ImmunoScience INDIA

ImmunoQuick

Dengue Combo (Ag + Ab)

Rapid Dengue Combo Test (Ag + Ab) - Device

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

INTENDED USE
ImmunoQuick Dengue Combo (Ag + Ab) test is an immunochromatographic assay for the qualitative detection of non- structural protein 1 (NS1) antigen and IgG/IgM Antibodies to Dengue virus in human serum/plasma.

PRINCIPLE
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 move 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.

Dengue IgG/IgM 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 Dengue specific recombinant antigens and streptavidin. If the sample contains detectable levels of the Dengue specific IgM and/ or IgG antibodies, it reacts with the gold conjugated Dengue specific recombinant antigens to form a complex. This complex moves further and Dengue specific IgM antibodies conjugate complex reacts with anti-human IgM antibodies (IgM test line) and the Dengue specific IgG antibodies react with the anti-human IgG antibodies (IgG test line) on the nitrocellulose membrane area to form colored band (test band)/s. The unbound complex and the Streptavidin 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.

CONTENTS OF KIT
1. Test Device
2. Package Insert
3. Desiccant pouch(Silica gel)
4. Assay Buffer (For Dengue IgG/IgM Test)
5. Plastic Dropper for Dengue NS1 Test
6. Plastic dropper/plastic capillary tube for Dengue IgG/IgM Test

OPTIONAL MATERIAL REQUIRED
1. Stop Watch
2. Sample container
3. Micropipette
4. Disposable gloves

PRECAUTIONS/KIT STORAGE AND STABILITY
1. Please read all the information in this package insert before performing the test. Pay particular attention to the position of the Control and Test lines.
2. Do not use after the expiration date printed on the foil pouch.
3. Store in the sealed pouch in a dry place in between temperature 4° C to 30° C. Do not freeze.
4. Do not use the test if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of the reach of children.

WARNINGS
1. Do not reuse the test.
2. Follow the instructions to get accurate results.
3. Use appropriate personal protective equipments.
4. Dispose off hygienically in Biohazard waste.
5. Do not touch the membrane.
6. Treat samples and used test as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the specimen sample or interchange the different specimen.
10. The manufacturer and distributor of this product shall not be liable for any loses, liability, claims, costs or damages whether direct or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

SPECIMEN COLLECTION
1. Testing should be performed as early as possible after collection. Do not leave serum/Plasma samples at room temperature for prolonged periods.

TEST PROCEDURE
1. Allow the Test Device, Assay Buffer and sample reach to room temperature (20°C to 30°C) before opening the foil pouch.
2. Remove the test and desiccant (Silica gel) from the pouch and check the Colour of desiccant pouch.It should be blue, if it has turned colorless or pink, discard the test and use another test.
3. Once opened, the test must be used immediately.

I] For Dengue NS1 Antigen Test:
i. Add two drops (approx. 90 µl) of serum or plasma sample in well 'S' by using Plastic Dropper.
ii. Start the timer.
iii. Read the result at 15 minutes. Do not read the result after 20 minutes.

II] For Dengue IgG/IgM Test:
i. Tighten the vial cap of the assay buffer bottle provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.
ii. Add 1 drop (10 µl) of serum or plasma sample using plastic dropper in well 'S'.

OR

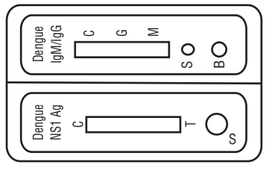
Draw the serum or plasma sample up to the mark using plastic capillary tube and add into the well 'S'.

OR

Alternatively, 10 µl of serum or plasma sample may be delivered using micropipette in well 'S'.

iii. Immediately dispense two drops (approx. 60 µl) of assay buffer in well 'B'.
iv. Start the timer.
v. Read the result at 15 minutes. Do not read the result after 20 minutes.

INTERPRETATION OF RESULTS

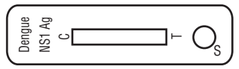


For Dengue NS1 Antigen Test:

Negative : If the colored line appears at the control side 'C' only.

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

Invalid : The test should be considered invalid if,
A) No line appear at 'C' and 'T' side.

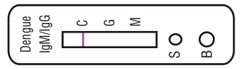


B) No line appear at 'C' side and line appear only at 'T' side

NOTE: The intensity of the color of test band (T) will vary depending upon the concentration of dengue NS1 antigen in specimen.

For Dengue IgG/IgM Test:

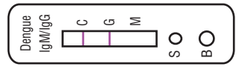
Negative : If the colored line appears at the control region 'C' only.



