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 spirochaete bacterium *Treponema pallidum*. The disease can also be transmitted congenitally hence its importance in antenatal screening. After infection, the host forms non-Treponemal anti-lipoidal antibodies (reagins) to the lipoidal material released from the damaged host cells as well as Treponema-specific antibodies. Serological tests for non-treponemal antibodies such as VDRL and RPR are useful as screening tests. Tests for Treponema specific antibodies such as TPHA, FTA-ABS and Rapid Tests for antibody are gaining importance as screening as well as confirmatory tests because they detect the presence of antibodies specific to *Treponema pallidum*.

VISITECT SYPHILIS is a rapid point of Point-of-Care, qualitative, two-site double antigen sandwich immunoassay. **VISITECT SYPHILIS** is a modified TPHA, which qualitatively detects the presence of the IgM and IgG 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 of the test device, the recombinant Treponema antigen-colloidal gold conjugate forms a complex with Treponema-specific antibodies in the sample. This complex moves further on the membrane to the test region where it is immobilized by the 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 Treponemal Infections Ref – 3 1980 +/- one double dilution to ensure sensitivity.

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Test	Device

Comprising of membrane assembly predispensed with recombinant Treponema pallidum antigen colloidal gold conjugate and colloidal gold conjugated rabbit IgG. Recombinant Treponema pallidum antigen on the test line and goat anti rabbit IgG on the control line. Disposable plastic dropper (25µl drop size). Desiccant bag.

Buf	8 ml

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 SYPHILIS 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.

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 adversly 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.

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.pertenue** 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.

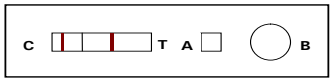
ASSAY PROCEDURE

1. Open the pouch and remove the device. Once opened, the device must be used immediately.
2. Dispense two drops (2 X 25µl **)** 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 treponemal 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.

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

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

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

		Visitect Syphilis		
		+	-	Totals
Panel 1	Primary	11	1	12
	Secondary	2	0	2
	Early Latent	5	0	5
	Latent	13	0	13
	Late Latent	8	3	11
	Late	1	0	1
	Negative	0	32	32
Panel 2	Positive	137	0	137
	Negative	1	687	688

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:

		Visitect Syphilis		
		+	-	Total
Panel 1	VDRL – TPHA +	29	1	30
Panel 2	VDRL + TPHA +	20	0	20
Panel 3	VDRL - TPHA -	0	30	30
Panel 4	VDRL + TPHA – FTAbs -	0	10	10
Panel 5	Lymes +	0	10	10
	Total	49	51	100

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

REFERENCES

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4. Clinical Diagnosis and Management by Laboratory Methods, John Bernard Henry, 17th Edition, 1979, W.B.Saunders Company.
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