Rapid Immunochromatographic Assay for detection of IgM antibodies to Chikungunya virus in human serum / whole blood

INTENDED USE
INSIGHT ChikV is a rapid, self-performing, two site sandwich immunoassay for the detection of IgM antibodies to Chikungunya virus in human serum / whole blood.

SUMMARY
Chikungunya, a virus belonging to the genus Alphavirus, is viral infection transmitted through the bite of an infected Aedes aegypti mosquito. The time between the mosquito bite and the onset of symptoms is usually 2-4 days. The acute illness usually lasts for 5-7 days. Symptoms generally seen are sudden onset of chills, high fever, petechia, maculopapular rash, arthralgia, photophobia and severe headache. However, certain patients continue to suffer from recurrent joint pains for years after the initial infection. INSIGHT ChikV is a rapid, self-performing, two site sandwich immunoassay for the detection of IgM antibodies to Chikungunya (Alphavirus) infection in human serum / whole blood and can be used to diagnose the illness 5 days after the onset of symptoms.

PRINCIPLE
INSIGHT ChikV is based on the principle of agglutinating sera on membrane and utilizes the technique of immunochromatography. The conjugate pad is impregnated with two components - Anti Human IgM and mouse IgG conjugated to colloidal gold. As the test specimen flows through the membrane assembly of the device, the Anti Human IgM and mouse IgG colloidal gold conjugate complexes with the IgM antibodies in the test specimen and travels on the membrane due to capillary action. This complex moves further on the membrane to the test region (T) where Chikungunya (Alphavirus) specific IgM antibodies if present in the test specimen bind to the antigens coated on the membrane, leading to formation of a pink/purple coloured band. The absence of this band in the test region (T) indicates a negative result. The unbound complex if any move further on the membrane and are subsequently immobilized by the goat anti mouse IgG antibodies coated on the membrane at the control region (C) forming a pink / purple coloured band. This control band acts as a procedural control and serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED
A. Each INSIGHT ChikV kit contains individual pouches, each containing a
1. Device: Membrane test assembly pre-dispensed with colloidal gold conjugated to Anti Human IgM and mouse IgG antibodies, Alphavirus Chikungunya antigen and goat anti mouse IgG antibodies at the respective regions.
2. Desiccant pouch.
B. Sample running buffer.
C. Package insert.

ADDITIONAL MATERIAL REQUIRED
Variable precision micropipettes 5-50 µl capacity, stopwatch.

STORAGE AND STABILITY
The sealed pouches in the test kit and the kit components may be stored between 4-30°C till the duration of the shelf life as indicated on the pouch/carton. DO NOT FREEZE.

NOTE
1. For in vitro diagnostic and professional use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimen as if potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
6. If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test device must be run.
7. Sample running buffer contains Sodium Azide (0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build-up in the plumbing.

SPECIMEN COLLECTION AND PREPARATION
1. INSIGHT ChikV uses human serum / whole blood as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
3. Though fresh serum specimen is preferable, in case of delay in testing, it may be stored at 2-8°C for maximum up to 48 hours.
4. Whole blood specimen collected with a suitable anticoagulant cannot be used, hence it is recommended to use fresh whole blood collected from finger prick.
4. Refrigerated serum specimen must be brought to room temperature prior to testing.
5. To obtain a good serum specimen, allow blood to clot completely. Centrifuge to obtain clear serum.
6. Do not use viscous/turbid, lipaemic, hemolysed, clotted and contaminated serum specimen.
7. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.

TESTING PROCEDURE
1. Bring the kit components of INSIGHT ChikV device to room temperature before testing.
2. Open a foil pouch by tearing along the “notch”.
3. Remove the testing device. Check the colour of the desiccant pouch. It should be blue. If the desiccant has turned colourless or pink, discard the test device and use another device. Once opened, the device must be used immediately.
4. Place the testing device on a flat horizontal surface and label the device with specimen identity.
5. Using a micropipette, carefully dispense exactly 5 µl of serum / 10 µl of whole blood specimen into the specimen port.
6. Rotate the cap of the sample running buffer bottle in anticlockwise direction to pierce the nozzle. Carefully dispense exactly 5 drops of sample running buffer into the specimen port.
7. Start the stopwatch. Read the results within 15 minutes. Do not interpret the results beyond 30 minutes.

INTERPRETATION OF RESULTS
Negative Result:
Only one pink / purple coloured band appears at the Control Region (C). This indicates absence of antibodies to Chikungunya (Alphavirus) infection.

Positive Result:
Two pink / purple coloured bands appear at the Control Region (C) and Test Region (T). This indicates that the sample contains detectable amount of antibodies to Chikungunya (Alphavirus) infection.

Invalid Result:
The test result is invalid if no band appears either at the Control Region (C) or Test Region (T). In such cases, verify the test procedure and repeat the test with a new INSIGHT ChikV device.

REMARKS
1. The deliberate slow reaction kinetics of INSIGHT ChikV is designed to maximize and enhance reaction time between sample capture and tracer elements to improve test sensitivity.
2. Most positive results develop within 15 minutes. However, certain sera sample may take a longer time to flow. Therefore, negatives should be confirmed only at 15 minutes. Do not interpret the results beyond 30 minutes.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
4. INSIGHT ChikV should be used as a screening test in clinically suspected cases only, and its results should be confirmed by other supplemental method before taking clinical decisions.

WARRANTY
This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY
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