CE

DIAGNOSTIC AUTOMATION, INC.

23961 Craftsman Road, Suite D/E/F, Calabasas, CA 91302
Tel: (818) 591-3030 Fax: (818) 591-8383
onestep@rapidtest.com
technicalsupport@rapidtest.com
www.rapidtest.com

IVD  See external label   96 tests REF 1411-1Z

Mumps IgM

Cat # 1411-1Z

Cat # Number	**1411-1Z**
Test	**Mumps IgM**
Method	**Enzyme Linked Immunosorbent Assay**
Principle	**Indirect ELISA : Antigen Coated Plate**
Detection Range	**Qualitative: Positive, Weak Positive, Negative Control**
Sample	**10µL**
Specificity	**100%**
Sensitivity	**100%**
Total Time	**~75min**
Shelf Life	**12-14 Months from the manufacturing date**

***** *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 Mumps IgM Enzyme-Linked Immunosorbent Assay (ELISA) is intended for the qualitative detection of IgM antibody in human serum to Mumps for the determination of immunological experience. The performance characteristics of this kit have not been established. **High complexity test.**

INTRODUCTION

The mumps virus is a member of the paramyxovirus group and the etiological agent of mumps in man. Mumps is a generalized illness usually accompanied by parotid (salivary gland) swelling and mild symptoms. It is also one of the most common causes of aseptic meningitis, encephalitis, and inflammation of the testes (orchitis), pancreas, and ovaries.

Parotitis as a presenting symptom in mumps infections is usually sufficiently diagnostic to preclude serological confirmation. However, a third of mumps infections are subclinical or unrecognized (1) and may require viral isolation and/or some other serological procedure to confirm or rule out mumps infection. An example of this is presenting orchitis or meningoencephalitis, the two most common complications of mumps infection, without salivary gland involvement. Virus isolation is time consuming and cumbersome and is usually an impractical procedure for the typical clinical laboratory. Current methods for serodiagnosis of mumps infections are *in-vitro* serum neutralization, hemagglutination-inhibition (HAI), indirect immunofluorescence, and complement fixation (CF) tests. Of these methods, neutralization is reportedly the most specific. However, the neutralization test requires 4-5 days to complete the test. HAI and CF are reportedly less sensitive than the neutralization test. These methods lack specificity, which limits their usefulness in determining immune status. The HAI test also requires pretreatment of test sera to remove nonspecific hemagglutination inhibitors from some sera.

Infection with mumps virus, whether symptomatic or subclinical, is generally thought to offer lifelong immunity. Anti-Mumps virus IgM appear 2-3 days after the occurrence of the first clinical symptoms (these remain 2-3 months), followed by the production of Mumps IgG antibodies which persist lifelong. following vaccination with live virus there is a seroconversion in 90% of cases, however, the titre is somewhat lower than in normal infections.

As first described by Engvall and Perlmann (2,3,4) and Van Weeman (5), Enzyme Immunoassays can be both specific and sensitive for the detection and measurement of serum proteins. The sensitivity, specificity, and reproducibility of enzyme-linked immunoassays can be comparable to other serological tests for antibody, such as immunofluorescence, complement fixation, hemagglutination and neutralization (6,7,8,9).

ELISA is as sensitive as the neutralization test and more sensitive than CF and HAI which makes it a reliable test for determination of immune status. The DAI Mumps IgM ELISA kit provides all the necessary reagents for the rapid determination and quantitation of IgM antibody to mumps virus in human sera.

