CMV IgM

Customer Support
Canada: 1-800-387-8378 (English speaking customers)
1-800-465-2675 (French speaking customers)
International: Call your Abbott Representative

This package insert must be read carefully prior to use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Note Changes Highlighted

Key to symbols used

- **REF**: List Number
- **IVD**: For In Vitro Diagnostic Use
- **S**: Store at 2-8°C
- **N**: Store at 15-30°C
- **CAUTION**: Handle human sourced materials as potentially infectious. Consult instructions for use. (Infection Risk)
- **Expiration Date**: Expiry Date
- **Legal Manufacturer**: Legal Manufacturer
- **Authorized Representative**: Authorized Representative
- **LOT**: Lot Number
- **CONTROL**: Negative Control
- **CONTROL**: Positive Control
- **REAGENT PACK**: Reagent Pack
- **REACTION VESSELS**: Reaction Vessels
- **MATRIX CELLS**: Matrix Cells
- **INDEX CAL**: Index Calibrator
- **SAMPLE CUPS**: Sample Cups

See REAGENTS section for a full explanation of symbols used in reagent component naming.
SUMMARY AND EXPLANATION OF THE TEST

Infections with cytomegalovirus (CMV), a member of the herpesvirus family, are common in humans and are usually mild and symptomless; however, infection can be serious in some groups, including newborns and immunocompromised individuals. Both seronegative individuals and infants may acquire CMV through perinatal transmission, nosocomial spread, and breast milk. In utero infection may result in severe, varying degrees of mental retardation, chronic lung disease, hearing loss, and neurologic problems. Congenitally infected infants may undergo primary clinical CMV infection with manifestations similar to those in newborns infected in utero. Congenital CMV infection may occur sporadically at any time during pregnancy; however, the risk of infection in the second trimester is the highest.

Owing to CMV’s ability to infect both lymphocytes and nonlymphocyte cells, CMV infection may also manifest in the digestive tract, respiratory tract, central nervous system, and other organs and tissues. CMV acquisition can occur through malignant fetal hematopoietic cells, birth by contact with infected maternal cells, or other means. Maternal CMV infection may be accompanied by clinical infection in the newborn (congenital CMV), although this is less common than perinatal infection. The newborn may acutely manifest primary infection with CMV, manifesting with mucous membrane involvement, or may develop slowly and persistently through infection with CMV. Women who have been infected with CMV, either during pregnancy or through transfusion, may be seronegative. Therefore, the risk of infection is dependent on the serologic status of the mother.

Owing to CMV infection’s rate of occurrence, serology is often used as a diagnostic test for CMV infection. CMV infections can be diagnosed by the detection of CMV antibodies in serum or plasma (potassium EDTA, sodium EDTA, sodium citrate, lithium heparin, or sodium heparin). The results may be used as an aid in the diagnosis of recent infection. The AxSYM CMV IgM assay is a qualitative method for the measurement of CMV-specific IgM antibodies in serum or plasma, which can be used as an aid in the diagnosis of recent infection.

The AxSYM CMV IgM assay is based on Microparticle Enzyme Immunoassay (MEIA) technology. The AxSYM Probe Cleaning Solution contains 2% Tetraethylammoniumhydroxide (TEAH). Other reagents used in the assay are Components containing Sodium Azide are classified per applicable European Community (EC) Directives as Harmful (Xn). The following are the appropriate Risk (R) and Safety (S) phrases.

R32 Harmful if swallowed.
S22 Contact with acids liberates very toxic gas.
S36 Wear suitable protective clothing.
S45 Contact with skin causes irritation and corrosion.
S55 May cause respiratory irritation. If inhaled, seek medical attention immediately.
S60 May cause death by inhalation.
S61 Avoid release to the environment. Refer to national and local regulations for transport, storage and disposal.

This product contains human sourced and/or potentially infectious materials. Some components are derived from human blood and have been tested and found to be nonreactive for HBsAg, HIV-1 Ag, and HIV-2 by licensed tests. Preservative: Sodium Azide. Contamination may be considered potentially infectious. It is recommended that these reagents and human sourced materials be handled with standard safety precautions. It is also recommended that these reagents and human sourced materials be handled with standard safety precautions. It is also recommended that these reagents and human sourced materials be handled with standard safety precautions.

