Subject/Title: **ASI HSV IgG EIA TEST**		Doc#: 830096AG
Effective Date: 02/18/16	Supersedes Revision/Date: Original	Revision: 02/18/16
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 type 1 and type 2 herpes simplex virus (HSV) in human serum by enzyme immunoassay. To aid in the evaluation of the patient's immunological history with HSV, including women of childbearing age. These reagents have not received FDA clearance for use in testing blood or plasma donors.

2.0 SUMMARY AND EXPLANATION OF THE TEST:

Herpes simplex virus is a ubiquitous pathogen of humans. Its clinical consequences are usually subclinical; however fatal infection may occur in neonates and immunocompromised hosts[1].

There are two immunologically related types of herpes simplex virus. Historically, Type 1 HSV has been associated with oral infections, and Type 2 HSV with genital infections. The association between virus type and site of infection is by no means specific however, and both types of HSV have been isolated from either oral or genital infections[2].

Serological tests which detect the presence of IgG antibodies to HSV, provide information regarding history of previous infection. IgG antibodies to HSV detected in newborns are most likely of maternal origin, inasmuch as maternal IgG crosses the placenta.
The HSV IgG EIA test has been designed to detect IgG antibody directed against either Type 1 or Type 2 HSV. 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. HSV 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 HSV 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 equal portions of sonicated Type 1 HSV (MacIntyre strain), and Type 2 HSV (MS strain) antigen.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 HSV IgG antibodies. Index values shown on vial label.
Calibrator 2*	0.3 ml. Human serum. Moderately reactive for HSV antibodies. Index values shown on vial label.
Positive Control*	0.3 ml. Human serum. Reactive for HSV antibodies. Index values shown on vial label.
Negative Control*	0.3 ml. Human serum. Nonreactive for HSV 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 1 liter 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 HSV IgG antibody 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 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, Substrate and Stop Reagent.

Subject/Title: ASI HSV IgG EIA TEST		Doc#: 830096AG
Effective Date: 02/18/16	Supersedes Revision/Date: Original	Revision: 02/18/16

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; and grossly contaminated samples should not be used.
9.5 Samples should not be heat-inactivated before testing.

10.0 PERFORMANCE OF TEST

Materials Provided:

96 Tests

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

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 may be used; for semi-quantitative assays, use Calibrator 1 and Calibrator 2.*

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 and the corresponding color.*

Subject/Title: ASI HSV IgG EIA TEST		Doc#: 830096AG
Effective Date: 02/18/16	Supersedes Revision/Date: Original	Revision: 02/18/16

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 25° C) 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. If control samples 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 control samples, 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 results, use a calibration curve consisting of two or more calibrators.

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

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

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 Calibrator 1 must be at least 0.6, when read against the reagent blank.
3. The absorbance value of the reagent blank should be less than 0.35.
4. The Negative Control must have an Index value less than 0.9.
5. The Positive Control must have an Index value within the range printed on the label.
6. To validate the upper range of the assay when performing the semi-quantitative procedure, 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 coated wells. The expected value ranges for these concentrated controls would be 1.5 times and 2 times respectively, the expected value ranges printed on the Positive Control label. The assay results for these controls must fall within the corrected ranges. Additional controls may be tested according to guidelines or requirements of local, state and/or federal regulations or accrediting organizations. It is recommended that users refer to NCCLS Document C24-A for guidance on appropriate quality control practices.
If any of these criteria are not met, the test is invalid and should be repeated.

Subject/Title: ASI HSV IgG EIA TEST		Doc#: 830096AG
Effective Date: 02/18/16	Supersedes Revision/Date: Original	Revision: 02/18/16

Interpretation of Results

Index Value	Interpretation
< 0.9	Negative for anti-HSV: presumed no previous exposure
0.9 - 1.1	Equivocal
> 1.1	Positive for anti-HSV; presumed exposure to HSV 1 or type 2 virus

The HSV IgG EIA cut-off value was initially based on the mean Index value plus three standard deviations, obtained when 49 serum specimens shown to be negative by another commercial test, were assayed by the HSV IgG EIA test. The cutoff value was subsequently challenged using a panel of 100 masked and coded serum specimens, which have been well characterized by EIA tests and western blots.

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 infective or disease stage.

The HSV IgG EIA test's analytical sensitivity for anti-HSV 1 and anti-HSV 2 individually has not been determined. A negative result does not preclude the patient having anti-HSV antibodies.

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. For an interpretation of seroconversion, the acute specimen result should be negation, and the convalescent specimen result should fall above the imprecision of the cutoff, i.e. 1.1 plus 10%, or 1.2.

