SYPHILIS RPR

Qualitative and semiquantitative determination of reagins associated to Lue

TEST SUMMARY

Syphilitic antibodies contained in the serum, cause the agglutination of cardiolipidic antigen suspension (V.D.R.L. modified) associated to carbon.
The microparticles of carbon facilitate distinction of agglutinated samples.

SAMPLES

Serum or plasma. Stability 2 days at 2-8°C or for longer time at -20°C.
Plasma have to be tested within 48 h after collection.
Bring to room temperature before testing.

REAGENTS

Suspension
Stabilized suspension of 0.003% cardiolipin, 0.020-0.022% lecithin, 0.09% cholesterol, 10% choline chloride, 0.0125 mol/L EDTA, 0.01% particulate carbon, in phosphate buffer, conservative and stabilizer.
It contains 0.1% thimerosal.

Positive control
Stabilized solution of anti-RPR antibodies of rabbit with a titre that gives a clear agglutination. It contains 0.95 g/l of sodium azide.

Negative control
Proteic solution not reactive with the suspension.
It contains 0.95 g/l of sodium azide.

REAGENTS PREPARATION

Reagents are ready for the use.
The suspension must be resuspended with much care. When the suspension becomes homogeneous by sweet inversion, pour off the provided quantity to testing in dispenser bottle inspiring with suitable needle.
When testing is terminated remove the suspension from dispenser bottle and rinse out the dispenser bottle and the needle with distilled water.
Stability: until the expiration date stated on the label, when stored at 2-8°C. Do not freeze.

MATERIAL REQUIRED BUT NOT SUPPLIED

Physiologic solution.
COD. AK00500 – AK00501 Slide and stirrers.

PRECAUTIONS

Reagent may contain not reactive and conservative components. It is opportune to avoid contacts with the skin and do not swallow.
Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

QUALITATIVE PROCEDURE

Reagents	Sample	Positive control	Negative control
Sample	50 µl (1 gt)	--	--
Positive control	--	50 µl (1 gt)	--
Negative control	--	--	50 µl (1 gt)
Suspension with dispenser needle	20 µl (1 gt)	20 µl (1 gt)	20 µl (1 gt)

Mix using disposable stirrers and spreading homogeneously the mixture on the slide, then, shake slide for 8 minutes by a sweet rotating motion or by a stirrer at 100 r.p.m and observe eventual agglutination using artificial light.

RESULTS INTERPRETATION

POSITIVE: A clear agglutination within 8 minutes.
NEGATIVE: No agglutination within 8 minutes.

In case of positivity it is opportune to titre semiquantitatively the serum.

SEMIQUANTITATIVE PROCEDURE

Prearrange serial dilution of the serum, pipetting in six slide areas, 50 µl of physiologic solution and 50 µl of sample in the first area. Using the same pipette (inspiring and discharging many times) mix carefully contents of first area and transfer 50 µl in the following area etc. Discharge 50 µl from last area. Dispense suspension, shake for 8 minutes, and observe agglutination. The titre is given by last clear agglutination. Procedure is in the scheme below:

Reagents	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6
Physiologic	50 µl	50 µl	50 µl	50 µl	50 µl	50 µl
Samples	50 µl	50 µl from 1	50 µl from 2	50 µl from 3	50 µl from 4	50 µl from 5
Discharge 50 µl from last area						
Suspension	20 µl	20 µl	20 µl	20 µl	20 µl	20 µl
Dilution	1 : 2	1 : 4	1 : 8	1 : 16	1 : 32	1 : 64

DIAGNOSTIC VALUES

Healthy people should show negative results using this method. Syphilis is caused by infection with the bacterium Treponema Pallidum which can be transmitted congenitally or by sexual contact.

NOTE

- The test can give false positivity in case of leprosy, LE, mononucleosis, Malaria or when reaction time are protracted.
- Positive samples must be tested also with kit TPHA. The final diagnosis must be based on results correlation of tests executed.
- All the reagents used, have been found negative in the reaction with HIV and HBsAg. However, they should be handled with care.
- If the results are incompatible with clinical presentation, they have to be evaluated within a total clinical study.

CALIBRATION

Positive and Negative control sera should be always used to distinguish an eventual background's agglutination of reactive.

TEST PERFORMANCE

Interferences
Any interferences are produced with:

Haemoglobin	≤ 1000 mg/dl
Bilirrubin	≤ 20 mg/dl
Lipids	≤ 1000 mg/dl

Rheumatoid factor shows interferences as from concentrations ≥ 300 UI/ml.

Sensitivity
The sensitivity of method is shown by bibliography as follow:

Sensitivity syphilis primary: 86%
Sensitivity syphilis secondary: 100%
Sensitivity syphilis latent: 98%
Sensitivity syphilis tertiary: 73%

Specificity
A comparison with an available commercial method gave following results on 77 samples compared, giving a specificity = 100%:

		LTA srl		
		+	-	TOT.
COMPETITORS	+	28	0	28
		100%	0%	
	-	0	49	49
		0%	100%	
	TOT.	28	49	77

WASTE DISPOSAL

Product is intended for professional laboratories. Waste products must be handled as per relevant security cards and local regulations.

PACKAGING

CODE AK00510	**(500 TESTS)**
Suspension	2 x 5 ml
Positive control	2 x 0.5 ml
Negative control	2 x 0.5 ml
Bottle RPR	1
Dispenser needle	1
Stirrers	250
Slide RPR	50

CODE AK00504	**(500 TESTS)**
Suspension	2 x 5 ml
Positive control	2 x 0.5 ml
Negative control	2 x 0.5 ml
Bottle RPR	1
Dispenser needle	1
Stirrers	250
Slide RPR	9

CODE AK00501	**(100 TESTS)**
Suspension	1 x 2 ml
Positive control	1 x 0.5 ml
Negative control	1 x 0.5 ml
Bottle RPR	1
Dispenser needle	1

CODE AK00500	**(200 TESTS)**
Suspension	1 x 4 ml
Positive control	1 x 0.5 ml
Negative control	1 x 0.5 ml
Bottle RPR	1
Dispenser needle	1

CODE AK00535	**Positive Control**
Positive control	2 x 0.5 ml

REFERENCES

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Larsen S A et al. Clinical Microbiology Reviews 1995; 8 (1): 1-21.
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Marry W Perrrman et al. Journal of Clinical Microbiology 1982; 16: 286-290.
Earle J et al. JAMA 1952; 4: 4167-473.
NCCLS EP7-P.

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SYMBOLS

IVD Only for IVD use
LOT Lot of manufacturing
REF Code number
Storage temperature interval
Expiration date
Warning, read enclosed documents
Read the directions
Biological risk

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