Diamedix®
A Subsidiary of ERBA Diagnostics, Inc.

Mumps IgG

Enzyme Immunoassay Test Kit
For *In Vitro* Diagnostic Use
Catalog No. 720-540 – 96 Tests

SUMMARY OF PROCEDURE

1. Prepare 1:21 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 (18-30°C) 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 absorbances at 450/600-630 nm against the reagent blank.

INTENDED USE

For the qualitative and semi-quantitative determination of IgG antibodies to Mumps virus in human serum of adults over eighteen years of age by indirect enzyme immunoassay as an aid in the diagnosis of Mumps infection. The evaluation of paired sera, to determine a significant increase in Mumps IgG antibody titer, can also aid in the diagnosis of acute infection by seroconversion determination through testing acute and convalescent sera. Performance characteristics have not been established on children.

SUMMARY AND EXPLANATION

Mumps virus is a member of the Paramyxoviridae family of viruses.[1, 2, 4] Mumps virions are pleomorphic, single stranded RNA viruses.[1] The disease is usually an acute, self-limited systemic illness most frequently occurring in children aged 5-19 years.[2,3] Recently there has been a shift in the epidemiology so that adult infections have become more common than before. This is due to under-immunized young currently entering the work force and colleges.[3,5] The most commonly recognized feature of the illness is the swelling of the parotid salivary glands on either or both sides of the face.[1,4] Fever, headache, and fatigue usually accompany the parotitis. Complications may include: meningitis, encephalitis, orchitis, oophoritis, polyarthritis, and pancreatitis.[2,4,6] Transmission of the virus is by droplet. The incubation period ranges from 2-4 weeks.

The Immunosimplicity (*Is)* Mumps IgG Test Kit is an EIA procedure intended for the qualitative and semi-quantitative detection of Mumps IgG antibodies.

PRINCIPLE OF THE PROCEDURE

Purified native Mumps antigen is bound to microwells. Diluted patient sera, Cut-Off Calibrator and controls are placed in the microwells and incubated. Anti-Mumps 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 aspiration 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). Color development above a certain level denotes the presence of antibody.

REAGENTS

Each Is-Mumps Test Kit contains reagents for 96 tests.

Antigen Wells	Twelve, 8-well microwell breakapart strips, color-coded yellow, coated with purified native Mumps antigen (Enders Strain ATCC#VR-106).
Cut-Off Calibrator	One vial with blue cap containing 0.5 ml of human serum or defibrinated plasma weakly reactive for Mumps, 0.1% sodium azide. The Cut-Off Calibrator is used to determine the cut-off of the assay.
Low Positive Control	One vial with white cap containing 0.25 ml of human serum or defibrinated plasma reactive for Mumps, 0.1% sodium azide. Assigned range printed on label. The Low Positive Control is used to control the low range of the assay.
Negative Control	One vial with black cap containing 0.25 ml of human serum or defibrinated plasma non-reactive for Mumps antibodies, 0.1% sodium azide. Assigned range printed on label. The negative control is used to control the negative range of the assay.

Note: Calibrators and Controls are prepared from separate lots of materials.

Sample **B** Diluent	One bottle with blue cap containing 60 ml Phosphate buffer with protein stabilizers. Contains Proclin® 300, 15 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 preservatives. Color-coded pink.
Substrate **HRP**	One amber bottle with brown cap containing 25 ml buffered TMB solution (3,3',5,5' tetramethyl-benzidine).
Stop **N** Solution	One bottle with white cap containing 30 ml of 1 N Sulfuric Acid. CAUTION: Acids are corrosive. Avoid contact with skin or eyes. If contact is made, flush area with copious amounts of water. See Precautions section.

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 serum dilution.
Reader capable of reading absorbance at 450 nm, reference at 600-630 nm (performance characteristics have not been established for a single wavelength reader).

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

REAGENTS: For *In Vitro* Diagnostic Use.

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 and HIV-I antibodies by FDA-approved third generation tests. However, because no method can offer complete assurance that HIV-1, Hepatitis B virus, 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.

ADDITIONAL PRECAUTIONS:

1. Do not interchange reagents from different reagent lots except for Sample B Diluent, Wash T Concentrate, Substrate HRP and Stop N Solution.
2. Do not use reagents beyond their expiration date. Expiration dates are printed on the reagent labels.
3. Store unused reagents at 2 to 8°C.
4. Incubations above or below the recommended temperatures or times may give erroneous results.
5. 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.
6. Antigen coated microwells should be stored with the desiccant in the resealable bag provided and returned to the refrigerator immediately after use.
7. (*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.*
8. The reported concentration of anti-Mumps 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, (Approved Standard - Procedures for the Handling and Processing of Blood Specimens, H18-A3). If paired sera analysis is to be performed, obtain the second sample at least two weeks after the first sample. Test both samples within the same assay.

