CE

TREPOLIPIN®

MODIFIED VDRL REAGENT

SUMMARY

Syphilis is a sexually transmitted (venereal) disease caused by the spirochaete *Treponema pallidum*. After infection the host forms Treponemal antibodies to Treponema pallidum, in addition the host also forms Non Treponemal antilipoidal antibodies in response to the lipoidal material released from the damaged host cell. These antibodies are traditionally referred to as 'REAGINS'.Cardiolipin, a phospholipid, reacts with the 'Reagins' to give a Non Treponemal flocculation reaction. Non Treponemal tests such as TREPOLIPIN® are of great value when used for screening and follow up of therapy.

PRESENTATION

REF	REF	10511505	10511050	10511100
REAGENT		5 x 5 ml	50 Tests	100 Tests
Control	+	-	0.4 ml	0.4 ml
Control	-	-	0.4 ml	0.4 ml
Reagent dropper		1	1	1

REAGENT

1. TREPOLIPIN® reagent: A ready to use stabilised emulsion of cardiolipin, lecithin and cholesterol.
2. Positive control, reactive with Trepolipin® reagent.
3. Negative control, non reactive with Trepolipin® reagent.

TREPOLIPIN® detects antilipoidal antibodies in serum, plasma and cerebrospinal fluid (CSF). As against the conventional VDRL reagents, test samples do not require heat inactivation.

Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity and performance.

REAGENT STORAGE AND STABILITY

1. Store the reagent at 2-8°C. DO NOT FREEZE.
2. Once opened the shelf life of the reagent vial is as described on the reagent vial label provided it is not contaminated.
3. Avoid exposure to elevated temperature and air, as the reagent is highly sensitive to denaturation and drying.

PRINCIPLE

When serum, plasma or cerebrospinal fluid (CSF) containing antilipoidal antibodies is reacted with TREPOLIPIN® reagent, a flocculation reaction is produced.

Flocculation is a positive test result and indicates presence of antilipoidal antibodies in the sample. No flocculation is a negative test result and indicates absence of antilipoidal antibodies in the sample.

NOTE

1. In vitro diagnostic reagent for laboratory or professional use only. Not for medicinal use.
2. Reagent contains 0.1 % Sodium Azide as preservative. Avoid contact with skin and rnucosa. On disposal flush with large quantities of water.
3. The antigen suspension should be gently but thoroughly mixed by swirling before testing to homogenise the reagent and improve test readability.
4. Performance of the reagent must be verified with positive and negative controls and it is recommended that controls be run with each test series.
5. Accessories provided with the kit only must be used for optimum results.

SAMPLE COLLECTION AND STORAGE

1. No special preparation of the patient is required prior to sample collection by approved techniques. Do not use hemolysed samples.
2. Fresh serum, plasma or CSF should be used for testing.
3. Haematogenous CSF should not be used for testing. For cloudy samples, centrifuge and use the clear supernatant for testing.

MATERIAL PROVIDED WITH THE KIT

1. Stabilised cardiolipin suspension.
2. Reagent dropper assembly for dispensing the antigen suspension.
3. Positive control, reactive with the reagent.
4. Negative control, non-reactive with the reagent.

ADDITIONAL MATERIAL REQUIRED

Conventional VDRL cavity slide (Glass), Microscope (with magnification of 100x), Pasteur Pipettes, Mechanical rotor (180 rpm), Isotonic saline.

NOTE: For TREPOLIPIN® 5 x 5 ml kit: Known reactive and non-reactive samples would be required additionally.

TEST PROCEDURE

Bring all reagents and samples to room temperature before testing.

1. Thoroughly mix the TREPOLIPIN® reagent suspension by gentle agitation before testing.
2. **With cerebrospinal fluid, the test specimen volume is 10 µl.**
3. For use with cerebrospinal fluid, each drop of TREPOLIPIN® reagent should be diluted with 20 µl of good isotonic saline before testing.

