ANTIBODY TO CYTOMEGALOVIRUS (CMV)
ABBOTT CMV TOTAL AB EIA

NOTE CHANGES HIGHLIGHTED

NAME AND INTENDED USE
ABBOTT CMV TOTAL AB EIA IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODY TO CYTOMEGALOVIRUS (CMV) IN HUMAN SERUM OR PLASMA AS AN INDICATION OF PAST OR CURRENT INFECTION WITH CMV. THIS PRODUCT IS INTENDED AS A SCREEN FOR THE PRESENCE OF ANTIBODY TO CMV IN BLOOD OR PLASMA DONORS AND SHOULD NOT BE USED AS AN AID IN THE DIAGNOSIS OF CMV INFECTION.

69-4081/R8

WARNING: A software upgrade and/or protocol edits may be required prior to implementing this assay. Please contact your local Customer Support Center.
NAME AND INTENDED USE

ABBOTT CMV Total Ab EIA is a solid phase enzyme immunoassay for the qualitative detection of antibody to cytomegalovirus (CMV) in human serum or plasma as an aid in the diagnosis of CMV infection.

SUMMARY AND EXPLANATION OF THE TEST

Cytomegalovirus (CMV) is one of the leading causes of congenital viral infections and has been associated with infections following blood transfusions, renal transplants and bone marrow transplants. Transfusion of blood from seropositive donors to seronegative recipients has been implicated as a source of CMV infection. The frequency of seropositivity to CMV in random blood donor populations worldwide has been reported to range from 40 to 60%. Generally, the incidence of post-transfusion infection is related to the number of units received rather than to the condition for which transfusion is given. A growing number of studies indicate that selection of seropositive blood donors may greatly reduce CMV infection in special risk seronegative recipients.

A variety of methods have been developed to detect antibodies to CMV including enzyme immunoassay, indirect fluorescent antibody (IFA), indirect hemagglutination (IHA), complement fixation (CF) and fluorescent immunoassay (FIA).

BIOPOLICAL PRINCIPLES OF THE PROEDURE

In the ABBOTT CMV Total Ab EIA, polystyrene beads coated with heat inactivated CMV antigen are incubated with diluted serum, plasma or appropriate controls. Any antibody to CMV that is present is bound to the antigen on the solid phase. After aspiration of the unbound material and washing of the beads, the beads are incubated in 1 N Sulfuric Acid (H2SO4). The antibody reacts with the bead and develops in proportion to the amount of antibody to CMV bound to the beads. Unbound enzyme conjugate is then aspirated and the beads are washed. Next, o-Phenylenediamine (OPD) is added to the beads and, after incubation, a yellow-orange color develops in proportion to the amount of antibody to CMV bound to the beads. The enzyme reaction is stopped by the addition of 1 N Sulfuric Acid. The absorbance of the reaction mixture is measured spectrophotometrically using a spectrophotometer with the wavelength set at 492 nm. The absorbance of Negative Calibrator/Positive Control and specimens is determined using a spectrophotometer with the wavelength set at 492 nm. The enzyme immunoassay, not described by Englund and Perlmutter and Van Waerebeek and Schumm (1976), are both specific and sensitive for detecting and measuring serum proteins.

The reagent used to calculate the CMV Total Ab EIA assay results is referred to as the Negative “Calibrator” (NC). Instrument and/or data management terminology does not affect assay results. This difference in terminology does not affect assay results.

REAGENTS

The product contains human sourced and/or potentially infectious components. Components sourced from human blood have been tested and found to be nonreactive for HBsAg, HIV-1 Ag, anti-HCV and anti-HIV-1/HIV-2. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human sourced materials should be considered potentially infectious.

It is recommended that these reagents and human specimens be handled in accordance with the OSHA Standard on Bloodborne Pathogens. This product contains human sourced and/or potentially infectious components. Components sourced from human blood have been tested and found to be nonreactive for HBsAg, HIV-1 Ag, anti-HCV and anti-HIV-1/HIV-2. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human sourced materials should be considered potentially infectious.

WARNINGS AND PRECAUTIONS

FOR IN VITRO DIAGNOSTIC USE

This product contains human sourced and/or potentially infectious components. Components sourced from human blood have been tested and found to be nonreactive for HBsAg, HIV-1 Ag, anti-HCV and anti-HIV-1/HIV-2. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human sourced materials should be considered potentially infectious.

