POINTE SCIENTIFIC
A MedTest Company

CMV IgM

IVD

REF **T8006-96** 96-Test Set

For in Vitro Diagnostic Use Only

Intended Use: For the qualitative detection of human IgM antibodies to cytomegalovirus (CMV) in human serum by enzyme immunoassay, to aid in the diagnosis of CMV infection. A positive result is presumptive for the detection of anti-CMV IgM antibodies and presumptive for the diagnosis of acute or recent CMV infection. These reagents have not received FDA clearance for use in testing blood or plasma donors.

Summary of Test

1. **Prepare 1:26 dilutions of Calibrator(s), Controls and samples in the test set Diluent. Mix well.**
2. **Place 100 µl of the dilutions in the Coated Wells; reserve one well for the reagent blank.**
3. **Incubate at room temperature for 30 ± 5 minutes.**
4. **Drain wells thoroughly. Wash wells 4 times with Wash Solution and drain.**
5. **Place 2 drops (or 100 µl) of Conjugate in wells.**
6. **Incubate at room temperature for 30 ± 5 minutes.**
7. **Drain wells thoroughly. Wash wells 4 times with Wash Solution and drain.**
8. **Place 2 drops (or 100 µl) of Substrate in wells.**
9. **Incubate at room temperature for 30 ± 5 minutes.**
10. **Stop the enzyme reaction with 2 drops (or 100 µl) of Stop Reagent.**
11. **Read absorbance at 405 nm against reagent blank.**

Summary and Explanation of Test

Cytomegalovirus (CMV) has been identified as a major causative agent of congenital abnormalities, including mental retardation and deafness in infants infected *in utero* (1, 2, 3). Subclinical infection may occur in adults as well as overt disease including hepatitis, pneumonitis, and cytomegalovirus induced mononucleosis (4). CMV infection can be transmitted to immunodeficient or immunosuppressed individuals, as a result of blood transfusion (5) or organ transplantation (6). In summary, pregnant women, neonates and immunocompromised individuals are at risk of developing clinically significant disease caused by CMV infection.

The diagnosis of CMV infection is frequently assisted by serological methods. The demonstration of CMV IgM antibodies is indicative of recent or current infection or, in the case of newborns, of congenital infection.

The CMV IgM EIA test is intended for the detection of IgM antibodies to CMV. Test results are obtained after one and one-half hours incubation time. They are objective and normalized as Index values, permitting uniformity of reporting.

Because enzyme immunoassays for IgM antibodies are performed with unfractionated serum, there are two potential sources of error. These include possible competition by CMV-specific IgG, leading to false negative results; and rheumatoid factor in the presence of CMV-specific IgG, leading to false positive results. The CMV IgM EIA test has been designed to minimize the likelihood of errors due to these causes.

Principle of the Test

Diluted samples are incubated in antigen-coated wells. *Absorbents have been included in the Diluent to neutralize the affects of rheumatoid factor and anti-CMV IgG antibody.* CMV antibodies (if present) are immobilized in the wells. Residual sample is eliminated by washing and draining, and conjugate (enzyme-labeled antibodies to human IgM) is added and incubated. If IgM antibodies to CMV are present, the conjugate will be immobilized in the wells. Residual conjugate is eliminated by washing and draining, and the enzyme-labeled substrate is added and incubated. In the presence of the enzyme, the substrate is converted to a yellow end product which is read photometrically.

Reagents

Coated Wells	Coated with CMV antigen, Strain: AD 169, partially purified from nuclear extracts of MRC-5 cells. 12 eight-well strips.
Well Support	One.
Diluent*	25 mL (pink color). Phosphate-buffered saline with a protein stabilizer, and absorbents for rheumatoid factor and human IgG.
Calibrator 1*	0.3 mL. Human serum. Strongly reactive for CMV IgM antibodies. Index value shown on vial label.
Calibrator 2*	0.3 mL. Human serum. Moderately reactive for CMV IgM antibodies. Index value shown on vial label.
Positive Control*	0.3 mL. Human serum. Reactive for CMV IgM antibodies. Index values shown on vial label.
Negative Control*	0.3 mL. Human serum. Non-reactive for CMV IgM antibodies.
Conjugate	12 mL (green color). Goat anti-human IgM labeled with alkaline phosphatase (calf)
Substrate	12 mL. p-nitrophenyl phosphate

Note: The substrate may develop a slight yellow color during storage. One hundred microliters of substrate should yield an absorbance value less than 0.35, when read in a microwell against air or water.

