CMV IgG EIA

Enzyme Immunoassay (EIA) for the Detection of CMV IgG Antibodies in Human Serum.

For In Vitro Diagnostic Use Only 25177 • 96 Tests
1 - INTENDED USE
For the detection of human IgG antibodies to cytomegalovirus 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 - SUMMARY AND EXPLANATION OF THE TEST
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.\textsuperscript{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.\textsuperscript{4} CMV infection can be transmitted to immunodeficient or
immunosuppressed individuals, as a result of blood transfusion\textsuperscript{5}
or organ transplantation.\textsuperscript{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 - PRINCIPLE OF THE TEST
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 - REAGENTS

**CMV IgG EIA Product Description**  
Catalog No. 25177 (96 Tests)

<table>
<thead>
<tr>
<th>Component</th>
<th>Contents</th>
<th>Preparation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coated Wells 12</td>
<td>• Coated with CMV antigen (strain AD 169)</td>
<td>Use as supplied. Return unused strips to pouch and reseal. Do not remove desiccant.*</td>
</tr>
<tr>
<td></td>
<td>• Pink wells</td>
<td></td>
</tr>
<tr>
<td>Well support 1 Frame</td>
<td>• Plate frame</td>
<td>Use as supplied.</td>
</tr>
<tr>
<td>Diluent** 1 bottle</td>
<td>• Phosphate-buffered saline with a protein stabilizer</td>
<td>Use as supplied.</td>
</tr>
<tr>
<td>Calibrator 1** 1 vial</td>
<td>• Human serum, strongly reactive for CMV antibodies</td>
<td>Dilute in Diluent as described.</td>
</tr>
<tr>
<td>Calibrator 2** 1 vial</td>
<td>• Human serum, moderately reactive for CMV antibodies</td>
<td>Dilute in Diluent as described.</td>
</tr>
<tr>
<td>Calibrator 2** 1 vial</td>
<td>• Human serum, reactive for CMV antibodies</td>
<td>Dilute in Diluent as described.</td>
</tr>
<tr>
<td>Positive Control** 1</td>
<td>• Human serum, reactive for CMV antibodies</td>
<td>Dilute in Diluent as described.</td>
</tr>
<tr>
<td>Negative Control** 1</td>
<td>• Human serum, non-reactive for CMV antibodies</td>
<td>Dilute in Diluent as described.</td>
</tr>
<tr>
<td>Conjugate** 2 bottles</td>
<td>• Goat anti-human IgG labeled with alkaline phosphatase (calf)</td>
<td>Use as supplied.</td>
</tr>
<tr>
<td></td>
<td>• Green color</td>
<td></td>
</tr>
<tr>
<td>Substrate*** 1 bottle</td>
<td>• p-Nitrophenyl phosphate</td>
<td>Use as supplied.</td>
</tr>
<tr>
<td>Wash Concentrate** 1</td>
<td>• Tris-buffered saline</td>
<td>Dilute in 1 liter of distilled or deionized water.</td>
</tr>
<tr>
<td></td>
<td>• Tween 20™</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• pH 8.0</td>
<td></td>
</tr>
<tr>
<td>Stop Reagent 1 bottle</td>
<td>• Trisodium phosphate 0.5 M</td>
<td>Use as supplied.</td>
</tr>
</tbody>
</table>

* The color of the desiccant does not affect the performance of the kit.  
** Contains 0.1% sodium azide.  
*** 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.

Store these reagents at 2-8°C up to the expiration date indicated on the bottle labels. Do not allow them to contact the skin or eyes. If contact occurs, wash with copious amounts of water. Do not remove desiccant.

