| Subject/Title: **ASI CMV IgG EIA TEST** | | Doc#: 820096AG |
|---|---|---|
| Effective Date: 02/17 | Supersedes Revision/Date: Original | Revision: 02/17 |
| Prepared by: ASI | QA Approval by: | Copy/Dept.: |

***FOR IN VITRO DIAGNOSTIC USE***

## 1.0 INTENDED USE

For the detection of human IgG antibodies to cytomegalovirus virus in human serum by enzyme immunoassay, as an aid in the determination of acute or reactivated infection with CMV. When used as a qualitative test, CMV IgG EIA aids in the assessment of the patient's immunological response to CMV. These reagents have not received FDA clearance for use in testing blood or plasma donors.

## 2.0 SUMMARY AND EXPLANATION

Cytomegalovirus (CMV) is the causative agent of cytomegalic inclusion disease, a generalized infection of infants caused by intrauterine or early post natal infection. The disease may cause severe congenital abnormalities, such as microcephaly, motor disability and mental retardation in infants[1, 2, 3]. Cytomegalovirus infection has also been associated with acquired hemolytic anemia, acute and chronic hepatitis, and an infectious mononucleosis-like syndrome. Subclinical infection may occur in adults[4]. CMV infection can be transmitted to immunodeficient or immunosuppressed individuals, as a result of blood transfusion[5] or organ transplantation[6].
Serological tests, such as the CMV IgG EIA test, which detect the presence of CMV IgG antibodies, can aid in the diagnosis of diseases caused by cytomegalovirus. 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 PROCEDURE

Diluted samples are incubated in antigen-coated wells. CMV 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 CMV 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 CMV antigen (strain AD 169). 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 CMV antibodies. |
| Calibrator 2* | 0.3 ml. Human serum. Moderately reactive for CMV antibodies. |
| Positive Control* | 0.3 ml. Human serum. Reactive for CMV antibodies. |
| Negative Control* | 0.3 ml. Human serum. Non-reactive for CMV 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 one 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 anti-CMV 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.
**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 dessicant, and stored in the refrigerator.

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**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 | 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.

## 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 Calibrator 2 may be used; for semi-quantitative assays, it is necessary to 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.*
**12.2** Transfer 100 µl of each diluted Calibrator, Control and patient sample to the wells.

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***Note:*** *Include one well which contains 100 µl of Diluent only. This will serve as the reagent blank and will be ultimately 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. Controls and calibrator(s) 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 semi-quantitative 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, or IU/ml 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 absorbance range of the spectrophotometer being used.

Test Validation Criteria
1. The Calibrator(s), Positive and Negative Controls must be included in each test run.
2. The absorbance values of Calibrator 1 and Calibrator 2, must be at least 0.8 and 0.4 respectively, 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. When performing qualitative tests, users may supply an alternative Positive Control if they wish.
If any of these criteria are not met, the test is invalid and should be repeated.

### Interpretation of Results

| Index Value | Interpretation |
|---|---|
| < 0.9 | Negative |
| ≥ 0.9 < 1.1 | Equivocal |
| ≥1.1 | Positive |

The CMV IgG EIA cut-off values were based on statistical analyses, i.e. mean + 3 standard deviations, of serum specimens shown to be negative by other legally marketed devices. They were validated in tests of known positive and negative specimens (please see Performance Characteristics).
When equivocal results are obtained, another specimen should be obtained two to three weeks 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.
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 75 to 95 percent increase in the CMV IgG EIA Index value,

corresponds to a two-fold increase in the CMV IgG antibody level; and a 150 to 190 percent increase in CMV IgG EIA Index value, corresponds to a four-fold increase in the CMV IgG antibody level.
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 and reassayed. The resulting Index value must be multiplied by the dilution factor. Example: If the specimen has been pre-diluted 1:5 before testing, the resulting Index value should be multiplied by 5.

**Expected Values**

The incidence of CMV antibodies is related to age, socio-economic condition, and geographic location of the test population[8, 9, 10]. Up to 80 % of U.S. and European blood donors exhibit serological evidence of previous CMV infection[11,12]. Serum specimens obtained randomly from one hundred and forty-three healthy South Florida blood donors were assayed by the CMV IgG EIA test. One hundred and one specimens (71 %) were positive for antibodies to CMV. The Index values ranged from 1.9 to 10.7. Excluding the results for twenty-two strongly positive specimens which gave absorbance values above the range of the reader, the mean value of the positives was 5.5. The remaining forty-two specimens (29 %) were negative.

## 15.0 LIMITATIONS OF PROCEDURE

The results obtained with the CMV IgG EIA test serve only as an aid to diagnosis and should not be interpreted as diagnostic in themselves. To detect seroconversion, paired specimens should be collected during the acute and convalescent stages of infection, and tested concurrently.
Positive results with cord blood should be interpreted with caution. The presence of IgG antibodies to CMV 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.
Definitive diagnosis of active CMV infection requires viral isolation. The presence of IgG antibody to CMV does not assure protection from disease.
Titration experiments (please see Figure 2) have shown that the upper limit of linearity for CMV IgG EIA Index values is approximately 6.

