VISITECT® SYPHILIS Ref OD016
Rapid test for detection of antibodies to Treponema pallidum
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
Syphilis is a sexually transmitted (venereal) disease caused by the spirochete bacterium Treponema pallidum. The disease can also be transmitted perinatally (umbilical cord) and during childbirth. Treatment is effective if given early. Diagnosis is usually made using serodiagnostic tests for Treponema-specific antibodies. Serum and plasma samples are required.

STORAGE
Do not repeatedly freeze-thaw the specimen 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.

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

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. 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 plasma, serum or whole blood 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 two drops (2 x 2μl) of serum, plasma or whole blood into the sample well 'A' using the dropper provided.
3. Add four drops of diluent buffer to well 'B'.
4. Read the results at the end of 30 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.

Depending on the concentration of anti Treponema antibodies in the specimen, positive results may appear as early as two minutes. Negative results must be confirmed only at the end of 30 minutes.

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

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 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.

INTRODUCTION AND INTENDED USE

Visitect SYPHILIS is a rapid point of Care, qualitative, two-site double antigen sandwich immunoassay. Visitect SYPHILIS is a modified TPHA, which qualitatively detects the presence of the IgG and IgM classes of Treponema-specific antibodies during syphilis infection. It can be used on whole blood, serum or plasma specimens with results being obtained within 30 minutes. For professional use only.

PRINCIPLE OF THE TEST

Visitect SYPHILIS utilizes the principle of immunochromatography, a unique two-site immunoassay on a membrane. As the test sample flows through the membrane assembly, a double antigen sandwich immunoassay is formed. This complex moves further along the membrane test region where it is immobilized by recombinant Treponema pallidum antigen coated on the membrane, leading to the formation of a pink to deep purple coloured line at the test region 'T' which confirms a positive test result.

Absence of this coloured line in test region 'T' indicates a negative test result. The unreacted conjugate, unbound complex, if any, and the colloidal gold conjugated rabbit IgG moves further along the membrane and are subsequently immobilized by the goat anti-rabbit IgG antibodies coated on the control region 'C' of the membrane assembly, forming a pink to deep purple coloured line. The control line serves to validate the test results.

Calibrated against the WHO Reference serum for Serodiagnostic tests for Treponema Infections Ref – 3 1980 +1: one double dilution to ensure sensitivity.

CONTENTS

Visitect SYPHILIS contains a plastic device:

- One Visitect® SYPHILIS test device
- One Visitect® SYPHILIS diluent buffer (8ml)
- One Visitect® SYPHILIS instruction leaflet

PRECAUTIONS

Visitect reagents do not contain dangerous substances as defined by current UK UKS (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 SYPHILIS diluent 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.

This 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 re-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

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Do not repeatedly freeze-thaw the 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.

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

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. 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.

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LIMITATIONS OF USE

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

No serological haemagglutination test can discriminate between antibody due to T. pallidum infection and antibody due to infection with other pathogenic treponemes, i.e. T. perniciosa and T. carateum.

No other interfering factors have been specifically identified however positive results should be confirmed, eg by FTA- Abs.

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.

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

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

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TROUBLESHOOTING

Use a separate disposable dropper 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

Reproducibility of VISICTECT Syphilis is 100% (+/- one double dilution).

In two Independent laboratories panels of sera were tested with the following results:

<table>
<thead>
<tr>
<th></th>
<th>Panel 1</th>
<th>Panel 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Primary</td>
<td>Secondary</td>
</tr>
<tr>
<td>Visitect Syphilis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*</td>
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</tr>
<tr>
<td>*</td>
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<td>2</td>
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<tr>
<td>Total</td>
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<td>2</td>
</tr>
</tbody>
</table>

These evaluations show an overall
Sensitivity 177/181 = 97.8%
Specificity 686/687 = 99.85%

In an Independent laboratory 5 Panels of sera were tested with the following results:

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<th></th>
<th>Panel 1</th>
<th>Panel 2</th>
<th>Panel 3</th>
<th>Panel 4</th>
<th>Panel 5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>VDRL – TPHa</td>
<td>VDRL + TPHa</td>
<td>VDRL – TPHa</td>
<td>VDRL + TPHa</td>
<td>Lymes +</td>
</tr>
<tr>
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<tr>
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<td>10</td>
<td>10</td>
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<tr>
<td>Total</td>
<td>30</td>
<td>20</td>
<td>30</td>
<td>10</td>
<td>10</td>
</tr>
</tbody>
</table>

These evaluations show an overall
Sensitivity 49/50 = 98%
Specificity 50/50 = 100%

REFERENCES

5. Data on File: Omega Diagnostics Ltd.

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