INSTRUCTIONS FOR USE

EN

Anti-Mumps Virus IgG

REF 9Z9281G
SM9Z9281G
9Z9281GB

IVD

CE

Rx Only

Σ 96

Σ 480

INTENDED USE

Anti-Mumps Virus IgG is intended for the qualitative detection of Mumps IgG antibody in human sera. When performed according to these instructions, the results of this test, together with other clinical information, may aid in the determination of immune status, and/or aid in the diagnosis of Mumps infections.

SIGNIFICANCE AND BACKGROUND

Mumps is an acute, generally self-limiting, contagious disease with moderate fever of short duration. Bilateral or unilateral parotitis is the most common clinical feature. Secondary involvement concerns the testes, ovaries, central nervous system and, more rarely, the pancreas, peripheral nerves, eye, inner ear, and other organs (1).

The incubation period for Mumps virus ranges between 18 and 21 days. Infections are spread by droplets via the upper respiratory route. Between 25 and 50 percent of all infections are silent. Immunity after infection appears to be life-long; however, silent re-infections may occur although it is probably an infrequent event. An attenuated live virus vaccine is available which induces lower levels of measurable antibody than natural infection (1, 2). Only one distinct antigenic type of Mumps virus is known. Some antigenic cross reactivity and anamnestic antibody responses exist with other paramyxoviruses, particularly Parainfluenza Type 1, in some serological tests (1, 2, and 3).

Many tests for the determination of antibodies to Mumps virus have been described. The traditional assays of viral neutralization, hemagglutination inhibition (HI), and complement fixation (CF) all have the drawbacks of either being too cumbersome for routine serological work, or have shortcomings with regard to sensitivity, and reliability. Both CF and HI suffer from a relatively low sensitivity, and cross reacting antibodies to other paramyxoviruses may pose a problem (1, 2). Both immunofluorescence (IFA) and ELISA tests have the advantages of being sensitive and capable of allowing the separate identification of IgG and IgM viral antibodies for both determination of immune status and diagnosis of acute infection (1, 2).

PRINCIPLE OF THE ASSAY

Anti-Mumps Virus IgG is designed to detect IgG class antibodies to Mumps virus in human sera. Creation of the sensitized wells of the plastic microwell strips occurs using passive adsorption with antigen. The test procedure involves three incubation steps:

1. Test sera (properly diluted) are incubated in antigen coated microwells. Any antigen specific 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 Mumps antibody immobilized on the solid phase in step 1. The wells are washed to remove unreacted 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.

TEST SYSTEM COMPONENTS

Materials Provided:

Each Test System contains the following components in sufficient quantities to perform the number of tests indicated on the packaging label. **NOTE:** The following components contain Sodium Azide as a preservative at a concentration of <0.1% (w/v): Controls, Calibrator, and SAVe Diluent®.

Kit Component	Quantity Σ96	Quantity Σ480	Description
PLATE	1	5	Plate: 96 wells configured in twelve, 1x8-well, strips coated with Mumps Virus antigen (Enders Strain). The strips are packaged in a strip holder and sealed in an envelope with desiccant.
CONJ	1	5	Conjugate: Conjugated (horseradish peroxidase) goat anti-human IgG (Fc chain specific) in 15mL, white-capped bottle(s). Ready to use.
CTRL +	1	2	Positive Control (Human Serum): 0.35mL, red-capped vial(s). 21X concentrate.
CAL	1	4	Calibrator (Human Serum): 0.5mL, blue-capped vial(s). 21X concentrate.
CTRL -	1	2	Negative Control (Human Serum): 0.35mL, green-capped vial(s). 21X concentrate.
DIL SPE	1	4	SAVe Diluent®: 30mL, green-capped, bottle(s) containing Tween-20, bovine serum albumin and phosphate-buffered-saline. Ready to use. **NOTE: The SAVe Diluent® will change color when combined with serum.**
SOLN TMB	1	5	TMB: 15mL, amber-capped, amber bottle(s) containing 3, 3', 5, 5' - tetramethylbenzidine (TMB). Ready to use.
SOLN STOP	1	3	Stop Solution: 15mL, red-capped, bottle(s) containing 1M H_2SO_4, 0.7M HCl. Ready to use.
WASH 10X	1	5	Wash Buffer Concentrate (10X): Dilute 1 part concentrate + 9 parts deionized or distilled water. 100mL, clear-capped, bottle(s) 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.**

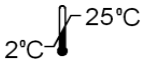
NOTE: The following components are not Test System Lot Number dependent and may be used interchangeably with the ZEUS ELISA Test Systems: TMB, Stop Solution, and Wash Buffer. SAVe Diluent® may be used interchangeably with any ZEUS ELISA Test System utilizing Product No. 005CC.