Wash Concentrate* 30 mL. Tris-buffered saline with Tween 20, pH 8.0. Prepare Wash Solution by adding the contents of the Wash Concentrate bottle to 1 liter of distilled or deionized water.

Stop Reagent 12 mL. Trisodium Phosphate 0.5 M.

*Contains 0.1% sodium azide.

Store these reagents according to the instructions on the bottle labels. Do not allow them to contact the skin or eyes. If contact occurs, wash with copious amounts of water.

Other Materials Required

1. Microplate washer
2. Pipettors for dispensing 8, 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. Dual or single wavelength readers may be used. Data on file.

Precautions

1. For in vitro diagnostic use.
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 FDA 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.
3. The concentrations of anti-CMV IgM in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity.
4. Avoid contact with open skin.
5. Never pipet by mouth.

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.

Xn HARMFUL

0.1% NaN_3

R 21/22: Harmful in contact with skin and if swallowed.

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 MSDS.

7. Do not interchange reagents from different reagent lots, except for Wash Concentrate, Substrate and Stop Reagent.
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 dessicant, and stored in the refrigerator.

Specimen Collection

Sera should be separated from clotted blood. 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. Multiple freeze-thaw cycles should be avoided. Samples containing visible particulate matter should be clarified by centrifugation; and hemolyzed, icteric or grossly contaminated samples should not be used. Samples should not be heat-inactivated before testing.

Test Procedure

Allow all reagents and patient samples to reach room temperature before use. Return them promptly to refrigerator after use. The test procedure follows:

1. Prepare 1:26 dilutions of test samples, Calibrator(s), Positive and Negative Controls, in the test set Diluent. For example: add 8 µl of sample to 200 µl of Diluent in a dilution well or tube, and mix well.

Note: A single Calibrator (Calibrator 2) may be used; or Calibrator 1 and Calibrator 2 may be used to prepare a calibration curve.

2. Place an appropriate number of Coated Wells in the Well Support.

Note: For combination testing (multiple assays per plate), the strips should be assembled on a white background with good lighting. Be sure to note the placement of each strip and the corresponding color.

3. 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 be ultimately used to zero the photometer before reading the test results, or it may be used as the zero point in a calibration curve.

4. Incubate the wells at room temperature (20 to 25° C) for 30 ± 5 minutes.
5. 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.
6. Place 2 drops (or 100 µl) of Conjugate into each well.
7. Incubate the wells at room temperature for 30 ± 5 minutes.
8. 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.
9. Place 2 drops (or 100 µl) of Substrate into each well.
10. Incubate at room temperature for 30 ± 5 minutes.
11. Place 2 drops (or 100 µl) of Stop Reagent into each well.
12. 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.

Calculation of Results

Test results may be calculated using a single calibrator (Calibrator 2), or using a calibration curve.

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.

Quality Control

1. The Calibrator(s), Positive and Negative Controls must be included in each test run.
2. The absorbance value of Calibrator 1 must be at least 0.4 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 equal to, or greater than 1.1, when using a single Calibrator (Calibrator 2). When using the calibration curve, the Positive control must have an Index value within the range printed on the label. Users may supply an alternative Positive Control if they wish.
6. The Negative and Positive Controls are intended to monitor for substantial reagent failure. The Positive Control will not ensure precision at the assay cutoff. Additional controls may be tested according to guidelines or requirements of local, state and/or federal regulations or accrediting organizations. For guidance on appropriate quality control practices, please refer to NCCLS document C24-A, *Internal Quality Control Testing: Principles and Definitions.*

Interpretation of Results

Index Value	Interpretation
< 0.9	Negative for anti-CMV IgM antibody
≥ 1.1	Positive for anti-CMV IgM antibody
≥ 0.9 < 1.1	Equivocal*

*Index values which fall between 0.9 and 1.1 indicate an equivocal result. Subsequent samples should be drawn at least fourteen days later and tested simultaneously with the initial sample. If the subsequent sample is positive, seroconversion has occurred, which may be indicative of recent infection. If the subsequent sample remains equivocal, antibody status is undetermined and the sample is deemed equivocal. Other clinical and serological evidence should be sought in these cases.

The presence of IgM antibody to CMV suggests recent or current infection.