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 1:21 dilutions of the Cut-Off Calibrator (in triplicate), controls and patient samples in Sample Diluent. (e.g., by addition of 10 µl sample to 200 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 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 as a reagent blank. This will ultimately be used to "zero" the photometer before reading test results.*
3. Allow the wells to incubate uncovered at room temperature (18-30°C) for 30 $\pm$ 5 minutes.
4. Aspirate or discard the contents of the wells. Remove any excess moisture in the wells by tapping on paper toweling. Wash the wells by rinsing 3 times with at least 300 µl 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 $\pm$ 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 $\pm$ 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 using a reference wavelength of 600-630 nm. The plate should be read within 60 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. If paired sera controls are desired, it is recommended that a four-fold dilution of a sample with an Index Value of between 3.0 and 4.0 is first made in Sample Diluent and then diluted according to assay procedures. The undiluted and 4-fold diluted material will provide a simulated serum pair. The four-fold dilution Index Ratio is compared against the established range.
2. The Positive and Negative Controls must be included in each test run.
3. The absorbance of the Blank must be < 0.25.
4. The absorbance of the Cut-Off Calibrator must be > 0.10 against the reagent blank.
5. The Positive and Negative Controls must be within their assigned ranges. The assigned range for the Positive Control is between 1.1 and 3.1.
6. Calibrators and Controls are made from separate lots of materials.

If any of these criteria are 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, or federal regulations or accrediting organizations. For guidance on appropriate quality control practices please refer to CLSI C24-A2, Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approval Guideline-Second Edition (formerly NCCLS document C24-A, Internal Quality Control Testing: 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 Mumps IgG antibody; result does not exclude Mumps infection. An additional sample should be tested within 4-6 weeks if early infection is suspected.
0.90 – 1.09	Equivocal for IgG antibodies to Mumps. Sample should be retested. If retest results are equivocal, the sample should be reported as equivocal, tested by another method, or a new sample should be tested*.
≥ 1.10	Mumps IgG antibody detected. Indicative of current or past infection.

* Equivocal samples that give positive results on retest should be reported as positive. Equivocal samples that give negative results on retest should be reported as negative.

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*-Mumps IgG Test Kit. The magnitude of the measured result, above the cutoff, is not indicative of the total amount of antibody present. The magnitude of the reported IgG level cannot be correlated to an endpoint titer".

When the assay is used semi-quantitatively, the following statement should be included when reporting results: "Timing of specimen collection for paired sera may be critical. In some patients, antibody titers may rise to significant levels and fall again to lower or undetectable levels within a month. Other patients may not develop significant antibody levels. Culture results, serology and antigen detection methods should all be appropriately used along with clinical findings for diagnosis".

4. Paired Sera

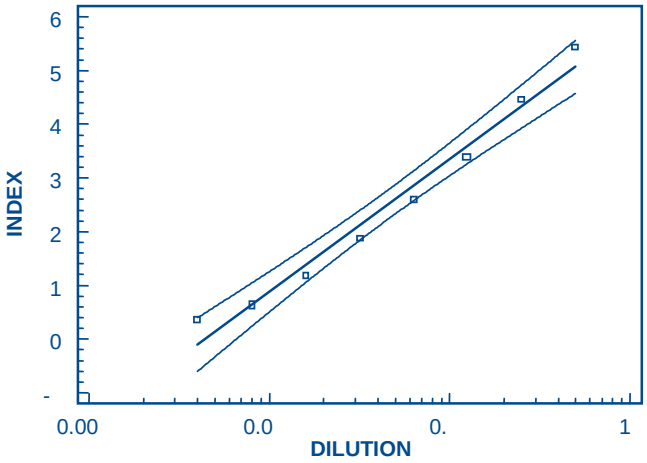
To determine a significant difference between acute/convalescent serum pairs, both specimens should be run within the same assay. The maximum value for the acute serum is 2.30. The maximum Index Value found for a convalescent serum using this criteria was 4.05. Therefore, the linearity of the assay is 1.10 - 4.05. If the acute serum result is > 2.30 the paired sera analysis cannot be used. Studies performed have shown that a 1.6-fold to a 2.2-fold (mean 1.9-fold ± 1.5 SD) increase in Index ratio (convalescent serum Index Value / acute serum Index Value) corresponds to a four-fold increase in Mumps IgG antibody titer, therefore any serum pair with an Index ratio > 1.6 is indicative of a significant antibody increase. Index ratios between > 1.4 to < 1.6 are considered equivocal for a significant antibody increase and require the user to either retest or obtain a new convalescent specimen within 2 weeks. Index ratios of < 1.4 are not indicative of a significant antibody increase between acute and convalescent specimens. An acute serum with an Index Value of < 0.9 and a convalescent serum with an Index of >1.10 is considered a seroconversion. It is not necessary to determine a significant antibody increase between acute and convalescent, it has already occurred. It is only necessary to determine a significant antibody increase for specimens which have an acute Index Value of > 0.90.

