Chikungunya IgM Rapid Test Kit
(Serum/Plasma/Whole Blood)

RTK-2017-CHI	English

For professional and in vitro diagnostic use only.

【INTENDED USE】

The Chikungunya IgM Cassette Rapid Test is alateral flow chromatographic immunoassay for the qualitative detection of IgM anti-chikungunyaviru (sCHIK) inhuman serum, plasma or whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with CHIK.Any reactive specimen with the Chikungunya IgM Cassette Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

【SUMMARY AND EXPLANATION OF THE TEST】

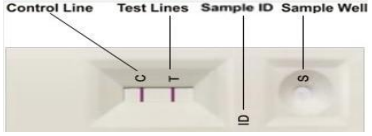
Chikungunya is a rare viral infection transmitted by the bite of an infected Aedes aegypti mosquito. It is characterized by a rash, fever and severe joint pain (arthralgias) that usually lasts for three to seven days. The name is derived from the Makonde word meaning "that which bends up" in reference to the stooped posture developed as a result of the arthritic symptoms of the disease. It occurs during the rainy season in tropical areas of the world, primarily in Africa, South-East Asia, southern India and Pakistan1-2.

The symptoms are most often clinically indistinguishable form those observed in dengue fever. Unlike dengue, hemorrhagic manifestations are relatively rare and most often the disease is a self-limiting, febrile illness. Dual infection of dengue and chikungunya is also possible as has been reported in India3. Therefore, it is very important to clinically distinguish dengue from CHIK infection.

CHIK is diagnosed based on serological analysis and viral isolation in mice or tissue culture. An IgM immunoassay is the most practical lab test method. The Cellex qChikungunya IgM Cassette Rapid Test utilizes recombinant antigens derived from its structure protein5; it detects IgM anti-CHIK in patient serum or plasma within 15 minutes. The test can be performed by untrained or minimally skilled personnel without cumbersome laboratory equipment.

【TEST PRINCIPLE 】

The Chikungunya IgM Cassette Rapid Test is a lateral flow Chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing CHIK antigens conjugated with colloidalgold (CHIK conjugates) and rabbit IgG-gold conjugates,2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with anti-human IgM reagent, and the C line is pre-coated with goat anti-rabbit IgG.



When an adequate volume of test specimen is dispensed into the sample well of the cassette the specimen migrates by capillary action across the cassette. The IgM antibody to CHIK, if present in the specimen, will bind to the CHIK conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM reagent forming a burgundy colored T line, indicating a CHIK IgM positive test result.

Absence of the T line suggests a negative result. The test contains an internal control (C line) which should exhibit a burgundy colored line of the immunocomplex of goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on the T line. If the C line does not develop, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

1. Individually sealed foil pouches containing:
   a. One cassette device
   b. One desiccant
2. Plastic droppers
3. Sample Diluent (1 bottle, 5 mL)
4. One package insert (instruction for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

1. Positive Control
2. Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer

WARNINGS AND PRECAUTIONS

For in Vitro Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15°C - 30°C) before use.
5. Do not use components from any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolyzed blood specimens for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Handle the negative and positive controls in the same manner as patient specimens.
12. The test results should be read within 15 minutes after a specimen is applied to the sample well or sample pad of the device. Reading the results after 15 minutes may give erroneous results.
13. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test device unopened at 2°C - 30°C. If stored at 2°C - 8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Plasma

Step 1: Collect blood specimen into a lavender, blue or green top collection tube by venipuncture.
Step 2: Separate the plasma by centrifugation.
Step 3: Carefully withdraw the plasma into new pre-labeled tube.

Serum

Step 1: Collect blood specimen into a red top collection tube by venipuncture.
Step 2: Allow the blood to clot.
Step 3: Separate the serum by centrifugation.
Step 4: Carefully withdraw the serum into a new pre-labeled tube.

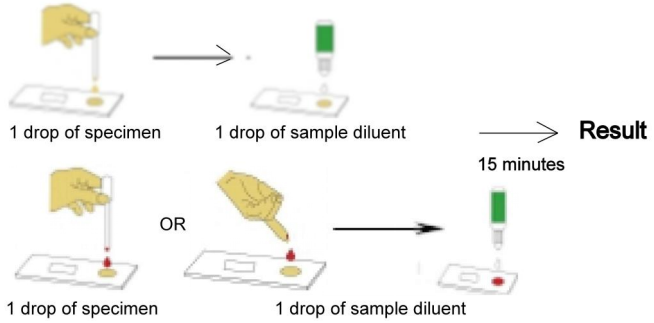
Test specimens as soon as possible after collecting. Store specimens at 2°C - 8°C if not tested immediately for up to 5 days. The specimens should be frozen at -20°C for longer storage.
Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.
Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

Whole Blood

Drops of whole blood can be obtained by either finger tip puncture or venipuncture. Do not use hemolyzed blood for testing.
Whole blood specimens should be stored in refrigeration (2°C - 8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.

