Subject/Title: **ASI MUMPS IgG EIA TEST**		Doc#: 860096AG
Effective Date: 10/26/17	Supersedes Revision/Date: 02/18/16 (**1**)	Revision: 10/26/17 (**2**)
Prepared by: ASI	QA Approval by:	Copy/Dept.:

FOR IN VITRO DIAGNOSTIC USE

1.0 INTENDED USE: For the qualitative and semiquantitative detection of human IgG antibodies to mumps virus in human serum by enzyme immunoassay. Individual serum specimens may be used for the determination of immune status. Paired (acute/convalescent) sera may be used to demonstrate seroconversion or significant rises in antibody level, as an aid in the diagnosis of primary infection.

2.0 SUMMARY AND EXPLANATION OF THE TEST:

Mumps is a generalized illness characterized by fever and by inflammation and swelling of the salivary glands, particularly the parotid glands. Mumps is usually not severe in children, but in the adult the inflammation may involve the ovaries or testes (orchitis). Mumps is also one of the most common causes of aseptic meningitis, and encephalitis. The etiological agent is a member of the paramyxovirus group.

Inflammation and swelling of the parotid glands (parotitis) in mumps infection is usually sufficiently diagnostic to preclude serological confirmation. However, inasmuch as one third of mumps infections are subclinical (1), viral isolation and/or some other serological procedure may be required. An example of the latter would be patients presenting with orchitis or meningoencephalitis, two of the most common sequelae of mumps infection, without salivary gland involvement.

Virus isolation is cumbersome, and time consuming, and is usually an impractical procedure for the typical clinical laboratory. Serodiagnosis of mumps infection has been accomplished by: neutralization, hemagglutination-inhibition (HI), indirect immunofluorescence and complement fixation (CF). These methods lack specificity, which limits their usefulness in determining immune status. The HI test also requires pretreatment of test sera to remove nonspecific inhibitors of hemagglutination.

Enzyme immunoassays (EIA, ELISA) are sensitive and specific for the detection and measurement of serum proteins[2, 3, 4]. Their sensitivity equals that of the neutralization test, and is greater than CF or HI. They are therefore, reliable tests for the determination of immune status.

The Mumps IgG EIA test is an ELISA test which utilizes a microwell format. Test results are obtained after one and one-half hours incubation time. They are objective and normalized as Index values, permitting uniformity of reporting.

3.0 PRINCIPLE OF THE PROCEDURE:

Diluted samples are incubated in antigen-coated wells. Mumps antibodies (if present) are immobilized in the wells. Residual sample is eliminated by washing and draining, and conjugate (enzyme-labeled antibodies to human IgG) is added and incubated. If IgG antibodies to mumps are present, the conjugate will be immobilized in the wells. Residual conjugate is eliminated by washing and draining, and the substrate is added and incubated. In the presence of the enzyme, the substrate is converted to a yellow end product which is read photometrically.

4.0 REAGENTS

Coated Wells	Coated with Mumps antigen (Enders strain). The antigen is an enriched sonicate of infected cells. 12 eight-well strips.
Well Support	One.
Diluent*	25 ml (pink color). Phosphate-buffered saline with a protein stabilizer.
Calibrator 1*	0.3 ml Human serum. Strongly reactive for mumps IgG antibodies. Index value shown on vial label.
Calibrator 2*	0.3 ml Human serum. Moderately reactive for mumps antibodies. Index value shown on vial label.
Positive Control*	0.3 ml Human serum. Reactive for mumps antibodies. Index value range shown on vial label.
Negative Control*	0.3 ml Human serum. Nonreactive for mumps antibodies.
Conjugate	12 ml (green color). Goat anti-human IgG labeled with alkaline phosphatase (calf).
Substrate	12 ml p-nitrophenyl phosphate. Note: The substrate may develop a slight yellow color during storage. One hundred microliters of substrate should yield an absorbance value less than 0.35, when read in a microwell against air or water.
Wash Concentrate*	30 ml Tris-buffered saline with Tween 20, pH 8.0. Prepare Wash Solution by adding the contents of the Wash Concentrate bottle to 1liter of distilled or deionized water.
Stop Reagent	12 ml Trisodium Phosphate 0.5 M.

* Contains 0.1% sodium azide.

Store these reagents according to the instructions on the bottle labels. Do not allow them to contact the skin or eyes. If contact occurs, wash with copious amounts of water.