The CMV IgM EIA cut-off values were based on statistical analyses, i.e. mean + 3 standard deviations (8), of 78 normal serum specimens. They were challenged in tests of positive and negative specimens (see Performance Characteristics).

Specimens which yield absorbance values above the range of the test set calibrator(s), 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.

Values obtained with different manufacturer's assay methods may not be used interchangeably. The magnitude of the reported IgM level cannot be correlated to an endpoint titer. The magnitude of the assay result above the cut-off is not an indicator of the total antibody present.

Specimens collected too early during the course of the disease may not contain anti-CMV IgM antibody. Furthermore, some individuals may not produce a detectable IgM response to CMV infection.

Limitations

CMV IgM test results are intended as an aid to the diagnosis of active or recent infection, and should not be considered diagnostic by themselves. They should be interpreted in conjunction with other clinical findings and diagnostic procedures.

This assay is not intended for viral isolation and/or identification.

The presence of IgM antibodies to CMV is considered to be presumptive evidence of primary infection; however, specific IgM has been reported in reactivation of latent infection and in reinfection. CMV IgM may remain detectable for as long as nine months in immunocompetent individuals, and for up to two years in immunosuppressed individuals.

Up to thirty percent of patients with heterophil antibody positive mononucleosis, have been reported to have heterotypic CMV IgM responses. This may be due to polyclonal stimulation of B lymphocytes by Epstein-Barr virus. It has been reported that varicella zoster virus may also cause heterotypic CMV IgM responses.

Rheumatoid factor in the presence of specific IgG may contribute to false positive results. The absorbent in the CMV IgM EIA Diluent is intended to neutralize the effects of rheumatoid factor. Studies have indicated that the absorbent was able to neutralize up to ninety-eight percent of the activity in a sample known to contain 3,328 IU/mL of rheumatoid factor activity.

The presence or absence of CMV IgG or IgM in pregnant women is of limited value in predicting congenital infection. The presence of CMV IgM in the circulation of newborns however, is indicative of congenital infection. Samples obtained early in the course of infection may not demonstrate IgM antibody. Therefore, it may be necessary to test another sample obtained seven to fourteen days later. When collecting cord blood, care should be taken to avoid contamination with maternal blood. It is advisable to confirm positive results in newborns with a follow-up test.

The assays performance characteristics have not been established for testing newborn specimens, or cord blood, or matrices other than human serum.

The assays performance characteristics were not established for visual result determination.

The IgM response to CMV infection may vary according to the individual. It has been reported that ten to thirty percent of infants infected congenitally, may fail to develop CMV IgM antibody responses. In addition, up to twenty-seven percent of adults with primary CMV infection may not demonstrate an IgM response. Therefore, the absence of demonstrable CMV specific IgM, does not necessarily rule out the possibility of active or recent CMV infection.

It has been suggested that samples containing high levels of CMV specific IgG, and low levels of CMV specific IgM, may yield false negative results. These conditions may exist in the sera of congenitally infected newborns due to the presence of maternal IgG.

The performance characteristics of the CMV IgM test with automated analyzers have not been established.

Expected Values

Studies performed with specimens obtained in the U.S., and in the United Kingdom, using the CMV IgM EIA test, revealed the following: The incidence of anti-CMV IgM antibody among normal, asymptomatic donors was 2 of 86, or 2.3 %. Among patients whose sera were submitted to clinical laboratories for diagnostic testing, the incidence was 45 of 78, or 57.7 %. These results are tabulated below in Tables 1 and 2.

Table 1.

a. Results of CMV IgM EIA Tests of 45 Archival Specimens (frozen), from Normal Asymptomatic South Florida Blood Donors. The Assays were Performed at Laboratory C, Miami, FL.

Index Value Ranges	Specimens	
< 1.1	43	95.6 %
≥ 1.1 to < 2.2	2	4.4 %
≥ 2.2 to < 4.4	0	0 %
≥ 4.4	0	0 %

b. Results of CMV IgM EIA Tests of 41 Archival Specimens (frozen), from Normal Asymptomatic Donors Obtained at Oxford, England. The Assays were Performed at Lab B, Oxford, England.

Index Value Ranges	Specimens	
< 1.1	41	100 %
≥ 1.1 to < 2.2	0	0%
≥ 2.2 to < 4.4	0	0 %
≥ 4.4	0	0 %

Table 2.

a. Results of CMV IgM EIA Tests of 16 Archival Specimens (frozen), from Patients Whose Sera were Submitted to a Clinical Laboratory in Tucker, GA, for Diagnostic Testing. The Assays were Performed at Lab C, Miami, FL.