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AxSYM CMV IgM Procedure

**REGENT PARTS**

- **IC79-66** Contains: AxSYM CMV IgM

**MATERIALS REQUIRED BUT NOT PROVIDED**

- AxSYM System
- **IC82-10** CMV IgM Controls
- **IC82-40** CMV IgM Index Calibrator
- **IC87-04** AxSYM CMV IgM Index Calibrator
- **IC87-01** AxSYM CMV IgM
- **IC88** SOLUTION (NEUTRALIZE, WASH, SOLUTION [SOLUTE])
- **IC84** SOLUTION (WASH)
- **IC30-65** AXSYM CMV IgM PROCEDURE SETUP SOLUTION
- **IC79-61** Pipettes or pipette tips (optional) to deliver the volumes specified on the Order screen.

**NOTE:** Please refer to the AxSYM System Operations Manual for a detailed description of instructions.

**SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS**

- A human serum (including serum collected in a sterile separator tube) or plasma collected to clot and then centrifuged (red blood cells removed) is submitted for AxSYM CMV IgM assay. The specimen must be stored at 4°C until testing. AxSYM IgM assay is not available if stored at 2-8°C or colder. Mix after thawing to ensure consistency in results and centrifugation at 10,000 × g for 30 minutes to remove clots and from hematocrit. The specimen should be stored at 4°C until testing. AxSYM IgM assay is not available if stored at 2-8°C or colder. Mix after thawing to ensure consistency in results and centrifugation at 10,000 × g for 30 minutes to remove clots and from hematocrit. The specimen should be stored at 4°C until testing.

- For optimal results, specimens should be free of fibrin, red blood cells, or other particulate matter.

- The AxSYM System does not provide the capability to verify sample type. It is the responsibility of the operator to verify the correct sample type(s) using the AxSYM CMV IgM assay.

- Specimens driven to properly indicated matrix, aka analytes, and turbidity must be classified by centrifugation at 10,000 × g for 10 minutes before testing. Elsewhere that complete information has been placed prior to centrifugation.

- Samples must be shipped frozen. Prior to shipment, specimens must be removed from the clot or red blood cells.

- When shipped, specimens must be packaged and labeled in compliance with applicable state, federal, and international regulations governing the transport of clinical specimens and infectious substances.

**SAMPLE VOLUME**

- The sample volume required to perform a single undiluted AxSYM CMV IgM test on the AxSYM System varies depending on the type of sample container used. For sample cups, a ROUTINE test requires 100 µL, and a STAT test requires 44 µL. For every additional AxSYM CMV IgM test performed (ROUTINE or STAT) from the same sample container, an additional 44 µL of sample is required.

- The sample cup minimum volumes for both ROUTINE and ROUTINE tests are calculated by the AxSYM System. They are displayed on the Order screen at the time the test(s) are entered into the AxSYM System Operations Manual. See Section 2, for a description of the Host-Order option.

- When shipped, specimens must be removed from any specimens used for auto-retest, the additional sample volume needed for the test will not be displayed on the Order screen at the time the test(s) are entered into the AxSYM System Operations Manual. See Section 2, for a description of the Host-Order option.

- To obtain the recommended volume requirements for the CMV IgM Index Calibrator and Controls, hold the bottles tightly and disperse a drop of Index Calibrator, Positive Control, or Negative Control into each respective sample cup. See the AxSYM System Operations Manual, Section 2, for sample volume requirements in primary or aliquot tubes and collection container requirements for multiple reagent packs.

**ASSAY PROCEDURE**

Sections 4 and 6 of the AxSYM System Operations Manual contain detailed steps for performing assay calibration and sample testing procedures. Prior to ordering tests, confirm that the System Inventory of Matrix Cells, bulk solutions, and waste levels are acceptable.

The AxSYM System does not provide the capability to verify sample type. It is the responsibility of the operator to verify the correct sample type(s) using the AxSYM CMV IgM assay.

- When testing is completed, it is recommended that the samples and the AxSYM CMV IgM Reagent Pack are introduced on the Sampling Center to maintain the on-board reagent pack size. Store at 2-8°C.

**SPECIMEN DILUTION PROCEDURES**

- The AxSYM CMV IgM assay is not available if stored at 2-8°C or colder. Mix after thawing to ensure consistency in results and centrifugation at 10,000 × g for 30 minutes to remove clots and from hematocrit. The specimen should be stored at 4°C until testing.