5.0 WARNINGS AND PRECAUTIONS

5.1 For *in vitro* diagnostic use.

5.2 Test samples, Calibrator(s), Controls and the materials that contact them, should be handled as potential biohazards. The calibrators and controls have been found to be negative for HIV, hepatitis B surface antigen and HCV antibodies by licensed tests. However, because no method can offer complete assurance that HIV, hepatitis B virus, HCV 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, or latest edition.

5.3 The concentrations 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.

5.4 Avoid contact with open skin.

5.5 Never pipet by mouth.

5.6 Certain of the test reagents contain sodium azide. Azides are reported to react with lead and copper in plumbing to form

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compounds that may detonate on percussion. When disposing of solutions containing sodium azide, flush drains with large volumes of water to minimize the build-up of metal-azide compounds.

5.7 R 21/22: Harmful in contact with skin and if swallowed.

5.8 S24/25 - 36/37/39: Avoid contact with skin and eyes. Wear suitable protective clothing, gloves and eye/face protection. For further information, refer to product SDS.

5.9 Do not interchange reagents from different reagent lots, except for Wash Concentrate, Diluent, Substrate and Stop Reagent.

5.10 Do not use reagents beyond their stated expiration date.

5.11 Incubation times recommended in the Test Procedure section should be adhered to.

5.12 Unused Coated Wells should be kept in their resealable bag with desiccant, and stored in the refrigerator.

5.13 Do not smoke, eat, drink, or apply cosmetics in areas where plasma/serum samples are handled.

6.0 HANDLING AND PROCEDURAL NOTES

6.1 In order to obtain reliable and consistent results, the instructions in the package insert must be strictly followed. Do not modify the handling and storage conditions for reagents or samples.

6.2 Do not use past the expiration date indicated on the kit.

7.0 STORAGE INSTRUCTIONS

Store all reagents at 2 to 8°C in an upright position when not in use. Do not freeze reagents.

8.0 INDICATIONS OF DETERIORATION

8.1 Turbidity or precipitation in controls is indicative of deterioration and the component should not be used.

8.2 Bacterial contamination of reagents or specimens may cause false positive results.

9.0 SPECIMEN COLLECTION AND STORAGE

9.1 Sera should be separated from clotted blood.

9.2 If specimens are not tested within 8 hours, they should be stored at 2 to 8°C for up to 48 hours. Beyond 48 hours specimens should be stored at -20°C or below.

9.3 Multiple freeze-thaw cycles should be avoided.

9.4 Samples containing visible particulate matter should be clarified by centrifugation; hemolyzed, icteric, or grossly contaminated samples should not be used.

9.5 Samples should not be heat-inactivated before testing.

9.6 Paired, acute/convalescent specimens should be collected ten to fourteen days apart, and tested concurrently

10.0 PERFORMANCE OF TEST

Materials Provided:

96 Tests

Coated Wells	12 eight well strips		Negative Control	0.3 ml
Well Support	1		Conjugate	12 ml
Diluent	25 ml		Substrate	12 ml
Calibrator 1	0.3 ml		Wash Concentrate	30 ml
Calibrator 2	0.3 ml		Stop Reagent	12 ml
Positive Control	0.3 ml			

Additional Materials Required

1. Microplate washer
2. Pipettors for dispensing 4, 100 and 200 µl
3. Timer
4. 1 or 2 liter container for Wash Solution
5. Distilled or deionized water
6. Dilution tubes or microwells
7. Microwell reader capable of reading absorbance at 405 nm. Dual wavelength readers are recommended. Dual or single wavelength readers may be used. Data on file.

11.0 TEST PROCEDURE

Preparation for the Assay

11.1 Allow all reagents and patient samples to reach room temperature before use. Return them promptly to refrigerator after use. The test procedure follows:

11.2 Prepare 1:51 dilutions of test samples, Calibrator(s), Positive and Negative Controls, in the test set Diluent. For example: add 4 µl of sample to 200 µl of Diluent in a dilution well or tube, and mix well.
Note: *For qualitative assays, a single Calibrator (Calibrator 2) may be used; for semiquantitative assays, use Calibrator 1 and Calibrator 2.*

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12.0 ASSAY PROTOCOL -

12.1 Place an appropriate number of Coated Wells in the Well Support.
Note: *For combination testing (multiple assays per plate), the strips should be assembled on a white background with good lighting. Be sure to note the placement of each strip.*

12.2 Transfer 100 µl of each diluted Calibrator, Control and patient sample to the wells.
Note: *Include one well which contains 100 µl of Diluent only. This will serve as the reagent blank and will ultimately be used to zero the photometer before reading the test results.*

12.3 Incubate the wells at room temperature (20 to 25ºC) for 30 ± 5 minutes.

12.4 Wash wells four times with at least 250 µl/well/wash. Do not allow the wells to soak between washes. Drain thoroughly after the last wash.