In summary, the following criteria are to be utilized for paired sera analysis:

* Both specimens must be tested concurrently.
* The acute serum must be < 2.30 and the convalescent serum must be ≤ 4.05 index ratio.
* An Index ratio of > 1.6 is indicative of a significant antibody increase.
* Index ratios between 1.4 and 1.6 are considered equivocal for significant antibody increase.
* Index ratios <1.4 are not indicative of a significant antibody increase.

Figure 1 illustrates the linearity of a representative sample. The Index values were compared to the log of the dilution.

FIGURE 1



y = 5.8175 + 2.466 Log (X)
r = 0.9873
95% CI for r = 0.9287 to 0.9978

CUT-OFF ESTABLISHMENT

The *Is*-Mumps IgG Test Kit cut-off value was established to identify those individuals without an apparent immunological experience to Mumps. Known positive samples were not incorporated for this determination. This device has been optimized for analytical, not clinical, sensitivity only. The optimal Cut-Off was determined by statistical analysis of the results of 20 sera shown to be negative for Mumps IgG antibodies in the *Is*-Mumps IgG Test Kit as well as other methods. The mean and standard deviation of the absorbance values for these sera were 0.161 and 0.082 respectively. The Cut-Off was determined as being equal to the mean plus 3 standard deviations, 0.161 + (3 x 0.082) = 0.41. The Cut-Off Calibrator has been titrated to equal this result. Therefore, the mean value of the Cut-Off Calibrator will be equal to the cut-off for the assay. To account for the inherent variations in EIA methods, an equivocal range of ± 10% has been included.

LIMITATIONS

1. Although mumps virus has been implicated with various syndromes, there has been no cross-reactivity testing performed with this assay or with other paramyxoviruses such as parainfluenza which are known to cross-react with mumps virus antibodies. Therefore, a definitive diagnosis of mumps may not be made without a comparable clinical picture. Culture results and clinical symptoms must be taken into consideration before a diagnosis of mumps can be determined.
2. The linearity of the assay has been determined to be from Index Values of 1.10 to 4.05. Serum pairs with acute values > 2.30 can not be used for paired sera analysis.
3. Assay performance characteristics have not been established for visual result determination.
4. The test should be performed on serum. The use of whole blood or plasma has not been established.
5. Results from immunosuppressed patients should be interpreted with caution.
6. The performance characteristics of the *Is*-Mumps IgG Test Kit with automated equipment other than the MAGO® Plus Automated EIA Processor have not been established.
7. Icteric, lipemic, hemolyzed, or heat inactivated sera may cause erroneous results and should be avoided.
8. The results obtained with the *Is*-Mumps IgG Test Kit serve only as an aid to diagnosis and should not be interpreted as diagnostic in themselves. Culture results and clinical symptoms must be taken into consideration before a diagnosis of mumps can be determined.
9. Performance characteristics have not been established in mumps vaccinated individuals.
10. A single positive result only indicates previous immunologic exposure. The level of antibody response or class of antibody response may not be used to determine active infection or disease stage.

EXPECTED VALUES

The prevalence of Mumps IgG antibodies in the normal population can vary depending on a number of factors such as age, geographical location, socio-economic status, race and testing method used. Due to vaccination programs, greater than 90% of the U.S. population demonstrates antibody to the virus.

In the present studies sera from 177 normal individuals of various ages and genders from different geographic locations were evaluated in the Mumps IgG Test Kit. Eleven samples (6.2%) were negative for antibodies to Mumps IgG. One hundred sixty-five samples (93.2%) were positive and one sample (0.6%) was equivocal for Mumps IgG antibodies. In unvaccinated populations, 92% of children have antibodies against mumps virus by age fifteen (7). 95% of adults have been shown to have antibodies against mumps virus (8). The age distribution and prevalence for this population is shown in Table 1. Histograms showing the distribution of Index Values of positive and negative Mumps IgG in a normal population are shown in Figures 2 and 3. Prevalence with this assay has not been adequately established with prospective data including the appropriate demographic information.

