Dengue NS1 Ag/Ab Combo Field Test Kit

(Whole Blood/Serum/Plasma)
Catalog No. WF1112F

Intend Use

The iCARE Dengue NS1 Ag/Ab Combo Field Test Kit is a rapid, serological, lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of anti-dengue virus IgM, IgG and dengue NS1 antigen (DEN1, 2, 3, 4) qualitatively in human whole blood, serum or plasma specimens. It is intended to be used by healthcare professionals as an aid in the diagnosis of infection with dengue viruses. The test only provides preliminary analysis results but not critical diagnosis criteria. Any use or interpretation of the test must be analyzed and confirmed with alternative testing method(s) and clinical findings based on professional judgment of healthcare providers.

Precautions

1. Do not use the test kit beyond the expiration date.
2. Do not use the kit if the pouch is punctured or not well sealed.
3. For in vitro use only. Do not swallow.
4. All specimens from the body should be treated as potentially infectious.
5. Contaminated blood may give incorrect test results.
6. Discard after first use. The test cannot be used more than once.

DISPOSAL: The used device has the risk of infection. Please dispose all used contents properly.

Each Kit Contains

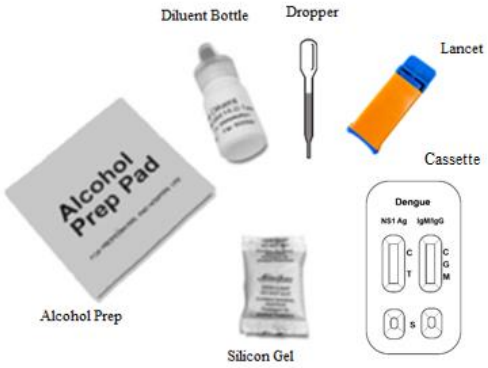
- Test cards individually foil pouched with a desiccant
- Plastic dropper
- Sample diluent
- Safety lancet
- Alcohol swab
- Package insert

Material Required But Not Provided:

Timer

Storage And Stability

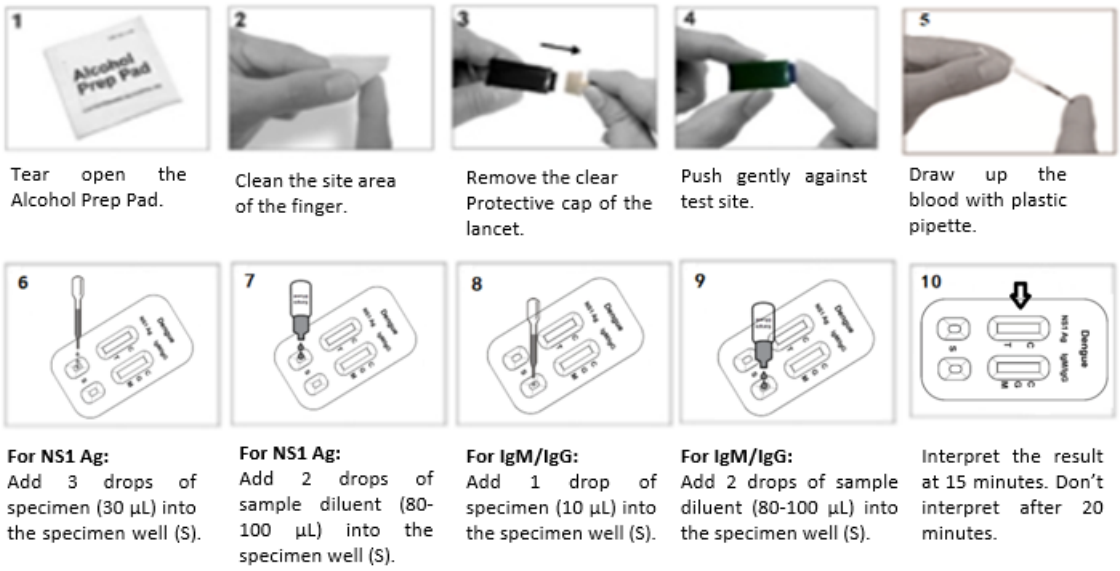
The kit must be stored at 2~30°C.



Do not open pouch until you are ready to test the sample.

Assay Procedures for Finger Blood

1. Bring the Dengue test card, sample diluent, alcohol swab, safety lancet, plastic dropper to room temperature.
2. Take out the test card from the sealed pouch.
3. To perform the test, please follow the steps closely as follow (from picture 1 to picture 10).



Tear open the Alcohol Prep Pad.

Clean the site area of the finger.

Remove the clear Protective cap of the lancet.

Push gently against test site.

Draw up the blood with plastic pipette.

For NS1 Ag:
Add 3 drops of specimen (30 µL) into the specimen well (S).

For NS1 Ag:
Add 2 drops of sample diluent (80-100 µL) into the specimen well (S).

For IgM/IgG:
Add 1 drop of specimen (10 µL) into the specimen well (S).

For IgM/IgG:
Add 2 drops of sample diluent (80-100 µL) into the specimen well (S).

Interpret the result at 15 minutes. Don't interpret after 20 minutes.

Assay Procedures at Clinics

1. Bring all reagents and specimens to room temperature.
2. Remove the test card from the foil pouch and place on a clean dry surface.
3. Identify the test card for each specimen or control.
4. For whole blood / serum / plasma testing:

4.1 For detection of dengue NS1 Antigen:

Fill the pipette dropper with the specimen. Hold the dropper vertically and transfer 3 drops of whole blood/serum/plasma specimen (approximately 30 µL) into the specimen well (S) making sure that there are no air bubbles. Then add 2 drops of sample diluent (approximately 80-100 µL) to the specimen well (S) immediately.