Principle of the Assay

Enzyme-Linked Immunosorbent Assays (ELISA) rely on the ability of biological materials, (i.e., antigens) to adsorb to plastic surfaces such as polystyrene (solid phase). When antigens bound to the solid phase are brought into contact with a patient's serum, antigen specific antibody, if present, will bind to the antigen on the solid phase forming antigen- antibody complexes. Excess antibody is removed by washing. This is followed by the addition of goat anti-human IgM globulin conjugated with horseradish peroxidase which then binds to the antibody-antigen complexes. The excess conjugate is removed by washing, followed by the addition of chromogen/substrate,

tetramethylbenzidine (TMB). If specific antibody to the antigen is present in the patient's serum, a blue color develops. When the enzymatic reaction is stopped with 1N H_2SO_4, the contents of the wells turn yellow. The yellow color, which is proportional to the concentration of antibody in the serum, can be read on a suitable spectrophotometer or ELISA microwell plate reader.(2, 3, 4, 5, 6) The sensitivity, specificity, and reproducibility of ELISAs can be comparable to other serological tests for antibody, such as immunofluorescence, complement fixation, hemagglutination and radioimmunoassays.

KIT PRESENTATION

Materials Supplied

Each kit contains the following components in sufficient quantities to perform the number of tests indicated on the package label.

1. **Purified Mumps antigen coated microassay plate**: 96 wells, configured in twelve 1x8 strips stored in a foil pouch with desiccant. (96T: one plate)
2. **Calibrator:** Human serum or defibrinated plasma. Sodium azide (< 0.1%) and pen/strep (0.01%) added as preservatives, with kit specific factor printed on vial label. The Calibrator is used to calibrate the assay to account for day-to-day fluctuations in temperature and other testing conditions. (96T: one vial, 0.4 mL) *
3. **Positive Control:** Human serum or defibrinated plasma. Sodium azide (< 0.1%) and pen/strep (0.01%) added as preservatives, with established range printed on vial label. The Positive Control is utilized to control the positive range of the assay. (96T: one vial, 0.4 mL) *
4. **Negative Control:** Human serum or defibrinated plasma. Sodium azide (< 0.1%) and pen/strep (0.01%) added as preservatives, with established range printed on vial label. The Negative Control is utilized to control the negative range of the assay (96T: one vial, 0.4 mL) *
5. **Horseradish-peroxidase (HRP) Conjugate**: Ready to use. Goat anti- human IgM, containing proclin (0.1%) and gentamicin as preservatives. (96T: one bottle, 16 mL)
6. **Serum Diluent Plus:** Ready for use. Contains goat/sheep anti-human IgG for serum absorption to remove competing IgG, with protein stabilizers and proclin (0.1%) as a preservative. (96T: two bottles, 45 mL each)
7. **Wash Buffer Type I (20X concentrate):** dilute 1 part concentrate + 19 parts deionized or distilled water. Contains TBS, Tween-20 and proclin (0.1%) as a preservative. (96T: one bottle, 50 mL)
8. **Chromogen/Substrate Solution Type I:** Tetramethylbenzidine (TMB), ready to use. The reagent should remain closed when not in use. If allowed to evaporate, a precipitate may form in the reagent wells. (96T: two one bottles, 15 mL each)
9. **Stop Solution:** Ready to use, contains a 1N H_2SO_4 solution. (96T: two one bottles, 15 mL each)

Additional Requirements

1. Wash bottle, automated or semi-automated microwell plate washing system.
2. Micropipettes, including multichannel, capable of accurately delivering 10-200 µL volumes (less than 3% CV).
3. One liter graduated cylinder.
4. Paper towels.
5. Test tube for serum dilution.
6. Reagent reservoirs for multichannel pipettes.
7. Pipette tips.
8. Distilled or deionized water (dH_2O), CAP (College of American Pathology) Type 1 or equivalent (19,20).
9. Timer capable of measuring to an accuracy of +/- 1 second (0 – 60 minutes).
10. Disposal basins and 0.5% sodium hypochlorite (50 mL bleach in 950 mL dH_2O).
11. Single or dual wavelength microplate reader with 450 nm filter. If dual wavelength is used, set the reference filter to 600-650 nm. Read the Operator's Manual or contact the instrument manufacturer to establish linearity performance specifications of the reader.

Note: Use only clean, dry glassware.

