AccuDiag™ Cytomegalovirus (CMV) IgA ELISA Kit

REF 1200-P1

IVD See External Label 2-8°C 96 Tests

Cytomegalovirus (CMV) IgA ELISA	
Principle	Indirect ELISA
Detection	Qualitative
Sample	5 µL serum/plasma
Incubation Time	75 minutes
Shelf Life	12 Months from the manufacturing date

PRODUCT FEATURES

- Very easy to use with little training
- Highly specific and consistent Assay
- Provides accurate results quickly
- Reading of results both visually and as absorbance data

INTENDED USE

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

SIGNIFICANCE AND SUMMARY

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. The antibodies present to Cytomegalovirus may be of the IgA, IgM and IgG. The physiological function of IgA and its clinical implication is still unclear. DIAGNOSTIC AUTOMATION ELISA CMV IgA is an accurate serologic method to detect CMV IgA antibody for identification of CMV infection.

ASSAY PRINCIPLE

Purified CMV antigen is coated on the surface of microwells. Diluted patient serum is added to wells, and the CMV IgA 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 IgA specific antibody in the sample. The results are read by a microwell reader compared in a parallel manner with calibrator and controls.

SPECIMEN COLLECTION AND PREPARATION

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.

REAGENTS

Materials provided with the kit

1. Microwell strips: Chlamydia Trachomatis antigen coated wells (12x8 wells)	
2. Sample Diluent: Blue color solution.	1 vial (22 ml)
3. Calibrator: Factor value (f) stated on label. Red Cap.	1 vial (150 µl)
4. Negative Control: Range stated on label. Natural Cap.	1 vial (150 µl)
5. Positive Control: Range stated on label. Brown Cap.	1 vial (150 µl)
6. Washing Concentrate 20x.	1 bottle (50 ml)
7. Enzyme Conjugate: Red color solution.	1 vial (12 ml)
8. TMB Chromogenic Substrate: Amber bottle.	1 vial (12 ml)
9. Stop Solution.	1 vial (12 ml)

REAGENT PREPARATION

1. Prepare 1x washing buffer. Prepare washing buffer by adding distilled or deionized water to 20 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 sample diluent. Mix well.
3. Dispense 100 µl of diluted sera, calibrator, and controls into the appropriate wells. For the reagent blank, dispense 100 µl sample diluent 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 15 minutes at room temperature.
8. Add 100 µl of Stop Solution to stop the reaction.
   Make sure there are no air bubbles in each well before reading
9. Read O.D. at 450 nm with a microwell reader.

RESULTS

1. To obtain the cut-off OD value: Multiply the OD of the calibrator by factor (f) printed on the label of the calibrator
2. Calculate the IgA index of each determination by dividing the OD values of each sample by the obtained OD value of cut-off.

For Example:
If Factor (f) is a variable value on label = 0.4.
This factor (f) is a variable value. It could be 0.35 or 0.5 etc. printed on label of the calibrator.

Obtained calibrator O.D. =1.100
Cut off O.D. = 1.100 X 0.4 = 0.44

Patient Sample O.D. = 0.580
IgA index = 0.580 / 0.44 = 1.32 (Positive Result)

Patient sample O.D. = 0.320
IgA Index = 0.320 / 0.44 = 0.73 (Negative Result)

INTERPRETATION

Negative
CMV A Index of less than 0.90 are negative for IgA antibody to CMV.

Equivocal
CMV A Index between 0.91 - 0.99 is equivocal. The sample should be retested.

Positive
CMV A Index of 1.0 or greater are positive for IgA antibody to CMV.

QUALITY CONTROL

The test run may be considered valid provided the following criteria are met:
1. If the O.D. value of the Calibrator is lower than 0.250, the test is not valid and must be repeated.
2. The CMV A Index for Negative and Positive Control should be in the range stated on the labels.

EXPECTED RANGES OF VALUES

Forty-nine serum specimens obtained from random, asymptomatic blood donors were tested with the DIAGNOSTIC AUTOMATION ELISA CMV IgA test. Of the 49 specimens, 12 were found to be positive (24.5 %) and 37 were found to be negative (75.5 %). Of these 12 IgA positive samples were found to be IgG positive also. Prevalence may vary depending on a variety of factors such as geographical location, age, socioeconomic status, race, type of test employed, specimen collection and handling procedures, clinical and epidemiological history.

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	**8.2%**	**7.4%**	**6.3%**
Inter-assay	**11.2%**	**8.5%**	**6.7%**

LIMITATIONS OF THE ASSAY

1. The test results should be used in conjunction with information available from the patient clinical evaluation and other available diagnostic procedures.
2. The results of specimens from immunosuppressed patients may be difficult to interpret.
3. Positive test results may not be valid in persons who have received blood transfusions or other blood products within the past several months.

STORAGE CONDITIONS

1. Store the kit at 2 - 8°C.
2. Always keep microwells 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.

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.

REFERENCES

1. Voler, 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.

MANUFACTURER AND BRAND DETAILS

ISO 13485:2016

bsi ISO 13485 Quality Management for Medical Devices CERTIFIED

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