OXALIS
Diagnostics Pvt. Ltd.

Rapichek
Dengue Combo (Ag + Ab)

Rapid Dengue NS1 Antigen and Dengue IgM/IgG Antibody Detection Test. Detection of Dengue NS1 Ag & differential detection of IgM & IgG antibodies in Human Serum/Plasma

INTRODUCTION

Dengue is a major health concern in many tropical and subtropical countries in the world. The accurate efficient diagnosis of primary dengue infection is important for clinical care and surveillance. A specific test is needed to confirm infection during the acute phase primary infections. Dengue is an enveloped flavivirus with 3 structural (c,pr M and E) and 7 nonstructural proteins (NS1, NS2, NS2B, NS, NS4A, NS4B, and NS5).

INTENDED USE

Dengue Combo (Ag+Ab) is a rapid qualitative immuno chromatographic test for the detection of Dengue NS1 Antigen & differential detection of IgM & IgG antibodies to dengue virus in human Serum/ Plasma. This test is for in vitro diagnostic use only and is intended as an aid in the earlier diagnosis of dengue infection & presumptive diagnosis between primary and secondary dengue infection.

PRINCIPLE

Dengue Combo (Ag+Ab) test device consist of two devices; one device for detection of Dengue NS1 antigen and second device for the differential detection of Dengue IgM/IgG antibodies in human Serum/ Plasma. Dengue NS1 antigen device contains two lines; "C" (Control Line) & "T" (Dengue NS1 Antigen Test Line), Test line is coated with antibodies, anti-dengue NS1 Ag. When a sample is added to the device, dengue NS1 antigen if present in the sample will bind to the anti- dengue NS1 conjugate making antigen antibodies complex. This complex migrates along the membrane to the test region and forms the visible line at "T" as antigen - antibody complex.

Dengue IgM/IgG test device contains three lines; "C" (Control Line), "M" (IgM test line) & "G" (IgG test line). IgM test line is coated with anti-human IgM and IgG test line is coated with anti-human IgG. When a sample is added to the device, IgM and IgG antibodies in the sample react with particles coated with dengue proteins. As this sample/ particle mixture migrates along the length of the test, the anti-dengue IgM or IgG antibody particle complex is captured by relevant IgM and / or IgG test bands located in the test device causing a color band/ s to form at IgM or IgG region of the test device window. The intensity of the test bands in the device will vary depending upon the amount of antibody present in the sample. The appearance of colour in a specific test region should be considered as positive for the particular antigen and / or antibody. A procedural control line should always develop in the test device window to indicate that the test has been performed properly. This test is intended for professional use and must be used by trained person.

MATERIALS PROVIDED

Dengue Combo (Ag+ Ab) test kit contains the following items to perform the assay.

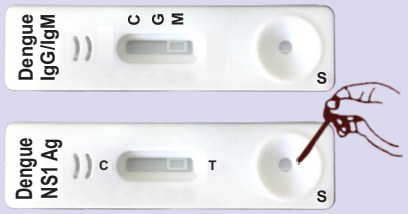
1. Dengue NS1 Ag & IgM/ IgG Ab combo test device packed with desiccant.
2. Antibody Buffer Solution
3. Product insert
4. Sample applicator for Dengue NS1 Ag & IgM/IgG Ab

Rapichek Combo (Ag+Ab) Test Procedure

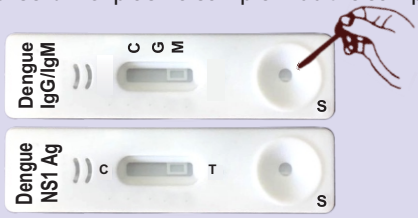
1. FIRST read carefully the Product Insert for how to use the Rapichek Dengue Combo (Ag+Ab) Kit.
2. Now open the kit and look for the following
   i) ComboTest device foiled pouch with a desiccant
   ii) Sample applicator for Dengue NS1 Ag & IgM/IgG Ab
   iii) Product Inserts
   iv) Buffer Solution (For Antibody test)
3. Next, look at the expiry date at the back of the pouch. Use another kit, if expiry date has passed. Open the pouch and look for the following.

COMBO TEST DEVICE

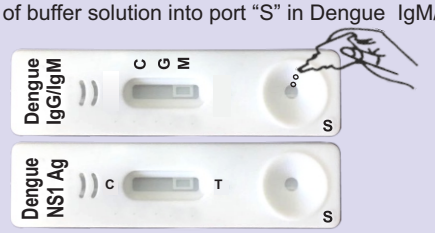
4. **For Dengue NS1 Ag Test**
   Add 2 drops (Approx. 40µl) of Serum/Plasma into Port "S" in Dengue NS1 device.



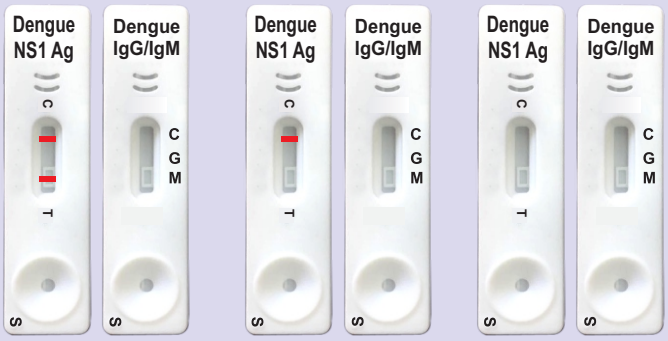
5. **For Dengue IgM/IgG Ab Test**
   Insert the sample applicator in the serum or plasma sample and fill the sample upto the notch of sample applicator. This will deliver Approx. 5 µl of serum or plasma sample. Add the sample in well "S".



