VISITECT® LEPTOSPIROSIS Ref OD146

Rapid test for detection of Leptospira IgM antibodies In Whole Blood, Serum or Plasma

Store at 4°C to 30°C. DO NOT FREEZE.

For in-vitro diagnostic use only.

INTRODUCTION AND INTENDED USE

Leptospirosis is a zoonotic bacterial disease found world-wide which is caused by pathogenic strains of Leptospira. Leptospira are motile spirochaetes which can be saprophytic or parasitic visible under dark ground illumination or electron microscopy. Infection occurs when water contaminated by infected urine from carrier animals enters the body through cuts or abrasions in the skin or intact mucosa of the mouth, nose or conjunctiva. Clinical symptoms include high fever, severe headache, chills,conjunctivitis, muscle pain and vomiting. The severe form of the disease results in kidney damage, liver failure and haemorrhages (Wiels Syndrome). Laboratory diagnosis of this disease is crucial as its symptoms could be mistaken for other haemorrhagic fevers such as Dengue Fever.

IgM antibodies can be detected two days after the onset of symptoms and these antibodies remain detectable for up to five months after infection. Unlike other diseases the detection of IgG is not as significant.

VISITECT LEPTO is a rapid, Point-of-Care, qualitative, two-site sandwich immunoassay for the determination of *Leptospira*-specific IgM in whole blood, serum or plasma samples.
For professional use only.

PRINCIPLE OF THE TEST

VISITECT LEPTO utilises the principle of Immunochromatography, a unique two-site immunoassay on a membrane. As the test sample flows through the membrane assembly within the test device, the coloured Rabbit anti human IgM -colloidal gold conjugate complexes with the IgM antibodies in the sample. This complex moves further on the membrane to the test region where it is immobilised by the Leptospira genus specific antigens coated on the membrane, leading to the formation of a pink coloured line which confirms a positive test result. Absence of this coloured line in the test region indicates a negative test result. The unreacted conjugate, unbound complex, if any, and the colloidal gold conjugated rabbit anti human IgM moves further along the membrane and are subsequently immobilised by the anti-rabbit antibodies coated on the control region forming a pink line. This control line serves to validate the test results.

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OD146

Test	Device

Comprising of membrane assembly predispensed with anti human IgM colloidal gold conjugated antibodies. Leptospira genus specific antigens on the test line and anti-rabbit antibodies on the Control line. A 5µl application loop and a desiccant bag.

Buf	6ml

Diluent Buffer. Solution of Trizma-Base.

INSTRUCTION LEAFLET	1

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 LEPTO 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.

Do not use haemolysed, contaminated or lipaemic serum for testing as this will adversly affect the results.

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. Thawed samples must be mixed prior to testing.

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.

Do not use haemolysed, contaminated or lipaemic plasma for testing as this will adversly affect the results.

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

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

Fresh whole blood samples may also be used with this kit. See Assay procedure for methodology.

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. Check the colour of the desiccant. It should be blue. If it has turned colourless or faint blue, discard the device and use another device.

LIMITATIONS OF USE

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

There is no reuse protocol for this product.

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.

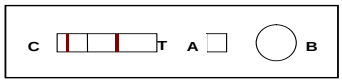
ASSAY PROCEDURE

1. Open the pouch and remove the device. Once opened, the device must be used immediately.
2. Dispense 10µl of whole blood, serum or plasma into well 'A' using two volumes from the 5µl applicator loop provided or using a micropipette set to deliver 10µl.
3. Add four drops of diluent buffer to well 'B' by holding the plastic dropper bottle vertically.
4. Read the results at the end of fifteen minutes.

RESULTS AND INTERPRETATION

Negative: Only one coloured line appears on the control region 'C' only.

Positive: A distinct coloured line appears on the control region 'C' and on the test region "T".



The test should be considered invalid if no line appears. Repeat the test with a new device.

TROUBLESHOOTING

Use a new applicator 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

Reproducability of **VISITECT LEPTOSPIRA** is 100% (+/- one double dilution).

	VISITECT LEPTOSPIRA		Totals
	+	-	
+	42	0	42
-	0	82	82
	42	82	124

Sensitivity 100%
Specificity 100%

REFERENCES

1. Silva et al., Behaviour of specific IgM, IgG and IgA class antibodies in human leptospirosis during the acute phase of the disease and during convalescence. J.Trop Med Hyg 98: 268-272, 1995.
2. W.J. Terpstra, G.S. Lighthart and G.J. Schoone. ELISA for the detection of specific IgM and IgG in human Leptospirosis. J. Gen. Microbiol. 131 (1985) 377-385.
3. Smits, H.L. et al., Lateral flow assay for the rapid serodiagnosis of human Leptospirosis. Clin. Diagn. Lab. Immunol. 8 (2001) 166-169.

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