However, because no method can offer complete assurance that HIV-1&2, Hepatitis B virus, Hepatitis C, or other infectious agents are absent,

these materials should be handled at the Biosafety Level 2 as recommended for any potentially infectious serum or blood specimen in the Centers for Disease Control/National Institutes of Health manual, "Biosafety in Microbiological and Biomedical Laboratories", 1993.

2. Never pipette by mouth.
3. Avoid contact with open skin and mucous membranes.
4. Certain of the test reagents contain Proclin® 300 as a preservative. When disposing of reagents containing Proclin® 300, flush drains with copious amounts of water to dilute the active components below active levels.
5. Reagents containing Sodium Azide:
   (a) **CAUTION**: Some reagents in this kit contain Sodium Azide as preservative. Sodium Azide may react with lead or copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up. For further information, refer to "Decontamination of Laboratory Sink Drains to Remove Azide Salts", in the Manual Guide – Safety Management No. CDC-22, issued by the Centers for Disease Control and Prevention, Atlanta, GA, 1976.

   European Communities Hazardous Substance Risk Phrases (Regulation (EC) No 1272/2008)

   H300 –Fatal if swallowed.
   H310 – Fatal if contact with skin.
   EUH032 – Contact with acids liberates very toxic gas.
   H410 – Very toxic to aquatic life with long lasting effect.
   P264 – Wash all exposed external body areas thoroughly after handling.
   P302+P352 – IF ON SKIN: Wash with plenty of water and soap.
   P301+P310/P330 – IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth.
   P270 – Do not eat, drink or smoke when using this product.
   P501 – Dispose of contents/container as hazardous waste.
   P391 – Collect spillage.
   P273 – Avoid release to the environment. Refer to special instructions/ Safety Data Sheet.
   (b) Sodium Azide inhibits horseradish peroxidase activity. Care must be taken to ensure that azide is not carried over from other reagents into conjugate and substrate steps.
6. Avoid contamination of the TMB Substrate Solution with conjugate or other oxidants, which will cause the solution to change color prematurely.
7. Do not interchange reagents from different reagent lots except for Sample **A** Diluent, Wash **T** Concentrate, Substrate **HRP**, and Stop **N** Solution.
8. Do not use reagents beyond their expiration date. Expiration dates are printed on the reagent labels.
9. Store unused reagents at 2 to 8°C.
10. Incubations above or below the recommended temperatures or times may give erroneous results.
11. The EIA method is a very sensitive technique. Maintain consistent pipetting technique, incubation times, and temperature conditions throughout the test procedure. Cross contamination between reagents can invalidate the test.
12. Antigen coated microwells should be stored with the desiccant in the resealable bag provided and returned to the refrigerator immediately after use.
13. (*Manual Procedure Only*) The washing procedure is very important and requires special attention. (Please refer to the Procedure section).

    Note: Improperly washed wells may give erroneous results.
14. The reported concentrations of anti-*M. pneumoniae* IgG in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity.

SPECIMEN COLLECTION

Whole blood should be collected by accepted medical techniques. Separated serum should remain at 22°C for no longer than 8 hours. If assays are not completed within 8 hours, serum should be refrigerated (2 - 8°C). If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -20°C. Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen sera to room temperature slowly and mix gently, avoiding foam formation. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Grossly contaminated, hemolyzed, lipemic, or icteric specimens should not be used. The CLSI (formerly NCCLS) provides recommendations for collecting and storing blood specimens (6).

CAUTION: *Serum samples must not be heat-inactivated prior to use.*

PROCEDURE

Allow all test components and patient samples to warm to room temperature before use. Invert reagent bottles gently several times before use. Return promptly to the refrigerator after use.

Prepare Wash Solution by adding 50 ml of Wash Concentrate (20X) to one liter of deionized or distilled H_2O.

MANUAL USERS:

1. Prepare 1:101 dilutions of the Cut-Off Calibrator (in triplicate), controls, and patient samples in Sample Diluent (e.g., by addition of 5 µl sample to 500 µl Sample Diluent).
2. Mix sample dilutions gently by withdrawing and expelling in a pipette tip 2 or 3 times or by vortex mixing for 2 or 3 seconds. Transfer 100 µl of diluted calibrator, controls, and diluted patient samples, to the antigen wells. Avoid formation of bubbles when transferring diluted samples.