STORAGE AND STABILITY

1. Store unopened kit between 2 and 8°C. The test kit may be used throughout the expiration date of the kit. Refer to the package label for the expiration date.
2. Unopened microassay plates must be stored between 2 and 8°C. Unused strips must be immediately resealed in a sealable bag with desiccant and returned to storage between 2 and 8°C.
3. Store HRP Conjugate Solution between 2 and 8° C.
4. Store the Calibrator, Positive and Negative Controls between 2 and 8°C.
5. Store Serum Diluent Plus and 20X Wash Buffer Type I between 2 and 8°C.
6. Store the Chromogen/Substrate Solution Type I between 2 and 8°C. The reagent should remain closed when not in use. If allowed to evaporate, a precipitate may form in the reagent wells.
7. Store 1X (diluted) Wash Buffer Type I at room temperature (21 to 25°C) for up to 5 days, or up to 1 week between 2 and 8°C.

Note: If constant storage temperature is maintained, reagents and substrate will be stable for the dating period of the kit. Refer to package label for expiration date. Precautions were taken in the manufacture of this product to protect the reagents from contamination and bacteriostatic agents have been added to the liquid reagents. Care should be exercised to protect the reagents in this kit from contamination. Do not use if evidence of microbial contamination or precipitation is present.

PRECAUTIONS

1. For non-US sale only.
2. The human serum components used in the preparation of the Controls and Calibrator in this kit have been tested by an FDA approved method for the presence of antibodies to human immunodeficiency virus 1 & 2 (HIV 1&2), hepatitis C (HCV) as well as hepatitis B surface antigen and found negative. Because no test method can offer complete assurance that HIV, HCV, hepatitis B virus, or other infectious agents are absent, specimens and human-based reagents should be handled as if capable of transmitting infectious agents.
3. The Centers for Disease Control & Prevention and the National Institutes of Health recommend that potentially infectious agents be handled at the Biosafety Level 2 (10).
4. The components in this kit have been quality control tested as a Master Lot unit. Do not mix components from different lot numbers except Chromogen/Substrate Solution Type I, Stop Solution, and Wash Buffer Type II. Do not mix with components from other manufacturers.
5. Do not use reagents beyond the stated expiration date marked on the package label.
6. All reagents must be at room temperature (21° to 25° C) before running assay. Remove only the volume of reagents that is needed. **Do not pour reagents back into vials as reagent contamination may occur.**
7. Before opening Control and Calibrator vials, tap firmly on the bench top to ensure that all liquid is at the bottom of the vial.
8. Use only distilled or deionized water and clean glassware.
9. Do not let wells dry during assay; add reagents immediately after completing wash steps.
10. Avoid cross-contamination of reagents. Wash hands before and after handling reagents. **Cross-contamination of reagents and/or samples could cause false results.**
11. If washing steps are performed manually, wells are to be washed three times. Up to five wash cycles may be necessary if a washing manifold or automated equipment is used.
12. **Sodium azide inhibits Conjugate activity. Clean pipette tips must be used for the Conjugate addition so that sodium azide is not carried over from other reagents.**
13. It has been reported that sodium azide may react with lead and copper in plumbing to form

explosive compounds. When disposing, flush drains with water to minimize build-up of metal azide compounds.
14. Never pipette by mouth or allow reagents or patient sample to come into contact with skin. Reagents containing proclin, sodium azide, and TMB may be irritating. Avoid contact with skin and eyes. In case of contact, flush with plenty of water.
15. If a sodium hypochlorite (bleach) solution is being used as a disinfectant, do not expose to work area during actual test procedure because of potential interference with enzyme activity.
16. Avoid contact of Stop Solution (1N sulfuric acid) with skin or eyes. If contact occurs, immediately flush area with water.
17. **Caution:** Liquid waste at acid pH must be neutralized prior to adding sodium hypochlorite (bleach) solution to avoid formation of poisonous gas. Recommend disposing of reacted, stopped plates in biohazard bags. See Precaution 3.
18. The concentrations of anti-Mumps in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity.