Index Value Ranges	Specimens	
< 1.1	5	31.2 %
≥ 1.1 to < 2.2	2	12.5 %
≥ 2.2 to < 4.4	6	37.5 %
≥ 4.4	3	18.8 %

b. Results of CMV IgM EIA Tests of 32 Archival Specimens (frozen), from Patients Whose Sera were Submitted to a Clinical Laboratory in Oxford, England, for Diagnostic Testing. At Least 14 of the Patients were Females of Childbearing Age. The Assays were Performed at Lab C, Miami, FL.

Index Value Ranges	Specimens	
< 1.1	23 {9}	71.9 %
≥ 1.1 to < 2.2	6 {3}	18.8 %
≥ 2.2 to < 4.4	1 {1}	3.1 %
≥ 4.4	2 {1}	6.2 %

{ } Females of childbearing age.

c. Results of CMV IgM EIA Tests of 30 Archival Specimens (frozen), from Patients Whose Sera were Submitted to a Clinical Laboratory in Oxford, England, for Diagnostic Testing. At Least 10 of the Patients were Females of Childbearing Age. The Assays were Performed at a Public Health Laboratory (Lab B), Oxford, England.

Index Value Ranges	Specimens	
< 1.1	5 {3}	16.7 %
≥ 1.1 to < 2.2	7 {1}	23.3 %
≥ 2.2 to < 4.4	18 {6}	60.0 %
≥ 4.4	0	0 %

{ } Females of childbearing age.

Performance Characteristics

Comparative Testing

The results of CMV IgM EIA tests correlate well with other commercial serological tests. Serum specimens obtained from: asymptomatic normal donors, and patients whose sera were submitted to clinical laboratories for CMV IgM screening, or diagnostic testing, were assayed by the CMV IgM EIA test and another commercial serological assay. The assays were performed at two independent laboratories (Lab A, Miami, FL and Lab B, Oxford, England), and at Laboratory C, Miami, FL. The results obtained in these studies are shown below in Tables 3, 4 and 5, respectively.

Table 3. Results of Tests of 60 Archival Patient Specimens Tested at Laboratory A Miami, FL, Using the CMV IgM EIA Test and Another Commercial Test.

Comparative	CMV IgM EIA					
Test #2	Positive	Negative	Equivocal		%	95%CI**
Positive	19{3}	2	2{1}	Relative sensitivity*	90.5	77.9 to 100
Negative	1	35{10}	1	Relative specificity*	97.2	91.9 to 100
* Excluding equivocal results				Overall Agreement*	94.7	88.9 to 100

** Calculated by the Normal Method (7).

{ } Females of childbearing Age.

Table 4. Results of Tests of 71 Archival Patient Specimens Tested at a Public Health Laboratory, Oxford, England (Laboratory B), Using the CMV IgM EIA Test and Another Commercial Test.

Comparative	CMV IgM EIA					
Test #1	Positive	Negative	Equivocal		%	95%CI**
Positive	25{7}	0	2{1}	Relative sensitivity*	100	88.8 to 100
Negative	0	44{2}	0	Relative specificity*	100	93.5 to 100
* Excluding equivocal results				Overall Agreement*	100	95.8 to 100

** Calculated by the Normal Method (7).

{ } Females of childbearing age.

Table 5. Results of Tests of 121 Archival Patient Specimens Tested at Laboratory C, Miami, FL, Using the CMV IgM EIA Test and Another Commercial Test.

Comparative Test #1	CMV IgM EIA Positive	Negative	Equivocal		%	95%CI**
Positive	38{5}	1{1}	4{1}	Relative sensitivity*	97.4	92.5 to 100
Negative	0	78{7}	0	Relative specificity*	100	98.7 to 100
				Overall Agreement*	99.1	97.5 to 100

* Excluding equivocal results

** Calculated by the Normal Method (7).

{ } Females of childbearing age.

Please be advised that "relative" sensitivity and specificity refers to the comparison of this assay's results to that of a similar assay. No judgement can be made on the comparison assay's accuracy to predict disease.

Cross-reactivity Study

Of fifty-three specimens which were unreactive in the CMV IgM EIA test, 5 were shown to contain moderate to high levels of IgM antibody directed against rubella virus, 5 against varicella zoster virus, 8 against Epstein-Barr virus (VCA), 16 against herpes simplex virus, 5 against toxoplasma, 10 against type A influenza virus, 10 against measles, and 10 against parvovirus.