   NOTE: Include one well, which contains 100 µl of Sample Diluent only, as the reagent blank. This will ultimately be used to "zero" the photometer before reading the test results.
3. Allow the wells to incubate at room temperature (18 - 30°C) for 30 ± 5 minutes.
4. Aspirate or discard the contents of the wells. Remove any excess moisture in the wells by tapping on paper toweling if necessary. Wash the wells by rinsing 3 times with at least 300 µl per well of Wash Solution. Remove excess moisture from the wells after washing. When using an automated washer, follow the manufacturer's instructions.
5. Place 100 µl of Conjugate into each well, avoiding bubble formation.
6. Allow the wells to incubate uncovered at room temperature (18 - 30°C) for 30 ± 5 minutes.
7. Wash the wells as described in Step 4 above.
8. Place 100 µl of Substrate into each well, avoiding bubble formation.
9. Allow the wells to incubate uncovered at room temperature (18 - 30°C) for 30 ± 5 minutes.
10. Place 100 µl of Stop Solution into each well, avoiding bubble formation.
11. Read the absorbance of each well at 450 nm and zero against the reagent blank. A suitable reference wavelength (e.g., 600-630 nm) reading should be used. Read the plate within 30 minutes of adding Stop Solution.

Automated EIA Processor Users:

When using an Automated EIA Processor, refer to the Operator's Manual for the test setup and procedures.

NOTE: *Automated EIA Processor users must validate their equipment to demonstrate that the results obtained are equivalent to those obtained using manual assay.*

QUALITY CONTROL

1. The Positive and Negative Controls must be included in each test run.
2. The absorbance of the reagent blank must be < 0.25.
3. The absorbance of the Cut-Off Calibrator must be ≥ 0.10.
4. The Positive and Negative Controls must be within their assigned ranges.

If any one of these criteria is not met, the results are invalid and the test should be repeated.

Note: Additional controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations. For guidance on appropriate quality control practices please refer to CLSI (formerly NCCLS) C24-A2, Statistical Quality Control for Quantitative Measurements: Principles and Definitions.

RESULTS

1. Calculation

Calculate the mean absorbance of the Cut-Off Calibrator. Note: When calculating the mean absorbance value for the Cut-Off Calibrator exclude any absorbance value that deviates by more than 15% from the mean of the three absorbance values. Use the mean of the remaining two replicates in calculations. Exclusion of more than one of the three absorbance values invalidates the run.

Determine the Index Value for each patient specimen or control using the following formula:

$$\frac{\text{Absorbance of Sample}}{\text{Mean Absorbance of Cut-Off Calibrator}} = \text{Index Value}$$

An Automated EIA Processor (e.g. MAGO® Plus Automated EIA Processor) will calculate results using the above formula and will print them automatically.

Example: *Absorbance values obtained for Cut-Off Calibrator:*
0.276, 0.288, 0.258 (after subtraction of blank).
Mean Absorbance of Cut-Off Calibrator = 0.274
Sample Absorbance = 1.150
Index Value = 1.150/0.274 = 4.2

2. Interpretation

Index Value	Interpretation
< 0.90	No detectable IgG antibodies to *M. pneumoniae*.
0.90 - 1.09	Equivocal for IgG antibodies to *M. pneumoniae*. Samples can be retested by another method or a new sample can be tested.
≥ 1.10	IgG antibodies to *M. pneumoniae* detected.

3. Reporting Results

When the Index Value is reported for a single specimen the following statement should be included "The following results were obtained with the Is-*Mycoplasma pneumoniae* IgG Test Kit. The magnitude of the measured result, above the cut-off, is not indicative of the total amount of antibody present. The magnitude of the reported IgG level cannot be correlated to an endpoint titer".

LIMITATIONS

1. The results obtained with the Is-*Mycoplasma pneumoniae* IgG Test Kit serve only as an aid to diagnosis and should not be interpreted as diagnostic in themselves.
2. Assay performance characteristics have not been established for visual result determination. Kit procedures or practices outside those in this package insert may yield questionable results.
3. The test should be performed on serum. The use of whole blood or plasma has not been established.
4. If the testing of 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 later. 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.
5. The use of hemolytic, lipemic, bacterially contaminated or heat inactivated specimens should be avoided.
6. Performance of this assay has not been established on spectrophotometry utilizing a single wavelength.
7. A single positive result only indicates previous immunologic exposure. The level of antibody response or class of antibody may both be required to determine active infection or disease stage.
8. The performance of this device has not been established on neonates and immunocompromised patients.
9. False positive results may occur with sera from patients with *Ureaplasma, Mycoplasma hominis, Mycoplasma genitalium*, pancreatitis, bacterial meningitis and other acute inflammatory disease. Cross-reactivity of this assay with antibodies to the above disease states has not been determined. Epidemiology of case, symptoms and other laboratory tests can help in differentiating these conditions from *Mycoplasma pneumoniae* infection.
10. *Mycoplasma pneumoniae* infection can have a long incubation period, thus elevated antibody titers in the acute specimen are common, and reinfection may occur. Therefore, seroconversions (negative to positive) are unusual.
11. The performance characteristics of the Is-*Mycoplasma pneumoniae* IgG Test Kit with automated equipment other than the MAGO Plus Automated EIA Processor have not been established.

