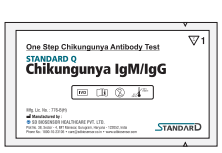
STANDARD Q
Chikungunya IgM/IgG
Rapid Kit

For *in vitro* use only

PLEASE READ BACK PAGE CAREFULLY BEFORE YOU PERFORM THE TEST

STANDARD

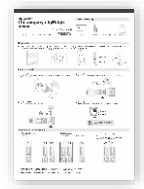
[Material Provided]



Cassette

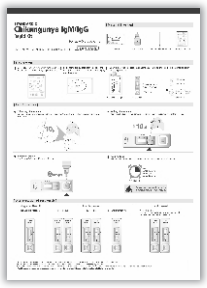
Buffer Bottle

Specimen transfer device

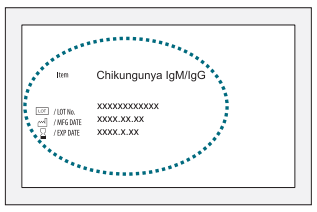

Instruction for use

[Preparation]

1 Carefully read the instruction for using the STANDARD Q Chikungunya IgM/IgG test.

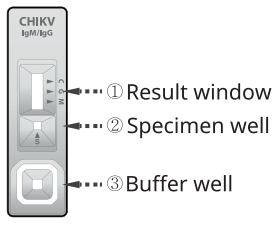


2 Look at the expiry date at the back of the cassette package. Use another lot, if expiry date has passed.

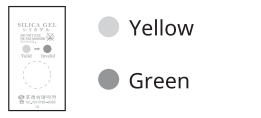


3 Open the cassette package & check the cassette and the color indicator silica gel in cassette package.

<Cassette Packaging>



<Cassette>

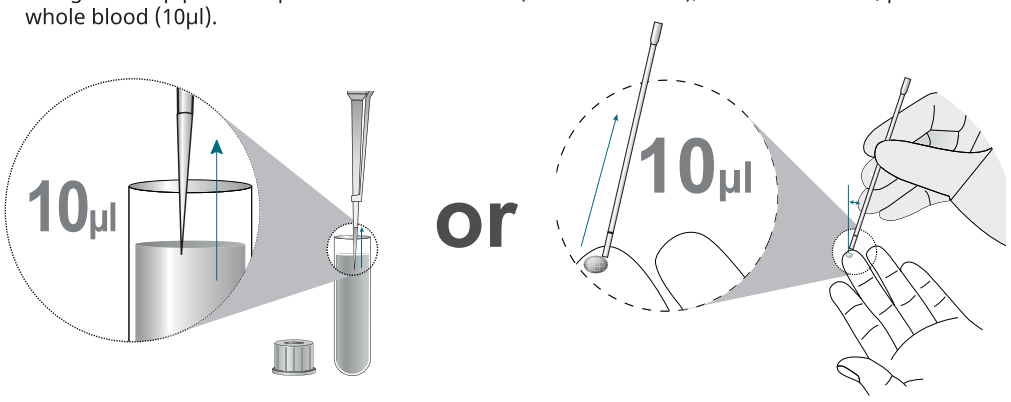


⚠ If yellow color of silica gel changes to green, do not use the cassette in the cassette package.

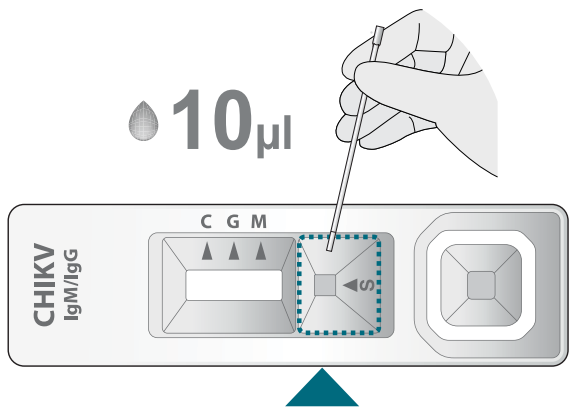
<Silica gel>

[Test Procedure]

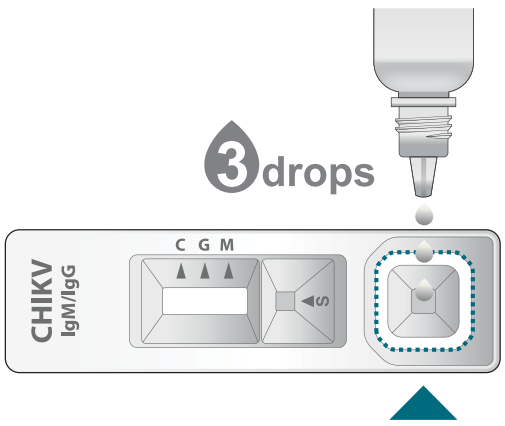
1 Collecting of Specimen
Using a micropipette or specimen transfer device(to the black line), collect the serum, plasma or whole blood (10µl).



