HI-Quik Dengue Combo (NS1+IgG/IgM) Rapid Card Test

For *In-Vitro* Diagnostic Use Only Store at 4°C to 30°C

INTENDED USE

Dengue Combo test is an immunochromatographic assay for the qualitative Detection of NS1 Antigen and IgM/IgG Antibodies to Dengue virus in human serum/plasma.

PRINCIPLE

A) Dengue NS1 Antigen Test: After **addition of the serum or plasma sample** to the sample well of the device containing a test strip, the sample moves on to the gold conjugate pad containing colloidal gold particles conjugated with Dengue NS1 antigen specific antibodies and rabbit IgG. If the sample contains detectable levels of the Dengue NS1 antigens it reacts with the gold conjugated Dengue NS1 antibodies to form a complex. This complex along with unbound gold particles moves on nitrocellulose membrane. The complex reacts with Dengue NS1 antibodies coated on nitrocellulose membrane at test side to form a colored band (Test Line). The unbound complex, unbound gold conjugate particles and the rabbit IgG conjugated colloidal gold particles move further to the goat anti-rabbit IgG coated control area to form a colored band (Control line). The appearance of test line and control line in respective area indicates the positive result. Appearance of only control line indicates a negative result. The control line acts as a procedural control. Control line should always appear if the test is performed as per the procedure and reagents are working properly.

B) Dengue IgM/IgG Test: After **addition of the serum or plasma and the assay buffer** to the sample well of the device containing a test strip, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with recombinant Dengue specific antigens and streptavidine. If the sample contains detectable levels of the Dengue specific IgM and IgG antibodies, it reacts with the gold conjugated recombinant Dengue specific antigens to form a complex. This complex moves further and Dengue specific IgM antibodies conjugate complex reacts with anti-human IgM test line and the Dengue specific IgG antibodies react with the anti-human IgG antibodies test line on the nitrocellulose membrane area to form colored band/s. The unbound complex and the Streptavidine conjugated colloidal gold particles move further to the Biotin coated control area to form a colored band (Control line). The appearance of test line/s and control line in respective area indicates the positive result. Appearance of only control line indicates a negative result. The control line acts as a procedural control. Control line should always appear if the test is performed as per the procedure and reagents are working properly.

Please read all the information in this package insert before performing the test.

- ✓ Do not use after the expiration date printed on the foil pouch.
- ✓ Store in the sealed pouch in a dry place at 4°C to 30°C. Do not freeze.
- ✓ Do not use if pouch is torn or damaged.
- ✓ Do not open the foil pouch until you are ready to start the test.
- ✓ Do not reuse the test device.
- ✓ Dispose of hygienically in domestic waste.
- ✓ Do not touch the membrane.
- ✓ Keep out of the reach of children.
- ✓ For in vitro diagnostic use. Not to be taken internally.
- ✓ Do not eat the desiccant in the package.

CONTENTS OF KIT

1. Test Device & Silica Gel in pouch 2. Package Insert 3. Assay Buffer for Dengue IgG/IgM 4. Plastic dropper for Dengue NS1 5. Plastic Dropper for Dengue IgM/IgG

MATERIALS NEEDED BUT NOT PROVIDED

1. Timer 2. Sample container 3. Micro pipette

SPECIMEN COLLECTION

1. Testing should be performed as early as possible after collection. Do not leave serum/Plasma at room temperature for prolonged periods.
2. The samples may be stored at 2°C to 8°C for up to 7 days or frozen at -20°C or lower for up to 30 days.

TEST PROCEDURE

A) For Dengue NS1 Antigen Test:

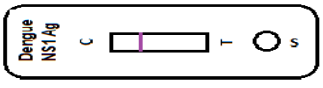
1. Allow the Test Device and sample reach to room temperature (20°C to 30°C) before opening the foil pouch.
2. Remove the Test Device and plastic Dropper from the pouch and use the test as early as possible.
3. Add two drops (i.e. approximately 90 µl) of serum or plasma sample in well 'S'.
4. Set the timer for 15 minutes.
5. Read the result at 15 minutes. Do not read the result after 20 minutes.

B) For Dengue IgM/IgG Test:

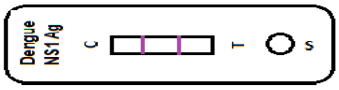
1. Allow the Test Device and sample reach to room temperature (20°C to 30°C) before opening the foil pouch.
2. Remove the Test Device and plastic Dropper from the pouch and use the test as early as possible.
3. Add 1 drop (10 µl of) serum or plasma sample in well 'S' and add two drops of assay buffer in well 'B'.
4. Set the timer for 15 minutes.
5. Read the result at 15 minutes. Do not read the result after 20 minutes.

INTERPRETATION OF RESULTS

For Dengue NS1 Antigen Test: Negative: If pink-red colored line appears at the control side 'C' only.



Positive: If colored lines appear at the control side 'C' and the test side "T".

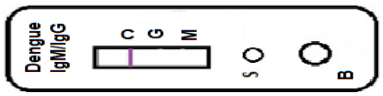


Invalid: The test should be considered invalid if "C" LINE does not appear.

NOTE: *The intensity of the pink red color at the test line side (T) will vary depending upon the concentration of dengue virus NS1 antigen in specimen.*

B) For Dengue IgM/IgG Test:

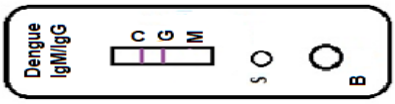
Negative:If pink-redcolored line appears at the control region 'C' only.



IgM Positive :A distinct colored line appears at the control region 'C' and at the test region 'IgM'.

IgG & IgM Positive:A distinct colored line appears at the control region 'C' and at the test region 'IgM'and 'IgG'.

IgG Positive: A distinct colored line appears at the control region 'C' and at the test region 'IgG'.



Invalid: The test should be considered invalid if "C" LINE does not appear

NOTE: *The intensity of the pink red color in the test line region will vary depending upon the infection.*

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal valid procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

PERFORMANCE CHARACTERISTICS

Internal Evaluation:

Dengue NS1: In an in-house study, total 275 samples were evaluated for sensitivity and specificity. We found the relative sensitivity was 100 % (i. e. 125/125) and the relative specificity was 100 % (i. e. 150/150). The results are summarized in the following table:

Sample	Total Number of samples tested	Rapid Dengue NS1 antigen Test		Sensitivity (%)	Specificity (%)
		Positive	Negative		
Dengue NS1 antigen positive serum Samples	100	100	0	100	-
Dengue NS1 antigen positive plasma Samples	25	25	0	100	-
Negative Human Serum Samples	100	0	100	-	100
Negative Human Plasma Samples	50	0	50	-	100

Cross reactivity was studied using Malaria Pf antigen positive blood samples, Malaria Pv antigen positive blood samples, no cross reactivity was observed.

Dengue IgG/IgM : In an in-house study, total 125 samples were evaluated for sensitivity and specificity. We found the relative sensitivity was 100 % (i. e. 50/50) and the relative specificity was 100 % (i. e. 75/75). The results are summarized in the following table:

Sample	Total Number of samples tested	Rapid Dengue IgM/IgG Test		Sensitivity (%)	Specificity (%)
		Positive	Negative		
Dengue IgM/IgG positive serum Samples	25	25	0	100	-
Dengue IgM/IgG positive Plasma Samples	25	25	0	100	-
Negative Human Serum Samples	50	0	50	-	100
Negative Human Plasma Samples	25	0	25	-	100

REFERENCES

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