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).

STORAGE CONDITIONS

2°C – 8°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 remain blue.
	Conjugate – DO NOT FREEZE.

	Unopened Kit, Calibrator, Positive Control, Negative Control, TMB, Sample Diluent.
	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 (6).
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 SAVe 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.

SPECIMEN COLLECTION

1. ZEUS Scientific 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 (4, 5). 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 (7).

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 for six Control/Calibrator determinations (one Reagent Blank, one Negative Control, three Calibrators and one Positive Control) per run. Run a Reagent Blank 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 - 8°C.

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

3. Prepare a 1:21 dilution (e.g.: 10µL of serum + 200µL of SAVe Diluent®) of the Negative Control, Calibrator, Positive Control, and each patient serum. **NOTE: The SAVe 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 patient specimen. Ensure that the samples are properly mixed. Use a different pipette tip for each sample.
5. Add 100µL of SAVe 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 5 times.
   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 1. and 2. 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.
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 the Reagent Blank well, at the same rate and in the same order as the specimens.
12. Incubate the plate at room temperature (20 - 25°C) for 10 - 15 minutes.

13. Stop the reaction by adding 50µL of Stop Solution to each well, including the Reagent Blank well, at the same rate and in the same order as the TMB. 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. Read the plate within 30 minutes of 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.

QUALITY CONTROL

1. Each time the assay is performed, the Calibrator must be run in triplicate. A Reagent Blank, Negative Control, and Positive Control must also be included.
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, Positive Control, and Negative Control 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, but will not ensure precision at the assay Cutoff.
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 Measurement Procedures for guidance on appropriate QC practices.

INTERPRETATION OF 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
	Cutoff OD	=	0.793 x 0.25 = 0.198
	Unknown Specimen OD	=	0.432
	Specimen Index Value/OD Ratio	=	0.432/0.198 = 2.18

2. **Interpretations:** Index Values/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 IgG antibodies to the Mumps virus detected. A non-reactive result indicates no current or previous infection with Mumps Virus. Such patients are presumed to be non-immune and are therefore susceptible to a primary infection. A non-reactive result may be obtained early in seroconversion of infected individuals. If this is suspected, obtain an additional specimen in three to five weeks for re-testing.

b. An OD ratio ≥1.10 indicates that IgG antibodies specific to the Mumps virus were detected. A reactive test result indicates a past or current infection, or prior vaccination against, the Mumps Virus. Results of this assay are qualitative. The magnitude of the ratio for positive specimens may not correlate with antibody titer.

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 specimens using an alternate serological method and/or re-evaluate by drawing another sample one to three weeks later.

LIMITATIONS OF THE ASSAY

1. Do not make a diagnosis solely on the basis of Anti-Mumps Virus IgG results. Interpret test results for anti-Mumps in conjunction with the clinical evaluation and the results of other diagnostic procedures.
2. If testing a particular sample occurs early during primary infection, no detectable IgG may be evident. If Mumps viral infection is suspected, a second sample should be taken at least 14 days later.
3. Interpret a non-reactive test result in an immunocompromised patient with caution.

EXPECTED RESULTS

The clinical study for this product included 200 random, routine specimens, which were sent to a reference laboratory for Mumps serology. With respect to this population, 24 of the 200 specimens (12.0%) were negative, 176 of the 200 (88.0%) were positive, and none of the 200 (0%) were equivocal.

