STANDARD Q
Dengue Ag+Ab Duo
Rapid Kit

For *in vitro* use only

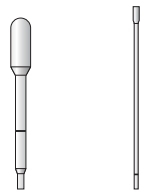
PLEASE READ BACK PAGE CAREFULLY BEFORE YOU PERFORM THE TEST

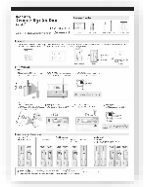
STANDARD

[Material Provided]

Cassette

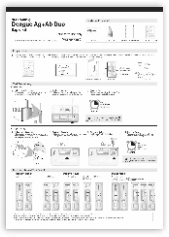
Buffer Bottle


Specimen transfer device

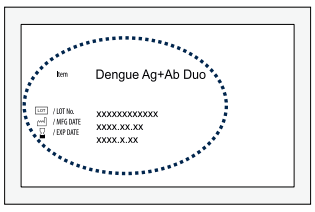

Instruction for use

[Preparation]

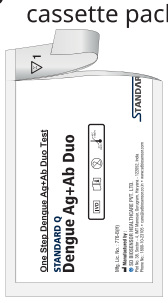
1 Carefully read the instruction for using the STANDARD Q Dengue Ag+Ab Duo test.



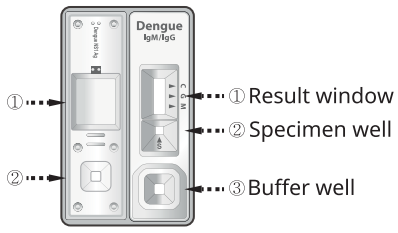
2 Look at the expiry date at the back of the cassette package. Use another lot, if expiry date has passed.



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



<Cassette Packaging>



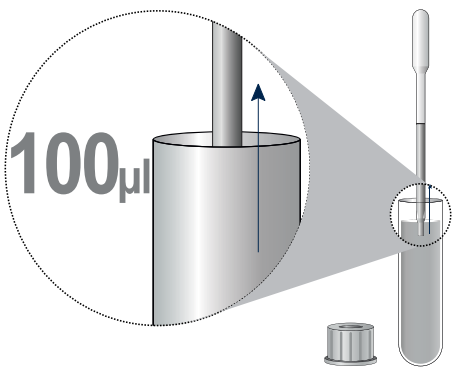
<Cassette>

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

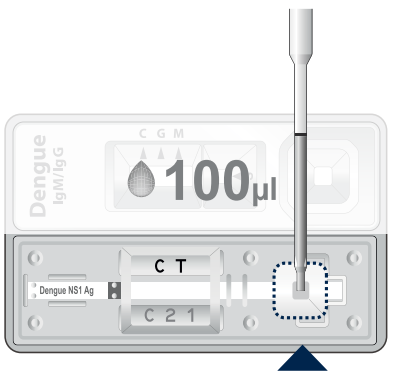
[Test Procedure]

1. Dengue NS1

1 Collecting of Specimen
Using a specimen transfer device, collect the serum, plasma or whole blood (100µl).



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

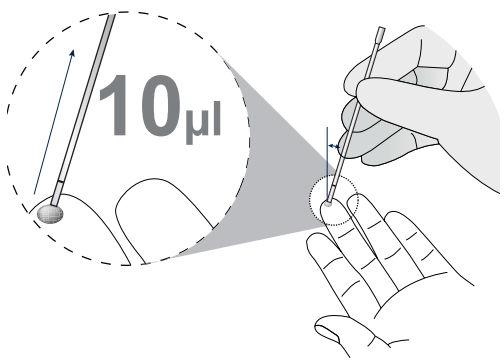


3 Reading Time
Read the test result after 15 minutes. The test can be read up to 30 minutes.

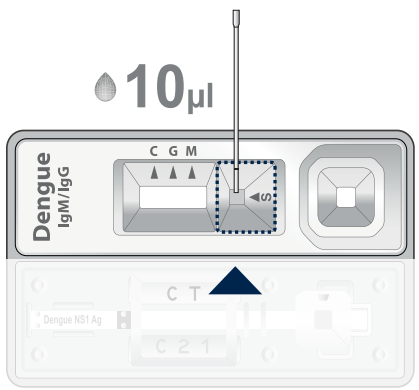
CAUTION Do not read test results after 30 minutes. It may give false results.

2. Dengue IgM/IgG

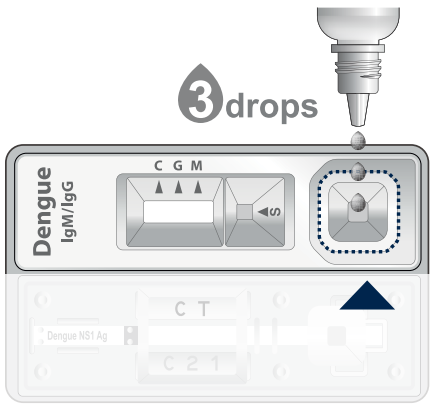
1 Collecting of Specimen
Using a specimen transfer device, collect the serum, plasma or whole blood (10µl) to the black line of the specimen transfer device.