### 5 - OTHER 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.
6 - PRECAUTIONS FOR USERS
For In Vitro Diagnostic Use

1. Test samples, Calibrator(s), Controls, and the materials that contact them should be handled as potential biohazards. The calibrators and controls have been tested and found to be non-reactive for HIV, hepatitis B surface antigen, and HCV antibodies by licensed tests. However, no method can offer complete assurance that HIV, hepatitis B virus, HCV, or other infectious agents are absent. Handle reagents and patient samples as if capable of transmitting infectious disease following recommended *Universal Precautions* for bloodborne pathogens as defined by OSHA\(^4\), Biosafety Level 2 guidelines from the current CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*\(^5\), WHO *Laboratory Biosafety Manual*\(^6\), and/or local, regional, and national regulations.

2. 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.

3. Avoid contact with open skin.


5. Certain test reagents contain dilute sodium azide, which may be harmful if enough is ingested (more than supplied in kit). Azides are reported to react with lead and copper in plumbing to form compounds that may detonate on percussion. If disposing of solutions containing sodium azide down drains, flush with large volumes of water to minimize the build-up of metal-azide compounds. Dispose of contents and container in accordance with local, regional, national, and international regulations.

6. For more hazard information, refer to the product Safety Data Sheet (SDS), which is available at www.bio-rad.com and upon request.
7. Any lot number of the following reagents may be used with this assay, provided they have the correct catalog number and are not used beyond their labeled expiration date:
   - Diluent - Catalog # 25186
   - Substrate - Catalog # 25192
   - Wash Concentrate - Catalog # 25190
   - Stop Reagent - Catalog # 25191

   **Do not mix any other reagents from different lots.**

8. Do not use reagents beyond their stated expiration date.

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

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

11. This product should be used by qualified personnel.

12. There are no health hazards associated with the intact desiccant packet. Do not cut, split, or otherwise compromise it as dusts that may be generated could pose a health hazard. If the desiccant has been compromised, do not remove it from the plate pouch.

7 - SPECIMEN COLLECTION, PREPARATION, AND STORAGE

Sera should be separated from clotted blood and stored at 2 to 8°C. short term, or frozen at -10°C or below for longer periods. Multiple freeze-thaw cycles should be avoided. Samples containing visible particulate matter should be clarified by centrifugation, and grossly contaminated samples should not be used. Samples should not be heat-inactivated before testing.

8 - TEST PROCEDURE

**Materials Provided**

See REAGENTS section on page 4.

**EIA Procedure**

1. Allow all reagents and patient samples to reach room temperature before use. Return them promptly to refrigerator after use.

2. Prepare working wash solution by adding entire bottle of Wash Concentrate (30 mL) to 1 liter of water. Once diluted, the wash solution can be stored at room temperature for up
to two months, or at 4°C until the expiration date printed on
the Wash Concentrate bottle.

3. 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 semi-quantitative assays, it is necessary to
use Calibrator 1 and Calibrator 2 to prepare a calibration
curve. The blank serves as the zero calibrator.

4. Place 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.

5. 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.

6. Incubate the wells at room temperature (20 to 25°C) for 30
± 5 minutes.

7. Wash wells four times, with at least 250 μL of wash solution
per well. Do not allow the wells to soak between washes.
Aspirate thoroughly after the last wash.

8. Place 2 drops (or 100 μL) of Conjugate into each well.

9. Incubate the wells at room temperature (20 to 25°C) for 30
± 5 minutes.

10. Wash wells four times with at least 250 μL of wash solution
per well. Do not allow the wells to soak between washes.
Aspirate thoroughly after the last wash.

11. Place 2 drops (or 100 μL) of Substrate into each well.

12. Incubate at room temperature (20 to 25°C) for 30 ± 5
minutes.

13. Place 2 drops (or 100 μL) of Stop Reagent into each well.
Tap the plate gently, or use other means to assure complete
mixing.

14. 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.

9 - QUALITY CONTROL

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 \( \geq 0.800 \), when read against the reagent blank.
3. The absorbance value of Calibrator 2 must be \( \geq 0.400 \), when read against the reagent blank.
4. The absorbance value of the reagent blank should be \(< 0.350\).
5. The Negative Control must have an Index value \(< 0.9\).
6. 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.
7. If any of these criteria are not met, the test is invalid and should be repeated. If the test is invalid, patient results cannot be reported.