ASSAY PROCEDURE

Step 1: Bring the specimen and the test components to room temperature if refrigerated or frozen. Mix the specimen well, prior to assay, once thawed.
Step 2: When ready to test, open the pouch at the notch and remove the device. Place the test device on a clean, flat surface.
Step 3: Be sure to label the device with the specimen's ID number.
Step 4: Fill the plastic dropper with the specimen.
Holding the dropper vertically, dispense 1 drop (about 30-45 µL) of serum/plasma or 1 drop of whole blood (about 40-50 µL) into the sample well making sure that there are no air bubbles.
Immediately add 1 drop (about 40-50 µL) of Sample Diluent to the sample well.



Step 5: Set up timer.
Step 6: Results can be read in 15 minutes. Positive results can be visible in as soon as 1 minute.
Do not read results after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

1. Internal Control: This test contains a built-in control feature, the C line. The C line develops after adding the specimen and sample diluent. If the C line does not develop, review the whole procedure and repeat the test with a new device.
2. External Control: Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
   a. New operator uses the kit, prior to performing the testing of specimens.
   b. A new lot of test kits is used.
   c. A new shipment of kits is used.
   d. The temperature used during storage of the kits fall outside of 2°C - 30°C.
   e. The temperature of the test area falls outside of 15° - 30°C.
   f.To verify a higher than expected frequency of positive or negative results.
   g. To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

1. **NEGATIVE RESULT**: If only the C line is developed, the test indicates that no detectable IgM anti-CHIK is present in the specimen. The result is negative.

2. **POSITIVE RESULT: If** both the C and the T lines are developed, the test indicates the presence of IgM anti-CHIK in the specimen. The result is positive.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

3. **INVALID: If** no C line is developed, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

An evaluation study was carried out at Unite de virologie, Institute de Medecine Tropicale de Service de Sante des Armees, Ministere De la Defense, France.

The evaluation specimen panel consisted of 72 specimens from recently infected individuals diagnosed by MAC-ELISA and 21 negative specimens containing 10 from other arbovirus infection, 3 from O'Nyong nyong infection, and 8 clean negative samples. The evaluation data are shown in the following table.

Reach Chikungunya IgM Cassette Rapid Test

MAC-ELISA	Positive	Negative	Total
Positive	65	7	72
Negative	0	21*	21
Total	65	28	93

Relative Sensitivity: 90.3%, Relative Specificity: 100%, Overall Agreement: 92.4%

LIMITATIONS OF TEST

1. The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of IgM anti-CHIK in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Chikungunya IgM Cassette Rapid Test is limited to the qualitative detection of IgM anti-CHIK in human serum, plasma or whole blood. The intensity of the test line does not have a linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable IgM anti-CHIK. However, a negative test result does not preclude the possibility of exposure to or infection with CHIK
4. A negative result can occur if the quantity of IgM anti-CHIK present in the specimen is below the detection limit of the assay or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor may affect expected results.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

1. Shah KV, Gibbs CJ Jr, Banerjee G. Virological investigation of the epidemic of haemorrhagic fever in Calcutta: isolation of three strains of Chikungunya virus. Indian J Med Res 1964; 52 :676-83.
2. Powers AM, Brault AC, Tesh RB, Weaver SC. Re-emergence of Chikungunya and O'nyong-nyong viruses: evidence for distinct geographical lineages and distant evolutionary relationships. J Gen Virol 2000; 81:471-9.
3. Myers RM and Carey DE. Concurrent isolation from patient of two arboviruses, Chikungunya and dengue type 2. Science 1967; 157:1307-8.
4. Thein S, La Linn M, Aaskov J, Aung MM, Aye M, Zaw A, Myint A. Development of a simple indirect enzyme-linked mmunosorbent assay for the detection of immunoglobulin M antibody in serum from patients Following an outbreak of chikungunya virus infection in Yangon, Myanmar. Trans R Soc Trop Med Hyg. 1992 86:438-42.
5. Yamamoto K, Hashimoto K, Ogata T Structural proteins of Chikungunya virus. Simizu B, J Virol. 1984 Jul;51(1):254-8.

【INDEX OF SYMBOLS】

	Manufacturer	Σ	Tests per kit		Do not reuse
IVD	For in vitro diagnostic use only		Use by	REF	Catalog #
	Store between 4-30° C	LOT	Lot Number		Consult Instructions for Use
	Do not use if package is damaged		Caution		Keep dry
EC REF	Authorized Representative		Keep away from sunlight		Date of manufacture

Shenzhen Nodford Industrial Co., Ltd.
Bldg A, Ganghongji High-tech Intelligent Industrial Park,Nanshan District, Shenzhen, Guangdong Province,China, 518055

EC REF **Luxus Lebenswelt GmbH**
Kochstr. 1, 47877, Willich, GermanWillich, Germany

CE