IgM Specificity Study

Seven serum specimens which contained CMV-specific IgM and CMV-specific IgG, were assayed by the CMV IgM EIA and CMV IgG tests, before and after treatment with 2-mercaptoethanol. This treatment denatures IgM but does not affect IgG antibodies. The results of this experiment are shown in Table 6, below.

Table 6. Results Obtained for CMV IgM EIA and CMV IgG EIA Assays of Seven Serum Specimens Containing CMV-specific IgG and IgM, Before and After Treatment with 2-mercaptoethanol.

Sample	CMV IgG (Index)		CMV IgM (Index)	
	Before	After	Before	After
1	4.9	4.4	1.1	0.1
2	7.8	7.1	1.6	0.1
3	11.0	9.8	1.5	0.1
4	9.8	10.4	4.1	0.2
5	5.3	4.6	1.7	0.1
6	4.6	5.0	1.9	0.1
7	2.1	1.9	2.4	0.0

After treatment with 2-mercaptoethanol, the CMV IgM antibodies in all seven specimens were neutralized, while the CMV IgG antibodies were not significantly affected. These results demonstrate that the CMV IgM EIA test is specific for detecting CMV IgM antibodies.

Precision

Eight serum specimens (2 negative and 6 positive) and the CMV IgM 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 Lab C. These results are shown below in Tables 7, 8 and 9 respectively.

Table 7. Results Intra-assay and Interassay Precision Tests Performed at Lab A. Values were calculated from CMV IgM EIA Index Values.

SAMPLE	INTRA-ASSAY MEAN INDEX	S.D	C.V. %	INTERASSAY MEAN INDEX	S.D	C.V. %
Pos. Control	1.6	0.138	8.7	1.8	0.150	8.5
Neg. Control	0.0	0.000	NA	0.0	0.008	NA
1	0.0	0.015	NA	0.0	0.026	NA
2	0.0	0.000	NA	0.0	0.001	NA
3	2.0	0.043	2.2	2.1	0.141	6.6
4	1.6	0.085	5.4	1.8	0.194	10.9
5	1.3	0.098	7.5	1.5	0.187	12.4
6	1.2	0.071	5.8	1.4	0.172	12.1
7	1.6	0.196	12.2	1.8	0.211	11.6
8	1.1	0.138	12.2	1.4	0.212	15.5

Table 8. Results Intra-assay and Interassay Precision Tests Performed at Lab B. Values were calculated from CMV IgM EIA Index Values.

SAMPLE	INTRA-ASSAY MEAN INDEX	S.D	C.V. %	INTERASSAY MEAN INDEX	S.D	C.V. %
Pos. Control	1.7	NA	NA	1.9	0.138	7.4
Neg. Control	0.0	NA	NA	0.0	0.004	NA
1	0.0	0.018	NA	0.1	0.021	NA
2	0.0	0.000	NA	0.0	0.039	NA
3	2.0	0.158	7.9	2.3	0.253	10.9
4	1.7	0.113	6.5	2.0	0.259	12.9
5	1.1	0.132	11.7	1.4	0.231	17.0
6	1.2	0.093	7.7	1.3	0.147	11.1
7	1.5	0.111	7.2	1.7	0.202	11.6
8	1.0	0.085	8.2	1.3	0.196	15.3

Table 9. Results Intra-assay and Interassay Precision Tests Performed at Lab C. Values were calculated from CMV IgM EIA Index Values.

SAMPLE	INTRA-ASSAY MEAN INDEX	S.D	C.V. %	INTERASSAY MEAN INDEX	S.D	C.V. %
Pos. Control	1.7	0.058	3.5	1.7	0.101	5.8
Neg. Control	0.0	0.058	NA	0.0	0.033	NA
1	0.1	0.000	NA	0.1	0.000	NA
2	0.0	0.000	NA	0.0	0.000	NA
3	2.0	0.153	7.5	2.1	0.109	5.1
4	1.7	0.058	3.3	1.9	0.001	5.5
5	1.5	0.058	3.9	1.6	0.088	5.7
6	1.5	0.058	3.8	1.7	0.113	6.8
7	1.7	0.115	6.7	1.9	0.141	7.6
8	1.5	0.058	3.9	1.6	0.101	6.5

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Temperature Limitations

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