10-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:

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

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 absorbance range of the spectrophotometer being used.

**Interpretation of Results**

<table>
<thead>
<tr>
<th>Index Value</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 0.9</td>
<td>Negative</td>
</tr>
<tr>
<td>≥ 0.9 and &lt; 1.1</td>
<td>Equivocal</td>
</tr>
<tr>
<td>≥ 1.1</td>
<td>Positive</td>
</tr>
</tbody>
</table>

The CMV IgG EIA cutoff 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.
The suggested method for reporting results is: The following results were obtained with the Bio-Rad CMV IgG EIA test. Values obtained with different manufacturers’ assay methods may not be used interchangeably. The magnitude of the reported IgG level cannot be correlated to an endpoint titer.

11-LIMITATIONS

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.

12-EXPECTED VALUES

The incidence of CMV antibodies is related to age, socio-economic condition, and geographic location of the test population.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.
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.

<table>
<thead>
<tr>
<th>Comparative Test #1</th>
<th>CMV IgG EIA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
</tr>
<tr>
<td>Positive</td>
<td>63</td>
</tr>
<tr>
<td>Negative</td>
<td>3</td>
</tr>
</tbody>
</table>

95% C.I.**
Relative sensitivity* 89.3 to 99.6
Relative specificity* 89.9 to 99.3
Overall Agreement* 92.3 to 98.9

* Excluding equivocal results
** Calculated by the Normal Method

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.

<table>
<thead>
<tr>
<th>Comparative Test #2</th>
<th>CMV IgG EIA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
</tr>
<tr>
<td>Positive</td>
<td>97</td>
</tr>
<tr>
<td>Equivocal</td>
<td>1</td>
</tr>
<tr>
<td>Negative</td>
<td>1</td>
</tr>
</tbody>
</table>

95% C.I.**
Relative sensitivity* 92.2 to 99.8
Relative specificity* 95.0 to 100
Overall Agreement* 94.1 to 99.5

* Excluding equivocal results
** Calculated by the Normal Method

FOR REFERENCE USE ONLY: DO NOT USE in place of package inserts provided with each test kit.
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.

<table>
<thead>
<tr>
<th>Comparative Test #3</th>
<th>CMV IgG EIA</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Equivocal</td>
<td>Negative</td>
</tr>
<tr>
<td>Positive</td>
<td>101</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Equivocal</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>0</td>
<td>42</td>
</tr>
</tbody>
</table>

95% C.I.**

| Relative sensitivity* | 96.4 to 100 |
| Relative specificity* | 91.6 to 100 |
| Overall Agreement*    | 97.5 to 100 |

* Excluding equivocal results
** Calculated by the Normal Method

The data obtained at Lab C and tabulated in Table 3 have 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.

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.
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 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 inter-assay precision tests performed at Lab A. Values were calculated from CMV IgG EIA Index values.

