

VISITECT® DENGUE ^{Ref} OD136

Rapid test for detection of Dengue IgG and IgM antibodies In Human Serum, Plasma or Whole Blood

Store at 4°C to 30°C. DO NOT FREEZE.
For in-vitro diagnostic use only.

INTRODUCTION AND INTENDED USE

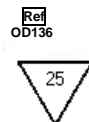
The Dengue fever virus (serotypes 1-4) belongs to the family of Flaviviridae, and has been reported in over 100 tropical and subtropical regions of the world threatening two fifths of the world's population. Dengue virus infection is considered significant in terms of morbidity, mortality and economic cost associated with the estimated 100 million cases of dengue fever occurring annually throughout the world. Dengue virus is transmitted by the day-biting urban species mosquitoes *Aedes aegypti* and *Aedes albopictus*. Dengue presents typically as a fever of sudden onset with headache, retroorbital pain, pain in the back and limbs (break-bone fever), lymphadenopathy and maculopapular rash. Patients diagnosed with dengue infection in endemic areas generally have secondary infection, whereas patients in non-endemic areas are usually diagnosed with primary infection. Specific antibody response to Dengue virus enables serodiagnosis and differentiation between primary and secondary dengue infections and detection of potentially life threatening conditions such as Dengue Haemorrhagic Fever (DHF) and Dengue Shock Syndrome (DSS).

VISITECT DENGUE is a rapid point - of - care, qualitative immunochromatographic test for the simultaneous detection of IgM and IgG antibodies to all four Dengue virus serotypes in human serum or plasma or whole blood within 20 minutes. The test can be used as a screening test for Dengue viral infection and as an aid for differential diagnosis of the self-limiting primary Dengue infections and the potentially fatal secondary Dengue infections in conjunction with other criteria. **VISITECT DENGUE** is a rapid Immunochromatographic test using highly specific immunodominant recombinant antigens from the Dengue virus envelope 'Env.' As an aid to differential diagnosis of Dengue virus infection. For professional use only.

PRINCIPLE OF THE TEST

VISITECT DENGUE utilizes the principle of Immunochromatography, a two site, self-performing immunoassay on a membrane. Monoclonal anti human IgM and monoclonal anti human IgG antibody are immobilized on nitrocellulose membrane as two individual test bands labelled G (IgG) and M (IgM) within the test window. As the test sample flows along the membrane assembly within the test device, the recombinant dengue virus envelope coated colloidal gold conjugate binds with specific antibodies (IgG and/or IgM) to Dengue virus, if they are present in the sample. This complex moves along the membrane to the test region where it is immobilized by the Monoclonal anti human IgG antibody and/or the monoclonal anti human IgM antibody coated on the membrane leading to formation of a red coloured band, which confirms a positive test result. Absence of these red bands indicates a negative test result. A procedural red control band in the Control region (C) appears when the test has been performed correctly as rabbit anti dengue IgG coated colloidal gold conjugate binds with anti rabbit IgG antibody which is immobilized on the nitrocellulose membrane, regardless of the presence or absence of anti-Dengue virus antibodies in the specimen and serves to validate the test performance.

CONTENTS



Test	Device
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Comprising of membrane assembly pre-dispensed with immunodominant recombinant dengue virus envelope protein coated colloidal gold conjugate and rabbit anti dengue IgG coated colloidal gold conjugate. Monoclonal anti human IgG at test region G. Monoclonal anti human IgM at test region M and anti rabbit IgG antibody at the control region 'C'.
Desiccant Bag

Buf	5 ml
Diluent Buffer. Solution of phosphate buffer.	

Capillary pipette (10µl volume indicated by black line).	25
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INSTRUCTION LEAFLET	1
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MATERIAL REQUIRED BUT NOT PROVIDED

Microtitre pipette (10µl)

PRECAUTIONS

VISITECT reagents do not contain dangerous substances as defined by current UK Chemicals (Hazardous Information and Packaging for Supply) regulations. All reagents should, however, be treated as potential biohazards in use and disposal. Final disposal must be in accordance with local legislation. Do not ingest.

VISITECT DENGUE. Diluent buffer contains 0.095% sodium azide as a preservative which may be toxic if ingested. Sodium azide may react with lead and copper plumbing to form highly explosive salts. On disposal, flush with large quantities of water.

STORAGE

Reagents must be stored at temperatures between 4°C to 30°C.

The kit will perform within specification until the stated expiry date as determined from date of product manufacture and stated on kit and components. Expiry date is the last day of the month on the pouch and the kit label. Do not use reagents after the expiry date.

Exposure of reagents to excessive temperatures should be avoided. Do not expose to direct sunlight.

DO NOT FREEZE DEVICE as this will cause irreversible damage.

SPECIMEN COLLECTION AND PREPARATION

Serum: Obtain a sample of venous blood from the patient and allow a clot to form and retract. Centrifuge clotted blood sample and collect clear serum. Fresh serum samples are required.

Serum may be stored at 2°C to 8°C for up to 48 hours prior to testing. If longer storage is required, store at -20°C for up to 6 weeks. A thawed sample must be mixed to ensure homogeneity prior to testing.

Do not repeatedly freeze-thaw specimens as this will cause false results.