SPECIMEN COLLECTION AND STORAGE

1. Handle all blood and serum as if capable of transmitting infectious agents.
2. Optimal performance of the kit depends upon the use of fresh serum samples (clear, non-hemolyzed, non-lipemic, non-icteric). A minimum volume of **50 µL** is recommended, in case repeat testing is required. Specimens should be collected aseptically by venipuncture (12). Early separation from the clot prevents hemolysis of serum.
3. Store serum between 2° and 8°C if testing wil l take place within two days. If specimens are to be kept for longer periods, store at -20°C or c older. Do not use a frost-free freezer because it may allow the specimens to go through freeze-thaw cycles and degrade antibody. Samples that are improperly stored or are subjected to multiple freeze-thaw cycles may yield erroneous results.
4. The NCCLS provides recommendations for storing blood specimens (Approved Standard Procedures for the Handling and Processing of Blood Specimens, H18-A. 1990) (12).

METHODS OF USE

Preparation for the Assay

1. All reagents must be removed from refrigeration and allowed to come to room temperature before use (21° to 25°C). Return all reagents to re frigerator promptly after use.
2. All samples and controls should be vortexed before use.
3. Dilute 50 mL of the 20X Wash Buffer Type I to 1 L with distilled and/or deionized H_20. Mix well.

Serum Treatment

Solid phase immunoassays for the detection of virus-specific IgM are known to be sensitive to interfering factors. This kit overcomes interference by treating samples prior to running the assay. The goat/sheep anti-human IgG in the Serum Diluent Plus Solution diminishes competing virus-specific IgG, which would be responsible for false negative reactions. False positives are similarly minimized by removing the IgG, thus neutralizing the bound rheumatoid factor in the samples.

Assay Procedure

1. Place the desired number of strips into a microwell frame. Allow four (4) Control/Calibrator determinations (one Negative Control, two Calibrators, and one Positive Control) per run. A reagent blank (RB) should be run on each assay. Check software and reader

requirements for the correct Control/Cutoff Calibrator configurations. Return unused strips to the sealable bag with desiccant, seal and immediately refrigerate.

Example Configuration:

Plate Location	Sample Description	Plate Location	Sample Description
1A	RB	2A	Patient #4
1B	NC	2B	Patient #5
1C	Cal	2C	Patient #6
1D	Cal	2D	Patient #7
1E	PC	2E	Patient #8
1F	Patient #1	2F	Patient #9
1G	Patient #2	2G	Patient #10
1H	Patient #3	2H	Patient #11

RB = Reagent Blank - well without serum addition run with all reagents. Used to blank reader.
NC = Negative Control
Cal = Calibrator
PC = Positive Control

2. Dilute test sera, Calibrator and Control sera 1:81 (e.g., 10 µL + 800 **µ**L) in Serum Diluent Plus. For manual dilutions it is suggested to dispense the Serum Diluent into the test tube first and then add the patient serum. Mix well (Vortexing recommended).
3. To individual wells add 100 **µ**L of diluted patient sera, Calibrator and Control sera. Add 100 **µ**L of Serum Diluent Plus to the reagent blank well. Check software and reader requirements for the correct reagent blank well configuration.
4. Incubate each well at room temperature (21°to 25°C) for **30 minutes +/- 2 minutes.**
5. Aspirate or shake out liquid from all wells. Using semi-automated or automated washing equipment add 250-300 **µ**L of diluted Wash Buffer to each well. Aspirate or shake out and turn plate upside down and blot on paper toweling to remove all liquid. Repeat the wash procedure two times (for a total of three washes) for semi-automated equipment or four times (for a total of five washes) for automated equipment. After the final wash, blot the plate on paper toweling to remove all liquid from the wells.

