INTRODUCTION AND INTENDED USE

Leptospirosis is a zoonotic bacterial disease found worldwide which is caused by pathogenic strains of Leptospira. Leptospira are mobile spirochaetes which can be saprophytic or parasitic visible under dark field 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 (Wahls Syndrome). Laboratory diagnosis of this disease is crucial as its symptoms could be mistaken for other haemorraghic 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 immunosay 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 immunocromatography, a unique two-site immunosay 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 antigen 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, unbond 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.

CONTENTS

Comprising of membrane assembly prespun with anti human IgM colloidal gold conjugated antibodies, Leptospira genus specific antigen on the test line and anti-rabbit antibodies on the control line. A 5ul application loop and a desiccant bag.

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 diluted buffer contains 0.05% 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 it to form and retract. Centrifuge clothed blood sample and collect clear serum. Fresh serum samples are required.

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

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

Serum samples 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.

In Whole Blood, Serum or Plasma

Rapid test for detection of Leptospira IgM antibodies

VISITECT LEPTOSPIROSIS Ref OD146

In Whole Blood, Serum or Plasma

Store at 4°C to 30°C. DO NOT FREEZE.

For in-vitro diagnostic use only.
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 VISICTECT LEPTOSPIRA is 100% (+/- one double dilution).

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<thead>
<tr>
<th>VISICTECT LEPTOSPIRA</th>
<th>Totals</th>
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<tr>
<td>+</td>
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Sensitivity 100%
Specificity 100%

REFERENCES


8142 Issue 2 Revised October 2003
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