PERFORMANCE CHARACTERISTICS

1. **Comparative Study**

A comparative study was conducted to demonstrate the equivalence of Anti-Mumps Virus IgG to two other ELISA test systems currently in commercial distribution. The performance of Anti-Mumps Virus IgG was evaluated in a two-site clinical investigation. Both clinical sites were located in Northeastern United States. For the comparative study, Site One utilized one commercially distributed ELISA test system (Commercial Test A), and Site Two utilized another commercially distributed ELISA test system (Commercial Test B). Briefly, there were a total of 233 specimens tested: 113 at Site One, and 120 at Site Two. All specimens were frozen one time and stored frozen until testing occurred. The age of the patients and gender were unknown. Specimens tested at Site One included 100 samples which were sent to a reference lab for routine Mumps serology, and 13 specimens which had been previously characterized as Mumps IgG negative. Specimens tested at Site Two included 100 specimens which were sent to a reference lab for routine Mumps serology, and 20 specimens which had been previously characterized as Mumps IgG negative. The results of this comparative study have been summarized in Tables 1 - 3.

Table 1: Calculation of Relative Sensitivity, Specificity, and Agreement; Clinical Site One

		Anti-Mumps Virus IgG Result			
		Positive	Negative	Equivocal	Total
Commercial Test A	Positive	88	3	0	91
	Negative	3	17	0	20
	Equivocal	0	2*	0	2
	Total	91	22	0	113

*Two samples (N5, 51) were equivocal on the Commercial assay. Repeat testing of the specimens resulted in repeatedly equivocal results. These equivocal specimens were excluded from all calculations.

Relative Sensitivity = 88/91 = 96.6% 95% Confidence Interval** = 93.0 - 100%
Relative Specificity = 17/20 = 85.0% 95% Confidence Interval** = 69.3 - 100%
Relative Agreement = 105/111 = 94.6% 95% Confidence Interval** = 90.4 - 98.8%
** 95% confidence intervals calculated using the normal method.

Table 2: Calculation of Relative Sensitivity, Specificity, and Agreement; Clinical Site Two

		Anti-Mumps Virus IgG Result			
		Positive	Negative	Equivocal	Total
Commercial Test B	Positive	85	3	0	88
	Negative	2	30	0	32
	Equivocal	0	0	0	0
	Total	87	33	0	120

Relative Sensitivity = 85/88 = 96.6% *95% Confidence Interval = 92.8 to 100%
Relative Specificity = 30/32 = 93.8% *95% Confidence Interval = 85.4 to 100%
Relative Agreement = 115/120 = 95.8% *95% Confidence Interval = 92.2 to 99.4%
*95% confidence intervals calculated using the normal method.

Table 3: Calculation of Relative Sensitivity, Specificity, and Agreement; Both Clinical Sites Combined

		Anti-Mumps Virus IgG Result			
		Positive	Negative	Equivocal	Total
Both Commercial Tests Combined	Positive	173	6	0	179
	Negative	5	47	0	52
	Equivocal	0	2*	0	2
	Total	178	55	0	233

*Two samples (N5, 51) were equivocal on Commercial Test A. Repeat testing of the specimens resulted in repeatedly equivocal results. These equivocal specimens were excluded from all calculations.

Relative Sensitivity = 173/179 = 96.6% **95% Confidence Interval = 94.0 to 99.3%
Relative Specificity = 47/52 = 90.4% **95% Confidence Interval = 82.4 to 98.4%
Relative Agreement = 220/231 = 95.2% **95% Confidence Interval = 92.5 to 98.0%
**95% confidence intervals calculated using the normal method.

2. **Reproducibility**

Reproducibility was evaluated as outlined in document number EP5-T2: Evaluation of Precision Performance of Clinical Chemistry Devices - Second Edition, as published by the National Committee for Clinical Laboratory Standards (NCCLS), Villanova, PA. Reproducibility studies were conducted at both of the clinical sites using the same specimens. Briefly, six specimens were tested, two relatively strong positive specimens, two specimens closer to the cutoff optical density, and two negative specimens. Additionally, the Test System's Negative and Positive Controls were included as two 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. Sites One and Two conducted this reproducibility study for a 20 day period for a total of 80 observations for each of the eight panel members. The results of this study are depicted in Table 4 below.