These precautions include, but are not limited to the following:

1. Wear gloves when handling reagents or specimens.
2. Do not pipette by mouth.
3. Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in areas where these materials are handled.
4. Clean and disinfect all spills of specimens or reagents using a tuberculocidal disinfectant such as 0.5% sodium hypochlorite, or other suitable disinfectant.
5. Discontinue and dispose of all supplies, reagents, and other potentially contaminated materials in accordance with local, state and federal regulations.

The reagents used to calculate the CMV Total Ab EIA assay results is referred to as the Negative “Calibrator” (NC). Instrument and/or data management terminology does not affect assay results.

1. Pipette 300 µL of OPD Substrate Solution into 5 EIA reaction tubes or acid washed/distilled or deionized water rinsed tubes.
2. Add 1.0 mL of the 5 N Sulfuric Acid under test to each of the five tubes.
3. Measure the A500 of the OPD Acid Solution against distilled or deionized water at 0 TIME.
4. Calculate the Mean Absorbance at 0 TIME and 120 MIN.
5. To be acceptable, acid must exhibit a Difference of less than 0.030 units in the values obtained at 0 TIME and 120 MIN.

ADDITIONAL REAGENTS AVAILABLE

1. N Sulfuric Acid. No. 7212-03 (10 mL).

REAGENT STABILITY

No. 6153 ABBOTT CMV Total Ab EIA Kit 100/500 Tests

1. 100/500 CMV (ADH5) Antigen Coated Beads (Inactivated).
2. 1 Vial (27 mL) Vial (115 mL) Enzyme Conjugate CMV Total Ab EIA: Antibody to Human Immunoglobulin (G) (Serum): Peroxidase (Horse-radish). Minimum Concentration: 20 mg/mL in protein stabilizers with Antimicrobial Agents.
3. 1 Vial (6 mL) Vial (5 mL) each) Positive Control CMV Total Ab EIA. "Negative Control (NC)."
4. 1 Vial (7 mL) Vial (10 mL) Negative Calibrator CMV Total Ab EIA: Inactivated CMV antigen in protein stabilizers with Antimicrobial Agents. Nonreactive for HBsAg, anti-HCV, HIV-1 Ag, and anti-HIV-1/HIV-2 by FDA licensed tests.
5. 1 Vial (40 mL) Vial (40 mL) each) Specimen Dilution Buffer CMV Total Ab EIA: Buffered Cell Serum with Antimicrobial Agents.
6. 10, 20, 30, 40 Tablets of 1 N Sulfuric Acid. No. 7212-01 (110 mL).
7. 1 Vial (10 mL)/3 Vials (10 mL each) Specimen Dilution Buffer CMV Total Ab EIA: Buffered Cell Serum with Antimicrobial Agents.
8. 1 Vial (10 mL)/3 Vials (10 mL each) Negative Calibrator CMV Total Ab EIA: Inactivated CMV antigen in protein stabilizers with Antimicrobial Agents. Nonreactive for HBsAg, anti-HCV, HIV-1 Ag, and anti-HIV-1/HIV-2 by FDA licensed tests.
9. 1 Bottle (220 mL) Diluent for OPD (o-Phenylenediamine dihydrochloride, sodium chloride). Minimum Concentration: 20 mg/mL in protein stabilizers with Antimicrobial Agents.
10. 1 Vial (220 mL) Diluent for OPD (O-PHENYLENEDIAMINE DIHYDROCHLORIDE, Sodium Chloride). Citrate-Phosphate Buffer containing 0.02% Hydrogen Peroxide.

Additional Reagents Available

1. 6 N Sulfuric Acid. No. 7212-03 (10 mL).

Handling Precautions

1. Do not use kit beyond the expiration date.
2. Do not mix reagents from different lots. SEE NOTE.
3. Make sure that each test lot is used with any ABBOTT EIA kit.
4. Avoid contamination of reagents and equipment.
5. Do not expose OPD reagents to strong light during storage or incubation.
6. Avoid contact of the OPD Substrate Solution and 1 N Sulfuric Acid to come in contact with any metal parts. Prior to use, rinse glassware used with OPD Substrate Solution with 1 N Sulfuric Acid to come in contact with any metal parts. Prior to use, rinse glassware used with OPD Substrate Solution with 1 N Sulfuric Acid to come in contact with any metal parts.
7. Keep away from food, drink and animal feeding
8. Wear suitable protective clothing, gloves and eyewear.

CAUTION: Do not open the bead bottle until it is at room temperature.