12.5 Place 2 drops (or 100 µl) of Conjugate into each well.

12.6 Incubate the wells at room temperature for 30 ± 5 minutes.

12.7 Wash wells four times with at least 250 µl/well/wash. Do not allow the wells to soak between washes. Drain thoroughly after the last wash.

12.8 Place 2 drops (or 100 µl) of Substrate into each well.

12.9 Incubate at room temperature for 30 ± 5 minutes.

12.10 Place 2 drops (or 100 µl) of Stop Reagent into each well.

12.11 Read and record the absorbance of the contents of each well at 405 nm against the reagent blank.
Note: *Adjust the photometer to zero absorbance at 405 nm against the reagent blank. Readings should be made within 2 hours after the reactions have been stopped.*

13.0 QUALITY CONTROL

Quality control requirements must be performed in accordance with applicable local, state, and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control Procedures. Controls and calibrator(s) with graded reactivity must be included. If they do not yield the expected response, the assay should be considered invalid and the assay repeated. If the repeat assay does not elicit the expected results for the controls and calibrator(s), discontinue use of the kit and contact ASI Technical Support at 800-654-0146.

14.0 INTERPRETATION OF RESULTS –

Calculation of Results
Qualitative results may be calculated using a single calibrator. For semiquantitative and quantitative results, use a calibration curve consisting of two or more calibrators.

Single Calibrator, Qualitative Determination (Calibrator 2)
Determine the Index value for each test sample (or Control) using the following formula:

$$\frac{\text{Calibrator 2 Index}}{\text{Calibrator 2 Absorbance}} \times \text{Test Sample Absorbance} = \text{Test Sample Index}$$

If the Calibrator is run in duplicate, use the average absorbance value to calculate results.

Calibration Curve
Alternatively, test results may be calculated from a three-point curve comprised of: Calibrator 1 (high-point), Calibrator 2 (mid-point) and the reagent blank (zero / origin), using a point-to-point curve fit.
The upper range of the curve may be expanded by adding additional points. For example: the concentration of Calibrator 1 may be increased 1.5-fold, and 2-fold, by adding 6 µl and 8 µl of Calibrator 1 to 200 µl of the test set Diluent, and transferring 100 µl of each dilution to coated wells. The Index values, assigned to these points, should be 1.5 and 2 times respectively, the value shown on the Calibrator 1 label. The extent to which the upper range of the standard curve may be expanded, will be limited by the Calibrator being used.

Test Validation Criteria
1. The Calibrator(s), Positive and Negative Controls must be included in each test run.
2. The absorbance value of the reagent blank should be less than 0.35.
3. The Negative Control must have an Index value less than 0.9. This control is used to validate the assay below the cutoff of the assay.
4. The Positive Control must have an Index value within the ranges printed on the label. When performing qualitative tests, users may supply alternative positive controls if they wish.
5. To validate the upper range of the assay when performing the semiquantitative procedures, the Positive Control may be run at higher concentrations. For example, the Positive Control may be assayed at 1.5-fold and 2-fold concentrations by adding 6 µl and 8 µl of the Positive Control, to 200 µl aliquots of the test set Diluent, and transferring 100 µl of each of these dilutions to the coated wells. The expected value ranges for these concentrated controls would be 1.5 times and 2 times respectively, the expected value range printed on the Positive Control label. The assay results for these controls must fall within the corrected ranges. Optionally, users may supply alternative positive controls if they wish.
   If any of these criteria are not met, the test is invalid and should be repeated.
6. The Negative and Positive Controls are intended to monitor for substantial reagent failure. The Positive Control will not ensure precision at the assay cutoff. Users may wish to establish an in-house control, having a quantitative value determined by replicate testing, at or near the cutoff of the assay, to monitor the precision of the assay cutoff. Additional controls may be tested according to guidelines or requirements of local, state and/or federal regulations or accrediting organizations.

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Interpretation of Results

Index Value	Interpretation
< 0.9	Negative for mumps IgG, presumed non-immune to mumps infection.
≥0.9 to < 1.1	Equivocal.
≥1.1	Positive for mumps IgG, presumed immune to mumps infection.

The Mumps IgG EIA cut-off was set at 1.1 on the basis of test results obtained with negative specimens. This cut-off value was challenged with positive and negative specimens in clinical studies, which compared the relative sensitivity and specificity of the Mumps IgG EIA test, to a similar diagnostic device.