EXPECTED VALUES

The prevalence of *Mycoplasma pneumoniae* IgG antibodies in the normal population can vary depending on a number of factors such as age, geographic location, socioeconomic status, and testing method used. The reported prevalence of *M. pneumoniae* antibodies generally varies from about 27% in 2 to 10 year olds to 71 % in persons 20 to 29 years of age. In the present studies, sera from 121 healthy blood donors (62 female and 59 male) were evaluated using the *Mycoplasma pneumoniae* IgG Test Kit. Of the 121 samples, 55 (45%) were found to be reactive (positive), 51 (42%) were found to be non-reactive (negative), and 15 (13%) sera were equivocal. The age distribution. geographical location and prevalence for this sample group is provided in TABLE 1. Histograms demonstrating the distribution of Index Values for the positive and negative samples are shown in FIGURES 1 and 2.

TABLE 1

	Number of Donors	Prevalence
Total Number	121	45.5%
Geographic Location: S. Florida	121	45.5%
Age		
2 - 10	11	27.3%
10 – 19	22	50.0%
20 – 29	17	70.6%
30 – 39	29	34.5%
40 – 49	20	60.0%
50 – 59	14	35.7%
60 – 74	8	25.0%

FIGURE 1
***Is-Mycoplasma* IgG Positive Population**

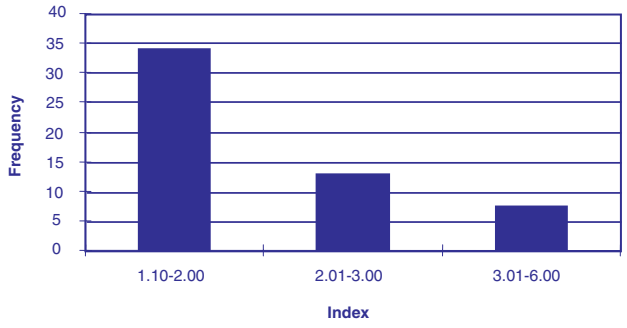
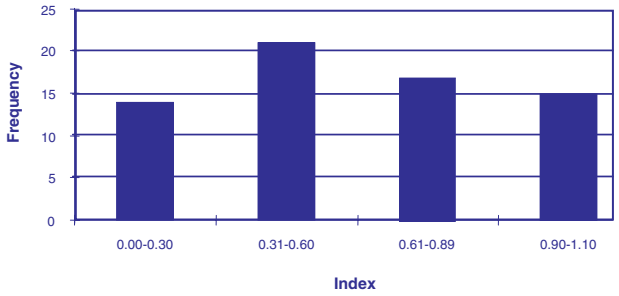


FIGURE 2
***Is-Mycoplasma* IgG Negative Population**



PERFORMANCE CHARACTERISTICS

A. Comparison Testing

A total of two hundred and twenty-three frozen retrospective serum samples were tested by both the manual and automated methods using the *Mycoplasma pneumoniae* IgG Test Kit. All samples were also tested manually using another commercially available test kit for the detection of *M. pneumoniae* IgG antibodies. All testing was performed by the manufacturer. TABLES 2 and 3 summarize the results obtained.

TABLE 2

Is-*Mycoplasma pneumoniae* IgG -Manual

		Is-Mycoplasma pneumoniae IgG		
		Positive	**Negative**	**Equivocal***
Another *M. pneumoniae IgG* ELISA	**Positive**	96	25	15
	Negative	0	56	1
	Equivocal*	2	25	3

Overall agreement = 152/177 = 85.9% 95% Confidence Interval = 80.7 – 91.0

* Equivocal results not included.

TABLE 3

Is-*Mycoplasma pneumoniae* IgG –MAGO Plus

		Is-Mycoplasma pneumoniae IgG		
		Positive	**Negative**	**Equivocal***
Another *M. pneumoniae IgG* ELISA	**Positive**	88	20	18
	Negative	1	60	2
	Equivocal*	9	21	4

Overall agreement = 148/169 = 87.6% 95% Confidence Interval = 82.6 – 92.5

* Equivocal results not included.

For the manual method, of the twenty-five samples that were negative in the *M. pneumoniae* IgG Test Kit and positive in the other EIA, nineteen were negative, three were positive, and three were equivocal when tested by a referee EIA method. For the MAGO Plus method, of the twenty samples that were negative in the *M. pneumoniae* IgG Test Kit and positive in the other EIA, thirteen were negative, five were positive, and two were equivocal when tested by a referee method. The sample that was positive in the *M. pneumoniae* IgG Test Kit and negative by the other EIA was negative in the referee method.