USE A CLEAN DISPOSABLE DISPOSERS FOR THE CONJUGATE SOLUTION TO AVOID NEUTRALIZATION.

Use the Negative Calibration and Positive Control as provided. They are available in special risk seronegative recipients. The frequency of seropositivity to CMV in random blood donor populations worldwide has been reported to range from 40 to 60%. Generally, the incidence of post-transfusion infection is related to the number of units received rather than to the condition for which transfusion is given. A growing number of studies indicate that selection of seropositive blood donors may greatly reduce CMV infection in special risk seronegative recipients. Due to the small particle size of the conjugated enzyme immunoassay, not described by Englund and Perlmutter and Van Waerebeek and Schumm (1976), are both specific and sensitive for detecting and measuring serum proteins.
INSTRUCTIONS FOR PREPARATION OF OPD SUBSTRATE SOLUTION

• Replace desiccant in bead bottle and tightly cap for storage.
• Use accurately calibrated equipment.

SPECIMEN COLLECTION AND PREPARATION

- Ensure that the specimen is added to the reaction well. If a specimen is not intact, it should not be used.
- Specimens with obvious microbial contamination should not be used.
- Do not use heat-inactivated specimens.
- If specimens are to be shipped, they should be packaged and labeled in compliance with applicable federal and international regulations covering the transport of clinical specimens and etiologic agents.
- Specimens may be shipped either ambient, refrigerated (2 to 8°C) or frozen (at -10°C or colder).
- All glassware or plastic materials coming into contact with the specimen must be free of any residue from previous specimens, reagents, or cleaning compounds.

STORAGE INSTRUCTIONS

- Store kit reagents and OPD diluent at 2 to 8°C. OPD Tablets and 1 N Sulfuric Acid may be stored at 2 to 30°C. Do not freeze kit reagents.

OPD PREPARATION CHART

<table>
<thead>
<tr>
<th>No. Tests</th>
<th>Tablets</th>
<th>Diluent</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>1</td>
<td>5 mL</td>
</tr>
<tr>
<td>43</td>
<td>3</td>
<td>15 mL</td>
</tr>
<tr>
<td>58</td>
<td>4</td>
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<td>73</td>
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<td>6</td>
<td>35 mL</td>
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<tr>
<td>103</td>
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<td>35 mL</td>
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<td>118</td>
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<td>40 mL</td>
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<tr>
<td>133</td>
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<td>45 mL</td>
</tr>
<tr>
<td>148</td>
<td>10</td>
<td>50 mL</td>
</tr>
</tbody>
</table>

NOTE: 300 µL of OPD Substrate Solution is required for each specimen or reaction well. CAUTION: Do not open OPD Tablet bottle until it is at room temperature.

PRECAUTIONS

- The OPD Substrate Solution MUST be dispensed to begin the OPD incubation step within 60 minutes of preparation and MUST NOT be exposed to strong light. Record the preparation time and expiration time of the OPD Substrate Solution.

INSTRUCTIONS FOR PREPARATION OF OPD SUBSTRATE SOLUTION

- Bring OPD Reagents and OPD Tablets to room temperature (15 to 30°C).

OPD Substrate Solution

- The OPD Substrate Solution should be colorless to pale yellow. A yellow-tinged OPD Substrate Solution is generally considered a sign of reagent instability or deterioration and must be discarded.

OPD REAGENTS

- Store kit reagents and OPD diluted at 2 to 8°C. OPD Tablets and 1 N Sulfuric Acid may be stored at 2 to 30°C. Do not freeze kit reagents.

MATERIALS PROVIDED

- 20 to 30 mL of rinse solution.
- Deionized water.
- Distilled or deionized water.
- Disinfectant as described in the Materials Provided section.

PRECAUTIONS

- Precision pipettes with disposable tips, EIA Pipetting Package (No. 7198), or similar equipment to deliver 1 mL (tolerance is ±5%), and 1 mL (tolerance is ±10%).
- Do not use heat-inactivated specimens.
- Specimens may be shipped either ambient, refrigerated (2 to 8°C) or frozen (at -10°C or colder).
- The correct ratio of anticoagulant quantity to specimen volume, as based anticoagulant may be used in the ABBOTT CMV Total AB EIA test. The correct ratio of anticoagulant to specimen volume, as recommended by the manufacturer of the anticoagulant, is required.
- Specimens containing precipitate may give inconsistent test results.
ABBOTT CMV TOTAL AB EIA TEST PROCEDURE

Preliminary Comments

Laboratories using the COMMANDER® Flexible Pipetting Center (FPC), Dynamic Incubator (D), or Parallel Processing Center (PPC) should refer to the appropriate COMMANDER® Operations Manual(s) and note special COMMANDER® instructions below. When using other automated instrumentation to deliver Negative Calibrator/Positive Control, specimen, or water bath to 38 to 42°C.