Table 4: Summary of Precision Testing Conducted at Clinical Sites 1 and 2

Specimen	Site	Mean Ratio	Result	SWR*	ST**	Days	Total	Overall % CV
MU-1	1	3.801	Positive	0.142	0.180	20	80	4.73
	2	4.235		0.338	0.515	20	80	12.15
MU-5	1	5.235	Positive	0.095	0.272	20	80	5.20
	2	6.384		0.437	0.861	20	80	13.49
MU-3	1	1.065	Near Cutoff	0.033	0.046	20	80	4.30
	2	0.773		0.092	0.165	20	80	21.38
MU-7	1	1.004	Near Cutoff	0.034	0.057	20	80	5.64
	2	0.741		0.079	0.174	20	80	23.42
MU-9	1	0.399	Negative	0.017	0.032	20	80	7.91
	2	0.136		0.044	0.071	20	80	51.81
MU-10	1	0.648	Negative	0.030	0.045	20	80	6.97
	2	0.377		0.048	0.122	20	80	32.33
Positive Control	1	7.170	Positive	0.148	0.547	20	80	7.63
	2	2.436		0.143	0.388	20	80	15.93
Negative Control	1	0.397	Negative	0.013	0.031	20	80	7.71
	2	0.197		0.048	0.087	20	80	44.09

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

3. **Cross Reactivity**

Studies were performed to assess interference in Anti-Mumps Virus IgG using sera which were negative for antibodies to Mumps, and which demonstrated antibodies to various other viruses. Results of this study are shown in Table 5.

Table 5: Cross Reactivity Analysis

Spec. I.D.	Mumps Result	Rubella		CMV		HSV-1		HSV-2		VCA		EBNA		Measles		VZV	
C5	0.69	2.36	(+)	0.99	±	2.16	(+)	1.74	(+)	3.31	(+)	2.51	(+)	2.07	(+)	1.17	(+)
D6	0.36	0.86	-	2.55	(+)	2.52	(+)	1.69	(+)	4.90	(+)	4.29	(+)	1.12	(+)	2.08	(+)
H6	0.54	2.79	(+)	3.67	(+)	1.74	(+)	1.71	(+)	2.29	(+)	7.98	(+)	0.92	±	0.88	±
D8	0.56	3.89	(+)	4.93	(+)	2.65	(+)	1.06	±	2.39	(+)	4.78	(+)	2.58	(+)	2.16	(+)
H8	0.28	2.38	(+)	7.51	(+)	1.69	(+)	0.93	±	6.79	(+)	5.40	(+)	2.70	(+)	3.25	(+)
F10	0.17	0.10	-	5.19	(+)	2.64	(+)	1.63	(+)	1.42	(+)	2.75	(+)	2.39	(+)	2.38	(+)
A11	0.12	0.07	-	2.78	(+)	1.81	(+)	0.87	-	1.13	(+)	4.60	(+)	0.73	-	1.96	(+)
G11	0.3	4.22	(+)	0.19	-	0.97	±	1.65	(+)	2.65	(+)	6.95	(+)	1.38	(+)	3.04	(+)
H11	0.5	0.89	-	3.85	(+)	2.64	(+)	2.28	(+)	2.93	(+)	2.74	(+)	1.08	±	1.28	(+)

NOTE: For all Test Systems indicated above, ≥ 1.10 is reactive (+), ≤ 0.90 is negative (-), and 0.91 - 1.09 is equivocal (±).

*All ELISA results indicated were generated using legally marketed ELISA IgG Test Systems manufactured by ZEUS Scientific.

This study with the sera listed above resulted in no detectable cross reactivity with these various IgG antibodies, and Anti-Mumps Virus IgG.

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GLOSSARY OF SYMBOLS

The following symbols **may** have been used in the labelling of this product or products associated with this product.

Symbol	Description	Symbol	Description
	Manufacturer		Keep away from sunlight
IVD	*In vitro* diagnostic medical device	PLATE	Plate
REF	Catalogue number	CONJ	Conjugate
Σ n	Sufficient for *n* tests	CTRL +	Positive Control
LOT	Batch code	CTRL -	Negative Control
	Use by	CAL	Calibrator
	Temperature limitation	DIL SPE	Sample Diluent
CONT	Contents	SOLN TMB	TMB
UDI	Unique Device Identifier	SOLN STOP	Stop Solution
	Consult the warnings and precautions	WASH 10X	Wash Buffer Concentrate (10X)
	Consult electronic instructions for use	EN	English
	Store in the upright position	Made in the USA	Made in the USA
RX Only	Applicable for U.S.A: Prescription *in vitro* diagnostic product		Corrosive
	Hazardous Communication	EC REP	European Commission Authorized Representative
CE	Conformity with Directive 98/79		

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For Customer Service and Technical Support inquiries outside the US, please contact your local Sebia subsidiary or authorized distributor.