One Step Zika IgG/IgM Antibody Test

Instructions For Use

Format: Cassette
Specimen: Serum/Plasma and Whole Blood
Catalog Number: A03-34-322

Japanese Distributor: ViroQuest Corporation

* Please read the instructions carefully before use
**INTENDED USE**
Artron One Step Zika IgG/IgM Antibody Test is a rapid, qualitative and convenient immunochromatographic in vitro assay for the deferential detection of IgG & IgM antibodies to Zika virus in human serum, plasma and/or whole blood samples. This assay only provides a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

**SUMMARY AND PRINCIPLE OF THE ASSAY**
Zika virus, first isolated in Uganda from a sentinel monkey in 1947, is an emerging arthropod borne virus (arbovirus) transmitted by Aedes (Stegomyia) mosquitoes. The virus belongs to the genus Flavivirus, family Flaviviridae, and is related to the dengue virus, which has similar epidemiology and transmission cycle in urban environments. In the past, only sporadic human Zika virus infections were reported. Serologic studies and virus isolations have demonstrated that the virus has a wide geographic distribution, including eastern and western Africa, the Indian subcontinent, Southeast Asia, and most recently, South America. Symptoms include arthralgia, oedema of extremities, mild fever, maculopapular rashes frequently pruritic, headaches, retro-orbital pain, non-purulent conjunctivitis, vertigo, myalgia and digestive disorders. Clinical symptoms of Zika disease appear after an incubation period ranging between three to twelve days. The symptoms are usually mild and short lasting – ranging from two to seven days. The infection may go unrecognized or be misdiagnosed as dengue.

Diagnosis of Zika virus infection includes PCR tests to detect viral DNA as well as additional tests to detect Zika Virus antibody (IgM) in serum. IgM for Zika Virus is typically detectable around three to five days after infection, but cross-reactivity with closely related dengue, yellow fever, Japanese encephalitis, and West Nile viruses is possible. However, these cross-reactive results have been noted to be more common in patients that denoted signs of previous flavivirus infections than patients with primary Zika Virus infection. For more efficient diagnosis, serum samples should be analyzed as early as possible, with a second test two to three weeks after that. Different profiles of humoral immune responses in primary and secondary Zika viral infections can be used for differential diagnosis. The presence of high titers of IgG antibodies does not interfere with the detection of IgM antibodies in the sample.

The principle of Artron One Step Zika IgG/IgM Antibody Test is an antibody-capture immunochromatographic assay for the simultaneous detection and differentiation of IgG & IgM antibodies to Zika virus in human serum, plasma, and/or whole blood samples. Zika virus-specific antigens are conjugated to a colloidal gold and deposited on the conjugate pad. A unique combination of anti-human IgG & IgM antibodies are immobilized on the test zone (T1 and T2) of the nitrocellulose membrane, as two individual test lines (IgG line and IgM line) in the test window of the test device. The IgG line (T1) in the test window is closer to the sample well and followed by IgM line (T2). When the sample is added, the gold-antigen conjugate is rehydrated and the Zika IgG and/or IgM antibodies, if any in the sample, will interact with the gold conjugated antigen. The antigen-antibody-gold complex will migrate towards the test window until the test zone (T1 and T2), where it will be captured by the relevant anti human IgG (T1) and/or anti-human IgM (T2), forming a visible pink line, indicating a positive result. If Zika antibodies are absent in the sample, no pink line will appear in the Test Zone, indicating a negative result.

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a pink control line in the Control Zone is an indication of an invalid result.

**PACKAGE CONTENTS**
- Pouch contents: Test Cassette, Desiccant.
- Sample buffer (3 ml) per bottle for 25 tests.
- Test instructions.

**MATERIALS REQUIRED (BUT NOT PROVIDED)**
- Lancet and blood collection device.
- Gloves.
- Clock or timer.

**WARNINGS AND PRECAUTIONS**
- For professional in vitro diagnostic use only. Do not reuse.
Do not use if the product seal or its packaging is compromised.
Do not use after the expiration date shown on the pouch.
Do not mix and interchange different specimens.
Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay.
Wash hands thoroughly after finishing the tests.
Do not eat, drink or smoke in the area where the specimens or kits are handled.
Clean up spills thoroughly with appropriate disinfectants.
Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, regional or national regulations.
Keep out of children’s reach.

SPECIMEN PREPARATION

- Blood samples may be collected by fingerstick or venipuncture, following routine facility procedures.
- For serum samples, collect blood in a tube without anticoagulant and allow it to clot.
- For plasma samples, collect blood in a tube containing anticoagulant.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- For whole blood samples, collect blood in a tube containing anticoagulant.
- Whole blood samples should be tested immediately after sample collection.
- The blood may be stored at 2°C to 8°C for up to three days if the tests cannot be performed immediately. The blood samples should attain room temperature prior to use.

TEST PROCEDURES

1. Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a flat surface.

2. Add 5 µl of blood sample with pipette to upper area (close to test window) of sample well of the test device (hold the pipette vertically and gently touch the end against the pad within the sample well for transferring).

3. Immediately add 2 drops (80 µl) of the assay buffer to the same sample well of the testing device.

4. Read the results in 10 minutes. Read results as shown under interpretation of results

NOTE: Strong positive specimens may produce positive result in as little as 1 minute and confirm negative results in 20 minutes.

RESULT INTERPRETATIONS

DO NOT INTERPRET RESULTS AFTER 30 MINUTES
QUALITY CONTROL
Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE AND STABILITY
- The test device in the sealed pouch should be stored at 2-30ºC. Do not freeze the test device.
- The bottle containing the buffer should be stored at 2-30ºC.
- The test device should be kept away from direct sunlight, moisture and heat.

LIMITATIONS
- Humidity and temperature can adversely affect results.
- The instructions for the use of the test should be followed during testing procedures.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- Although the test demonstrates superior accuracy in detecting antibodies against Zika virus, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

MANUFACTURER CONTACT INFORMATION

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