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.

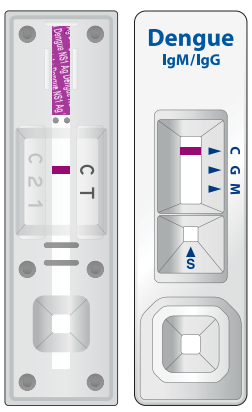


4 Reading Time
Read the test result after 15 minutes.
The test can be read up to 30 minutes.

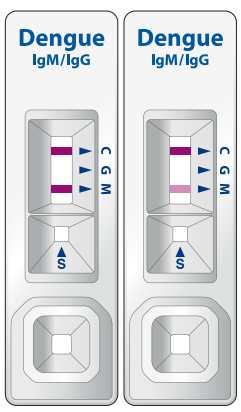
CAUTION Do not read test results after 30 minutes. It may give false results.

[Interpretation of Test Result]

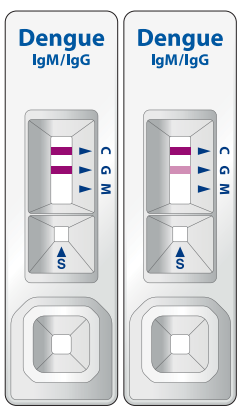
Negative Result
No Dengue infection



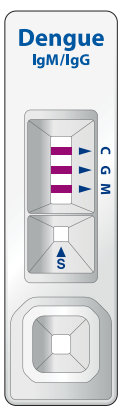
Positive result
IgM Positive



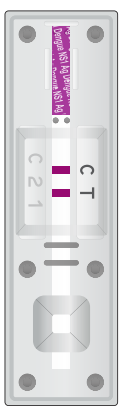
IgG Positive



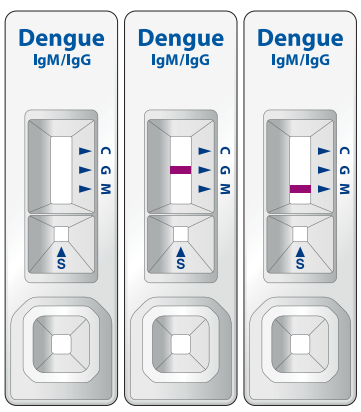
IgM and IgG Positive



NS1 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 NS1 (T) or 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.**

EXPLANATION AND SUMMARY

[Introduction]

Dengue viruses, transmitted by *Aedes aegypti* & *Aedes albopictus* mosquitoes, are widely distributed throughout the tropical and subtropical areas of the world. There are four known distinct serotypes of Dengue virus (DEN-1, DEN-2, DEN-3 and DEN-4). Rapid and reliable tests for primary and secondary infections of Dengue are essential for patient management. An infected person experiences the acute symptoms of Dengue when there is a high level of the virus in the bloodstream. As the immune response fights the Dengue infection, the person's B cells begin producing IgMs and IgGs antibodies that are released in the blood and lymph fluid, where they recognize and neutralize the Dengue virus and viral molecules such as the Dengue non-structural protein 1 (NS1) antigen.

[Intended Use]

STANDARD Q Dengue Ag+Ab Duo is an immunochromatographic assay for the detection of Dengue NS1 antigens & IgM/IgG antibodies against Dengue virus in human serum, plasma or whole blood specimen. The kit is for *in vitro* use only. This is intended for professional use only for an initial screening test.

[Test Principle]

STANDARD Q Dengue Ag+Ab Duo Kit has two cassettes. For NS1 Ag Cassette, the rapid test membrane is coated with an anti-Dengue NS1 on the test line. The specimen is added directly to the specimen well and interacts with monoclonal anti-Dengue NS1-gold in the conjugate pad. This specimen interacts with monoclonal anti-Dengue NS1-gold moves along membrane to the test line via capillary action to react with the anti-Dengue Ns1 on the test line. If NS1 antigen is present, a visible line will appear at the test line. In IgM/IgG Ab cassette, monoclonal anti-human IgM and monoclonal anti-human IgG are immobilized at two individual test lines respectively (M, G line) on the membrane. Inactivated Dengue virus in the antigen pad and anti-Dengue-env-gold in gold conjugate pad release by adding buffer and react with anti-Dengue IgM or IgG in human patient specimen. Human IgM and IgG in patient serum migrate and react with monoclonal anti-human IgM and IgG respectively on the membrane. If human anti-Dengue IgM or IgG exist in patient serum, the individual test line appear visible band respectively forming the complex with anti-human IgM/IgG, human IgM/IgG, inactivated Dengue virus, and anti-Dengue-env-gold, which means a positive test results. The visible line at the control region should always appear if the assay is performing correctly.

