

ELISA Kit for Antibody IgM to Cytomegalovirus (CMV)

Catalog No.: Z7010001

[NAME AND INTENDED USE]

***ELISA Kit for Antibody to **Cytomegalovirus (CMV)** *** is an *in vitro* enzyme immunoassay for the detection of Anti-CMV antibodies IgM in human serum or plasma. It is for diagnosis of early infection and epidemic survey.

[PRINCIPLE]

This kit uses capture ELISA method to detect anti-CMV antibodies IgM in serum or plasma. The anti-human IgM (μ chain) antibody is coated on the multi-wells plate. The HRP conjugated recombinant CMV antigen serves as tracer. TMB is substrate for HRP. The enzyme reaction with substrate TMB produces a color change, and the intensity of the absorbance at 450 nm indicates the presence or absence of Anti-CMV antibodies IgM in the sample. The test is specific, sensitive, reproducible and easy to operate. It is for blood screen of CMV infection.

[INSTRUMENT]

8 x 12 wells plate reader and washer

[MATERIALS PROVIDED] 96 tests

1. Antibody Coated Microwell Plate	1 block (96wells)
2. Enzyme Conjugant	1 bottle (12ml)
3. Negative Control Serum	1 vial (0.5ml)
4. Positive Control Serum	1 vial (0.5ml)
5. Concentrated Wash Buffer (20x)	1 bottle (50ml)
6. Substrate A	1 bottle (6ml)
7. Substrate B	1 bottle (6ml)
8. Stop Solution	1 bottle (6ml)
9. Plastic Bag	1 bag
10. Seal Paper	2 pieces
11. Manual	1 each

[SAMPLE COLLECTION AND PRESERVATION]

Blood serum samples are routinely prepared from vein. Blood plasma sample are routinely prepared with routine amount of anticoagulant such as heparin or sodium citrate. Sample can be stored at 4°C if tested within five days. Sample can be stored at -20°C at least for 3 months. Avoid hemolysis and repetitive freeze and thaw of samples. Samples with cloud or precipitation should be centrifugated or filtered before test. Prevent serum from bacteria contamination during collection and storage.

[TEST PROCEDURE]

- Bring *** ELISA Kit for Antibody to **Cytomegalovirus (CMV)** *** (all reagents), and samples to room temperature before use (approximately 30 minutes).
- Dilute concentrated wash buffer 1:20 with ddH₂O
- For each test, set one blank, two positive and three negative controls. Add 20 μ l positive and negative control serum into positive and negative control wells respectively without sample diluent.
- Add 20 μ l test serum into test wells.
- Add enzyme conjugant 100 μ l into the wells except the blank well, mix thoroughly.
- Cover wells with seal paper, incubate for 60 minutes at 37°C.
- Discard the liquid in all wells and fill the wells with wash solution (300 μ l per well). Lay aside for 15 seconds, discard the liquid in all wells and fill the wells with wash solution. Repeat 5 times and dry wells after last wash.

- Add substrate A and B one drop or 50 μ l respectively to each well, mix gently, protected from light and lay aside for 15 minutes at 37°C.
- Add one drop of stop solution (50 μ l) into each well to stop the reaction, including blank well.
- Measure the absorbance at 450 nm against the blank, or measure the absorbance at 450 nm/630 nm.

[INTERPRETATION OF RESULTS]

Colorimetric Method

Cut Off Value calculation:

COV = 0.1 + the average OD of negative controls, (if the average OD of negative controls is below or equal to 0.05, calculate it as 0.05),

Positive OD₄₅₀ of sample \geq COV

Negative OD₄₅₀ of sample < COV

[LIMITATION]

The testing is for qualitative and assistant diagnosis. Confirmation of infection should refer to the clinical and other diagnosis.

[QUALITY CONTROL]

If the OD of positive controls is not below 1.0, OD of negative is not higher than 0.1, the assay result is validated. Otherwise, repeat the test.

[PRECAUTIONS]

- The samples should be fresh, avoid hemolysis, bacteria growing, and repetitive freeze and thaw.
- Do not interchange reagents between kit lots. The seal paper can't be used repeatedly.
- Mix reagents well before use. If crystal form in certain reagents, such as wash buffer, it can be used without problems after warm up and mix well.
- Follow instruction exactly during assay, especially in temperature and time for reactions. All pipetting devices should be used with care and calibrated regularly following the manufacturer's instructions.
- Put the remained reagents to the sealed pouch, and return to 2~8°C in time.
- To prevent cross-contamination, wear gloves and working suits throughout the procedure, and execute the disinfection and isolation regulations strictly. Dispose of all samples and materials used to perform the test. The 5.0g/L liquid sodium hypochlorite solution or 121°C high pressure steam may be used to disinfect samples and materials before disposal

[PACKAGE SIZE]

96 tests/Kit

[STORAGE AND STABILITY]

Store the kit at 2~8°C.

[PERFORMANCE CHARACTERISTICS]

Sensitivity \geq 98 %

Specificity \geq 95 %

Precision CV(%) \leq 15% (n=10)

[EXPIRATION]

The shelf life is 12 months. Do not use the kit beyond its expiration date.

This Kit is for Research Use Only