RPR Carbon kit (Syphilis)

Qualitative and semiquantitative determination
by slide agglutination of antigens to Syphilis

100 tests **REF 6006**

PRINCIPLE

Syphilis or Lue is a venereal infectious disease, whose etiological agent is Treponema Pallidum. The infection is transmitted through wounds on skin. Treponema antigenic structure is not completely known, but three different kinds of antigens can be distinguished: lipoid antigen, proteic antigen and polysaccharide antigen.
The diagnosis can be performed directly on Treponema Pallidum (TPHA method) or indirectly (serum diagnosis), highlighting specific antibodies anti-Treponema (reagins).
This kit is based on identification of anti-antigen lipoid antibody by flocculation reaction (VDRL). The lipoid antigen is represented by an alcoholic extract of ox heart with the addition of cholesterol and lecithin. This extract is called Cardiolipin. Bound with carbon molecules (RPR method), cardiolipin in the presence of specific antibodies in the sample forms some aggregates indicating positivity.

REAGENTS

Kits components: **REF 6006**
REAGENT 1 (liquid, white cap) **1 x 2 ml**
Carbon microparticles bound with cardiopilin in suspension, ready to use.
***REAGENT 2** (liquid, red cap) **1 x 1 ml**
Positive control, ready to use.
REAGENT 3 (liquid, blue cap) **1 x 1 ml**
Negative control, ready to use.
WARNING: the reagents contain sodium azide (< 0.1%) as preservative. Handle with caution and avoid ingestion and contact with skin.
SLIDE **17 pieces**
STIRRER **100 pieces**

(*) Dangerous reagents are marked by an asterisk. Read MSDS.

STABILITY: sealed and stored at 2-8°C, reagents are stable up to the expiration date on the label.

SAMPLE

Fresh serum, avoid lipemic or contaminated hemolytic sera.
STABILITY: 2 days at 2-8°C, 1 month at -20°C.

PREPARATION OF THE REAGENTS

Let the reagents reach room temperature before use. Shake the Reagent 1 accurately before use. Make sure all carbon particles are in suspension and not deposited on the bottom of the vial.

MANUAL PROCEDURE OF THE QUALITATIVE TEST

Pour the reagents into the circles on the slides, as per the following table:

	Sample	Pos. Control	Neg. Control
Sample	50 µl		
Reagent 2		1 drop (50 µl)	
Reagent 3			1 drop (50 µl)
Reagent 1	20 µl	20 µl	20 µl

Mix the drops with a stirrer, spreading them over the entire surface of the circle. Put the slide on an automatic shaker at 100 rpm for 8 minutes. Examine macroscopically the presence or absence of visible agglutination.

READING OF THE RESULTS

The sample is positive if high quantities of aggregates are visible (agglutinate between the carbon sensitized particle and reagin) in the middle or on the edges of the test area. If the aggregates are just a few and distributed on the edges, the positivity can be defined as weak. When the liquid looks uniform and aggregate-free, the sample is negative (any presence of carbon particles located in the middle of the test area should not lead to define the sample as positive). Positive samples have to be tested once more by the semiquantitative procedure, in order to identify the titer.

MANUAL PROCEDURE WITH THE SEMIQUANTITATIVE TEST

Dilute the sample with saline solution as follows:

Dilution	1:2	1:4	1:8	1:16	1:32	1:64	1:128

Proceed on each dilution as for the qualitative test, adding 20 µl of Reagent 1 to each dilution.

RESULTS

The last dilution which highlights macroscopic aggregates corresponds to the sample titer.

REFERENCE VALUES

Positive results mean the presence of “Luetic reagins”, defined by a non-treponemal method. Reagins in serum are usually not detected.

NOTES

1. Longer reaction times may give false positive results.
2. Always compare the results with the controls.
3. False positive results can be found in leprosy, L.E.S. and viral pneumonia cases.
4. All reagents have been deactivated and tested for HIV I and II, HBsAg and HCV antibodies. However, they should be treated as potentially infectious.

REFERENCES

Available upon request.

KEY SYMBOLS

IVD	In Vitro diagnostic medical device
LOT	batch number
REF	catalog number
	temperature limits
	use by
	caution
	read instructions for use

IVD CE Ed. 03 - Jan 2016 MS

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