****IMPORTANT NOTE:** Regarding steps 5 and 8 - Insufficient or excessive washing will result in assay variation and will affect validity of results. Therefore, for best results the use of semi-automated or automated equipment set to deliver a volume to completely fill each well (250-300 µL) is recommended. A total of five (5) washes may be necessary with automated equipment. **Complete removal of the Wash Buffer after the last wash is critical for the accurate performance of the test. Also visually ensure that no bubbles are remaining in the wells.**

6. Add 100 **µ**L Conjugate to each well, including the reagent blank well. Avoid bubbles upon addition as they may yield erroneous results.
7. Incubate each well at room temperature (21°to 25°C) for **30 minutes +/- 2 minutes.**
8. Repeat wash as described in Step 5**.
9. Add 100 **µ**L Chromogen/Substrate solution (TMB) solution to each well, including reagent blank well, maintaining a constant rate of addition across the plate.
10. Incubate each well at room temperature (21°to 25°C) for **15 minutes +/- 2 minutes.**
11. Stop reaction by addition of 100 µL of Stop Solution (1N H_2SO_4) following the same order of Chromogen/Substrate addition, including reagent blank well. Tap the plate gently along the outsides to mix contents of the wells. The plate may be held up to one (1) hour after addition of the Stop Solution before reading.
12. The developed color should be read on an ELISA plate reader equipped with a 450 nm filter.

If dual wavelength is used, set the reference filter to 600-650 nm. The instrument should be blanked on air. The reagent blank must be less than 0.150 Absorbance at 450 nm. If the reagent blank is ≥ 0.150, the run must be repeated. Blank the reader on the reagent blank well and then continue to read the entire plate. Dispose of used plates after readings have been obtained.

QUALITY CONTROL

For the assay to be considered valid the following conditions must be met:

1. Calibrator and Controls must be run with each test run.
2. Reagent blank (when read against air blank) must be < 0.150 Absorbance (A) at 450 nm.
3. Negative Control must be ≤ 0.250 A at 450 nm (when read against reagent blank).
4. Each Calibrator must be ≥ 0.300 A at 450 nm (when read against reagent blank).
5. Positive Control must be ≥ 0.250 A at 450 nm (when read against reagent blank).
6. The ISR (Immune Status Ratio) Values for the Positive and Negative Controls should be in their respective ranges printed on the vials. If the Control values are not within their respective ranges, the test should be considered invalid and the test should be repeated.
7. Additional Controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations.
8. Refer to NCCLS C24A for guidance on appropriate Quality Control practices (11).
9. If above criteria are not met on repeat testing, contact DAI Technical Services. 8.

INTERPRETATION

Calculations

1. Mean Calibrator O.D. (Optical Density) - Calculate the mean O.D. value for the Calibrator from the two Calibrator determinations.
2. Correction Factor - To account for day-to-day fluctuations in assay activity due to room temperature and timing, a Correction Factor is determined by DAI for each lot of kits. The Correction Factor is printed on the Calibrator vial.
3. Cutoff Calibrator Value - The Cutoff Calibrator Value for each assay is determined by multiplying the Correction Factor by the mean Calibrator O.D. determined in Step 1.

4. ISR Value - Calculate an Immune Status Ratio (ISR) for each specimen by dividing the specimen O.D. Value by the Cutoff Calibrator Value determined in Step 3.

Example

O.D's obtained for Calibrator	= 0.38, 0.40
Mean O.D. for Calibrator	= 0.39
Correction factor	= 0.50
Cutoff Calibrator Value	= 0.50 x 0.39 = 0.20
O.D. obtained for patient sera	= 0.60
ISR Value	= 0.60/0.20 = 3.00

Analysis

1. The patients' ISR (Immune Status Ratio) values are interpreted as follows:

ISR Value	Results	Interpretation
≤ 0.90	Negative	No significant level of detectable IgM antibody to Mumps.
0.91-1.09	Equivocal	Samples should be retested. See number 2 below.
≥ 1.10	Positive	Significant level of detectable IgM antibody to Mumps, Indicative of current recent infection.

2. Samples that remain equivocal after repeat testing should be retested on an alternate method, e.g., immunofluorescence assay (IFA).