To determine a significant difference between acute/convalescent serum pairs, both specimens should be assayed concurrently. Dose response experiments performed at Laboratory C, have shown that a 50 to 75 percent increase in the HSV IgG EIA Index value, corresponds to a two-fold increase in the HSV IgG antibody level; and a 100 to 150 percent increase in HSV IgG EIA Index value, corresponds to a four-fold increase in the HSV IgG antibody level. The upper limit of the convalescent serum should fall within the range of the upper Calibrator (Calibrator 1). If the convalescent serum does not fall within this range, it should be pre-diluted in the test set sample Diluent, and reassayed. The resulting Index value should be multiplied by the dilution factor. *Example: If the specimen has been pre-diluted 1:2 before testing, the resulting Index value should be multiplied by 2.* The clinical significance of anti-HSV titer rises has not been established.

Specimens which yield absorbance values above the range of the test set calibrator(s), or the microwell reader, may be pre-diluted in the test set Diluent prior to being further diluted (1:51) for the assay. The resulting Index value must be multiplied by the dilution factor. *For example, a specimen may be diluted up to 1:2 before testing. The resulting Index value should be multiplied by 2.*

The suggested reporting method for results is: The following results were obtained with the Bio-Rad HSV IgG EIA test. 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 results obtained with the HSV IgG EIA test serve only as an aid to diagnosis and should not be interpreted as diagnostic in themselves.

Serological procedures for HSV are not intended to replace viral isolation and identification. The results of serological tests should be used in conjunction with information available from clinical evaluation and other diagnostic procedures.

A single serum should not be used to aid in the diagnosis of recent infection. Paired specimens should be collected during the acute and convalescent stages of infection, and tested concurrently to detect significant antibody increases. The semi-quantitative procedure should be used when testing paired sera only.

A negative serological test does not exclude the possibility of past infection. Following primary HSV infection, antibody may fall to undetectable levels and then be boosted by later clinical infection with the same, or heterologous virus type. Such an occurrence may lead to incorrect interpretations of seroconversion and primary infection, or negative antibody status. In addition, samples obtained too early during primary infection may not contain detectable antibody. Some persons may fail to develop detectable antibody after herpes simplex virus infection.

The presence of IgG antibodies to HSV 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. The performance characteristics of the HSV IgG EIA test with immunocompromised patients, pre-transplant patients, neonatal or cord blood, or matrices other than serum have not been established.

Specific antibodies to either type of HSV do not confer immunity, and will not protect against future infections.

The performance characteristics of the HSV IgG EIA test with semi-automated instruments have not been established.

Subject/Title: ASI HSV IgG EIA TEST		Doc#: 830096AG
Effective Date: 02/18/16	Supersedes Revision/Date: Original	Revision: 02/18/16

Titration experiments (please see Figure 2) have shown that the upper limit of linearity for HSV IgG EIA Index values is approximately 20.

16.0 EXPECTED VALUES

Serological reactivity with HSV varies according to age, geographical location, sexual behavior and socio-economic conditions. Thirty-five percent of children five years of age have been found to be seropositive for antibodies to type 1 HSV, in contrast to only 1% being seropositive for antibodies to type 2 HSV. Eighty percent of the population will be positive for type 1 HSV antibodies by age 25, and the incidence of antibodies to type 2 HSV also increases with the age of the population[3].

Serum specimens obtained from 207 normal South Florida blood donors were assayed at Laboratory C, Miami, FL, using the HSV IgG EIA test. One hundred and sixty-nine samples (82 %) were positive for IgG antibodies to HSV, thirty (14 %) were negative, and eight (4 %) were equivocal. The positive samples yielded Index values between 1.2 and 55.6, with a mean Index value of 31.5. The incidence of HSV IgG EIA Index values is shown in table 1.

Table 1. Results of tests of 207 Specimens (100% frozen), from Normal South Florida Donors, Performed at Laboratory C (Miami, FL), Using the HSV IgG EIA Test. Forty (19 %) of the Specimens Tested were Obtained from Women of Childbearing Age.

Index Value Ranges	Specimens	
< 1.1	38 {2}	18 %
≥1.1 - <10	25 {2}	12 %
≧10	144 {36}	70 %

{ } Number of female donors of childbearing age.

One hundred and twenty-two women of childbearing age (18 to 45 years) were identified in the clinical studies. They ranged in age from 18 to 45, with a mean age of 31. Of these, 103 (84 %) were positive, 2 (2 %) were equivocal, and 17 (14 %) were negative, when tested by the HSV IgG EIA test. The incidence of the HSV IgG EIA Index values obtained for these women is shown in table 2.

Table 2. Results of tests of 122 Specimens, from Women of Childbearing Age (18-45), Performed at Laboratory A (W. Columbia, SC), Laboratory B (Miami, FL) and at Laboratory C (Miami, FL), Using the HSV IgG EIA Test.