**QUALITY CONTROL PROCEDURES**

**CALIBRATION**

The AxSYM CMV IgM assay must be calibrated by testing two replicates of the CMV IgM Index Calibrator. Perform 4 tests of this index calibrator into a sample cup. A single sample of each of the CMV IgM Index Calibrator and Host-Order option are used for evaluating the assay calibration.

The AxSYM CMV IgM calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:

- A reagent pack is added to the system.

- Controls are out of their specified range.
A diagnosis of an unsuspected primary CMV infection must not be based solely upon Epstein-Barr Virus (EBV) is known to be a potent B-Cell stimulator. Infections with CMV may appear in this field, refer to the AxSYM System Operations Manual, Sections 1 and 2. Some results may contain information in the Flags field. For a description of the flags that may be used by the AxSYM System.

LIMITATIONS OF THE PROCEDURE
- Specimens with Index Values in the range of 0.400 to 0.499 are considered equivocal. Specimens with Index Values of less than or equal to 0.399 are considered negative.
- Allowable value, the result is invalid. The test request will be moved to the Exceptions List for an explanation of the corrective actions for the error code. Refer to the AxSYM System Operations Manual, Section 6, for an explanation of the calibration validity parameters.

EXPECTED VALUES
- It has been reported that CMV specific IgM antibody was not detectable in 10-30% of women experiencing primary CMV infections or reinfection as well as in neonates born to mothers with CMV infection. The results may vary in these patients.

SPECIFIC PERFORMANCE CHARACTERISTICS
- The assay was claimed to be suitable for the detection of IgM antibody in serum samples from antibody-negative donors. Sensitivity and specificity were determined using assay positive and negative controls.

DEFINITION
- The AxSYM System has the capability to generate a Levey-Jennings plot of each assay's performance. Refer to the AxSYM System Operations Manual, Section 5. At the discretion of the laboratory, selected quality control rules may be applied to the quality control performance. Refer to the AxSYM System Operations Manual, Section 10, for further troubleshooting testing information.

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The within-run and total precision were evaluated by calculating the standard deviation (SD) and percent coefficient of variation (%CV) of each control and panel member as determined with a variance component analysis for a random effects model. The %CV ranges of the reproducibility study for all control members were each tested in replicates of three.

Panel Member 1 (Serum)
Panel Member 2 (Heparin)
Panel Member 3 (Sodium Citrate)
Panel Member 4 (Heparin)
Panel Member 5 (Heparin)
Panel Member 6 (Heparin)
Panel Member 7 (Sodium Citrate)
Panel Member 8 (Sodium Citrate)
Panel Member 9 (Sodium Citrate)
Panel Member 10 (EDTA)

Representative data; results in individual laboratories may vary from these data.

### Table 1a

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Mean</th>
<th>SD (SD)</th>
<th>%CV (SD)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative Control</td>
<td>0.110</td>
<td>0.010</td>
<td>9.1</td>
<td>14.5</td>
</tr>
<tr>
<td>1</td>
<td>0.107</td>
<td>0.009</td>
<td>8.4</td>
<td>13.2</td>
</tr>
<tr>
<td>2</td>
<td>0.110</td>
<td>0.009</td>
<td>8.4</td>
<td>13.2</td>
</tr>
<tr>
<td>3</td>
<td>0.107</td>
<td>0.009</td>
<td>8.4</td>
<td>13.2</td>
</tr>
<tr>
<td>Positive Control</td>
<td>0.060</td>
<td>0.005</td>
<td>8.3</td>
<td>13.8</td>
</tr>
<tr>
<td>1</td>
<td>0.059</td>
<td>0.005</td>
<td>8.1</td>
<td>13.6</td>
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<td>2</td>
<td>0.060</td>
<td>0.005</td>
<td>8.3</td>
<td>13.8</td>
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<tr>
<td>3</td>
<td>0.059</td>
<td>0.005</td>
<td>8.1</td>
<td>13.6</td>
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</table>

### Table 1b

<table>
<thead>
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<th>Site Index</th>
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<th>%CV (SD)</th>
<th>Total</th>
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<tbody>
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<td>1</td>
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<td>0.009</td>
<td>8.4</td>
<td>13.2</td>
</tr>
<tr>
<td>4</td>
<td>0.107</td>
<td>0.009</td>
<td>8.4</td>
<td>13.2</td>
</tr>
</tbody>
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### Table 1c

