

Duo zika and dengue IgM / IgG rapid Test

Intended use

One step confirmed duo zika and dengue virus IgG/IgM combo test is for *in vitro* diagnostic use only. This test is an immunochromatographic assay for fast and easy test to detect zika and dengue antibody, and help to distinguish qualitatively.

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.

Zika virus is transmitted by *Aedes* mosquitoes, also a similar transmitter for dengue virus. In order to exclude dengue infections, duo zika/dengue IgG/IgM rapid test can distinguish the infection caused by either zika or dengue infection.

Assay principle

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

The individual Zika test has over 80% in sensitivity and 95% specificity for zika IgG and IgM test; while dengue test has over 90% and 95% sensitivity and specificity for dengue antibody test, separately.

Kit Components

Each test kit contains:

1. A pouch
2. the pouch contains a cassette containing two test windows, one for zika and one for dengue test.
3. One 20 ul plastic pipette
4. Each 20 tests with one 3 ml dropper bottle with assay buffer

Stability and Storage Conditions

duo zika and dengue 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

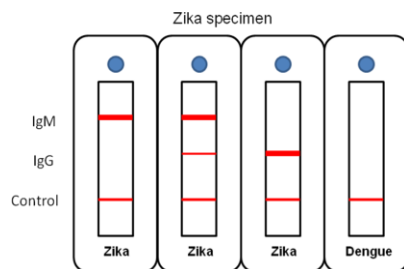
Serum or plasma is used for this device. The test works best on fresh samples. If testing cannot be done immediately, they should be stored at 2-8°C after collection for up to 3 days. If testing can not be done within 3 days, serum can be stored frozen at -20°C or colder.

Test Procedure

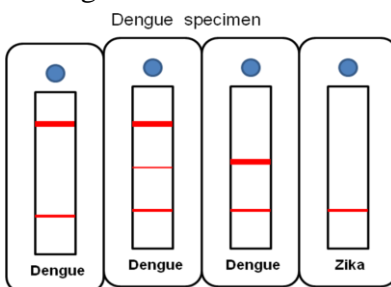
1. Remove test cards from the pouches before your test, lay over a clean flat surface.
2. In case, the tested samples are in frozen status, the sample has to be sit in room temperature to completely thawing, and mixed well for test.
3. Add 20ul serum or plasma to zika and dengue test sample wells equally by using included pipette.
4. Follow adding sample, add two drops assay buffer from the dropper bottle for each test.
5. Results are then read 15 to 30 minutes, make sure control line is always positive.

Reading the Test Results

1. Zika infection



2. Dengue infection



4. Indeterminate

If there is any cross-reaction each other, the sample have to go to the next step for zika nucleotide test to confirm or exclude dengue infection.

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.

Result analysis:

1. Zika specimen: zika IgM positive, dengue IgG/IgM all negative, confirm the infection is caused by zika virus.
2. Zika specimen: zika IgM / IgG positive, dengue IgG/IgM all negative, confirm the infection is caused by zika virus.
3. Zika specimen: zika IgG positive, dengue IgG/IgM all negative, confirm the infection is caused by zika virus.
4. Dengue specimen: dengue IgM Positive, zika IgG/IgM all negative, confirm the infection is caused by dengue virus.
5. Dengue specimen: dengue IgG/IgM positive, zika IgG/IgM all negative, confirm the infection is caused by dengue virus.
6. Dengue specimen: dengue IgG positive, zika IgG/IgM all negative, confirm the infection is caused by dengue virus.
7. Suspected zika specimen: show any signal both on zika and dengue test, please go to the next step to test zika nucleotide to conform if it is zika infection.
8. Suspected dengue specimen: show any signal both on zika and dengue test, please go to the next step to test zika nucleotide to exclude if it is zika infection

Limitation of the Test

This instruction should be followed carefully and performed properly.

Assayplus duo zika and dengue IgM/IgG test is designed to detect antibodies against zika and dengue virus in serum or plasma. 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.