RAPID PLASMA REAGIN – RPR CARBON ASSAY

CAT NO	DESCRIPTION	PACK SIZE
SYPRPR1	RPR FULL KIT (Positive and Negative Control, Stirrers, Dispensing Bottle, Test Cards and Needle)	125 T
SYPRPR2	RPR FULL KIT (Positive and Negative Control, Stirrers, Dispensing Bottle, Test Cards and Needle)	250 T
SYPRPR3	RPR FULL KIT (Positive and Negative Control, Stirrers, Dispensing Bottle, Test Cards and Needle)	500 T
SYPRR01	RPR CARBON ANTIGEN ONLY (Needle)	1x2ml (100T)
SYPRR02	RPR CARBON ANTIGEN ONLY (Needle)	1x5ml (250T)
SYPRR03	RPR CARBON ANTIGEN ONLY (Needle)	1x10ml (500T)
SYPPNC	SYPHILIS CONTROL SET	2x5x1ml

Intended Use:

The RPR carbon antigen reagent is a non-treponemal preparation specially developed for the rapid detection and semi-quantitation by co-agglutination on a slide or microplate of plasma reagins, a group of antibodies directed against tissue components produced by almost every patient infected with *Treponema pallidum*. For in-vitro diagnostic use by trained professionals only.

Appearance, Preparation and Stability:

Reagents are provided ready to use. Ensure that the carbon antigen reagent is well mixed before use.

Unopened products are stable up to when stored tightly capped at 2 - 8°C. Opened vials are also stable up to expiry when stored without contamination and tightly capped at 2 - 8°C. DO NOT FREEZE.

Reagent Composition:

RPR CARBON ANTIGEN REAGENT	**Stabilised suspension of particulate carbon with cardiolipin antigen.**
POSITIVE CONTROL	**Human serum Positive for RPR**
NEGATIVE CONTROL	**Human serum Negative for RPR**

Precautions:

All human blood components have been tested negative for HBsAg, HCV, HIV 1&2 antibodies by FDA approved methods. However, as no known test methods offer total assurance, all kit components should be handled as though potentially infectious.

All reagents contain 0.1% sodium azide. Sodium azide is a poison. Do not ingest the reagent.

Specimen Collection:

Use Fresh serum or plasma samples. Do not use samples that are contaminated, excessively haemolysed, extremely turbid or lipaemic.

Materials required but not provided:

Automatic pipettes, saline solution, mechanical rotator.

Procedure:

Qualitative Assay:

i) Bring all reagents to room temperature (25°C).
ii) Place 50 µl of sample into a circle marked on the test card.
iii) Spread the sample evenly over the test circle area.
iv) Shake the vial of RPR antigen to ensure even mixing.
v) Add one drop (17.5 µl) of the RPR reagent to the sample.
vi) Place test card on a card rotator and rotate at 100 RPM for 8 minutes.
vii) Read and interpret results visually in good light.
viii) It is recommended that positive and negative controls are run with each batch of test samples.
ix) Return unused antigen from dropper bottle to glass vial.

Semi-Quantitative assay:

i) For each sample to be tested place with an automatic pipette 50 µl of saline solution into each of the 5 circles on the reaction card. Do not spread the saline.
ii) To circle 1 add 50 µl of test sample and using the same tip mix the saline solution and the sample by repeated aspiration and expulsion. Transfer 50 µl of the mixed solution to the 2nd circle.
iii) Continue with this 2 fold serial dilution in a similar manner up to the 5th circle and then discard 50 µl from the 5th circle. Final sample dilutions will be 1/2, 1/4, 1/8, 1/16, 1/32.
iv) Test each dilution as described in steps 3-7 for the Qualitative assay.

Interpretation:

Strong Reactive: Large clumps of Carbon particles with a clear background

Reactive: Large Clumps of Carbon particles more dispersed than the Strong Reactive pattern

Weak Reactive: Small Clumps of Carbon with a light grey background

Trace Reactive: Slight clumping of Carbon Particles Typically seen as a button of aggregates in the centre of the test circle or dispersed around the edge of the circle

Non-Reactive: Typically a smooth grey pattern or a Button of non-aggregated carbon particles in the centre of the test circle.

Limitations:

The result from this test should not be used as the sole criteria for the diagnosis of syphilis, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated and a different test method used to confirm any positive findings.

References:

1. McGrew BE et al. Am J Med Tech, 34, 634 (1968)
2. Portnoy J et al US public health report, 75, 985-988 (1960).

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		

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