

Zika IgG/IgM rapid Test for specific zika antibody in serum/plasma or whole blood

Assay+

Intended use

One step zika virus IgG/IgM test is for in vitro diagnostic use only. This test is an immunochromatographic assay for fast and easy test to detect zika antibody.

Introduction

Zika virus is a member of genus flavivirus, transmitted by Aedes mosquitoes, the same Aedes mosquitoes are also the carrier and the transmitter of dengue virus. Aedes mosquitoes distribute in tropical and subtropical regions throughout the world. The clinical symptoms of zika infection includes fever, conjunctivitis, transient arthritis / arthralgia and maculopapular rash, usually starting from face to spread out the body. Currently no specific treatment is available for zika infection. Except the symptoms described above, zika infection can cause microcephaly, even fatality for new born baby and Guillain–Barré syndrome for adult.

one step zika rapid test can detect over 80% zika IgG and IgM in sensitivity and over 96% for specificity without the cross-reaction with dengue.

Assay principle

The recombinant zika antigens are used for each test individually, serum/plasma or whole blood from zika infection is loaded to zika test device, the specific Zika antibodies in specimen will bind to gold-conjugated zika antigen forming zika antibody – colloid gold - zika antigen complex. While the complex migrating along nitrocellulose membrane, the complex is captured by the test lines coated with anti-human IgG or IgM causing a pink to deep pink band at the IgG or IgM test line.

Kit Components

Each test kit contains:

1. A pouch
2. the pouch contains a zika test cassette
3. One 20 ul plastic pipette
4. Each 20 tests with one 5 ml dropper bottle with assay buffer

Stability and Storage Conditions

Zika IgG/IgM test kit is stable at room temperature between 10-28°C for one and half year in the unopened pouches.

DO NOT FREEZE the kit or expose to temperature extremes.

General Precautions

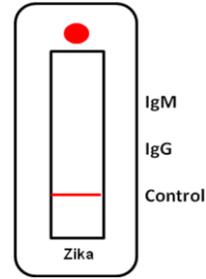
- The test is for *In Vitro* diagnosis only.
- Appropriate infection control and handling procedures should be followed – do not smoke, eat or drink in the area where the test is to be performed. Use suitable clothing and gloves when handling samples and when performing the test.
- Do not pipette any samples or reagents by mouth.
- All materials should be considered as potentially infectious. To disinfect, either autoclave materials at 121.5°C for 1 hour or treat with Sodium hypochlorite (1 percent solution).
- Do not use test beyond the expiration date indicated.

Sample Collection

Serum or plasma is used for this device. The test works best on fresh samples. If testing cannot be done immediately, they should be stored at 2-8°C after collection for up to 3 days. If testing can not be done within 3 days, serum or plasma can be stored frozen at –20°C or colder.

Test Procedure

1. Remove test cards from the pouches before your test, lay over a clean flat surface.
2. In case, the tested samples are in frozen status, the sample has to be sit in room temperature to completely thawing, and mixed well for test.
3. Add 10ul serum/plasma or whole blood to zika sample well by using included pipette.
4. Follow adding sample, add three drops assay buffer from the dropper bottle .
5. Results are then read 15 to 30 minutes, make sure control line is always positive.



4. Indeterminate

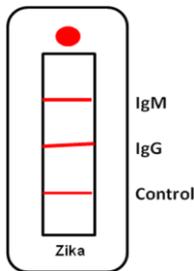
If control line shows negative, the test is invalid.

5. Quality Control:

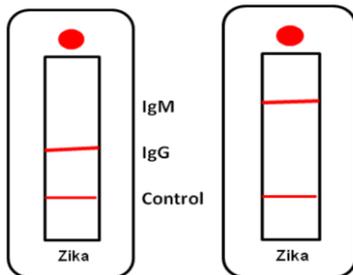
A known positive and negative control should be run to insure proper performance. All control tests should be handled in the same manner as patient samples.

Reading the Test Results

1. Zika IgG and IgM positive



2. Zika IgG or IgM positive



3. Zika IgG or IgM negative

Limitation of the Test

This instruction should be followed carefully and performed properly.

Assay+ zika IgM/IgG test is designed to detect antibodies against zika virus in serum /plasma or whole blood. Testing of any other body fluids has not been validated and may not yield appropriate results.

Establishment of zika infection has to combine clinical information for analysis, a final diagnosis should be confirmed by other more specific test method.