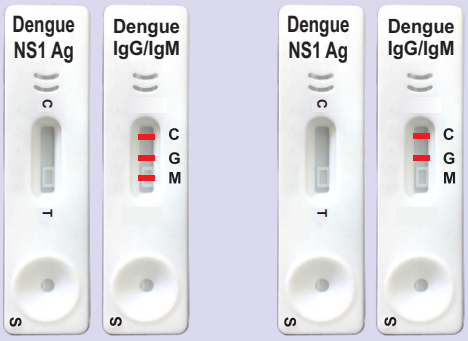
Add 2 drops of buffer solution into port "S" in Dengue IgM/IgG Device



6. **INTERPRET TEST RESULTS AT THE END OF 15 MINUTES**
   Caution : Do not read test results after 20 minutes, since it may give incorrect results.
7. **Interpretation of Test Results**
   A. For Dengue NS1 Ag Test
   NOTE : Do not consider the result if 'C' line does not appear.

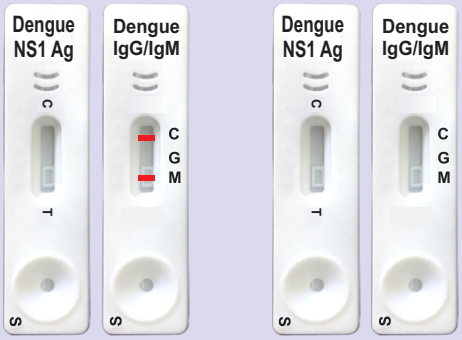


B. For Dengue IgM/IgG Test



DENGUE IgM/IgG POSITIVE

DENGUE IgG POSITIVE



DENGUE IgM POSITIVE

DENGUE IgM/IgG INVALID

KIT STORAGE AND STABILITY

1. The test device should be stored at 2°C to 40°C. DO NOT FREEZE.
2. The test device is sensitive to humidity as well as to heat.
3. Do not use the test device beyond expiration date. Expiration date of this kit is as indicated on the kit cartons as well as on the individual pouches.
4. Do not use the kit if the pouch is damaged or the seal is broken.
5. Do not re-use test device.

SPECIMEN COLLECTION, STORAGE & PRECAUTION

Plasma or Serum

I. **Plasma :** Collect the whole blood into the collection tube (containing anticoagulants such as EDTA ,Heparin or Qxalate by venipuncture and then centrifuge blood to get plasma specimen.

II. **Serum :** Collect the whole blood in to the collection tube (Not containing anticoagulants) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum.

Note :

If the plasma or serum specimens are not tested immediately, they should be refrigerated at 2-8°C.(For storage period more than 2 weeks, freezing is recommended. The samples should be brought to room temperature (20-30°C) prior to use.

Plasma or serum specimen containing precipitate may yield inconsistent test results. Such specimen must be clarified prior to assaying.

LIMITATIONS OF THE TEST :

1. The test is for *In Vitro Diagnostic Use* only.
2. This detects the presence of Dengue NS1 antigen & IgM & IgG antibodies to dengue virus in the specimen and should not be used as a sole criteria for diagnosis of dengue virus infection.
3. Serological cross-reacivity across the flavivirus group(Dengue virus, St.Louis encephalitis,Japanese encephalitis,West Nile and Yellow fever virus)is common.
4. As with diagnostic tests, all results must be correlated with other clinical findings. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of an early infection of dengue virus.
5. This is qualitative and only a screening test. Therefore, isolation of virus, antigen detection in fixed tissues. RT - PCR and serological tests like haemagglutination inhibition test, more specific alternative diagnosis method must be used in order to obtain a confirmation of dengue virus infection.

PERFORMANCE CHARACTERISTICS

(A)The **Dengue NS1 Antigen** rapid detection test kit has been tested with **NS1** positive and negative clinical samples confirmed by ELISA. The results obtained are as follows :

Sr. No.	Sample Type	Total No.of Samples Confirmed by ELISA	Test Results of **Rapichek Dengue NS1 Ag Rapid Detection Test**		Sensitivity (%)	Specificity (%)
			NS1 Positive	NS1 Negative		
1	NS1 Positive	52	51	1	98.08	-
2	NS1 Negative	190	0	190	-	100

(B)The **Dengue IgM/IgG Antibody** rapid detection test kit has been tested with Dengue positive and negative clinical samples confirmed by ELISA. The results obtained are as follows :

Sr. No.	Sample Type	Total No. of Samples Confirmed by ELISA	Test Results of **Rapichek Dengue IgM & IgG (Ab) Rapid Detection Test**			Sensitivity (%)	Specificity (%)
			IgM Positive	IgG Positive	IgM/IgG Negative		
1	Dengue IgM Positive	86	84	0	2	97.67	-
2	Dengue IgG Positive	66	0	65	1	98.48	-
3	Dengue IgM/IgG Negative	237	0	0	237	-	100

References

1 Alcons S., Talarmin A, Debruyne M.,Falconor V., Flamand M 2002, Enzyme-linked immunosorbent assay specific to dengue virus type 1 non structural protien Ns1 reveals circulation of the antigen in the blood during acute phase of disease in patients experiencing primary or secondary infectionsJ.Clin,Microbiol40:376-381

2 Kumarswamy V.Wahab AH, Chua SK, Hassan Z, Chem YK, etl.: Evaluation of a commercial dengue NS1 antigen-capture ELISA for laboratory diagnosis of acute dengue virus infection. J Virol Methods 2007,140:75-79.

Disclaimer :

Every precaution has been taken to ensure the diagnostic ability and accuracy of this product. This product is used outside of the control of the manufacturer and the distributor and the result may accordingly be affected by environmental factors and or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

Warning :

The Manufactures and Distributors of this product shall not be liable for any loses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

Marketed By :

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