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Link do produktu: http://www.novazym.sklep.pl/chikungunya-iggigm-combo-test-20-szt-p-4115.html

Chikungunya IgG/IgM Combo Test (20 szt.)

Opis produktu

Quick Profile? - Chikungunya IgG/IgM Combo Test

Chikungunya virus (CHIKV) 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. CHIKV 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 CHIKV reservoir during epidemic periods. In Africa, some animals constitute the virus reservoir during non-epidemic periods sustaining virus circulation. Clinical signs of CHIKV 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 CHIKV. 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 arborviral infections including dengue. There is no specific therapy for CHIKV infection. Patients are symptomatically treated with anti-inflammatory medication. The death rate is not high, but excess mortality has been observed occurring together with larger CHIKV outbreaks. Diagnosis is based on the detection of virus by molecular methods or by virus culture in the first days of infection before an antibody response is evident. IgM anti-CHIKV is detectable two to three days at the onset of symptoms and persist for several weeks up to three months. CHIKV specific IgG appears soon after IgM antibodies and persist for years.

TEST PRINCIPLE:

QuickpProfile? ChikV IgG/IgM Combo Test utilizes the principle of Immuno-chromatography. Mouse anti-human IgM and human IgG antibodies are immobilized on the nitrocellulose membrane respectively, as two individual test lines (IgM line and IgG line) in the test window of the test device. The IgG line in the test window is closer to the sample well and followed by IgM line. As the test sample flows through the membrane within the test device, the colored?chikungunya specific recombinant antigen-colloidal gold conjugate complexes with specific antibodies (IgM and/or IgG) of chikungunya virus, if 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 results. Absence of this colored band in the test window indicates a negative test result. A built-in control line will always appear in the test window when the test has performed properly, regardless of the presence or absence of anti-Dengue virus antibodies in the specimen.

REAGENTS AND MATERIALS SUPPLIED:

Each kit contains:
1. QuickpProfile? ChikV IgG/IgM Combo Test Card in foil pouch
2. Sample Buffer
3. Five (5) ?L Capillary Pipet
4. Instructions for Use

MATERIALS NOT PROVIDED:

1. Sepcimen collection container
2. Timer

STORAGE AND STABILITY:

The sealed pouches in the test kit may be stored between 4-30?C for the duration of the shelf life as indicated on the pouch.

PRECAUTIONS:

1. This kit is for IN VITRO diagnostic use only.
2. This kit is for PROFESSIONAL use only.
3. Read the instructions carefully before performing the test.
4. This product does not contain any human source materials.
5. Do not use kit contents after the expiration date.
6. Handle all specimens as potentially infectious.
7. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infective material. When the assay procedure is completed, dispose specimens after autoclaving them at 121? C for at least 20 min. Alternatively, they can be treated with 0.5% Sodium Hypochlorite for 1-2 hours before disposal.
8. Do not pipette reagent by mouth and no smoking or eating while performing assays.
9. Wear gloves during the whole procedure.

SPECIMEN COLLECTION AND PREPARATION:

1. No prior special preparation of the patient is required before sample collection by approved techniques.
2. The test works best on fresh whole blood / serum / plasma samples. If testing cannot be performed immediately, serum / plasma may be stored at 2-8?C up to 3 days in case of delay in testing. For long-term storage, serum / plasma specimens can be frozen at -20?C for 3 months or -70?C for longer period. Blood samples collected with a suitable anticoagulant such as EDTA or Heparin or Oxalate may be stored at 2-8?C up to 3 days. Blood samples should not be frozen.
3. Repeated freezing and thawing of the specimen should be avoided.
4. Do not use haemolysed, clotted, contaminated, lipamic and viscous/turbid specimen.
5. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.
6. Do not inactivate the sample by heating.
7. Shipment of specimens should comply with local regulations for transportation of etiologic agents.

Procedure:

1.

Bring the kit components to room temperature before testing.

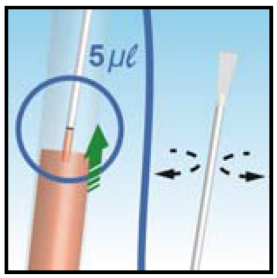
2.

Open the pouch and reomove the Card. Once opened, the test card must be used immediately

3.

Label the test card with patient's identity.

4.



Apply 5µl of serum, plasma or whole blood to the "S1" area indicated by **arrow mark.**

5.

Add 2 drops of sample buffer to well marked as "**S**".

6.

At the end of 20 minutes read the results. A strong positive sample may show result earlier.

Note: Result after 20 minutes may not be accurate.

Interpretation of results:

<table>
<tr><th colspan="3">Positive</th></tr>
<tr>
<td> 
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<td> 
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<td> 
</td>
</tr>
<tr>
<td>**Both IgG/IgM Positive**</td>
<td>**IgM Positive**
IgG Negative</td>
<td>**IgG Negative**
IgM Positive</td>
</tr>
<tr>
<td>Control line and both test lines appear. It indicate the possibility of acute infection.</td>
<td>Both control line and the second test line (the higher test line) appear. It indicates the possibility of early infection.</td>
<td>Both control line and the second test line (the lower test line which is closer to the sample well) appear. It indicates the possibility of the past infection.</td>
</tr>
</table>

<table>
<tr><th colspan="2">Negative</th></tr>
<tr>
<td> 
</td>
<td>Only control line appears.</td>
</tr>
</table>

<table>
<tr><th colspan="5">Invalid</th></tr>
<tr>
<td> 
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<td> 
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<td> 
</td>
<td>The test result is invalid if a colored band does not form in the control region. The sample must be re-tested, using a new test device.</td>
</tr>
</table>

QUALITY CONTROL:

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which is not provided with this test kit may be commercially available.

LIMITATIONS:

1. The test is for qualitative detection of anti-chikungunya antibody in human serum, plasma or blood sample and does not indicate the quantity of the antibodies.
2. The test is for in vitro diagnostic use only.
3. As in case of all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test but should rather be made after all the clinical findings have been evaluated.

PERFORMANCE CHARACETERISTICS:

Accuracy:

QuickProfileTM ChikV IgG/IgM Combo Test was evaluated on sixty positive patient samples and 40 negative samples. From healthy blood donors. The agreement is 100%.

Blood compounds:

QuickProfileTM ChikV IgG/IgM Combo Test has tested samples with high Rheumatoid Factor (RF), Bilirubin, Triglycerol and Hemoglobin. The results showed that these compounds had no effect on the specificity of the assay up to the listed concentration.

Rheumatoid factor 167 IU/ml
Bilirubin 218 IU/ml
Triglycerol 24.68 mL/L
Hemoglobin 9 mg/ml