VDRL CARBON ANTIGEN

INTENDED USE
The Plasmatec VDRL Carbon Particle Antigen is a modified form of VDRL Antigen containing microparticulate carbon (1). It is designed for use in flocculation tests for the serodiagnosis of syphilis. The carbon particles aid the macroscopic reading of the results. Weak reactive results can be easily and clearly distinguished from non-reactive patterns which display a macroscopically smooth and even appearance. This antigen is suitable for use in both Manual slide tests and Automated Reagin tests (2).

WARNINGS AND PRECAUTIONS
For in vitro diagnostic use only
For professional use only

Health and Safety warnings:
All patient samples and reagents should be treated as potentially infectious and the user must wear protective gloves, eye protection and laboratory coats when performing the test.
Non disposable apparatus must be sterilised after use by an appropriate method.
Disposable apparatus must be treated as biohazardous waste and autoclaved or incinerated.
Spillages of potentially infectious material should be absorbed and disposed of as above. The site of spillage must be sterilised with disinfectant or 70% alcohol.
Do not pipette by mouth.

Analytical precautions:
Do not modify the test procedure.
Do not dilute or modify the reagents in any way.
Allow all reagents and samples to reach room temperature (18 to 30ºC) before use.
Do not interchange reagents from different kit batches.

COMPOSITION
Kit contents:
?? VDRL Carbon Antigen
?? Pack insert.

STORAGE AND SHELF LIFE
Store at 2-8ºC. Ensure cap is fully tightened.
Do not use reagents after the stated expiry date.
Discard reagents if they become contaminated or do not demonstrate the correct activity with controls.

MATERIALS AND EQUIPMENT REQUIRED BUT NOT PROVIDED.
For slide test.
1. Test slides.
2. Accurate MicroPipette for delivery of 18 & 50ul
3. Automatic Rotating Table (optional).

SPECIMEN
Plasma, unheated or heated serum may be used. Test material should be free from bacterial contamination and non-haemolysed.

PROCEDURE
Principle:
Syphilis is a venereal disease caused by the spirochaete micro-organism T.pallidum. As the organism cannot be cultured on artificial media the diagnosis of syphilis depends on the correlation of clinical data with the detection of specific antibody by serological tests. Serological screening tests for syphilis using cardiolipin and lecithin as antigens are simple to perform but may give rise to a small proportion of false positive results because the tests use non-treponemal antigens.
The test antigen is a modified form of VDRL Antigen containing microparticulate carbon which aids the macroscopic reading of results. A reactive result is indicated by agglutination which is readily visible without the aid of a microscope. Weak- reactive results can be easily and clearly distinguished from non-reactive patterns which display a macroscopically smooth and even appearance.

(1) Automated Reagin Test (ART)
Plasmatec VDRL Carbon Antigen may be used in single or multichannel Autoanalyser equipment. The large pack size is intended for automated use. Equipment manufacturer’s instructions should be read carefully since the condition of the equipment can severely influence test results. It is recommended that the day’s requirements are removed after shaking, the remaining antigen should be returned to the refrigerator. To ensure consistent results the antigen should be allowed to reach room temperature before use and stirred continuously during use. Positive control sera should be run in parallel with test series.

(2) Manual slide test
1. Spread one drop (0.05ml) of the sample to fill the ring slide.
2. Shake the antigen and add one drop (0.02ml) to the sample under test.
3. Rotate the slide for eight minutes at 100 rev/minute.
4. Inspect macroscopically in good light. Weak and trace reactivies show characteristic small aggregates around the periphery of the liquid.
5. Positives will show large black aggregates.
6. Negative samples give a smooth grey result.

INTERPRETATION OF RESULTS
Reactives display characteristic agglutination ranging from slight (Weak-reactive) to intense (Reactive). Very weak reactive results are characterised by small agglutinates around the periphery of the test area. Negatives do not exhibit this reaction and display a macroscopically smooth and even appearance.
PERFORMANCE CHARACTERISTICS AND LIMITATIONS OF THE METHOD

In common with all Reagin tests, Plasmatec VDRL Carbon Antigen may give a small proportion of false positive results. Such reactions can be caused by diseases such as infectious mononucleosis, leprosy, lupus erythematosus, vaccinia and virus pneumonia. Positive test specimens should be subject to further serological studies (i.e. TPHA, FTA, and ABS) since, as with any serological testing procedure, the diagnosis of syphilis should not be made on a single reactive result.

In common with other serological tests Plasmatec VDRL Antigen test cannot distinguish between syphilis and other pathogenic treponemal infections, e.g. Yaws. Clinical evidence should always be considered when making a diagnosis of treponemal infections.

QUALITY CONTROL

Positive and negative control sera should be used to verify the test

REFERENCES

(2) Mcgrew, B.E. et al., Amer. J. Med Tech., 34 634 (1968a)
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(2) Norris, L. C. Automation in Clinical Chemistry, 1 157 New York Mediad., (1968)
(2) Stout, G.W. et al., J. Conference of Public Health Lab. Directors, 26 7 (1968)