<table>
<thead>
<tr>
<th>SAMPLE</th>
<th>INTRA-ASSAY</th>
<th></th>
<th></th>
<th>INTER-ASSAY</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN INDEX</td>
<td>S.D.</td>
<td>C.V. %</td>
<td>MEAN INDEX</td>
<td>S.D.</td>
<td>C.V. %</td>
</tr>
<tr>
<td>Pos. Control</td>
<td>3.8</td>
<td>0.265</td>
<td>7.0</td>
<td>3.7</td>
<td>0.244</td>
<td>6.6</td>
</tr>
<tr>
<td>Neg. Control</td>
<td>0.3</td>
<td>0.017</td>
<td>NA</td>
<td>0.3</td>
<td>0.022</td>
<td>NA</td>
</tr>
<tr>
<td>1</td>
<td>4.7</td>
<td>0.577</td>
<td>12.4</td>
<td>5.1</td>
<td>0.646</td>
<td>12.8</td>
</tr>
<tr>
<td>2</td>
<td>2.4</td>
<td>0.231</td>
<td>9.8</td>
<td>2.5</td>
<td>0.217</td>
<td>8.6</td>
</tr>
<tr>
<td>3</td>
<td>0.4</td>
<td>0.029</td>
<td>NA</td>
<td>0.5</td>
<td>0.059</td>
<td>NA</td>
</tr>
<tr>
<td>4</td>
<td>5.0</td>
<td>0.651</td>
<td>13.1</td>
<td>5.4</td>
<td>0.711</td>
<td>13.2</td>
</tr>
<tr>
<td>5</td>
<td>0.5</td>
<td>0.015</td>
<td>NA</td>
<td>0.5</td>
<td>0.059</td>
<td>NA</td>
</tr>
<tr>
<td>6</td>
<td>2.7</td>
<td>0.551</td>
<td>20.7</td>
<td>3.1</td>
<td>0.556</td>
<td>18.1</td>
</tr>
<tr>
<td>7</td>
<td>1.9</td>
<td>0.265</td>
<td>13.9</td>
<td>2.0</td>
<td>0.330</td>
<td>16.6</td>
</tr>
<tr>
<td>8</td>
<td>1.5</td>
<td>0.058</td>
<td>3.9</td>
<td>1.7</td>
<td>0.219</td>
<td>13.2</td>
</tr>
</tbody>
</table>

Table 5: Results intra-assay and inter-assay precision tests performed at Lab B. Values were calculated from CMV IgG EIA Index values.

<table>
<thead>
<tr>
<th>SAMPLE</th>
<th>INTRA-ASSAY</th>
<th></th>
<th></th>
<th>INTER-ASSAY</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN INDEX</td>
<td>S.D.</td>
<td>C.V. %</td>
<td>MEAN INDEX</td>
<td>S.D.</td>
<td>C.V. %</td>
</tr>
<tr>
<td>Pos. Control</td>
<td>2.7</td>
<td>0.115</td>
<td>4.2</td>
<td>2.9</td>
<td>0.169</td>
<td>5.9</td>
</tr>
<tr>
<td>Neg. Control</td>
<td>0.1</td>
<td>0.000</td>
<td>NA</td>
<td>0.3</td>
<td>0.172</td>
<td>NA</td>
</tr>
<tr>
<td>1</td>
<td>4.4</td>
<td>0.306</td>
<td>6.9</td>
<td>4.0</td>
<td>0.391</td>
<td>9.8</td>
</tr>
<tr>
<td>2</td>
<td>2.1</td>
<td>0.153</td>
<td>7.4</td>
<td>2.1</td>
<td>0.148</td>
<td>7.0</td>
</tr>
<tr>
<td>3</td>
<td>0.2</td>
<td>0.000</td>
<td>NA</td>
<td>0.2</td>
<td>0.000</td>
<td>NA</td>
</tr>
<tr>
<td>4</td>
<td>4.7</td>
<td>0.451</td>
<td>9.5</td>
<td>4.8</td>
<td>0.548</td>
<td>11.3</td>
</tr>
<tr>
<td>5</td>
<td>0.3</td>
<td>0.000</td>
<td>NA</td>
<td>0.3</td>
<td>0.033</td>
<td>NA</td>
</tr>
<tr>
<td>6</td>
<td>2.5</td>
<td>0.100</td>
<td>4.0</td>
<td>2.6</td>
<td>0.112</td>
<td>4.4</td>
</tr>
<tr>
<td>7</td>
<td>1.8</td>
<td>0.252</td>
<td>13.7</td>
<td>1.8</td>
<td>0.305</td>
<td>16.5</td>
</tr>
<tr>
<td>8</td>
<td>1.4</td>
<td>0.038</td>
<td>4.2</td>
<td>1.4</td>
<td>0.083</td>
<td>5.9</td>
</tr>
</tbody>
</table>

Table 6: Results intra-assay and inter-assay precision tests performed at Lab C. Values were calculated from CMV IgG EIA Index values.

<table>
<thead>
<tr>
<th>SAMPLE</th>
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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 using 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.
14-REFERENCES