When equivocal results are obtained, another specimen should be obtained ten to fourteen days later, and tested in parallel with the initial specimen. If the second specimen is also equivocal, the patient is negative for primary or recent infection, and equivocal for antibody status. If the second sample is positive, the patient can be considered to have a primary infection. The conversion of an individual patient's serum from negative to positive for antibodies to the infectious agent in question, is defined as seroconversion, and indicates active or recent infection.

Differences in the antibody levels observed in acute/convalescent serum pairs which are greater than the imprecision of the assay, i.e. > 30% (Mean intra-assay CV + 3 SD, see tables 5, 6 and 7), are considered significant. To determine a significant difference between acute/convalescent serum pairs, both specimens should be assayed concurrently. Dose response experiments performed at laboratory C (Miami, FL), have shown that a 50 to 80 percent difference in the Mumps IgG EIA Index value, corresponds to a two-fold difference in the mumps IgG antibody level; and a 100 to 160 percent difference in Mumps IgG EIA Index value, corresponds to a four-fold difference in the mumps IgG antibody level. Use the following formula to calculate the percentage difference between acute/convalescent specimens:

$$\left| \frac{\text{Index}_{\text{(Convalescent)}} - \text{Index}_{\text{(Acute)}}}{\text{Index}_{\text{(Acute)}}} \right| \times 100 = \text{Percent Difference}$$

To interpret the differences observed between acute/ convalescent paired sera, use the table below:

Interpretation of Differences for Acute / Convalescent Serum Pairs

Percent Difference (Index Value)	Equivalent Difference (Antibody Level)
< 50	< 2 - fold
≥50 ≤ 80	2 - fold
> 80 < 100	> 2 – fold < 4 fold
≥100 ≤ 160	4 - fold
>160	> 4 - fold

Specimens which yield absorbance values above the range of the test set calibrator(s), may be reported as greater than the Index value of the uppermost point of the calibration curve. Alternatively, such specimens may be pre-diluted in the test set Diluent and reassayed. The resulting Index value must be multiplied by the dilution factor for reporting. *Example: If the specimen has been pre-diluted 1:5 before testing, the resulting Index value should be multiplied by 5.*

Values obtained with different manufacturer's assay methods may not be used interchangeably. The magnitude of the reported IgG level cannot be correlated to an endpoint titer. When the assay is used qualitatively, the magnitude of results above the cut-off is not an indicator of total antibody present.

15.0 LIMITATIONS OF THE PROCEDURE

The assay performance characteristics of vaccinees have not been established.

The results obtained with the Mumps IgG EIA test serve only as an aid to diagnosis and should not be interpreted as diagnostic in themselves. The prevalence of the analyte in the population being tested, will affect the assay's predictive value.

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.

Paired specimens should be collected during the acute and convalescent stages of infection, and tested concurrently to detect significant antibody increases. The acute phase sample should be collected early in the infection, preferably within 7 days of the onset of symptoms, and the convalescent phase sample one to two weeks after the first sample, but not earlier than 10 days after the onset of symptoms. The semiquantitative procedure should be used when testing paired sera. Serum specimens obtained during the acute phase of infection may be negative by serological tests.

Timing of specimen collection for paired sera may be critical. In some patients, antibody titers may rise to significant levels and fall 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.

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The assay performance characteristics have not been established for matrices other than serum.
If the assay is used with cord blood as the specimen source, positive results should be interpreted with caution. The presence of IgG antibodies to mumps in cord blood may be the result of passive transfer of maternal antibody to the fetus. A negative result however, may be helpful in ruling out infection. Performance characteristics have not been determined with neonatal or cord blood.

The performance characteristics of the Mumps IgG EIA test with specimens obtained from immunosuppressed individuals have not been established. Titration experiments (please see Figure 2) have shown that the upper limit of linearity for Mumps IgG EIA Index values is approximately 7.

16.0 EXPECTED VALUES

The incidence of antibodies to mumps may vary according to patient age and geographical location. Mumps is predominantly a disease of childhood with 90 % of infections occurring before 15 years of age. Mumps is not as contagious as the exanthematous childhood diseases, e.g. measles and chicken pox, and many children escape infection; thus disease in adults is not uncommon. Subclinical infections, detectable immunologically, are also much more frequent than in other common childhood diseases.