2 Adding of Specimen
Add the collected serum, plasma or whole blood to the specimen well of the cassette.



3 Adding of Buffer
Add 3 drops (90µl) of buffer into buffer well.

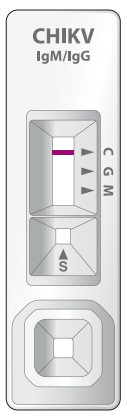


4 Reading Time
Read the test result after 15 minutes. The test can be read up to 30 minutes.

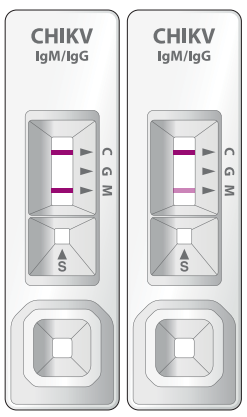
CAUTION Do not read test results after 30 minutes. It may give false results.

[Interpretation of Test Result]

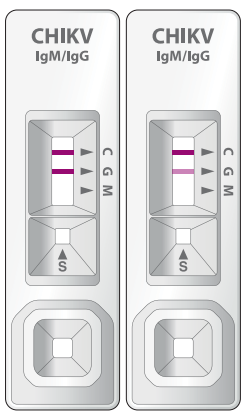
Negative Result
No Chikungunya infection



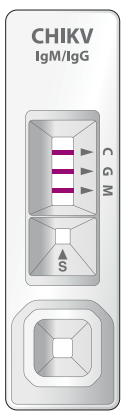
Positive result
IgM Positive



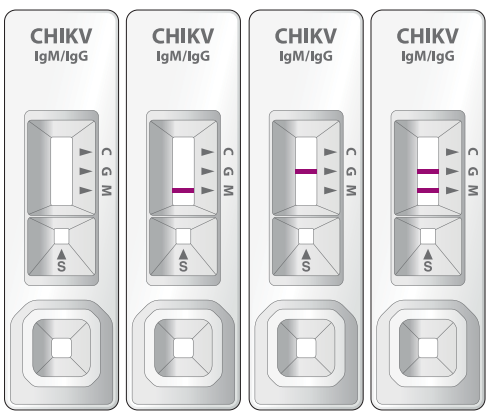
IgG Positive



IgM and IgG Positive



Invalid result
No control line.
It is recommended that the specimen should be re-tested with a new cassette.



1.A colored band will appear in the top section of the result window to show that the test is working properly. This band is control line (C).
2.A colored band will appear in the top lower section of the result window. This band is test line of IgM/IgG (M, G).
3.Even if the control line is faint, or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted as a positive result.
*** Positive results should be considered in conjunction with the clinical history and other data available to the physician.**

STANDARD Q Chikungunya IgM/IgG Test

SD BIOSENSOR

EXPLANATION AND SUMMARY

[Introduction]

Chikungunya is the arboviral disease caused by Chikungunya virus. Chikungunya virus is a genus of *alpha* virus and is transmitted by *Aedes* mosquitoes especially *Aedes albopictus* and *Aedes aegypti* are the presumed vector. Chikungunya disease does not often result in death, but the symptoms can be severe and disabling. The common symptoms of Chikungunya are fever, rash, arthralgia, and joint pain. Since some of these clinical symptoms are similar to symptoms of Dengue, Chikungunya can be misdiagnosed as Dengue in the common Dengue outbreak areas. In this state, STANDARD Q Chikungunya IgM/IgG Test provides significantly fast and easy system to identify Chikungunya infection and enables supportive definite diagnosis of Chikungunya.

[Intended Use]

STANDARD Q Chikungunya IgM/IgG Test is an immunochromatographic assay for the detection of IgM/IgG antibodies against Chikungunya virus in human serum, plasma, or whole blood specimen. This test kit is for *in vitro* use only. This is intended for professional use, only for an initial screening test.

