



DIAGNOSTIC AUTOMATION, INC.

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IVD



See external label



2°C-8°C



Σ=96 tests

REF

Cat # 1202Z

Cytomegalovirus CMV IgM

Cat # 1202Z

Test	CMV IgM ELISA
Method	ELISA: Enzyme Linked Immunosorbent Assay
Principle	ELISA - Indirect; Antigen Coated Plate
Detection Range	Qualitative Positive; Negative control & Cut off
Sample	5ul Serum
Specificity	97%
Sensitivity	98 %
Total Time	~90 min
Shelf Life	12 -18 Months

** Laboratory results can never be the only base of a medical report. The patient history and further tests have to be taken into account*

NAME AND INTENDED USE

The DIAGNOSTIC AUTOMATION ELISA, CMV IgM is intended for use in the detection of IgM antibodies to Cytomegalovirus (CMV) infection.

SUMMARY AND EXPLANATION OF THE TEST

Cytomegalovirus is a herpes virus and a leading biological factor causing congenital abnormalities and complications among those who receive massive blood transfusions and immunosuppressive therapy. About half of pregnant women who contract a primary infection spread the disease to their fetus. When acquired in-utero, the infection may cause mental retardation, blindness, and/or deafness.

Serological tests for detecting the presence of antibody to CMV can provide valuable information regarding the history of previous infection, diagnosis of active or recent infection, as well as in screening blood for transfusions in newborns and immuno-compromised recipients. DIAGNOSTIC AUTOMATION ELISA CMV IgM is an accurate serologic method to detect CMV IgM antibody for identification of CMV infection.

PRINCIPLE OF THE TEST

Purified CMV antigen is coated on the surface of microwells. Diluted patient serum is added to wells, and the CMV IgM specific antibody, if present, binds to the antigen. All unbound materials are washed away. After adding enzyme conjugate, it binds to the antibody-antigen complex. Excess enzyme conjugate is washed off and TMB Chromogenic Substrate is added. The enzyme conjugate catalytic reaction is stopped at a specific time. The intensity of the color generated is proportional to the amount of IgM specific antibody in the sample. The results are read by a microwell reader compared in a parallel manner with calibrator and controls.

MATERIALS PROVIDED

1. Microwell Strips: purified CMV antigen coated wells	(12X8 wells)
2. Absorbent Solution: Black Cap	1 vial (22 mL)
3. Calibrator: Factor value (f) stated on label. Red Cap	1 vial (150µL)
4. Negative control. Range Stated on label. Natural Cap	1 vial (150µL)
5. Positive control. Range stated on label. Green Cap	1 vial (150µL)
6. Washing Concentrate 10X: White Cap	1 Bottle (100 mL)
7. Enzyme Conjugate: Red color solution	1 vial (12 mL)
8. TMB Chromogenic Substrate: Amber bottle	1 vial (12mL)
9. Stop Solution	1 vial (12 mL)

STORAGE AND STABILITY

1. Store the kit at 2 - 8 ° C.
2. Always keep micro wells tightly sealed in pouch with desiccants. We recommend you use up all wells within 4 weeks after initial opening of the pouch.
3. The reagents are stable until expiration of the kit.
4. Do not expose test reagents to heat, sun or strong light during storage or usage.

WARNINGS AND PRECAUTIONS

1. Potential biohazardous materials: The calibrator and controls contain human source components which have been tested and found non-reactive for hepatitis B surface antigen as well as HIV antibody with FDA licensed reagents. However, as there is no test method that can offer complete assurance that HIV, Hepatitis B virus or other infectious agents are absent, these reagents should be handled at the

Biosafety Level 2, as recommended in the Centers for Disease Control/National Institutes of Health manual, "Biosafety in Microbiological and Biomedical Laboratories." 1984.

2. Do not pipette by mouth. Do not smoke, eat, or drink in the areas in which specimens or kit reagents are handled.
3. The components in this kit are intended for use as a integral unit. The components of different lots should not be mixed.
4. This product contains components preserved with sodium azide. Sodium azide may react with lead and copper plumbing to form explosive metal azide. On disposal, flush with a large volume of water.

SPECIMEN COLLECTION AND HANDLING

1. Collect blood specimens and separate the serum.
2. Specimens may be refrigerated at 2 - 8 ° C for up to seven days or frozen for up to six months. Avoid repetitive freezing and thawing of serum sample.

PREPARATION FOR ASSAY

1. Prepare 1x washing buffer. Prepare washing buffer by adding distilled or deionized water to 10 x wash concentrate to a final volume of 1 liter.
2. Bring all specimens and kit reagents to room temperature (20-25 °C) and gently mix.