Plasma: Obtain a sample of venous blood from the patient and add to plasma collection vial. Centrifuge sample and collect clear plasma. Fresh plasma samples are required.

Plasma samples may be stored at 2°C to 8°C for up to 72 hours prior to testing.

Fresh whole blood samples may also be used with this kit.

Do not use, contaminated or lipaemic samples for testing as this will adversely affect the results.

REAGENT PREPARATION

Devices and samples should be brought to room temperature (20°C to 25°C) and mixed gently prior to use.

In case the pouch has been stored at 4°C to 8°C, allow at least 30 minutes for the device to come to room temperature.

LIMITATIONS OF USE

The use of samples other than serum, plasma or whole blood have not been validated in this test.

There is no reuse protocol for this product.

Serological cross reaction within the flavi virus group (Dengue virus, St. Louis encephalitis, Japanese encephalitis, West Nile fever and Yellow fever) is common.

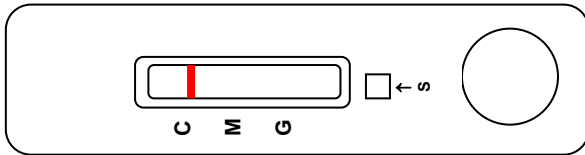
A low or suspected positive result should be re-assessed. Diagnosis should not be made solely on the findings of one clinical assay. When making an interpretation of the test it is strongly advised to take all clinical data into consideration.

ASSAY PROCEDURE

1. Open the pouch and remove the device. Once opened, the device must be used immediately.
2. Using a clean unused capillary pipette or a Microtitre pipette add 10µl to the square sample port labelled "S". 10µl volume is indicated on the capillary pipette by a black line.
3. Add 4 drops (100µl) of Buffer to the round port holding the plastic dropper bottle vertically.
4. Read the results at the end of 20 minutes. Do not read the results after 20 minutes as late readings can give false results.

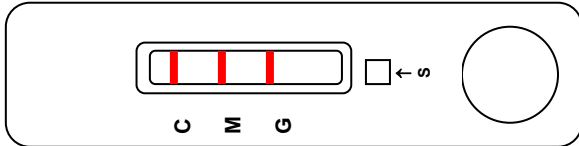
RESULTS AND INTERPRETATION

Negative Result:

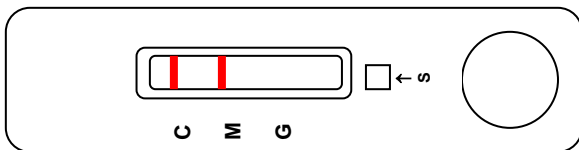


The presence of only the single red coloured band in the control region "C" indicates the absence of specific antibodies against Dengue virus or that the amount of antibodies is below the detection limit of the test.

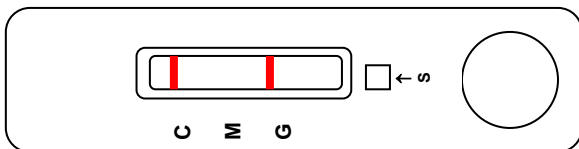
Positive Test Result:



1) In addition to the Control band in the control region 'C', appearance of bands in the test window at region "G" (IgG) and in the test window region at region "M" (IgM) indicates the presence of Dengue virus specific IgG and IgM antibodies. (Acute secondary infection)



2) In addition to the Control band in the control window 'C', appearance of a band in the test window only at region " M " (IgM) indicates the presence of Dengue virus specific IgM antibodies. (Acute primary infection)



3) In addition to the Control band in the control window 'C', the appearance of a band in the test window only at region "G" (IgG) indicates the presence of Dengue virus specific IgG antibodies. (Acute secondary infection / Past infection)

The test should be considered invalid if the control line does not appear. Repeat the test with a new device.

Depending on the concentration of Dengue antibodies in the specimen, positive results may start appearing as early as 2 minutes; negative results must be confirmed only at the end of 20 minutes. Do not read results after 20 minutes as late reading may give false results.

TROUBLESHOOTING

Use a separate sample loop for each sample to prevent cross contamination.

Prior to the start of the assay bring all reagents to room temperature (20°C to 25°C).

For use by operatives with at least a minimum of basic laboratory training.

Do not use damaged or contaminated kit components.

EVALUATION DATA

In a study, one hundred known positive samples and three hundred known negative samples as defined by clinical condition, HI and EIA were tested with VISITECT DENGUE. The results obtained were as follows:

	VISITECT DENGUE		Total Samples	Sensitivity
	+	-		
HI Positive	159	9	168	94.64%
EIA Positive	22	0	22	100%
Total	181	9	190	95.26%

	VISITECT DENGUE		Total Samples	Specificity
	+	-		
HI Negative	14	225	239	94.1%
Additional Clinical Dengue Negative	0	18	18	100%
Japanese encephalitis Positive	0	25	25	100%
Yellow Fever Positive	0	25	25	100%
Malaria (p falciparum) Positive	0	25	25	100%
Malaria (p vivax) Positive	0	25	25	100%
Total	14	343	357	96.08%

Sensitivity $159/168 + 22/22 = 181/190 = 95.26\%$

Total Specificity $343/357 = 96.08\%$

Reproducibility of VISITECT DENGUE is 100% (+/- one double dilution).

REFERENCES

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