B. Precision

To determine the precision of the *Mycoplasma pneumoniae* IgG Test Kit, six sera, as well as the calibrator and kit controls were assayed in triplicate in two separate runs on three different days. The intra- and interassay precision is shown in TABLE 4.

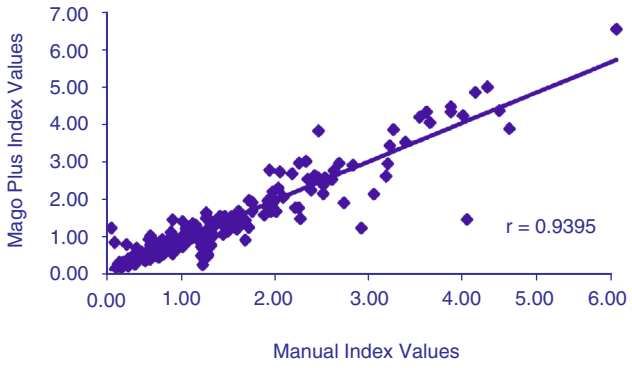
TABLE 4

SERUM	INTRA-ASSAY DAY 1			INTRA-ASSAY DAY 2			INTRA-ASSAY DAY 3			INTERASSAY		
	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%
A (NEG)	0.294	0.018	6.2	0.302	0.011	3.8	0.301	0.020	6.5	0.299	0.0163	5.4
B (NEG)	0.463	0.011	2.3	0.464	0.013	2.7	0.414	0.029	7.1	0.447	0.0299	6.7
C (POS)	1.765	0.050	2.9	1.833	0.099	5.4	1.806	0.065	3.6	1.801	0.0756	4.2
D (POS)	2.033	0.015	0.7	2.198	0.195	8.9	1.989	0.061	3.1	2.073	0.1443	7.0
E (POS)	2.556	0.157	6.1	2.446	0.226	9.2	2.310	0.037	1.6	2.437	0.1827	7.5
F (POS)	2.754	0.144	5.2	2.694	0.143	5.3	2.600	0.062	2.4	2.683	0.1320	4.9
C/O Cal	1.021	0.072	7.0	1.013	0.033	3.3	1.024	0.063	6.2	1.019	0.0551	5.4
LPC	1.490	0.150	10.1	1.529	0.104	6.8	1.579	0.041	2.6	1.533	0.1082	7.1
NC	0.220	0.013	5.9	0.227	0.007	3.3	0.223	0.015	6.9	0.223	0.0120	5.4

C. Correlation of Manual and MAGO Plus Results

The *M. pneumoniae* IgG Test Kit has been developed for automated as well as manual use. To demonstrate the equivalence of the manual and MAGO Plus procedures, the results of 233 serum samples tested by both methods were plotted. A scattergram and regression line of the results obtained is shown in FIGURE 3. The data indicate good correlation with a Pearson Correlation Coefficient (r) of 0.9395.

FIGURE 3: Manual vs. MAGO Plus Result Correlation



D. MAGO Plus Precision

The precision of the *Mycoplasma pneumoniae* IgG Test Kit when performed on the MAGO Plus Automated EIA Processor was determined by assaying six sera, as well as the calibrator and kit controls, in triplicate in two separate runs on three different days. The intra- and interassay precision is shown in TABLE 5.

TABLE 5

SERUM	INTRA-ASSAY DAY 1			INTRA-ASSAY DAY 2			INTRA-ASSAY DAY 3			INTERASSAY		
	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%
A (NEG)	0.352	0.013	3.8	0.308	0.032	10.3	0.363	0.027	7.5	0.341	0.034	10.0
B (NEG)	0.530	0.122	23.0	0.467	0.026	5.5	0.493	0.072	14.5	0.497	0.082	16.6
C (POS)	1.882	0.094	5.0	1.760	0.137	7.8	1.927	0.091	4.7	1.856	0.126	6.8
D (POS)	1.748	0.127	7.3	1.948	0.250	12.8	1.840	0.145	7.9	1.846	0.191	10.3
E (POS)	3.297	0.154	4.7	3.273	0.267	8.1	3.195	0.179	5.6	3.255	0.198	6.1
F (POS)	3.152	0.052	1.7	2.642	0.336	12.7	3.135	0.164	5.2	2.976	0.318	10.7
C/O Cal	1.178	0.048	4.0	1.070	0.121	11.3	1.058	0.068	6.4	1.079	0.096	8.9
LPC	1.373	0.110	8.0	1.318	0.078	5.9	1.323	0.057	4.3	1.338	0.084	6.2
NC	0.213	0.020	9.2	0.217	0.027	12.6	0.295	0.052	17.5	0.242	0.051	21.2

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