
INSTRUCTION

QNow® Rapid Tests for Human CMV Antibody

Cat#: 850301 for kit of 10 tests

Kit Component:

QNow® CMV antibody rapid test (Cat # 250301), 10 tests
Sample dilution buffer (Cat # 921010), 5ml
QNow® CMV antibody positive control (Cat # 950301), ready to use, 0.25 ml



Introduction

Congenital cytomegalovirus (CMV) belongs to the Herpesviridae family, and shares the characteristic ability to cause persistent and latent infections. At least 70% of the population in developed countries, and over 90% of people in developing countries is seropositive [1-3]. Although a CMV infection is typically asymptomatic in healthy persons, immunocompromised individuals including AIDS patients, organ recipients and newborns are at high-risk of developing life-threatening complications. More importantly, it remains one of the most dangerous infectious agents for an unborn baby, affecting 40,000 newborns each year in the United States, even though CMV infection can be controlled in immunocompromised patients by available antiviral drugs [4, 5].

In a typical herpes virus infection, the IgM is the first responder and normally used as a transient marker of primary infection [6, 7] although it can be produced during viral reactivation or reinfection with a different virus strain [8-10]. IgG, especially high avidity IgG which has stronger aggregate strength to bind multiple antigenic epitopes of virus, appears much later [11]. The presence of IgM or/and IgG will establish the status of virus infection.

Principles of the Procedure

QNow® CMV Antibody Rapid Test is an immunochromatographic membrane assay that uses antigens to detect CMV antibodies present in a sample. A mixture of antigens representing immunodominant epitopes of CMV and a control antibody are immobilized on a membrane support as two distinct lines. Another mixture of antigens is labeled with europium fluorescent beads to allow visualization of the formation of immunocomplex composed of the CMV antibodies and the antigens. The test detects both IgM and IgG from serum, plasma, or whole blood.

To perform the test, 10 ul of a sample is applied directly to the sample port of the test cassette, followed by 100ul of the sample dilution buffer. CMV antibodies present in the sample bind on the antigens labeled with the europium fluorescent beads. The antigen-antibody-beads complexes migrate along the test strip, where they are captured by the immobilized detection antigens, forming the Test Line (T). Immobilized control antibody captures the overflow complexes, forming the Control Line (C). The appearance of both a T Line and a C Line indicates the presence of CMV antibody (IgM or IgG) in the sample.

The test results are read with a QNow® reader (see instructions for the reader). Alternatively, the fluorescent lines can be visualized under UV light (365nm).

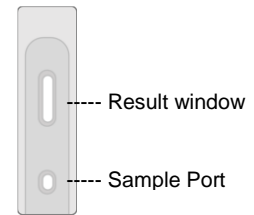
Intended Use

QNow® CMV antibody rapid test is for detection of anti-CMV antibodies in a sample (serum, plasma, or blood). This test is for research use only.

Test Procedure

1. All tests are performed at room temperature. Allow the package to warm to room temperature for 15 minutes prior to taking test cassettes out of the moisture barrier bags to avoid condensation.

2. Take out a test cassette, place it on a flat level surface with the right-side-up. Pipette ~10 ul of sample into the sample port, making sure that the sample is directly applied on the center of the sample pad. Add 100 ul of sample dilution buffer immediately. To test the positive control sample, add 110 ul positive control directly to the sample port, do not add buffer.
3. Wait for 20 minutes for the assay to develop. Read the result with a QNow® reader. Alternatively, the fluorescent lines can be visualized under UV light (365nm).



Result Interpretation

With the QNow® reader, the results are interpreted using the peak height value of the test line. Tests with peak value larger than two-fold of that of the background are “Positive”.

When visualized under a UV light (365nm), the appearance of the test line indicates positive CMV antibodies in the test sample.

Precautions

1. Keep test cassette sealed in its foil pouch until just before use.
2. Some components in the test uses streptavidin and biotin. High levels of biotin in testing samples may interfere with the assay.

Storage and Stability

Store kit dry at 4°C. Do not freeze.

References

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