EXPECTED VALUES

Serological findings in Mumps infection are strongly dependent on the stage and duration of the clinical symptoms. To obtain a final diagnosis the patient history and clinical symptoms as well as laboratory findings should be taken into consideration. See Table 2 Diagnostic Relevance for Mumps Antibodies (14, 15, 16, 17).

Table 1
Diagnostic Relevance for Mumps Antibodies

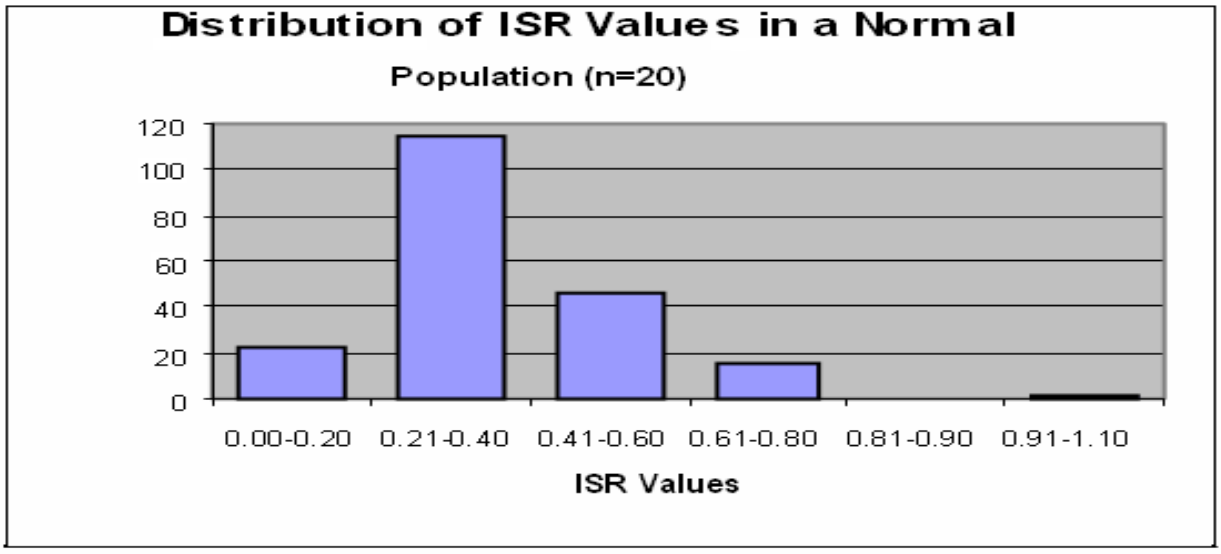
IgG Antibody	IgM Antibody	Interpretation	Recommendation
(-)	(-)	No specific antibody detectable. However, infection is possible.	None
(+)	(-)	Probable previous infection, vaccination, or reinfection is possible.	Monitoring of IgG antibodies (Sera collection within 3-4 weeks), a significant rise in IgG antibodies in the absence of IgM indicates a possible reinfection.

(-)	(+)	Primary infection is probable.	Monitoring of IgG and IgM antibodies; changes of titre indicate seroconversion; confirmatory tests e.g. IFA, KBR
(+)	(+)	Recent infection, reinfection, or vaccination is probable.	Monitoring of IgG and IgM antibodies; changes of titre indicate seroconversion confirmatory tests e.g. IFA, KBR

A total of 200 random serum samples collected from US blood centers; 100 from blood centers in California and 100 from blood centers on the US east coast were tested to establish the expected values in a population of male and female donors of ages 18-65 with no known clinically apparent Mumps infection. Table 1 summarizes the distribution of DAI Mumps IgM assay ISR Values observed for the population.

