137 mm x 218 mm

CE

CARBOGEN®

RAPID PLASMA REAGIN (RPR) CARD TEST / CARBON ANTIGEN FOR SYPHILIS TESTING

SUMMARY

Syphilis is a sexually transmitted (venereal) disease caused by the spirochete *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.'
The Rapid Plasma Reagin (RPR) / Carbon Antigen test is a macroscopic nonTreponemal flocculation test for the detection and quantitation of antilipoidal antibodies. Non-Treponemal tests like CARBOGEN® are of great value when used for screening and follow up of therapy.

REAGENTS

1. CARBOGEN® reagent: A particulate carbon suspension coated with lipid complexes.
2. Positive control, reactive with the CARBOGEN® reagent.
3. Negative control, non reactive with the CARBOGEN® reagent.

CARBOGEN® detects antilipoidal antibodies in serum or plasma. As against the conventional V.D.R.L. reagents, test samples do not require heat inactivation.
Each batch of reagent undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity and performance.

REAGENT STORAGE AND STABILITY

Store the reagent at 2-8°C. DO NOT FREEZE. Once opened the shelf life of the reagent vial is as described on the reagent vial label provided it is not contaminated. Do not use reagents after the expiry date. Avoid exposure to elevated temperatures and air, as the reagent is highly sensitive to denaturation and drying.

PRESENTATION

REF	REF	10514005	10514050	10514100	10514250
RPR Carbon Ag/Tests	E	5.0 ml	50 Tests	100 Tests	250 Tests
Control	+	-	0.4 ml	0.4 ml	0.4 ml
Control	-	-	0.4 ml	0.4 ml	0.4 ml
Disposable slides with eight reaction circles		-	7	13	32
Disposable sample / control dispensing pipettes		-	50	100	250
Rubber Teat		-	1	2	2
Reagent dropper for dispensing carbon antigen		-	1	1	1
Mixing stick ladder		-	2	4	10
Package Insert		1	1	1	1

PRINCIPLE

During the testing procedure, the specimen, serum or plasma is mixed with the CARBOGEN® reagent and allowed to react for eight minutes. If antilipoidal antibodies are present in the specimen, they will react with the CARBOGEN® reagent forming visible black floccules. If antilipoidal antibodies are not present in the specimens, there will be no flocculation.

NOTE

1. In vitro diagnostic reagent for laboratory or professional use only. Not for medicinal use.
2. The reagents contain 0.1% Sodium azide as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
3. The reagents that are derived from human source have been tested for HBsAg and Anti-HIV antibodies and are found to be non-reactive. However handle the material as if infectious.
4. CARBOGEN® RPR / Carbon Antigen should be gently but thoroughly mixed before testing to disperse the carbon particles uniformly and improve test readability.
5. Performance of the reagent must be verified with positive and negative controls and it is recommended that controls be run with each test series.
6. Accessories provided with the kit only must be used for optimum results.
7. Do not use damaged or leaking reagents.

SAMPLE COLLECTION AND STORAGE

1. No special preparation of the patient is required prior to sample collection by approved techniques. Hemolysed or lipemic samples are not suitable for testing.
2. Fresh serum or plasma should be used for testing.
3. Samples not tested immediately may be stored at 2-8^{0}C for upto 48 hours.
4. Hazy samples should be centrifuged. Use clear supernatant for testing.

MATERIAL PROVIDED WITH THE RPR KIT

1. Carbon Antigen.
2. Positive control, reactive with the reagent.
3. Negative control, non-reactive with the reagent.
4. Disposable slides with eight reaction circles.
5. Disposable sample / control dispensing pipettes.
6. Mixing sticks.
7. Rubber teats.
8. Reagent Dropper for dispensing the Carbon Antigen.

ADDITIONAL MATERIAL REQUIRED,

Stop watch, High intensity light source, Isotonic saline, Pipettes, Test tubes, Mechanical rotor at 180 r.p.m. circumscribing a circle 2 cm in diameter on a horizontal plane.

Note: For CARBOGEN® Carbon Antigen 5.0 ml: - Item Nos. 2-7 listed above under RPR kit, would be required additionally.

TEST PROCEDURE

Bring reagent and samples to room temperature before testing.

Thoroughly mix the CARBOGEN® reagent suspension by gentle agitation before testing.

Qualitative Method

1. Pipette one drop (50 µl) of the test specimen, positive and negative controls onto separate reaction circles of the disposable slide using a sample-dispensing pipette.
2. Add one drop of well-mixed CARBOGEN® reagent next to the test specimen, positive control and negative control by using the reagent dropper provided with the kit. Do not let the dropper tip touch the liquid on the slide.
3. Using a mixing stick mix the test specimen and the CARBOGEN® reagent thoroughly spreading uniformly over the entire reaction circle.
4. Immediately start a stopwatch. Rotate the slide gently and continuously either manually or on a mechanical rotor at 180 r.p.m.
5. Observe for flocculation macroscopically at 8 minutes.

Quantitative Method

1. Using isotonic saline prepare serial dilutions of the test sample positive in the qualitative method 1:2, 1:4, 1:8, 1:16,1:32, 1:64, 1:128 and so on.
2. Perform the qualitative test procedure using each dilution as test specimen.
3. The titre is reported as the reciprocal of the highest dilution, which shows a positive test result.

INTEPRETATION OF TEST RESULTS

Qualitative methods

- Large and Medium black floccules against white background : Reactive
- Small black floccules against white background : Weakly Reactive
- No floccules, even grey background : Non reactive

Flocculation is a positive test result and indicates the presence of antilipoidal antibodies in the test specimen.

No Flocculation is a negative test result and indicates the absence of antilipoidal antibodies in the test specimen.

Quantitative Method

The titer of antilipoidal antibodies is the highest dilution of the test sample giving a positive test result.

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 absence of supporting clinical, historical or epidemiological evidence, reactive results must be confirmed with more specific Treponemal tests.
4. It is strongly recommended that results of the test should be correlated with clinical findings to arrive at the final diagnosis.
5. Dispose all used and contaminated material as per Standard Biohazard Safety Guidelines.
6. The reagent dropper provided for dispensing the Carbon Antigen should be thoroughly cleaned with distilled water and air dried after use, to ensure that it does not contaminate the reagent during subsequent use.

7. Very slight roughness should be interpreted as a negative test result.
8 Non-treponemal tests such as RPR are known to suffer from a high degree of biological false positives in many conditions such as pregnancy,malaria and many other infectious diseases.
9. Non-treponemal tests such as RPR 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 samples.

PERFORMANCE CHARACTERISITICS

The results of 100 serum samples obtained with CARBOGEN® were compared with those obtained using commercial reagent (A) with similar characteristics and another commercial reagent (B) (modified VDRL reagent) with another method.

Test Result	CARBOGEN®	A	B
+ VE	46	46	46
- VE	54	54	54

The results of CARBOGEN® correlate 100% with both 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 the package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

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3. Clinical diagnosis and management by laboratory methods, 17th Edition, edited by John Bernand Henry, pgs 1139-1142.
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5. Data on file: Tulip Diagnostics (P) Ltd.

SYMBOL KEYS

Temperature limitation	Manufacturer	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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PS

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EC REP

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