Serum samples obtained randomly from 89 normal adult South Florida blood donors (64 % male and 36 % female) were assayed at Laboratory C, Miami, FL, using the Mumps IgG EIA test. Eighty-two samples (92 %) were positive for IgG antibodies to mumps, one (1 %) was equivocal, and six (7 %) were negative. The positive samples yielded Index values between 1.2 and 15.1. The mean Index value was 4.1. The incidence of these values is shown in table 1.

Table 1. Results of tests of 89 Random Specimens (100% frozen), from Normal Adult South Florida Donors, Performed at Laboratory C (Miami, FL), Using the Mumps IgG EIA Test. Twenty-seven Percent of the Specimens Tested were Obtained from Women of Childbearing Age.

Index Value Ranges		Specimens
< 1.1	7	8 %
≥1.1 to < 5	63 {20}	71 %
≥5 to < 10	18 {4}	20 %
≥10 to < 15	0	0 %
≥15	1	1 %

{ } Number of specimens obtained from women of childbearing age.

17.0 PERFORMANCE CHARACTERISTICS

Comparative Testing
Mumps IgG EIA test results correlate well with results of other serological tests. Sera from normal blood donors were assayed for the presence of mumps IgG antibodies, using the Mumps IgG EIA test and another commercially available EIA test, at two independent laboratories (Lab A, Miami, FL, and Lab B, W. Columbia, SC), and at Laboratory C (Miami, FL). These results are shown below in tables 2, 3 and 4, respectively.

Table 2. Results of Tests of 165 Specimens (100% frozen), from South Florida, Performed at Laboratory A (Miami, FL), Using the Mumps IgG EIA Test and Another Commercial EIATest.

	Comparative			Mumps IgG EIA	
Test	Positive	Equivocal	Negative	%	95%CI
Positive	132	5	2	Relative sensitivity* 98.5	94.7 to 99.9**
Equivocal	0	1	1		
Negative	1	3	20	Relative specificity* 95.0	76.2 to 99.9**
				Overall agreement* 98.1	94.5 to 99.6**

* Excluding equivocal results

** Calculated by the Exact Method.

Table 3. Results of tests of 153 Specimens (100% fresh, not frozen), Performed at Laboratory B (W. Columbia, SC), Using the Mumps IgG EIA Test and Another Commercial EIATest.

	Comparative			Mumps IgG EIA	
Test	Positive	Equivocal	Negative	%	95%CI
Positive	136	1	0	Relative sensitivity* 100	97.3 to 100**
Equivocal	2	1	0		
Negative	1	3	9	Relative specificity* 90	55.5 to 99.7**
				Overall agreement* 99.3	96.2 to 100**

* Excluding equivocal results

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** Calculated by the Exact Method.

Table 4. Results of tests of 174 Specimens (100% frozen), from South Florida, Performed at Laboratory C (Miami, FL), Using the Mumps IgG EIA Test and Another Commercial EIA Test.

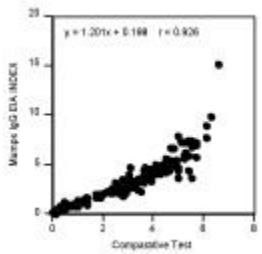
	Comparative			Mumps IgG EIA	
Test	Positive	Equivocal	Negative	%	95%CI
Positive	131	1	0	Relative sensitivity* 100	97.2 to 100**
Equivocal	4	2	2		
Negative	1	6	27	Relative specificity* 96.4	81.6 to 99.9**
				Overall agreement* 99.4	96.6 to 100**

* Excluding equivocal results

** Calculated by the Exact Method.

Please be advised that the term relative refers to the comparison of this assay's results to that of a similar assay. There was no attempt to correlate the assay's results with disease presence or absence. No judgment can be made on the comparison of the assay's accuracy to predict disease.

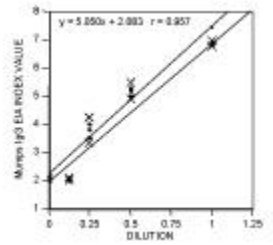
Figure 1. Results of Tests of 174 Serum Specimens Performed at Laboratory C (Miami, FL) Using the Mumps IgG EIA Test and Another Commercial EIA Test.



Titration curve

Several strongly positive serum specimens were serially diluted (two-fold) in triplicate, and assayed by the Mumps IgG EIA test. Typical results are shown in Figure 2.

Figure 2. Titration Curve for a Strongly Positive Specimen.



The triplicate data for each dilution are shown as points, the 95 % confidence limits for each set of triplicate data are indicated by (x's), and the 95 % confidence limits for the slopes and y-intercepts are represented by straight lines. The formula for the linear regression for the triplicate data is shown in Figure 2.