TABLE 1

	Number of donors	Prevalence
Total Number	177	93.2%
Geographic Locations:		
Various	177	93.2%
Age		
2 – 10	13	100%
11 – 20	20	100%
21 – 40	48	87.5%
41 – 60	57	93.1%
61 – 80	31	96.8%
81 – 91	7	85.7%

FIGURE 2
Prevalence of Positive Mumps IgG in a Normal Population

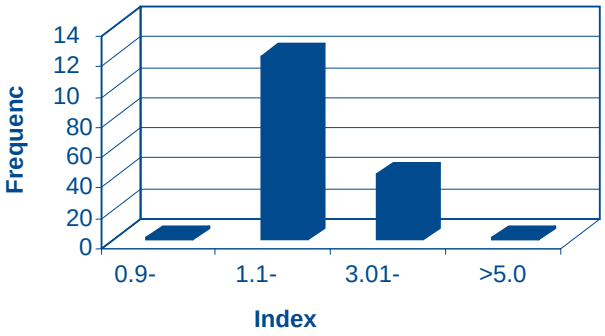
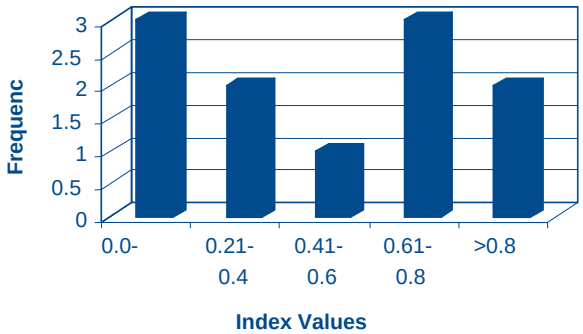


FIGURE 3
Prevalence of Negative Mumps IgG in a Normal Population



PERFORMANCE CHARACTERISTICS

A. Comparison with Another ELISA Test

Fresh sera from one hundred and seventy-three patients were tested at a clinical commercial laboratory, located in the Mid-Atlantic area, using the *Is*-Mumps IgG Test Kit and a commercially available kit for Mumps IgG antibodies. The data in Table 2 show the relative sensitivity, specificity and overall agreement of the *Is*-Mumps IgG Test Kit versus this commercial Mumps IgG ELISA.

TABLE 2
***Is*-Mumps IgG Test Kit**

		POSITIVE	* EQUIVOCAL	NEGATIVE
Other ELISA	POSITIVE	160	0	0
	* EQUIVOCAL	0	0	0
	NEGATIVE	3**	3***	10

				95% CI
Relative Sensitivity	= 160/160	=	100%	97.7% - 100%
Relative Specificity	= 10/13	=	76.9%	46.2% - 95.0%
Overall Agreement	= 170/173	=	98.3%	95.0% - 99.6%

* Equivocal results were excluded from calculations.

** 3/3 sera were positive by IFA.

*** 3/3 sera were positive by IFA.

NOTE: Please be advised that 'relative' refers to the comparison of the 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's accuracy to predict disease.

B. Reproducibility

To determine the reproducibility of the *Is*-Mumps IgG Test Kit, four positive and two negative sera were assayed ten times each in three different runs at three different sites. The 3 sites included: the manufacturer, a research and development laboratory, and a clinical commercial laboratory. The intra- and interassay reproducibility obtained at each site is shown in Tables 3, 4 and 5.

TABLE 3
Site #1- Intra-Assay and Interassay Reproducibility

SERUM	INTRA-ASSAY RUN 1		INTRA-ASSAY RUN 2		INTRA-ASSAY RUN 3		INTERASSAY	
	MEAN INDEX	CV%	MEAN INDEX	CV%	MEAN INDEX	CV%	MEAN INDEX	CV%
A (POS)	1.11	4.26	1.17	8.82	1.24	8.90	1.17	8.70
B (POS)	1.26	5.19	1.34	6.04	1.38	4.82	1.33	6.36
C (POS)	1.95	9.02	2.02	5.33	2.17	4.22	2.05	7.55
D (POS)	1.74	7.27	1.64	6.67	1.73	7.68	1.70	7.48
E (NEG)	0.15	40.25	0.18	25.53	0.23	21.39	0.18	32.18
F (NEG)	0.14	39.81	0.13	39.09	0.16	39.88	0.14	39.03