Prior to beginning the assay procedure, bring all reagents to room temperature (15 to 30°C) and mix gently. Adjust the Dynamic Incubator or water bath to 38 to 42°C.

Assay three Negative Calibrators and two Positive Controls with each run of specimens. An assay run is defined as a minimum of three Negative Calibrators, two Positive Controls, and 495 specimens on 20-well or 60-well trays. Ensure that all reaction trays containing Negative Calibrator/Positive Control and specimen are subjected to the same processing and incubation times. This may require maintenance of specific time intervals between processing trays. Once the assay has been started, complete all subsequent steps without interruption.

If more than or equal to -0.020 and less than or equal to 0.040 in order for the substrate blank relative to that of the water tube must be greater than or equal to -0.020 and less than or equal to 0.040 in order for the assay to be valid.

If the substrate blank is valid, use it to blank the instrument. Read the Negative Calibrator and Positive Control, then read the specimen. If both substrate blanks are invalid, the run must be repeated.

ASSAY PROCEDURE (See Preliminary Comments and PROCEDURAL NOTES)

Laboratories using the COMMANDER® Flexible Pipetting Center (FPC) and Parallel Processing Center (PPC) should follow procedures in the appropriate COMMANDER® Operations Manual(s). When using other automated instrumentation to deliver Negative Calibrator/Positive Control (FPC) and Assay Update Diskette Version 2.02 or higher, pipette COMMANDER® Reagent Blanking Beads only.

NOTE: Use ABBOTT COMMANDER® Reagent Blanking Beads only. Do not pipette specimen or Conjugate outside of well or high up on well rim as it may not be removed in subsequent washings and may cause test interference.

When using a Bead Dispenser, remove cap from bead bottle, attach Bead Dispenser and dispense beads into wells.

Avoid strong light during color development.

Use of a separate disposable pipette tip for each specimen and Negative Calibrator/Positive Control in order to avoid cross-contamination.

NOTE: DO NOT DISPENSE SPECIMEN DILUENT INTO TRAYS PRIOR TO PIPETTING ON THE FPC.

When using an automated pipetting device, such as a COMMANDER® Flexible Pipetting Center, verify that the correct FPC assay protocol has been selected for processing.

Station: reagent dispenser assignment:

1. Conjugate 230 µL
2. Acid 300 µL

When using the COMMANDER® Flexible Pipetting Center, verify that the correct FPC assay protocol has been selected for processing.

Station: reagent dispenser assignment:

1. Conjugate 230 µL
2. Acid 300 µL

CAUTION: Verify that dispensing equipment delivers specified sample and/or reagent volumes and does not introduce cross contamination.

When using an automated pipetting device, such as a COMMANDER® Flexible Pipetting Center, verify that the correct FPC assay protocol has been selected for processing.

Station: reagent dispenser assignment:

1. Conjugate 230 µL
2. Acid 300 µL

1. Pipette 200 µL of the Negative Calibrator or Positive Control into the appropriate reaction tray wells. 1 Negative Calibrator and 2 Positive Controls.

2. Pipette 10 µL of test specimen into the appropriate well.

3. Add 200 µL of Specimen Dilution Buff to each well containing a test specimen. Do not add dilution buffer to Negative Calibrator/Positive Control wells.

4. Gently tap trays.

5. Add one bead to each well containing a Calibration, Control or test specimen.
6. Apply cover seal; tap tray gently.
7. Incubate at 38 to 42°C for 20 to 25 minutes in a Dynamic Incubator or water bath.
8. Remove and discard cover seal. Wash each bead immediately.

**SECOND INCUBATION**

9. Add 200 µL of Conjugate to each reaction well.
10. Apply new cover seal; tap tray gently.
11. Incubate at 38 to 42°C for 28 to 32 minutes in a Dynamic Incubator or water bath.
12. Remove and discard cover seal. Wash each bead immediately.