ACTIVE INGREDIENTS OF MAIN COMPONENT

[Materials Provided]

Components	
Cassette	Buffer bottle
Specimen transfer device	Instruction for use

[Reagents Composition]

Components	Composition (per Test)
Cassette (NS1)	• Gold conjugate : Monoclonal anti-Dengue NS1-gold (0.052± 0.0104 µg), Chicken IgY-gold (0.03± 0.006 µg) • Test line (T) : Monoclonal anti-Dengue NS1 (0.75± 0.15 µg) • Control line (C) : Monoclonal anti-Chicken IgY (0.75± 0.15 µg)
Cassette (IgM/IgG)	• Gold conjugate : Monoclonal anti-Dengue-env-gold (0.05± 0.01 µg) • Antigen Pad : Inactivated Dengue virus • Test line (M) : Monoclonal anti-human IgM (0.37± 0.074 µg) • Test line (G) : Monoclonal anti-human IgG (0.225± 0.045 µg) • Control line (C) : Goat anti-mouse IgG (0.6± 0.12 µg)

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-coagulants 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 from 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 to the black line of the specimen transfer device.
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 Dengue Ag+Ab Duo 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]

• Dengue NS1

1. Using a specimen transfer device, collect the serum, plasma or whole blood (100µl).
2. Add the collected serum, plasma or whole blood to the specimen well of the cassette.
3. Read the test result after 15 minutes. The test can be read up to 30 minutes.

• Dengue IgM/IgG

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

• For checking Dengue NS1 Ag cassette

1. Negative result: Only band ("C" Control line) within the result window indicates a negative result.
2. Positive result : Two colored bands ("C" Control line and "T" Test line) within the result window indicate Dengue NS1 positive
3. 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.

• For checking Dengue IgM/IgG Ab cassette

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 Dengue IgM positive.
3. IgG Positive result : Two colored bands ("C" Control line and "G" Test line) within the result window indicate Dengue IgG positive.
4. IgM & IgG positive result : Three colored bands ("C" Control line, "M" Test line & "G" Test line) within the result window indicate Dengue 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 Dengue NS1 and Dengue IgMs/IgGs in the specimen and should not be used as the sole criteria for the diagnosis of Dengue 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 Dengue NS1 Ag or anti-Dengue 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 Dengue Ag+Ab Duo 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 Dengue Ag+Ab Duo Test: Total 860 specimen were evaluated for sensitivity and specificity. The STANDARD Q Dengue Ag+Ab Duo kit got a high correlation with reference test (ELISA and RT-PCR).

Reference		STANDARD Q Dengue Ag+Ab Duo (NS1)		Total Result
		Positive	Negative	
RT-PCR	Positive	184	14	198
	Negative	3	222	225
Total Result		187	236	423
Sensitivity and Specificity		Sensitivity: 184/198 (92.9%) Specificity:222/225 (98.7%)		

Reference		STANDARD Q Dengue Ag+Ab Duo (IgM)		Total Result
		Positive	Negative	
ELISA	Positive	77	2	79
	Negative	12	346	358
Total Result		89	348	437
Sensitivity and Specificity		Sensitivity: 77/79 (97.5%) Specificity:346/358 (96.6%)		

Reference		STANDARD Q Dengue Ag+Ab Duo (IgG)		Total Result
		Positive	Negative	
ELISA	Positive	140	4	144
	Negative	11	282	293
Total Result		151	286	437
Sensitivity and Specificity		Sensitivity: 140/144 (97.2%) Specificity:282/293 (96.2%)		

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 of 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.

BIBLIOGRAPHY

1. Dengue guidelines for diagnosis, treatment, prevention and control, World Health Organization, New Edition 2009.
2. Kliks SC, Nimmanitya S, Nisalak A, Burke DS, Evidence that maternal Dengue antibodies are important in the development of Dengue hemorrhagic fever in infants, Am J Trop Med Hyg Jan, 38(2):411-419, 1988.
3. Dengue haemorrhagic fever: Diagnosis, treatment, prevention and control, World Health Organization 2nd Edition, 1997.
4. Ludolfs D. et al. , Serological differentiation of infections with Dengue virus serotypes 1 to 4 by using recombinant antigens, J Clin Microbiol, 40(11):4317-4320, 2002.
5. Matthew T. R. et al. Dengue virus pirates human platelets, Blood, 126(3):286-287, 2015.
6. Guzman M. G. et al. Dengue: A continuing global threat, Nat Rev Microbiol, 8:S7–S16, 2010.

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