Qualitative Method

1. Pipette 50 µl of serum or plasma to the VDRL slide cavity.
2. Dispense one drop of TREPOLIPIN® reagent to the surface of the test sample in the same cavity using the reagent dropper provided.
3. Rotate the slide continuously at 180 rpm for four minutes, observing for flocculation.
4. Read the results macroscopically or microscopically at four minutes.
5. All positive test results may be further tested by the quantitative test procedure.

Quantitative Method

1. Pipette 100 µl of isotonic saline into seven test tubes.
2. Pipette 100 µl of the test sample into the first test tube.
3. Transfer 100 µl of the diluted test sample from the first tube to the second tube.
4. Continue the serial dilution of the test sample till dilutions of 1:2, 1:4,1:8, 1:16, 1:32,1:64, 1:128 are achieved.
5. Transfer 50 µl of each dilution of the test sample from tubes I to 7 to a conventional VDRL slide.
6. Dispense one drop of TREPOLIPIN® reagent to each dilution of the sample on the VDRL slide.
7. Rotate the slide continuously at 180 rpm for four minutes.
8. Observe for flocculation macroscopically or microscopically at four minutes.

INTERPRETATION OF RESULTS

Qualitative Method

Flocculation is a positive test result and indicates presence of antilipoidal antibodies in the test sample.
No flocculation is a negative test result and indicates absence of antilipoidal antibodies in the test sample. The strength of flocculation may vary, depending upon the degree of positivity of the test sample.

Quantitative Method

The antilipoidal antibody titre is the highest dilution of the test sample giving a positive test result (flocculation).

REMARKS

1. Quantitative procedure must be performed to determine the response to treatment and detect reinfection.
2. False positive reactions occur not infrequently and have been attributed to a variety of acute and chronic conditions.
3. In the absence of supporting clinical, historical or epidemiological evidence, reactive results must be confirmed with more specific Treponemal tests.
4. It is recommended that results of the test should be correlated with clinical findings to arrive at the final diagnosis.
5. Microscopic evaluation of test results requires well-trained and experienced professional. It is recommended that few known negatives should be run with each batch of the tests so as to familiarise and differentiate effectively the appearance of non reactive samples from the reactive ones.
6. Non-treponemal tests such as Modified VDRL are known to suffer from high degree of biological false positives in many conditions such as pregnancy, malaria and many other infectious diseases.
7. Non-treponemal tests such as Modified VDRL are known to have prozone/hook effect in samples that have a high titre of reagents leading to a false negative result. It is usually recommended to run the tests in two dilutions i.e.with neat sample and 1:8 diluted sample.

PERFORMANCE CHARACTERISITICS

The results of 100 serum samples obtained with TREPOLIPIN® were compared with those obtained using commercial reagent (A) with similar characteristics.

SPECIMEN DATA	TREPOLIPIN®	A
+ VE	46	46
- VE	54	54

The results of TREPOLIPIN® correlate 100% with the commercial reagents used for evaluation.
Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of VDRL negative and VDRL positive samples. No variations were found in the outcome of different tests.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1. Pang Born, Mary C., Isolation and purification of serologically active phospholipid from Beef heart. J. Biol. Chem., 143:247, 1942.
2. J. Venereal Disease inform., 27-169,1946.
3. Data on file: Tulip Diagnostics (P) Ltd.

SYMBOL KEYS

	Temperature limitation		Manufacturer	Σ	Contains sufficient for <n> tests
	Use by		Consult Instructions for use	CONTROL +	Positive control
	Date of Manufacture	REF	Catalogue Number	CONTROL -	Negative control
LOT	Batch Number/ Lot Number	IVD	*In vitro* Diagnostic Medical Device	REAGENT	Description of reagent
	This side up	PS	Production Site	EC REP	Authorised Representative in the European Community

TULIP DIAGNOSTICS (P) LTD.

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EC REP

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