**COLOR DEVELOPMENT**

**NOTE:** The following procedure should be used with the Quantum™ II or Quantumatic™. For PPC processing refer to the PPC Operations Manual. Laboratories using Quantum™ II should read this assay as follows: Wash 3

- Pipette 300 µL of freshly prepared OPD Substrate Solution into two empty tubes (substrate blanks) and then into each tube containing a bead.
- Incubate the bead at room temperature (15 to 30°C) for 20 to 32 minutes.
- Add 1 mL of 1 N Sulfuric Acid to each tube. Agitate to mix. **READING**

- Blank the instrument with the appropriate substrate blank at 492 nm.
- Determine absorbance of Negative Calibration/Positive Control and performance within 2 hours of addition of acid.

**ENGINEERING**

**ASSAY NAME:** CMV Total AB SCN

**SONS:** 492.600

**MP DATE:** 11/18/99

**PPC ASSAY PROTOCOL**

**ASSAY PARAMETERS**

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<th>Assay Number</th>
<th>(As assigned by Operator)</th>
<th>Assay Name</th>
<th>CMV TOTAL AB EIA SCN</th>
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<td>Min Dispensed Time 3</td>
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</table>

| Minimum Value | 0.600                      |

**Laboratories using software versions 5.00, 6.00, 6.10 or 6.11 must create an edited assay protocol. Edit PPC Assay Protocol #18 to change the negative gray zone (%) to 0.0. Laboratories using the Quantum™ II should process the ABBOTT CMV Total AB EIA using the Assay Protocol CMV TOTAL AB EIA SCN (#33) as provided in the software without editing. If the CMV TOTAL AB EIA SCN Assay Protocol is not available, contact your Abbott Representative for access to the assay protocol.**

**FLUIDITY**

**COLOR DEVELOPMENT**

- **A**
- **B**
- **C**
- **D**

**Restoration: A**

**Minimum Value:** 0.500

**Unknowns**

**Restoration:**

- **A**
- **B**
- **C**
- **D**

**Flag:**

- **A**
- **B**
- **C**
- **D**

**Laboratories using the Quantum™ II, Module A, List Number greater than 4045-97 should process the ABBOTT CMV Total AB EIA using the assay protocol as provided in the software without editing. Laboratories using the Quantum™ II, Module A, List Number 4045-96 or 97 must create an edited assay protocol. Edit mode 1.13 to change the assay name to CMV Total AB EIA SCN and the negative gray zone to 0.0. No other assay protocol parameters require edits. Verify that the edited protocol values and assay name match the protocol values below.**

**QUANTUM™ II PROTOCOL**

- **Name:** CMV Total AB SCN
- **Filters:** 492.600
- **Path Length:** +1.11
- **Negative Controls**
- **Reagent:**
- **Negative Value Option:**
- **Cutoff:**
- **Unknowns**
- **Restoration:**
- **Flag:**

- Laboratories using the Quantum™ II, Module A, List Number 4045-96 or 97 must create an edited assay protocol. Edit mode 1.13 to change the negative gray zone to 0.0.
2.	 Calculation of Negative Calibrator Mean Absorbance (NCx)

Determine the Mean of the Negative Calibrator Values.

\[
\text{NCx} = \frac{\text{Total NCx}}{\text{No. of Pos-2 Controls}}
\]

Example:

Total NCx = \[\text{Sum of all NCx values}\]
No. of Pos-2 Controls = 2

NCx = \[\frac{\text{Total NCx}}{2}\]

3.	 Calculation of Positive Control Mean Absorbance (PCx)

Determine the Mean of the Positive Control Values.

\[
\text{PCx} = \frac{\text{Total PCx}}{\text{No. of Pos-2 Controls}}
\]

Example:

Total PCx = \[\text{Sum of all PCx values}\]
No. of Pos-2 Controls = 2

PCx = \[\frac{\text{Total PCx}}{2}\]

4.	 Assay Run Validity Criteria

For the run to be valid, the difference between the mean absorbance of the Positive Control and Negative Calibrator (P-N) must be greater than or equal to 0.040. If not, the test should be repeated.

\[
\text{P-N} = \text{PCx} - \text{NCx}
\]

Example:

PCx = 1.050
NCx = 0.030

P-N = 1.050 - 0.030 = 1.020

RESULTS

When a COMMANDER® PPC, Quantum™ II or Quantumatic™ is used, all calculations below are performed automatically.

1. Calculation of the Cut-off Value

The Cut-off Value is the mean absorbance of the Negative Calibrator plus 0.075.