ASSAY PROCEDURE

1. Place the desired number of coated strips into the holder.
2. Prepare 1:40 dilutions by adding 5 µl of the test samples, negative control, positive control, and calibrator to 200 µl of absorbent solution. Mix well.
3. Dispense 100 µl of diluted sera, calibrator, and controls into the appropriate wells. For the reagent blank, dispense 100 µl absorbent solutions in 1A well position. Tap the holder to remove air bubbles from the liquid and mix well. Incubate for 30 minutes at room temperature.
4. Remove liquid from all wells. Repeat washing three times with washing buffer.
5. Dispense 100 µl of enzyme conjugate to each well and incubate for 30 minutes at room temperature.
6. Remove enzyme conjugate from all wells. Repeat washing three times with washing buffer.
7. Dispense 100 µl of TMB Chromogenic Substrate to each well and incubate for 30 minutes at room temperature.
8. Add 100 µl of 2 N HCl to stop reaction. Make sure there are no air bubbles in each well before reading
9. Read O.D. at 450 nm with a Microwell reader.

CALCULATION OF RESULTS

1. To obtain cut off OD value: Multiply the OD of Calibrator by Factor (f) printed on label of calibrator.
2. Calculate the CMV IgM Index of each determination by dividing the OD value of each sample by obtained OD value of cut off.

For example:

If the factor (f) value on label = 0.4

Obtained Calibrator O.D. = 1.100

Cut-off O.D. = 1.100 X 0.4 = 0.44

Patient sample O.D. = 0.580

CMV IgM Index = 0.580 / 0.44 = 1.32 (Positive Result)

Patient sample O.D = 0.320

CMV IgM Index = 0.320 / 0.44 = 0.73 (Negative Result)

QUALITY CONTROL

The test run may be considered valid provided the following criteria are met:

1. The O.D. value of the reagent blank against air from a microwell reader should be less than 0.250.
2. If the O.D. value of the Calibrator is lower than 0.250, the test is not valid and must be repeated.
3. The CMV M Index for Negative and Positive Control should be in the range stated on the labels.

INTERPRETATION

Negative: CMV M Index of less than 0.90 are negative for IgM antibody to CMV.

Equivocal: CMV M Index between 0.91 - 0.99 is equivocal. Sample should be retested.

Positive: CMV M Index of 1.0 or greater are positive for IgM antibody to CMV.

PERFORMANCE CHARACTERISTICS

Precision:

The precision of the assay was evaluated by testing three different sera of eight replicates over 3 days. The intra-assay and inter-assay C.V. are summarized below:

	Negative	Low positive	Positive
Intra-assay	7.8%	6.0%	5.8%
Inter-assay	8.9%	7.4%	6.2%

LIMITATIONS OF THE TEST

1. To prevent false negative and false positive IgM test results caused by the presence of specific IgG and rheumatoid factor (RF) in some specimens, reagents provided in this kit has been formulated to resolve these interferences. However, specimens with extremely high RF and high autoimmune antibodies, the possibility of these interferences cannot be ruled out entirely.
2. As with other serological tests, the results obtained with the CMV IgM ELISA serve only as an aid to diagnosis and should be interpreted in relation to other clinical and diagnostic findings.
3. IgM responses may vary in different individuals. It has been reported that 10-30 % of infants may fail to develop IgM antibody responses despite congenital CMV infection. Furthermore, up to 27 % of adults with primary CMV infection may not demonstrate an IgM response. Thus, the absence of CMV-specific IgM does not necessarily exclude the possibility of CMV infection.
4. The presence or absence of CMV IgG or IgM in pregnant women is of limited value in predicting congenital CMV infection. However, the presence of specific IgM in the circulation of the newborn is indicative of infection. Since serum samples obtained too early in infection may not contain detectable IgM antibody, a subsequent sample should be obtained 7 to 14 days later and test. In the case of cord blood, care should be taken to avoid contamination by maternal blood, and it is prudent to confirm positive IgM antibody results by testing a follow-up specimen from the newborn.

REFERENCES

1. Voller, A., J.E. Bidwell, et al. Manual of clinical immunology. Chapter 69. Rose, N. and Friedman, H. eds. Am. Soc. Microbiol. p.506, 1985.

2. Cremer, N.E. Antibodies in serodiagnosis of viral infection. p. 73. In Lennett E.H. ed. Laboratory diagnosis of viral infection. MerceL Dekker, Inc., New York, 1985.
3. Starr, S.E. and H.M. Friedman. "Human CMV." Chapter 65. In Manual of Clin. Microbiol., 4th ed., Lennett, E.H. et al ed. Am. Soc. Microbiol. pp. 771-719, 1985.

Date Adopted	Reference No.
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