Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

CE

# OneStep *Chikungunya IgG/IgM Combo*) RapiCard™ InstaTest

REF **174110-25-23**

*A Rapid Qualitative Immunochromatographic Test for the Simultaneous Detection of IgG and IgM Antibodies to Chikungunya Virus in Human Whole Blood, Serum or Plasma*

IVD See external Label 4-30°C ∑= 1 Test

## INTENDED USE

ChikV IgG/IgM RapiCard InstaTest is a rapid immunochromatographic assay for the simultaneous detection of IgG and IgM antibodies to Chikungunya virus in human whole blood, serum or plasma. The assay is used as a screening test for Chikungunya viral infection.

## SUMMARY AND EXPLANATION

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. 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 arborviral infections including chikungunya virus. There is no specific therapy for chikungunya virus 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 chikungunya virus 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.

ChikV IgG/IgM RapiCard InstaTest is a new generation rapid Immuno-chromatographic test using recombinant chikungunya viral antigens of both wild type and mutant type to detect specific antibody response.

## TEST PRINCIPLE

ChikV IgG/IgM RapiCard InstaTest 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- ChikV antibodies in the specimen.

## 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 2-8ºC up to 3 days in case of delay in testing. For long-term storage, serum / plasma specimens can be frozen at -20ºC for 3 months or -70ºC for longer period. Blood samples collected with a suitable anticoagulant such as EDTA, Heparin or Oxalate may be stored at 2-8ºC 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 hemolyzed, clotted, contaminated, lipamic and viscous/turbid specimen.
5. Specimen containing precipitates or particulate matter must be centrifuged and only the clear supernatant is to be 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.

## MATERIALS AND COMPONENTS

### Materials provided with the test kit

1. ChikV IgG/IgM RapiCard InstaTest Card in foil pouch
2. Sample Buffer
3. Five (5) µL Capillary Pipet
4. Instructions for Use

### Materials required but not provided

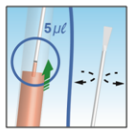
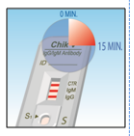
1. Specimen collection container
2. Timer

Diagnostic Automation/ Cortez Diagnostics, Inc.
21250 Califa St, Suite 102 and 116, Woodland Hills, CA 91367 USA Phone: 818-591-3030, Fax : 818-591-8383
Email: onestep@rapidtest.com Website: www.rapidtest.com

Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

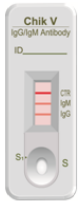
CE

## ASSAY PROCEDURE

| | |
|---|---|
| 1 | Bring the kit components to room temperature before testing. |
| 2 | Open the pouch and remove the test card. Once opened, the test card must be used immediately. |
| 3 | Label the test card with the specimen's identification. |
| 4 |   Apply 5µL of serum, plasma or whole blood to the "**S1**" area indicated by the **arrow mark**. |
| 5 |  Add 2 drops of sample buffer to well area marked as "**S**". |
| 6 |  At the end of 15 minutes read the results. A strong positive sample may show result earlier. ***Note: Result after 15 minutes may not be accurate.*** |

## RESULTS

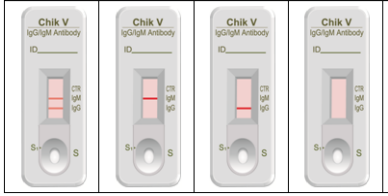
**POSITIVE**

|  |  |  |
|---|---|---|
| **Both IgG/IgM Positive** | **IgM Positive IgG Negative** | **IgM Negative IgG Positive** |
| Control line and both test lines appear. It indicate the possibility of acute infection. | Both control line and the second test line ( the higher test line ) appear. It indicates the possibility of early infection. | 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. |

**NEGATIVE**

Only control line appears.

**INVALID**



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.

## PERFORMANCE CHARACTERISTICS

**Accuracy**

ChikV IgG/IgM RapiCard InstaTest was evaluated on 78 positive patient samples and 85 negative samples from healthy blood donors. The agreement is 100%.

Blood compounds

ChikV IgG/IgM RapiCard InstaTest 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 |

## 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 are not provided with this test kit may be commercially available.

## LIMITATIONS OF PROCEDURE

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.

## STORAGE

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

## REFERENCE


1. Chikungunya virus infection: an overview, Claudia Caglioti, et al. New Microbiology, Vol. 36, 211-227, 2013
2. CDC Chikungunya Fact Sheets, www.cdc.gov/chikungunya (2015)


**ISO 13485**
**ISO 9001**

**Diagnostic Automation/ Cortez Diagnostics, Inc.**
**21250 Califa St, Suite 102 and 116, Woodland Hills, California 91367 USA**

| | |
|---|---|
| **Date Adopted** | **2016-04-20** |
| REF 174110-25-23 | **OneStep *Chikungunya IgG/IgM Combo*) RapiCard™ InstaTest** |
| EC REP | **CEpartner4U, Esdoornlaan 13, 3951DB Maarn. The Netherlands.** www.cepartner4u.eu |
| **Revision Date: 2016-01-26** | |


Diagnostic Automation/ Cortez Diagnostics, Inc.
21250 Califa St, Suite 102 and 116, Woodland Hills, CA 91367 USA Phone: 818-591-3030, Fax : 818-591-8383
Email: onestep@rapidtest.com Website: www.rapidtest.com


COR CODE #23