todylaboratories®

Latex Reagents

RPR Carbon SYPHILIS CARD TEST

A qualitative and Semi- quantitative rapid card test for the detection of
Non-Treponema (reagin) in serum or plasma

IVD

For In-Vitro diagnostic and professional use only

Store at 2 to 8 ℃

Product code: C12LX1009-100 (100 tests)
C12LX1009-500 (500 tests)

INTENDED USE
For the qualitative and quantitative detection of Non-Treponema in serum or plasma.

INTRODUCTION & PRINCIPLE
Besides other antibodies, *Treponema Pallidium* produces non-Treponemal antibodies (reagin) in syphilitic persons. These antibodies can be detected by RPR antigen. RPR card test is a macroscopic screening test for the qualitative and Semi-quantitative detection of reagin antibodies in serum or plasma. The kit contains RPR antigen which is based on the easy to use VDRL carbon antigens. In the presence of the reagin, the antigen causes flocculation of the carbon particles, which appears as black clumps. The charcoal particles contained in the antigen suspension enhances the visual appearance of the coagglutination in positive samples.

MATERIALS
MATERIALS PROVIDED
- RPR carbon antigen reagent.
- Positive and negative controls.
- RPR test cards.
- Plastic sticks.

MATERIALS NEEDED BUT NOT PROVIDED
- Saline 0.9%.
- Rotator (100rpm).
- Accurate pipette to deliver 50 µl .
- Timer.

PRECAUTIONS
- Always use a new pipette tip for every test.

STORAGE AND STABILITY
- The reagents in this kit should be stored in an upright position and refrigerated between 2 to 8°C **. Never Freeze.** Test cards need not to be refrigerated and can be kept at room temperature.
- Reagents should be brought to room temperature and mixed well to obtain a uniform suspension of carbon particles.

PREPARING THE SPECIMEN
- RPR kit can be used with either unheated plasma or heated serum samples.
- Serum samples can stay stable for up to 5 days if stored at 2 to 8 °C.
- Plasma samples collected with EDTA can stay stable up to 24 hours if stored at 2 to 8 °C.

PROCEDURES
QUALITATIVE PROCEDURE
1. Bring reagents to room temperature.
2. Dispense 50µl of sample onto a single circle on the test card.
3. Repeat step 2 for the positive and negative controls.
4. Spread the sample of each test specimen over the entire test circle.
5. Mix the carbon antigen suspension well.
6. Dispense one drop (16 µl) of the carbon antigen onto each test circle containing specimen. Do not mix the antigen with the sample.
7. Using the rotator, rotate the card at 100rpm for **8 minutes**.
8. Read the results in good light immediately after 8 minutes.
9. Don't read the results after more than 8 minutes.

READING THE QUALITATIVE RESULTS
POSITIVE
- If large aggregates appear in the center or the periphery of the test circle containing the sample, then the test should be read as positive (reactive)
- If the aggregates are visible, but weak or small, then the test should be read as weak positive (weakly reactive).
- If test is positive, then results should be confirmed by the quantitative procedure mentioned below.

NEGATIVE
If no aggregates appear and the specimen has smooth grey appearance (non-reactive)

SEMI-QUANTITATIVE PROCEDURE
1. Dispense 50µl of 0.9% saline to test circles numbered 2 to 5. Saline should not be spread. Dispense 50 µl of specimen onto test circle 1.
2. Dispense 50 µl of specimen onto test circle 2. Prepare serial two-fold dilutions by drawing the mixture up and down the pipette 5-6 times avoid any bubble formation. Transfer 50 µl from circle 2 to 3, to 4 and to 5. Dispose 50 µl from circle 5 after mixing.
3. Starting from circle 5 and onto 4,3,2 and 1, mix and spread the serum over the entire area of each test circle.
4. Continue with steps 6-9 of the qualitative procedure.

READING THE SEMI-QUANTITATIVE RESULTS
The dilution of the circles are as follows:

Circle	1	2	3	4	5
Dilution	-	1:2	1:4	1:8	1:16

The titer of the sample is read as follows (P:Positive, N:Negative)

Positive	- P	N	N	N	N
Positive 1:2	P	P	N	N	N
Positive 1:4	P	P	P	N	N
Positive 1:8	P	P	P	P	N
Positive 1:16	P	P	P	P	P

Positive and negative results are read as in the reading qualitative results procedure.

If the result in circle 5 is positive, then further dilution to 1:32, 1:64, 1:128 and 1:256 is required. Use steps 3 in semi-quantitative procedure and steps 6-9 in qualitative procedure to obtain the required dilutions.
**The titer , in the semi- quantitative method , is defined as the highest dilution showing a positive results.

LIMITATION
- This test provides a presumptive diagnosis of syphilis. Physicians should evaluate all clinical and laboratory findings before making a definitive diagnosis.
- In positive specimens, it is recommended to confirm the result by another serological test such as the TPHA.

REFERENCES

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2. Larsen S.A., *et. al.*, ata on file, Treponemal Research and Immunology lab, CDC.
3. McGrew B.E., Stout G.W., Falcon V.H., AM. J. Med. Techs., 34:634, 1969
4. Manual of Tests for Syphilis, PHS publication No.411, 1969.

Rev. aug 2016 lo / amc 30.03.2018

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	Catalogue Number		Store at
IVD	For In-Vitro Diagnostic use		Caution
Σ	Number of tests in the pack		Read product insert before use
LOT	Lot (batch) number		Manufacturer
	Fragile, handle with care		Expiry date
	Manufacturer fax number		Do not use if package is **damaged**
	Manufacturer telephone number		