[Test Principle]

STANDARD Q Chikungunya IgM/IgG Test Kit has "M", "G" test lines and "C" control line. Monoclonal anti-human IgM and monoclonal anti-human IgG are immobilized at two individual test lines respectively (M, G line) on the nitrocellulose membrane. The IgM line in the result window is closer to the specimen well and followed by IgG line. Inactivated Chikungunya virus in the antigen pad and monoclonal anti-Chikungunya E1-gold in the conjugate pad release by adding assay diluent and react with anti-Chikungunya IgM or IgG in patient specimen. If human anti-Chikungunya IgM or IgG exist in patient serum, plasma, capillary whole blood and venous whole blood, the individual test line appear visible band respectively forming the complex with anti-human IgM/IgG, human IgM/IgG, inactivated Chikungunya virus, and anti-Chikungunya E1-gold, which means a positive test results. The violet line at the control region should always appear if the assay is performed correctly.

MATERIALS PROVIDED

Components	
Cassette	Buffer bottle
Specimen transfer device	Instruction for use

KIT STORAGE AND STABILITY

Store the RDT box at room temperature, 2-40℃ / 36-104℉, out of direct sunlight. Material provided are stable until the expiration date printed on the RDT box. Do NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

• Serum

1. Collect the venous whole blood into the commercially available plain tube, NOT containing anti-coagulant such as heparin, EDTA and sodium citrate by venipuncture and leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
2. If serum in the plain tube is stored in a refrigerator at 2-8℃ / 36-46℉, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be at below -20℃ /-4℉.
3. They should be brought to room temperature prior to use.

• Plasma

1. Collect the venous whole blood into the commercially available anti-coagulant tube (heparin,EDTA or sodium citrate) by venipuncture and centrifuge blood to get plasma specimen of supernatant.
2. If plasma in an anti-coagulant tube is stored in a refrigerator at 2-8℃ / 36-46℉, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be at below -20℃ /-4℉.
3. They should be brought to room temperature prior to use.

[Whole Blood]

• Capillary whole blood

1. Capillary whole blood should be collected aseptically by fingertip.
2. Clean the area to be lanced with an alcohol swab.
3. Squeeze the end of the fingertip and pierce with a sterile lancet.
4. Collect the capillary whole blood by using micropipette or specimen transfer device(to the black line) for the testing.
5. The capillary whole blood must be tested immediately after collection.

• Venous whole blood

1. Collect the venous whole blood into the commercially available anti-coagulant tube (heparin, EDTA or sodium citrate) by venipuncture.
2. If venous whole blood in an anti-coagulant tube is stored in a refrigerator at 2-8℃ / 36-46℉, the specimen can be used for testing within 1-2 day after collection.
3. Do not use hemolyzed blood specimen.

CAUTION

- Anticoagulants such as heparin or EDTA do not affect the test result.
- As known relevant interference, hemolytic specimen, rheumatoid factors-contained specimen and lipaemic, icteric specimen can lead to impair the test result.
- Use separate specimen transfer device for each specimen in order to avoid cross-contamination of either specimen which can cause erroneous results.

TEST PROCEDURE

[Preparation]

1. Carefully read the instruction for using the STANDARD Q Chikungunya IgM/IgG Test.
2. Look at the expiry date at the back of the cassette package. Use another lot, if expiry date has passed.
3. Open the cassette package and check the cassette and the color indicator silica gel in cassette package.

[Test Procedure]

1. Using a micropipette or specimen transfer device(to the black line), collect the serum, plasma or whole blood (10μl).
2. Add the collected serum, plasma or whole blood to the specimen well of the cassette.
3. Add 3 drops (90μl) of buffer into the buffer well of the cassette.
4. Read the test result after 15 minutes. The test result can be read up to 30 minutes.

INTERPRETATION OF TEST RESULTS

1. Negative result: Only band ("C" Control line) within the result window indicates a negative result.
2. IgM Positive result : Two colored bands ("C" Control line and "M" Test line) within the result window indicate Chikungunya IgM positive.
3. IgG Positive result : Two colored bands ("C" Control line and "G" Test line) within the result window indicate Chikungunya IgG positive.
4. IgM & IgG positive result : Three colored bands ("C" Control line, "M" Test line & "G" Test line) within the result window indicate Chikungunya IgM & IgG positive.
5. Invalid result : If the control band ("C" control line) is not visible within the result window, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. Re-test with a new cassette

CAUTION

- Even if the control line is faint, or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted as a positive result.
- Positive results should be considered in conjunction with the clinical history and other data available to the physician.