## 16.0 PERFORMANCE CHARACTERISTICS

Comparative Testing
CMV IgG EIA test results correlated very well with results of other serological tests. Sera from normal blood donors were assayed for the presence of CMV IgG antibodies, using the CMV IgG EIA test and three other commercial tests, at two independent laboratories (Lab A, Atlanta, GA, and Lab B, Gainesville, FL), and at Laboratory C (Miami, FL). These results are shown below in Tables 1, 2 and 3, respectively.

**Table 1. Results of Tests of 152 Specimens (58% frozen and 42% fresh), from North and South Carolina, Alabama, Georgia and Florida, Performed at Laboratory A (Atlanta, GA), Using the CMV IgG EIA Test and Another Commercial Test.**

| Comparative | CMV IgG EIA | | | | |
|---|---|---|---|---|---|
| Test #1 | Positive | Equivocal | Negative | | 95%CI** |
| Positive | 63 | 0 | 2 | Relative sensitivity* | 89.3 to 99.6 |
| Negative | 3 | 3 | 81 | Relative specificity* | 89.9 to 99.3 |
| * Excluding equivocal results | | | | Overall Agreement* | 92.3 to 98.9 |
| ** Calculated by the Exact Method[13]. | | | | | |

**Table 2. Results of tests of 163 Specimens (66% frozen and 34% fresh), from North, Central and South Florida, Performed at Laboratory B (Gainesville, FL), Using the CMV IgG EIA Test and Another Commercial Test.**

| Comparative | CMV IgG EIA | | | | |
|---|---|---|---|---|---|
| Test #2 | Positive | Equivocal | Negative | | 95%CI** |
| Positive | 97 | 0 | 4 | Relative sensitivity* | 92.2 to 99.8 |
| Equivocal | 1 | 0 | 0 | | |
| Negative | 1 | 2 | 58 | Relative specificity* | 95.0 to 100 |
| * Excluding equivocal results | | | | Overall Agreement* | 94.1 to 99.5 |
| ** Calculated by the Exact Method[13]. | | | | | |

**Table 3. Results of tests of 143 Specimens (100% frozen), from South Florida, Performed at Laboratory C (Miami, FL), Using the CMV IgG EIA Test and Another Commercial Test.**

| Comparative | CMV IgG EIA | | | | |
|---|---|---|---|---|---|
| Test #2 | Positive | Equivocal | Negative | | 95%CI** |
| Positive | 101 | 0 | 0 | Relative sensitivity* | 96.4 to 100 |
| Equivocal | 0 | 0 | 0 | | |
| Negative | 0 | 0 | 42 | Relative specificity* | 91.6 to 100 |
| * Excluding equivocal results | | | | Overall Agreement* | 97.5 to 100 |
| ** Calculated by the Exact Method[13]. | | | | | |

The data obtained at Lab C and tabulated in Table 3, has been plotted below in Figure 1. Twenty-two specimens which were strongly positive in both assays, which gave results above the range of the reader, are not shown.

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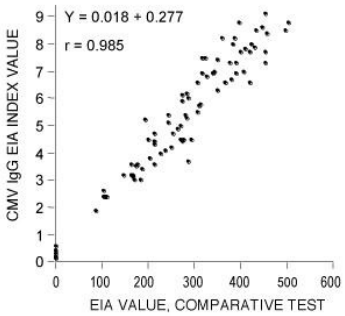
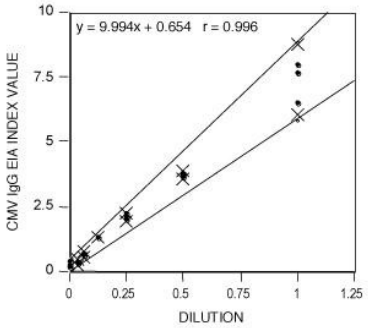
**Figure 1. Results of Tests of 121 Serum Specimens Performed at Lab C, Using the CMV IgG EIA Test and Another Commercial Test.**




**Titration curve**
Several strongly positive serum specimens were serially diluted (two-fold) in triplicate, and assayed by the CMV 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.

The results of the titration / dose response experiments were analyzed in order to relate changes in the CMV IgG EIA Index values to actual differences in antibody level. This analysis showed that a 75 to 95 percent increase in the CMV IgG EIA Index value, is equivalent to a two-fold increase in the antibody level; and a 150 to 190 percent increase in the Index value, indicates a four-fold change in the antibody level.

Specificity
The CMV IgG EIA test is specific for IgG antibodies directed against cytomegalovirus, and does not to cross-react with antibodies directed against other members of the herpes virus group. In tests of eleven sera which were negative for CMV antibody, all eleven were positive for varicella-zoster and Epstein-Barr antibodies, and six of eleven were positive for herpes simplex type 1 and type 2 antibodies.