Table 2
Distribution of DAI Mumps IgM
(Catalog # 2325960) Assay ISR Values from 200 US Individuals

DAI Mumps IgG 1PFC Kit (Product #1411Z) **ISR Range**		**Number of Specimens**	**Percent of Total**
Low	**High**		
0.00	0.20	22	11.0%
0.21	0.40	114	57.0%
0.41	0.60	46	23.0%
0.61	0.80	16	8.0%
0.81	0.90	0	0%
0.91	1.10	2	1.0%



LIMITATIONS OF USE

1. The user of this kit is advised to carefully read and understand the package insert. Strict adherence to the protocol is necessary to obtain reliable test results. In particular, correct sample and reagent pipetting, along with careful washing and timing of the incubation steps are essential for accurate results.
2. The results of ELISA immunoassays performed on serum from immunosupressed patients must be interpreted with caution.
3. 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.
4. This device is not intended for the determination of immune status. It is intended for the determination of immune response to indicate primary infection or virus reactivation. 5. The absence of detectable IgM antibody does not rule out the possibility of recent or current infection. If Mumps infection is still suspected, obtain a second specimen 5-7 days later and repeat the testing. Often, however, at the time of presentation, IgM antibodies are in decreasing concentrations.
6. Specific IgG may compete with the IgM for sites and may result in a false negative.
7. Results of this test should be interpreted by the physician in the light of other clinical findings and diagnostic procedures.
8. A negative test for Mumps (IgM) does not exclude current Mumps infection. The sample may have been collected before development of demonstrable antibody or after antibody still detectable.
9. Icteric, lipemic, hemolyzed, or heat inactivated sera may cause erroneous results and should be avoided.
10. Kit procedures or practices outside those in this package insert may yield questionable results.

PERFORMANCE CHARACTERISTICS

Note: The performance characteristics of this kit have not been established.

Agreement

A study was conducted to compare the Mumps IgM ELISA kit (Catalog # 1411-1Z) with the Mumps IgM ELISA kit (Catalog # 1411-11). The study included 295 specimens consisting of samples from a random normal population, first trimester prenatal serum samples and known positive and negative samples.

The results are presented in Table 3:

Table 3
Agreement
Mumps IgM ELISA Kit
(Catalog # 1411-1Z)

	+	-	Eq
+	13	0	0
-	0	277	0
Eq	0	0	5

Mumps IgM ELISA Kit

Agreement = 295 / 295 100 %

Precision

Intra-Assay Precision

Table 4 presents the results of six (6) samples individually pipetted in groups of ten 10) in a single assay

Table 4
Intra-Assay Precision

	n	Mean ISR	Std Dev	%CV
Serum 1	10	1.95	0.16	8.12%
Serum 2	10	1.49	0.04	2.36%
Serum 3	10	1.24	0.06	4.99%
Serum 4	10	2.99	0.11	3.75%
Serum 5	10	0.16	0.00	2.89%
Serum 6	10	0.19	0.01	4.18%

Inter-Assay Precision

Table 5 presents the summary of the Inter-Assay precision data determined by replicate testing of six (6) samples individually pipetted in groups of (10) in three (3) separate assays.

Table 5
Inter-Assay Precision

	Assay 1	Assay 2	Assay 3	N	Mean ISR	Std Dev	%CV
Serum 1	1.95	2.35	1.72	30	2.01	0.30	15.10%
Serum 2	1.49	1.76	1.36	30	1.53	0.20	13.23%
Serum 3	1.24	1.31	1.16	30	1.24	0.10	8.17%
Serum 4	2.99	0.70	3.28	30	3.32	0.36	10.92%
Serum 5	0.16	0.20	0.18	30	0.18	0.02	9.54%
Serum6	0.19	0.24	0.20	30	0.21	0.02	11.72%

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Date Adopted	Reference No.
2011-03-01	DA-Mumps IgM-2011

DIAGNOSTIC AUTOMATION, INC.
23961 Craftsman Road, Suite D/E/F, Calabasas, CA 91302
Tel: (818) 591-3030 Fax: (818) 591-8383
ISO 13485-2003

Revision B Date: 08-29-2013