<table>
<thead>
<tr>
<th>Category</th>
<th>n</th>
<th>CMV IgM Interpretation</th>
<th>Negative</th>
<th>Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen</td>
<td>1</td>
<td>AxSYM Negative</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Specimen</td>
<td>2</td>
<td>AxSYM Positive</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Specimen</td>
<td>3</td>
<td>AxSYM Equivocal</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Specimen</td>
<td>4</td>
<td>AxSYM None</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
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### Table 2

#### AxSYM CMV IgM Assay Reproducibility Ranges

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Mean</th>
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</tr>
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<td>0.005</td>
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<tr>
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<td>0.005</td>
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<tr>
<td>3</td>
<td>0.059</td>
<td>0.005</td>
<td>8.1</td>
<td>13.6</td>
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### Table 3

#### Initial Agreement: Comparison of AxSYM CMV IgM Assay vs. the Consensus Interpretation of Three EIAs

<table>
<thead>
<tr>
<th>Category</th>
<th>n</th>
<th>CMV IgM Interpretation</th>
<th>Negative</th>
<th>Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen</td>
<td>1</td>
<td>AxSYM Negative</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Specimen</td>
<td>2</td>
<td>AxSYM Positive</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Specimen</td>
<td>3</td>
<td>AxSYM Equivocal</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Specimen</td>
<td>4</td>
<td>AxSYM None</td>
<td>2</td>
<td>2</td>
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</tbody>
</table>

### Table 4

#### Immunological Results for Discordant Specimens

<table>
<thead>
<tr>
<th>Category</th>
<th>n</th>
<th>CMV IgM Interpretation</th>
<th>Negative</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Specimen</td>
<td>1</td>
<td>AxSYM Negative</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Specimen</td>
<td>2</td>
<td>AxSYM Positive</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Specimen</td>
<td>3</td>
<td>AxSYM Equivocal</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Specimen</td>
<td>4</td>
<td>AxSYM None</td>
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### Table 5

#### Comparison of AxSYM CMV IgM Assay vs. theResolved Specimen Interpretation

<table>
<thead>
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<th>Category</th>
<th>n</th>
<th>CMV IgM Interpretation</th>
<th>Negative</th>
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</tr>
</thead>
<tbody>
<tr>
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<td>1</td>
<td>AxSYM Negative</td>
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<td>1</td>
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<td>0</td>
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<td>3</td>
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<tr>
<td>Specimen</td>
<td>4</td>
<td>AxSYM None</td>
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<td>2</td>
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### Table 6

#### Resolution Testing

<table>
<thead>
<tr>
<th>Category</th>
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</tr>
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<tbody>
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<td>AxSYM Negative</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Specimen</td>
<td>2</td>
<td>AxSYM Positive</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Specimen</td>
<td>3</td>
<td>AxSYM Equivocal</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Specimen</td>
<td>4</td>
<td>AxSYM None</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>
In the series in which CMV IgG was detected.

specimen in the series in which CMV IgG was detected. In the remaining two pregnant

15 of the 17 pregnant females, the AxSYM CMV IgM assay result was positive at the first

In the remaining 20 recipients, the AxSYM CMV IgM assay result was negative. CMV infection was detected by virus isolation (culture) from

bleeds from 40 liver transplant recipients. There was no evidence of CMV infection in 11 of

was not available for resolution.

AxSYM Equivocals excluded from calculation.

Overall 1,269 41 742/761 275/280 185/187 1,202/1,228

Donors - Serum 488 12 192/193 93/96 b 185/187 c 470/476

Pregnant Females 773  27 546/563 181/183 c NT 727/746

RESOLVED RELATIVE SPECIFICITY

Overall 109 9 46/46 48/51 3/3 97/100

Donors - Serum 8 1 3/3 0/1 b 3/3 c 6/7

Pregnant Females 101 8 44/44 45/48 2/2 96/100

RESOLVED RELATIVE SPECIFICITY

Overall 702 9 343/346 339/341 14/15 308/322

Donors - Serum 284 3 143/145 142/147 1/1 241/245

Pregnant Females 418 6 200/201 197/194 13/15 747/777

NT = Not Tested

Table 6

BIBLIOGRAPHY