Precision
Eight serum specimens (2 negative and 6 positive) and the CMV 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 4, 5 and 6 respectively.

**Table 4. Results Intra-assay and Interassay Precision Tests Performed at Lab A. Values were calculated from CMV IgG EIA Index Values.**

| | INTRA ASSAY | | | INTERASSAY | | |
|---|---|---|---|---|---|---|
| SAMPLE | MEAN | S.D | C.V% | MEAN | S.D | C.V% |
| Pos. Control | 3.8 | 0.265 | 7.1 | 3.7 | 0.244 | 6.6 |
| Neg. Control | 0.3 | 0.017 | NA | 0.3 | 0.022 | NA |
| 1 | 4.7 | 0.577 | 12.4 | 5.1 | 0.646 | 12.8 |
| 2 | 2.4 | 0.231 | 9.8 | 2.5 | 0.217 | 8.6 |
| 3 | 0.4 | 0.029 | NA | 0.5 | 0.059 | NA |

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|---|---|---|---|---|---|---|
| 4 | 5.0 | 0.651 | 13.1 | 5.4 | 0.711 | 13.2 |
| 5 | 0.5 | 0.015 | NA | 0.5 | 0.059 | NA |
| 6 | 2.7 | 0.551 | 20.7 | 3.1 | 0.556 | 18.1 |
| 7 | 1.9 | 0.265 | 13.9 | 2.0 | 0.330 | 16.6 |
| 8 | 1.5 | 0.058 | 3.9 | 1.7 | 0.219 | 13.2 |

**Table 5. Results Intra-assay and Interassay Precision Tests Performed at Lab B. Values were calculated from CMV IgG EIA Index Values.**

| | INTRA ASSAY | | | INTERASSAY | | |
|---|---|---|---|---|---|---|
| SAMPLE | MEAN | S.D | C.V% | MEAN | S.D | C.V% |
| Pos. Control | 2.7 | 0.115 | 4.2 | 2.9 | 0.169 | 5.9 |
| Neg. Control | 0.1 | 0.000 | NA | 0.3 | 0.172 | NA |
| 1 | 4.4 | 0.306 | 6.9 | 4.0 | 0.391 | 9.8 |
| 2 | 2.1 | 0.153 | 7.4 | 2.1 | 0.148 | 7.0 |
| 3 | 0.2 | 0.000 | NA | 0.2 | 0.000 | NA |
| 4 | 4.7 | 0.451 | 9.5 | 4.8 | 0.548 | 11.3 |
| 5 | 0.3 | 0.000 | NA | 0.3 | 0.033 | NA |
| 6 | 2.5 | 0.100 | 4.0 | 2.6 | 0.112 | 4.4 |
| 7 | 1.8 | 0.252 | 13.7 | 1.8 | 0.305 | 16.5 |
| 8 | 1.4 | 0.58 | 4.2 | 1.4 | 0.083 | 5.9 |

**Table 6. Results Intra-assay and Interassay Precision Tests Performed at Lab C. Values were calculated from CMV IgG EIA Index Values.**

| | INTRA ASSAY | | | INTERASSAY | | |
|---|---|---|---|---|---|---|
| SAMPLE | MEAN | S.D | C.V% | MEAN | S.D | C.V% |
| Pos. Control | 2.9 | 0.200 | 6.9 | 3.0 | 0.179 | 5.9 |
| Neg. Control | 0 | 0.000 | NA | 0 | 0.133 | NA |
| 1 | 4.4 | 0.000 | 0.0 | 4.4 | 0.273 | 6.2 |
| 2 | 2.0 | 0.208 | 10.6 | 2.1 | 0.217 | 10.4 |
| 3 | 0.0 | 0.058 | NA | 0.1 | 0.044 | NA |
| 4 | 5.3 | 0.493 | 9.2 | 5.3 | 0.363 | 6.8 |
| 5 | 0 | 0.000 | NA | 0.1 | 0.097 | NA |
| 6 | 2.7 | 0.115 | 4.3 | 2.7 | 0.179 | 6.6 |
| 7 | 1.6 | 0.100 | 6.3 | 1.7 | 0.120 | 7.2 |
| 8 | 1.4 | 0.100 | 7.1 | 1.4 | 0.101 | 7.0 |

CDC Panel Results

The following information was obtained with the Centers for Disease Control and Prevention (CDC) serum panel for CMV serology assays, which was tested by the CMV 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 66 positive and 34 negative samples. The CMV IgG EIA test demonstrated 99 % (99 of 100) total agreement with the CDC results. Of the results obtained by Laboratory C, there was 100 % (66 of 66) agreement with the positive results and 97 % (33 of 34) agreement with the negative specimens.

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**18.0 TECHNICAL INFORMATION:** 801-489-8911 and 800-654-0146.

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