Example:

NCx = 0.030
Cut-off Value = NCx + 0.075
= 0.030 + 0.075 = 0.105

2. Calculation of the Unknown

Test specimens with absorbance values greater than or equal to the Cut-off Value are reactive by the ABBOTT CMV Total AB EIA and may be considered positive for antibody to CMV. Test specimens with absorbance values less than the Cut-off Value are nonreactive and may be considered negative for antibody to CMV.

LIMITATIONS OF THE PROCEDURE

• The ABBOTT CMV Total AB EIA is not intended for use in the diagnosis of CMV infection.
• The procedure and interpretation of results sections in the ABBOTT CMV Total AB EIA package insert must be followed exactly when testing human serum or plasma specimens for the presence of antibodies to CMV.
• This assay was designed and validated for use with human serum or plasma from individual patients and donor specimens. Pooled specimens must not be used as the accuracy of their test results has not been validated.
• Performance has not been established using cadaver specimens or body fluids other than human serum or plasma.
• Do not use heat-inactivated specimens.
• A test result that is nonreactive does not exclude the possibility of exposure to or infection with CMV. Nonreactive results in this assay in individuals with prior exposure to CMV may due to antibody levels below the limit of detection of this assay or lack of antibody reactivity to the CMV antigens used in this assay.
• Failure to add specimen to the procedure could result in a false nonreactive test result. Repeat testing should be considered when there is clinical suspicion of CMV infection.

EXPECTED VALUES

The incidence of antibodies to CMV in blood donors throughout the United States has been reported to be as low as 14.8% and as high as 82%. The incidence of seropositivity increases with age and is higher in lower socioeconomic groups. The performance characteristics of ABBOTT CMV Total AB EIA were evaluated in two separate studies that included specimens from a total of 8312 random blood donors. The incidence of CMV seropositivity as determined by the ABBOTT CMV Total AB EIA was 51.07% in Study 1 and 50.10% in Study 2.

SPECIFIC PERFORMANCE CHARACTERISTICS

ASSAY REPRODUCIBILITY

Assay reproducibility was determined by assaying an eight-member panel consisting of specimens from five individuals. Six panel members were matched serum and plasma specimens from each of three CMV antibody nonreactive individuals. The matched serum and plasma specimens from two of the three individuals were spiked with CMV antibody positive serum to borderline and reactive values. Two panel members were sourced from two CMV antibody positive individuals. Using these materials, multiple technicians at three sites tested the panel in replicates of three over three consecutive days. The intra- and inter assay standard deviation (SD) and percent coefficient of variation (%CV) were analyzed with a variance components analysis. Using a realistic analysis of variance-model (Table 1).

Mean S/CO is defined as the mean sample absorbance divided by the calculated Cut-off Value.
RELATIVE SPECIFICITY AND DETECTABILITY

Five blood centers evaluated a total of 2312 random blood donor specimens by ABBOTT CMV Total AB EIA and IHA in Study 1 (Table III). Thirty-three specimens were uninterpretable by IHA, 89 of the remaining 2289 specimens were concordant, 103 (4.5%) were discordant and 2173 (95.5%) were negative. Relative specificity was calculated to be 99.60% [(2995 - 12)/2995] with a 95% confidence interval of 99.35 to 99.82%.

Three blood centers evaluated a total of 6000 random blood donor specimens by ABBOTT CMV Total AB EIA and an agglutination assay in Study 2 (Table II). Of these specimens, 50.10% (3005/6000) were positive for antibody to CMV as determined with ABBOTT CMV Total AB EIA and agglutination was 95.93% [(2785/2909) with a 95% confidence interval of 93.90 to 95.97%.

Results of these specimens, 50.10% (3005/6000) were positive for antibody to CMV as determined with ABBOTT CMV Total AB EIA and agglutination was 95.93% [(2785/2909) with a 95% confidence interval of 93.90 to 95.97%.

A total of 27 CMV antibody negative sera, positive for antibodies to one or more members of the family Herpesviridae, were tested: Epstein-Barr, Herpes Simplex and Varicella-Zoster. All 27 sera were negative with the ABBOTT CMV Total AB EIA. A total of 24 CMV antibody negative sera containing rheumatoid factor were tested with the ABBOTT CMV Total AB EIA. Twenty-three of these 24 specimens were negative with the ABBOTT CMV Total AB EIA. A total of 11 serum specimens from CMV infected pediatric patients was tested and all specimens were positive for anti-CMV with the ABBOTT CMV Total AB EIA.

BIBLIOGRAPHY


