

This reagent kit is for quantitative estimation of Reagin antibodies produced in response to infectious disease called Syphilis in human.

#### PRINCIPLE:

The RPR antigen reagent consists of antigen coated with carbon particles. The specimen when allowed to react with the reagent in the test circle of the disposable card, produce an agglutination in presence of Reagin antibodies.

#### CLINICAL SIGNIFICANCE:

Treponema pallidum is a causative agent for a chronic-infectious disease called syphilis. Primary mode of transmission of syphilis is through sexual contact. Disease shows stages of development marked by certain symptoms. In primary stage of infection, within 3 weeks, primary chancre appears at the site of infection. The chancre disappears in 2-4 weeks and if untreated, syphilitic lesions such as skin rash and mucosal ulcers develops in different parts of body within few months that marks the secondary stage. Secondary symptoms disappears spontaneously and a dormant stage may be there without any external symptoms of illness. A tertiary stage follows this dormant period and which is characterized by neurologic problems, infiltrative tumours, vascular problems. Diagnosis of syphilis is based on the detection of "Reagin" type of antibody employing cardiolipin antigen. After infection, two main types of antibodies are produced in the host a) Reagin antibodies, b) Treponemal antibodies. Reagin antibodies are rapidly produced as compared to Treponemal antibodies.

#### SAMPLE COLLECTION & STORAGE:

- Fresh clear, unhemolysed serum preferred
- Plasma collected with EDTA, heparin or oxalate may also be used.

#### PRECAUTION:

- Estrom reagents are for In Vitro diagnostic use only.
- Avoid use of hemolysed or contaminated sample.
- All the Reagents and specimen should be brought to room temperature prior to use.
- Drying of Reagent on the test circle of disposable card can cause erroneous result.
- RPR Test results should be read immediately after rotation of slide under high intensity lamp or strong day light.

#### KIT CONTENTS:

##### (a) REAGENTS

- Reagent 1. RPR antigen
- Reagent 2. Positive Control
- Reagent 3. Negative Control

##### (b) ACCESSORIES

- Disposable test cards (10 circles)
- Antigen dropper
- Plastic dropper
- Mixing stick

#### REAGENT STORAGE AND STABILITY:

All the reagents are stable at 2-8°C up to expiry date.

#### PROCEDURE:

- Place one drop of (50 µl) each of positive control, Negative control and sample in separate circles of disposable test card.
- After gently swirling RPR antigen suspension, place one drop (15-20 µl) by antigendropper.
- Using disposable mixing stick mix and spread the liquid on entire area of test circle.
- Rock the slide gently for 2min. and observe for appearances of agglutination.

#### RESULT INTERPRETATION:

No Agglutination	Negative Result
Black aggregates seen within 2 min	Positive Result.

#### LIMITATIONS:

1. In the condition like malaria, lepromatous leprosy, collagen disease, rheumatoid arthritis, infectious mononucleosis, ratbitefever, rubella, mumps, measles, leptospirosis, relapsing fever the RPR antigen cardiolipin may show biological false positive (BFP) reaction. In such cases, a positive reaction should be confirmed by other treponemal test like TPI (Treponema pallidum immobilisation), FTA (fluorescent Treponemal Antibody) test Rprcf (Reiter protein complement fixation)
2. False negative results may be seen in early and latent stage of the disease.

#### BIBLIOGRAPHY:

- N.C. Dey. Medical Bacteriology 6th edition (1970) R 390-396
- Pertney J. (1963). Modification of rapid plasma reagin (RPR) card test, for use in large scale testing. Am. J. Clin., Path, 40, 473-479.
- Stevens, R.W. and Stroebe; E.J (1970); Clin. Path. 53, 32

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	Attention, see instructions for use		Consult Instructions For Use
	For in vitro diagnostic use only		Catalog #
	Store between 2-8°C		Lot Number
	Do not use if package is damaged		Date of Manufacturing
	Manufacturer		Use by