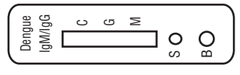
Positive for dengue IgG and IgM : In addition to the control band, two colored bands appear at regions 'IgG' and 'IgM' in the test window.

Positive for dengue IgM : In addition to the control band, one colored band appears only at region 'IgM' in the test window.

Positive for dengue IgG : In addition to the control band, one colored bands appears only at region 'IgG' in the test window.

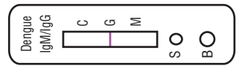


Invalid: The test should be considered invalid if,
A) No line appears at 'C', 'IgM' and 'IgG' regions.

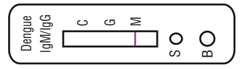


B) No line appears at 'C' region and line appear at 'IgM' and 'IgG' regions.

C) No line appears at 'C' and 'IgM' regions and line appear at 'IgG' region.



D) No line appears at 'C' and 'IgG' regions and line appear at 'IgM' region.



NOTE: The intensity of the color at respective test region will vary depending upon concentration of respective antibody in the sample.

PERFORMANCE CHARACTERISTICS
Internal Evaluation (For Dengue NS1 Antigen Test):
In an in-house study, total 270 samples were evaluated for sensitivity and specificity. We found the relative sensitivity was 100 % (i. e. 70/70) and the relative specificity was 100 % (i. e. 200/200).

The results are summarized in the following table:

Sample	Total Number of Samples Tested	Rapid Dengue Combo Test (Ag+Ab) Device - Dengue NS1 Ag Test		Sensitivity (%)	Specificity (%)
		Positive	Negative		
Dengue NS1 Antigen Positive Serum Sample	50	50	0	100	-
Dengue NS1 Antigen Positive Plasma Sample	20	20	0	100	-
Negative Human Serum Sample	100	0	100	-	100
Negative Human Plasma Sample	100	0	100	-	100

External Evaluation (For Dengue NS1 Antigen Test):
In an external study, total 150 samples were evaluated for sensitivity and specificity. Relative sensitivity was 100 % (i. e. 50/50) and the relative specificity was 100 % (i. e. 100/100). Positive Predictive Value (PPV) and Negative Predictive Value (NPV) for the test was 100 %.

The results are summarized in the following table:

Sample	Total Number of Samples Tested	Rapid Dengue Combo Test (Ag+Ab) Device - Dengue NS1 Ag Test		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
		Positive	Negative				
Positive Sample	50	50	0	100	-	100	-
Negative Sample	100	0	100	-	100	-	100

Internal Evaluation (For Dengue IgG/IgM Test):

In an in-house study, total 270 samples were evaluated for sensitivity and specificity. We found the relative sensitivity was 100 % (i. e. 70/70) and the relative specificity was 100 %. (i. e. 200/200).

The results are summarized in the following table:

Sample	Total Number of Samples Tested	Rapid Dengue Combo Test (Ag+Ab) Device - Dengue IgG/IgM Test		Sensitivity (%)	Specificity (%)
		Positive	Negative		
Dengue IgG/IgM Positive Serum Sample	50	50	0	100	-
Dengue IgG/IgM Positive Plasma Sample	20	20	0	100	-
Dengue IgG/IgM Negative Serum Sample	100	0	100	-	100
Dengue IgG/IgM Negative Plasma Sample	100	0	100	-	100

External Evaluation (For Dengue IgG/IgM Test):

In an external study, total 160 samples (60 Positive and 100 Negative) were evaluated for sensitivity and specificity. Relative sensitivity was 100 % (i. e. 60/60) and the relative specificity was 100 % (i. e. 100/100). Positive Predictive Value (PPV) and Negative Predictive Value (NPV) for the test was 100 % .

The results are summarized in the following table:

Sample	Total Number of Samples Tested	Rapid Dengue Combo Test (Ag+Ab) Device - Dengue IgG/IgM Test		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
		Positive	Negative				
Dengue IgG Positive Sample	30	30	0	100	-	100	-
Dengue IgM Positive Sample	30	30	0	100	-	100	-
Dengue Negative Sample	100	0	100	-	100	-	100

LIMITATIONS

This test provides presumptive diagnosis of Dengue. A confirmed Dengue diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

DISCLAIMER

The all precaution shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results.

REFERENCES

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6. Innis BL, and Nisalak A, et al: An enzyme-linked immunosorbent assay to characterize dengue infections where denude and Japanese encephalitis co-circulate. Am. J. Trap. Med. Hygiene. 1989: 40: 418-427.

IVD	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
LOT	Lot Number
30°C 4°C	Store at 4°C to 30°C
	Single Use
Σ	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
i	Read package insert before use

MANUFACTURED BY

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