Specificity

The Mumps IgG EIA test is specific for IgG antibodies directed against mumps virus, and does not cross-react with the other viruses. Of six specimens which were unreactive in the Mumps IgG EIA test, 2 were shown to contain moderate to high levels of IgG antibody directed against cytomegalovirus, 3 against herpes simplex virus, 6 against varicella-zoster virus and 6 against Epstein-Barr virus. The IgG antibodies directed against cytomegalovirus, herpes simplex virus, varicella-zoster, and Epstein-Barr virus were detected using commercially available enzyme immunoassays.

Precision

Eight serum specimens (2 negative and 6 positive) and the Mumps IgG EIA Positive and Negative Controls, were assayed in triplicate, on three separate occasions. The precision experiments were performed manually at two independent laboratories (Lab A and Lab B), and at Laboratory C. These results are shown below in tables 5 through 8, respectively.

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Table 5. Results of Intra-assay and Interassay Precision Tests Performed at Lab A. Values were calculated from the Mumps IgG EIA Index values.

	INTRA-ASSAY			INTERASSAY		
SAMPLE	MEAN INDEX	S.D.	C.V. %	MEAN INDEX	S.D.	C.V. %
Pos. Control	4.4	0.092	2.1	4.9	0.583	11.9
Neg. Control	0.0	0.005	NA	0.1	0.000	NA
1	0.1	0.161	NA	0.2	0.000	NA
2	0.2	0.054	NA	0.2	0.188	NA
3	1.7	0.300	17.1	1.5	0.269	17.4
4	3.2	0.280	8.7	3.0	0.314	10.5
5	3.4	0.280	8.3	3.2	0.389	12.2
6	4.5	0.423	9.3	4.3	0.352	8.2
7	3.3	0.120	3.7	3.1	0.210	6.9
8	3.8	0.280	7.3	3.5	0.340	9.9

Table 6. Results of Intra-assay and Interassay Precision Tests Performed at Lab B. Values were calculated from the Mumps IgG EIA Index values.

	INTRA-ASSAY			INTERASSAY		
SAMPLE	MEAN INDEX	S.D.	C.V. %	MEAN INDEX	S.D.	C.V. %
Pos. Control	2.6	0.077	3.0	2.4	239	10.0
Neg. Control	0.4	0.215	NA	0.4	0.000	NA
1	0.4	0.014	NA	0.4	0.000	NA
2	0.5	0.049	NA	0.5	0.084	NA
3	0.5	0.131	25.1	0.6	0.125	22.6
4	1.6	0.058	3.7	1.8	0.276	15.6
5	0.9	0.027	2.9	1.2	0.323	26.2
6	1.4	0.037	2.6	2.0	0.607	30.5
7	0.8	0.010	1.6	1.0	0.180	18.3
8	2.3	0.080	3.6	2.6	0.230	8.9

Table 7. Results of Intra-assay and Interassay Precision Tests Performed at Lab C. Values were calculated from the Mumps IgG EIA Index values.

	INTRA-ASSAY			INTERASSAY		
SAMPLE	MEAN INDEX	S.D	C.V. %	MEAN INDEX	S.D	C.V. %
Pos. Control	3.0	0.127	4.2	2.9	0.121	4.2
Neg. Control	0.5	0.030	NA	0.6	0.122	NA
1	0.5	0.000	NA	0.6	0.127	NA
2	0.6	0.046	NA	0.7	0.109	NA
3	2.7	0.373	13.9	2.6	0.217	8.5
4	4.3	0.329	7.6	4.3	0.224	5.2
5	4.0	0.215	5.3	4.1	0.161	3.9
6	5.1	0.304	5.9	5.2	0.353	6.8
7	4.4	0.140	3.3	4.4	0.150	3.4
8	4.0	0.240	5.9	4.0	0.270	6.6

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Table 8. Interlaboratory Precision. Tests Were Performed at Lab A, Lab B and Lab C. Values were calculated from the Mumps IgG EIA Index values.

	INDEXES		
SAMPLE	MEAN	S.D	C.V.%
Pos. Control	3.4	0.315	9.3
Neg. Control	0.4	0.041	NA
1	0.4	0.042	NA
2	0.5	0.127	NA
3	1.6	0.204	13.1
4	3.0	0.272	9.0
5	2.8	0.291	10.2
6	3.8	0.437	11.5
7	2.8	0.182	6.4
8	3.4	0.280	8.3

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