Index Value Ranges	Specimens	
< 1.1	19	16 %
≥ 1.1 - < 10	16	13 %
≥ 10	87	71%

17.0 PERFORMANCE CHARACTERISTICS

CDC Panel Results

The following information was obtained with the Centers for Disease Control and Prevention (CDC) serum panel for CMV / HSV serology assays, which was tested at Laboratory C by the HSV IgG EIA test. The results are presented as a means to convey further information on the performance of this assay with a masked, characterized serum panel. This does not imply an endorsement by the CDC.

The panel consists of 72% positive and 28% negative samples. The HSV IgG EIA test demonstrated 95% total agreement with the CDC results. Of the results obtained by HSV IgG EIA, there was 93% agreement with the positive specimens, and 100% agreement with the negative specimens.

Comparative Testing

HSV IgG EIA test results correlated well with results of other serological tests. Sera from normal blood donors were assayed for the presence of HSV IgG antibodies, using the HSV IgG EIA test and two other commercial tests, at two independent laboratories (Lab A, W. Columbia, SC, and Lab B, Miami, FL), and at Laboratory C (Miami, FL). These results are shown below in tables 3, 4 and 5, respectively.

Table 3. Results of tests of 203 Specimens (17 % frozen), Obtained in South Carolina, and Tested at Lab A, W. Columbia, SC, Using the HSV IgG EIA Test and Another Commercial Test. Thirty-one (15 %) of the Specimens Tested were Obtained from Women of Childbearing Age.

Comparative	HSV IgG EIA				
Type 1 HSV Test #1	Positive	Equivocal	Negative		95%CI
Positive	143 {23}	2 (1)	2	Relative sensitivity*	* 95.1 to 99.8**
Equivocal	0	0	0		
Negative	16 {4}	4 {2}	36 {7}	Relative specificity*	*58.1 to 83.1***
				Overall Agreement	**86.8 to 99.9***
Type 2 HSV					
Positive	134 {22}	0	1	Relative sensitivity*	95.9 to 100**
Equivocal	1	0	1		
Negative	24 {5}	6 {3}	36 {7}	Relative specificity*	47.6 to 72.4***
				Overall Agreement*	82.5 to 91.9***

* Excluding equivocal results
**Calculated by the Exact Method
***Calculated by the Normal Method (4).
{ } Number of female donors of childbearing age.

Subject/Title: ASI HSV IgG EIA TEST		Doc#: 830096AG
Effective Date: 02/18/16	Supersedes Revision/Date: Original	Revision: 02/18/16

Table 4. Results of tests of 200 Specimens (90% frozen), Obtained in South Florida, and Tested at Lab B, Miami, FL, Using the HSV IgG EIA Test and Another Commercial Test. Fifty-one (26 %) of the Specimens Tested were Obtained from Women of Childbearing Age.

Comparative Test #2	Positive	HSV IgG EIA Equivocal	Negative		95%CI
Type 1 HSV					
Positive	144 {37}	0	1	Relative sensitivity*	96.2 to 100**
Negative	18 {4}	5 {1}	32 {11}	Relative specificity*	50.7 to 77.3***
				Overall Agreement*	86.1 to 94.4***
Type 2 HSV					
Positive	144 {37}	0	1	Relative sensitivity*	96.2 to 100**
Negative	18 {4}	5 {1}	32 {11}	Relative specificity*	50.7 to 77.3***
				Overall Agreement*	86.1 to 94.4***

* Excluding equivocal results
**Calculated by the Exact method
***Calculated by the Normal Method (4).
{ } Number of female donors of childbearing age.

Table 5. Results of tests of 207 Specimens (100% frozen), Obtained in South Florida, and Tested at Lab C (Miami, FL), Using the HSV IgG EIA Test and Another Commercial Test. Forty (19 %) of the Specimens Tested were Obtained from Women of Childbearing Age.

Comparative Type 1 HSV Test #1	Positive	HSV IgG EIA Equivocal	Negative		95%CI
Positive	158 {36}	0	0	Relative sensitivity	97.1 to 100**
Negative	11 {2}	8	30 {2}	Relative specificity*	59.6 to 86.7***
				Overall Agreement	91.3 to 97.6***
Type 2 HSV					
Positive	153 {35}	0	0	Relative sensitivity	97.6 to 100**
Negative	16 {3}	8	30 {2}	Relative specificity*	51.5 to 79.0***
				Overall Agreement*	88.2 to 95.7***

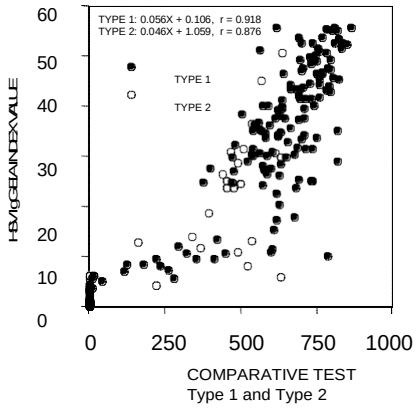
* Excluding equivocal results
**Calculated by the Exact Method
***Calculated by the Normal Method (4).
{ } Number o f female donors of childbearing age.

