OXALIS
Diagnostics Pvt. Ltd.

Rapichek
Chikungunya Igm / IgG

Rapid Test for Detection of Chikungunya IgM/IgG Antibodies – Device & Components

For In-Vitro Diagnostic Use Only. Store at 4°C to 30°C

OVERVIEW

Chikungunya virus (Chik V) is a mosquito-transmitted alpha virus belonging to the Togaviridae family, first isolated in Tanzania in 1952. Three lineages with distinct genotypic and antigenic characteristics have been identified. Chikungunya virus is endemic to some parts of Africa and causes recurrent epidemic waves in Asia and the Indian subcontinent. At the end of 2013 the virus emerged in the Americas. Human beings serve as the main chikungunya virus reservoir during epidemic periods. In Africa, some animals constitute the virus reservoir during non-epidemic periods sustaining virus circulation. Clinical signs of chikungunya virus infection include sudden onset fever and severe arthralgia (joint pain) affecting mainly the extremities but also the larger joints.Erratic,relapsing, and incapacitating joint pain is the hallmark of chikungunya virus. Up to 12% of patients still have chronic joint pain three years after the onset of their illness. Other symptoms of the infection (headache, fatigue and rash) are common among many arboviral infections including chikungunya virus.

INTENDED USE

This is a rapid, in vitro, qualitative lateral flow immunoassay for the detection of IgG/IgM antibodies against Chikungunya from human serum, plasma or whole blood samples.

PRINCIPLE

The test device utilizes a strip containing a strip coated with anti-human IgM and Anti - human IgG antibodies are immobilized along with control specific antibodies on the nitrocellulose membrane as three individual test lines (control, IgM line and IgG line). When sample and buffer is added in sample well, the test sample flows through the membrane within the test device and chikungunya specific recombinant antigen conjugated colloidal gold conjugate forms complexes with chikungunya specific antibodies (IgM and/or IgG) present in the sample. This complex moves further on the membrane to the test region where it is captured by the anti-human IgM and/or human IgG antibodies coated on the membrane leading to formation of a colored band, which indicates a positive test result. Absence of this colored band in the test window indicates a negative test result. A control line will always appear in the test window when the test has performed properly,regardless of the presence or absence of anti- Chik V IgG and/or IgM antibodies in the specimen.

MATERIAL PROVIDED

1. Test Device with desiccant
2. Plastic Dropper
3. Package Insert
4. Assay Buffer

OPTIONAL MATERIAL MAY REQUIRE BUT NOT PROVIDED

1.Calibrated micropipette capable of delivering 10 or 20 µl sample Accurately.
2.Stop watch.
3.Disposable gloves

PRECAUTIONS / KIT STORAGE AND SATBILITY

1.Please read all the information in this package insert before performing the test. Pay particular attention to the position of the Control and Test lines.
2.Do not use after the expiration date printed on the foil pouch.
3.Store in the sealed pouch in a dry place in between temperature 4°C to 40°C. Do not freeze.
4.Do not use if pouch is torn or damaged.
5.Do not open the foil pouch until you are ready to start the test.
6.Keep out of the reach of children. whether positive or negative, in the use of this product

WARNING

1.Do not reuse the test.
2.Follow the instruction to get accurate results.
3.Use appropriate personal protective equipment.
4.Dispose of hygienically as per local regulatory requirements.
5.Do not touch the membrane.
6.Treat blood samples and used tests as potentially infectious. Avoid contact with skin.
7.For in vitro diagnostic use. Not to be taken internally.
8.Do not eat the desiccant in the package.
9.Do not mix the specimen sample or interchange the different specimen.

SPECIMEN COLLECTION

Fresh anti-coagulated whole blood should be used as a test sample. EDTA or Heparin or Oxalate or Tri-sodium Citrate can be used as suitable anticoagulants. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then store the specimen at 2°C to 8°C for up to three days before testing. Clotted or contaminated blood samples should not be used for performing the test. Fresh blood from finger prick/ puncture may also be used as a test specimen.

TEST PROCEDURE

1. Bring the kit components to room temperature before testing.
2.Open the pouch and retrieve the test and desiccant pouch. Check the color of the desiccant. It should be blue, if it has turned colorless or pink, discard the test and use another test. Once opened, the test must be used immediately.
3. Label the test with patient's identity.
4. Tighten the vial cap of the assay buffer provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.
5. Add 1 drop (10 µl) of serum or plasma or 2 drop (20 µl) of whole blood in the sample port 'S'.
6. Add 2 drops of assay buffer in the sample port 'S'.
7.Read the results at the end of 15 minutes. Do not read the result

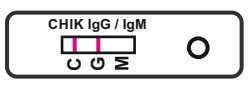
INTERPRETATION OF RESULTS

NEGATIVE for Chikungunya IgM / IgG Antibody : If colored band appears at the control region 'C'

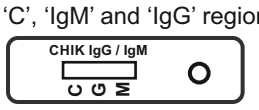
Positive for Chikungunya IgM and IgG Antibodies : In addition to the control band, two Colored bands appear at regions 'IgG' and 'IgM' in the test window.

Positive for Chikungunya IgM : In addition to the control band, one Colored band appears only at region 'IgM' in the test window.

Positive for Chikungunya IgG: In addition to the control band, one Colored band appears only at region 'IgG' in the test window.



INVALID: The test should be considered invalid if
A)No line appears at 'C', 'IgM' and 'IgG' regions.



B)No line appears at 'C' region and line appear at 'IgM' and 'IgG' regions.

C)No line appears at 'C' and 'IgM' region and line appear at 'IgG' region.

D)No line appears at 'C' and 'IgG' region and line appear at 'IgM' region.

LIMITATIONS

1. As with all diagnostic tests, the test result must always be correlated with clinical findings.
2. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context. When it seems indicated, reference correlation should be considered.
3. Any modification to the above procedure and / or uses of other reagents will invalidate the test procedure.
4. The test is limited to the detection of IgG/IgM antibodies against Chikungunya, Other clinically available tests are required if questionable results are obtained. 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.

PERFORMANCE CHARACTERISTICS

Total 193 samples were evaluated for specificity & sensitivity. sensitivity was found to be 100% (61/61) and relative specificity was found 100% (132/132).

The Positive predictive value (PPV) and Negative Predictive value (NPV) for the test was 100 %.

No cross reactivity found with HCG, TSH, Bilirubin, High Abs positive samples observed.

DISCLAIMER

The all precautions shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results.

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