LIMITATION OF TEST

1. The test procedure, precautions and interpretation of result for this test must be followed strictly when testing.
2. This test detects the presence of Chikungunya IgMs/IgGs in the specimen and should not be used as the sole criteria for the diagnosis of Chikungunya virus infection.
3. Test results must be considered with other clinical data available to the physician.
4. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
5. Neither the quantitative value nor the rate of anti-Chikungunya IgM/IgG concentration can be determined by this qualitative test.
6. Failure to follow the test procedure and interpretation of test result may adversely affect test performance and/or produce invalid results.

QUALITY CONTROL

[Internal Quality Control]

STANDARD Q Chikungunya IgM/IgG Kit has test line and control line on the surface of each cassette. All the test line and control line in result window are not visible before applying specimen. The control line is used for procedural control. It will appear if the test has been performed correctly and the reagents are functional. If it does not appear, the test results are not valid and the test must be repeated. In addition, good laboratory practice recommends the daily use of control materials to confirm the test procedure and to verify proper test performance.

PERFORMANCE CHARACTERISTICS

- The sensitivity and specificity of STANDARD Q Chikungunya IgM/IgG Test Total 560 specimen were evaluated for sensitivity and specificity. The STANDARD Q Chikungunya IgM/IgG Test got a high correlation with ELISA test.

Reference		STANDARD Q Chikungunya IgM/IgG(IgM)		Total Result
		Positive	Negative	
ELISA	Positive	21	0	21
	Negative	6	253	259
Total Result		27	253	280
Sensitivity and Specificity		Sensitivity: 100% (21/21) Specificity: 97.7% (253/259)		

Reference		STANDARD Q Chikungunya IgM/IgG(IgG)		Total Result
		Positive	Negative	
ELISA	Positive	21	0	21
	Negative	1	258	259
Total Result		22	258	280
Sensitivity and Specificity		Sensitivity: 100% (21/21) Specificity: 99.6% (258/259)		

WARNINGS & PRECAUTIONS

1. Do not re-use the kit.
2. Do not use the cassette if the cassette package is damaged or the seal is broken.
3. Do not use buffer bottle of another lot.
4. Do not smoke, drink or eat while handling specimen.
5. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after the tests are done.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Handle all specimens as if they contain infectious agents.
8. Observe established precautions against microbiological hazards throughout testing procedures.
9. Dispose off all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and bio- hazard wastes must be handled and discarded in accordance with all local, state and national regulations.
10. Silica gel in cassette package is to absorb moisture and keep humidity from affecting products. If the moisture indicating silica gel beads change from yellow to green, the cassette in the cassette package should be discarded.
11. For *in vitro* diagnostic use only.
12. Do not use the kit contents beyond the expiration date printed on the outside the box.
13. Immediately perform the test after removing the test device from the cassette package.
14. Discard the cassette immediately after reading result.

BIBLIOGRAPHY

1. Chikungunya, an epidemic arbovirosis, THE LANCET Infectious Diseases, Volume 7, Issue 5, May 2007, Pages 319-327.
2. World Health Organization, Media centre, Chikungunya, Fact sheet, Updated April 2016 (http://www.who.int/mediacentre/factsheets/fs327/en/)
3. Chikungunya virus: evolution and genetic determinants of emergence, Current Opinion in Virology, Volume 1, Issue 4, October 2011, Pages 310-317.
4. Structural changes of envelope proteins during alphavirus fusion. Nature. 2010, 468: 705-708. 10.1038/nature09546.
5. Individual expression of sindbis virus glycoproteins. E1 alone promotes cell fusion. Virology. 2003, 305: 463-472. 10.1006/viro.2002.1771.
6. Clinical burden of chikungunya virus infection. Lancet Infect Dis. 2008;8:2 -3.
7. Chikungunya outbreaks-the globalization of vectorborne diseases. N Engl J Med. 2007;356:769 -771.
8. Molecular and serological diagnosis of Chikungunya virus infection. Pathol Biol (Paris) 2007;55.

CAT **RK024-20**
Issue date : 2018.03

SD/024/IN/01-00

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CAT Catalogue number | Note | IVD *In vitro* Diagnostics | Consult Instructions for Use | Contains Sufficient for <n> Tests | Caution | *Do not re-use* | *To indicate the temperature limitation in which the package has to be stored* | *Date of manufacture* | *Use by* | LOT Batch code | *Manufacturer*