Users are advised that "relative sensitivity and specificity" in tables 3, 4 and 5 refers to the comparison of this 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 judgement can be made on the comparison assay's accuracy to predict disease.

Eleven specimens which were positive by the HSV IgG EIA test, were negative for HSV type 1 and type 2 antibodies by comparative test # 1 (Table 5 above). When these specimens were retested using another commercial device for HSV antibodies, three of the specimens were positive and eight were negative.

The data obtained at Laboratory C and tabulated in table 5, has been plotted below in Figure 1.

Figure 1. Results of Tests of 207 Serum Specimens Performed at Lab C (Miami, FL) Using the HSV IgG EIA Test and Another Commercial Test.

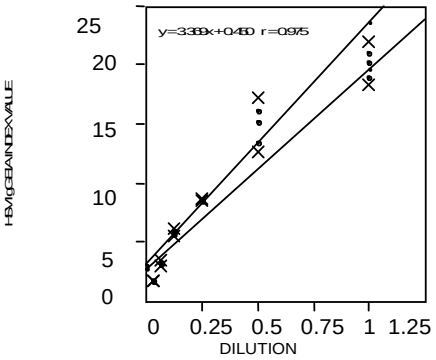


Titration curve

Subject/Title: ASI HSV IgG EIA TEST		Doc#: 830096AG
Effective Date: 02/18/16	Supersedes Revision/Date: Original	Revision: 02/18/16

Several strongly positive serum specimens were serially diluted (two-fold) in triplicate, and assayed by the HSV 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 HSV IgG EIA test is specific for IgG antibodies directed against HSV, and does not cross-react with other herpes viruses. Of 9 specimens which were unreactive in the HSV IgG EIA test, 4 were shown to contain moderate to high levels of IgG antibody directed against cytomegalovirus, 5 against varicella zoster virus, and 5 against Epstein-Barr virus, using commercially available enzyme immunoassays.

Assays of serum specimens which had been subjected to western blot analysis, have indicated that the HSV IgG EIA test is capable of detecting both HSV antibody types (1 & 2), with comparable efficacy. The HSV IgG EIA test detected HSV antibody in 54 (93.1%) of 58 sera known to contain type 1 HSV antibody, and in 35 (97.2%) of 36 sera known to contain type 2 HSV antibody. Of the five specimens which were negative by the HSV IgG EIA assay, 4 contained type 1 HSV antibody only and 1 contained type 2 HSV antibody only.

Precision

Eight serum specimens (2 negative and 6 positive) and the HSV IgG EIA Positive and Negative Controls, were assayed in triplicate, on three separate occasions. The precision experiments were performed at Lab C. These results are shown below in table 6.

Table 6. Results Intra-assay and Interassay Precision Tests Performed at Lab C Using a Positive Control and Samples Giving Index values Close to the Cutoff. Values were calculated from the HSV IgG EIA Index values.

	INTRA ASSAY			INTERASSAY		
SAMPLE	MEAN	S.D	C.V. %	MEAN	S.D.	C.V. %
Pos. Control	1.8	0.058	3.1	1.8	0.060	3.4
Neg. Control	0.3	0.000	NA	0.3	0.044	NA
1	0.1	0.000	NA	0.1	0.033	NA
2	0.1	0.000	NA	0.1	0.000	NA
3	1.3	0.115	9.1	1.2	0.073	5.8
4	3.0	0.173	5.8	3.0	0.136	4.5
5	6.8	0.153	2.3	6.9	0.335	4.9
6	1.6	0.100	6.3	1.6	0.090	5.8
7	1.4	0.000	0.0	1.4	0.033	2.4
8	1.5	0.058	3.8	1.5	0.067	4.4

18.0 REFERENCES

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3. Maza, de la, L.M. and Peterson, E.M., Med. Clin. N. Am., 67: 1059-1073,1983.
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Subject/Title: **ASI HSV IgG EIA TEST**		Doc#: 830096AG
Effective Date: 02/18/16	Supersedes Revision/Date: Original	Revision: 02/18/16

19.0 TECHNICAL INFORMATION: (801) 489-8911 or (800) 654-0146

	Manufactured for: Arlington Scientific, Inc. 1840 N Technology Drive, Springville, UT 84663 (USA)		JB Morphet Ltd. 34 Ashdale Road Kesgrave Suffolk IP5 2PA United Kingdom
	Lot No.		Expiration Date
	96 Tests		Catalog No.
	In vitro diagnostic use only		Temperature Limitations