4.2 For detection of anti-dengue virus IgM/IgG:

Fill the pipette dropper with the specimen. Hold the dropper vertically and transfer 1 drop of whole blood/serum/plasma specimen (approximately 10 µL) into the specimen well (S) making sure that there are no air bubbles. Then add 2 drops of sample diluent (approximately 80-100 µL) to the specimen well (S) immediately.

5. Interpret test results at 15 minutes. A positive result may be interpreted early, however read any negative at 15 minutes to ensure sample is negative and not a low concentration of syphilis antibodies. Do not interpret the result after 20 minutes.

It is recommended to run a known positive control and negative control in each performance to ensure the assay procedure.

Reading The Test Results

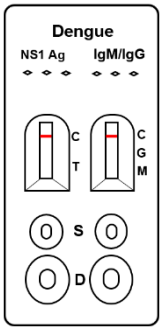
1. **NEGATIVE**: One colored line appears in the control line region (C). No colored line appears in the test line region (T, G or M lines), indicating that neither dengue NS1 antigen nor anti-dengue virus antibodies are detected. The result is negative or non-reactive.

2. **INVALID**: Control line fails to appear, the test is invalid regardless of any color in the test line region (T, G or M lines). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, stop using the test kit immediately and contact your local distributor.

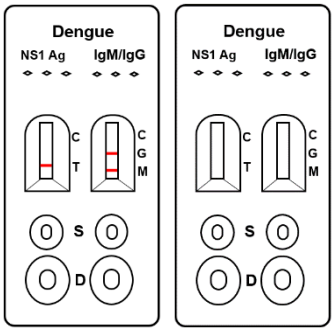
3. **POSITIVE**: Colored line(s) should be in both the control line region (C) and in the test line region (T, G and/or M lines).

NOTE: The intensity of the color in the test line region (T, G and/or M lines) will vary depending on the titer of dengue NS1 antigen or anti-dengue virus antibodies present in the specimen. Therefore, the presence of any test line, no matter how faint, within the designated observation time, indicates a positive result.

1. NEGATIVE



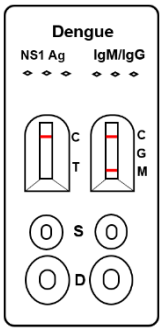
2. INVALID



3. POSITIVE

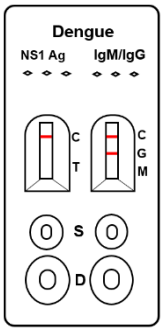
IgM

Positive



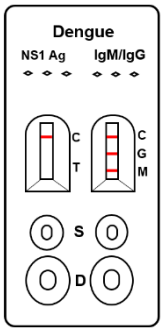
IgG

Positive



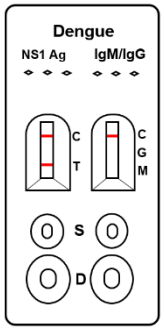
IgM/IgG

Positive



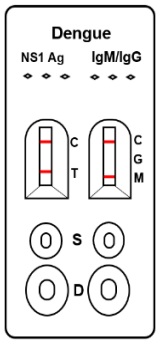
NS1 Ag

Positive



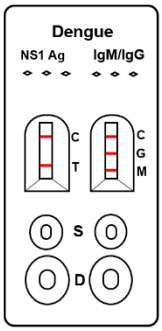
NS1 Ag/IgM

Positive



NS1 Ag/IgM/IgG

Positive



PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The iCARE Dengue NS1 Ag/Ab Combo Field Test Kit has been evaluated with a reference commercial ELISA test using clinical specimens. Test results are presented in the tables below.

Clinical performance for **Dengue NS1 Ag Test**

iCARE Dengue NS1 Ag/Ab Combo Field Test Kit	NS1 Ag ELISA Test		
	Positive	Negative	Total
Positive	117	2	119
Negative	3	278	281
Total	120	280	400

Sensitivity (Positive Percent Agreement): 97.50% = 117/120 (95% CI: 92.91%~99.15%)
Specificity (Negative Percent Agreement): 99.28% = 278/280 (95% CI: 97.43%~99.80%)
Accuracy (Overall Percent Agreement): 98.75% = (117+278)/400 (95% CI: 97.11%~99.46%)

Clinical performance for **Dengue IgM Test**

iCARE Dengue NS1 Ag/Ab Combo Field Test Kit	IgM ELISA Test		
	Positive	Negative	Total
Positive	49	1	50
Negative	1	299	300
Total	50	300	350

Sensitivity (Positive Percent Agreement): 98.00% = 49/50 (95% CI: 89.50%~99.65%)
Specificity (Negative Percent Agreement): 99.66% = 299/300 (95% CI: 98.14%~99.94%)
Accuracy (Overall Percent Agreement): 99.42% = (49+299)/350(95% CI: 97.94%~99.84%)

Clinical performance for **Dengue IgG Test**

iCARE Dengue NS1 Ag/Ab Combo Field Test Kit	IgG ELISA Test		
	IgG Positive	Negative	Total
IgG Positive	39	0	39
IgG Negative	1	260	261
Total	40	260	300

Sensitivity (Positive Percent Agreement): 97.50% = 39/40 (95% CI: 87.12%~99.56%)
Specificity (Negative Percent Agreement): 100% = 260/260 (95% CI: 98.54%~100%)
Accuracy (Overall Percent Agreement): 99.66% = (39+260)/300(95% CI: 98.14%~99.94%)

Limitations

1. As it is with any diagnostic procedure, a confirmed diagnosis should only be made after all clinical and laboratory findings have been evaluated.
2. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of syphilis antibody.

If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of syphilis infection.

Bibliography

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