TABLE 4
Site #2- Intra-Assay and Interassay Reproducibility

SERUM	INTRA-ASSAY RUN 1		INTRA-ASSAY RUN 2		INTRA-ASSAY RUN 3		INTERASSAY	
	MEAN INDEX	CV%	MEAN INDEX	CV%	MEAN INDEX	CV%	MEAN INDEX	CV%
A (POS)	1.188	6.38	1.248	6.53	1.371	9.35	1.269	9.63
B (POS)	1.384	10.51	1.338	6.38	1.515	6.57	1.412	9.43
C (POS)	2.110	6.94	1.976	6.74	2.247	8.75	2.111	9.09
D (POS)	1.673	4.86	1.738	7.98	1.949	5.05	1.787	8.92
E (NEG)	0.227	9.44	0.247	15.95	0.314	11.60	0.263	18.86
F (NEG)	0.175	8.14	0.198	4.37	0.228	8.18	0.200	13.02

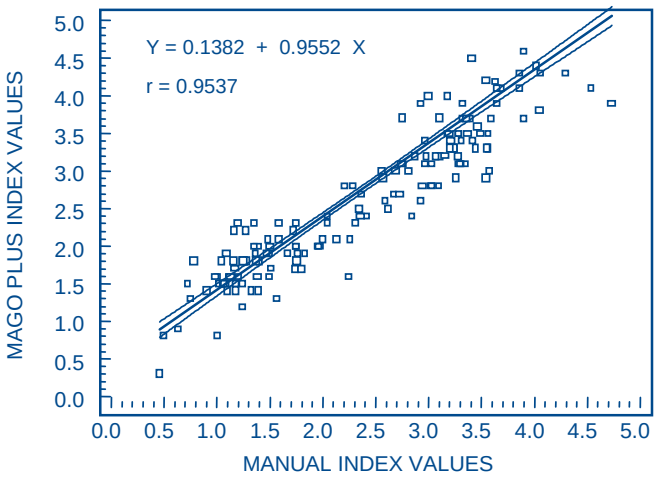
TABLE 5
Site #3- Intra-Assay and Interassay Reproducibility

SERUM	INTRA-ASSAY RUN 1		INTRA-ASSAY RUN 2		INTRA-ASSAY RUN 3		INTERASSAY	
	MEAN INDEX	CV%	MEAN INDEX	CV%	MEAN INDEX	CV%	MEAN INDEX	CV%
A (POS)	1.21	10.20	1.24	7.00	1.18	6.15	1.21	8.04
B (POS)	1.31	4.49	1.31	2.57	1.31	5.12	1.31	4.06
C (POS)	2.10	7.04	2.08	5.84	2.09	6.51	2.09	6.28
D (POS)	1.83	5.75	1.71	8.72	1.67	4.69	1.74	7.54
E (NEG)	0.28	34.40	0.24	15.53	0.16	24.35	0.23	35.19
F (NEG)	0.20	15.41	0.21	8.87	0.16	15.88	0.19	17.49

C. Correlation of Manual and MAGO Plus Results

The *Is*-Mumps 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 153 serum samples, tested by both methods, were plotted. A scattergram and regression line of the results obtained with 95% confidence intervals is shown in Figure 4. The data indicate good correlation with a Pearson Correlation Coefficient of 0.954.

FIGURE 4
Manual vs. MAGO Plus Result Correlation



D. MAGO Plus Reproducibility

The reproducibility of the assay when performed on the MAGO® Plus Automated EIA Processor was determined by assaying six sera ten times each in three different runs. Table 6 shows the intra-and interassay reproducibility obtained using the MAGO Plus.

TABLE 6
Site #2- Intra-Assay and Interassay Reproducibility-MAGO Plus

SERUM	INTRA-ASSAY RUN 1		INTRA-ASSAY RUN 2		INTRA-ASSAY RUN 3		INTERASSAY	
	MEAN INDEX	CV%	MEAN INDEX	CV%	MEAN INDEX	CV%	MEAN INDEX	CV%
A (POS)	1.2	9.26	1.3	10.04	1.2	9.91	1.2	10.03
B (POS)	1.4	11.60	1.5	6.92	1.5	13.06	1.5	11.50
C (POS)	2.2	10.96	2.3	8.93	2.3	8.72	2.2	9.62
D (POS)	1.9	10.27	1.9	8.06	1.8	8.42	1.9	8.84
E (NEG)	0.2	28.41	0.2	0.00	0.2	23.57	0.2	21.19
F (NEG)	0.1	0.00	0.1	28.75	0.1	28.75	0.1	23.79

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Rev. 5 – June 15

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