# ULTIMA R.P.R. TEST KIT

| Code | Product Name | Pack Size |
|---|---|---|
| SE111A | ULTIMA R.P.R. TEST KIT | 50 T |
| SE111B | ULTIMA R.P.R. TEST KIT | 100 T |
| SE111D | ULTIMA R.P.R. TEST KIT | 500 T |
| SE111E | ULTIMA R.P.R. TEST KIT | 5 X10 ML |

BEACON

## INTENDED USE :

This Diagnostic reagent kit is used for detection of antibodies produced in mankind in response to the stimulation by disease known as syphilis.

## PRINCIPLE :

RPR test is a modified version of Wassermann's reaction in which the antigens coated with carbon particle are allowed to react with the sample and if the antibodies for syphilis are present the flocculation will occur on the slide due to aggression of carbon particle. If the sample does not contain the antibody then there will not be any flocculation and it will give clear back ground, this will indicate negative reaction.

## CLINICAL SIGNIFICANCE :

Syphilis is caused by the organism Treponema pallidium. This organism is an obligatory parasite of mankind. It is a delicate spiral organism of 8 to 14 u by 0.2 u size with terminal flagella. It is very difficult to study them as they can not be stained by ordinary analine dyes neither can be grown in laboratory on artificial medium. Syphilis caused by Tr. pallidium is a contagious venereal disease marked by lesions on the skin and other organs of the body. By the mode of its transmission the Disease is classified as acquired or congenital. In the primary stage i.e. after 2-6 week of incubation a hard sore is developed at the site of infection, whereas in the secondary stage i.e. after 6 to 12 weeks of incubation malaise, moderate fever lesion on skin or mucous membrane, sore throat, lymph node enlargement, affections of bones, eyes or other organs and large number of organisms in serous secretions can be seen. The tertiary stage of the disease which may soon follow secondary stage or be delayed for many years, can be characterised by commonest lesions of many internal organs and skin, syphilitic aortitis and meningeal involvements.

## Contents :

Reagent 1 : R.P.R. Antigen
Reagent 2 : Positive Control
Reagent 3 : Negative Control

Control provided are sufficient for 10% positive and 10% Negative test.

## SAMPLE :

Fresh serum or plasma separated by using EDTA, heparin or oxalate as anticoagulant is preferred. Venostasis to be avoided.

## STORAGE AND STABILITY:

All reagents are stable till expiry date mentioned on the label when stored at 2-8° C away from direct light.

## PROCEDURE :

**Screening test :**

1. Place one drop of serum/Plasma (50 µl)on the slide with disposable serum dropper.
2. After gently mixing R.P.R. antigen suspension place one drop (15-20 µl) by antigen dropper.
3. Mix well and spread out the liquid on entire area of the circle by using disposable mixing stick.
4. Rock the slide gently for 6 minutes and observe under good light source for appearance of carbon particle clumping.

**Semi quantitative test:**

1. Place 50 µl of 0.9 % saline solution in 2nd, 3rd, 4th and 5th circles of the card by using micropipette. Do not spread the saline solution.
2. Using micropipette, add 50 µL sample in 1st and 2nd circle.
3. Mix sample with saline in 2nd circle by drawing the mixture up and down for 5 times in the micropipette. Avoid bubble formation.
4. Aspirate 50 µL from 2nd circle and transfer to 3rd circle. Repeat the same successively upto 5th circle.
5. Aspirate 50 µL from the 5th circle and discard it.
6. After gently mixing RPR antigen suspension place one drop (15 to 20 µL) by antigen dropper in each diluted sample drop.
7. Mix well and spread out the liquid on entire area of circle by using disposable mixing stick.
8. Rock the slide gently for 6 minutes and observe under good light source for appearance of carbon particle clumping.
9. If the highest dilution tested (1:16) is reactive, continue as follows :

a) Prepare a 1: 50 dilution of non reactive serum in 0.9% saline to be used for making 1:32 and higher dilutions of the specimen to be tested.
b) Prepare 1:16 dilution of the test specimen by adding 0.1 ml of serum to 1.5 ml of 0.9% normal saline. Mix it thoroughly.
c) Place 50 µL of the 1:50 non reactive serum diluent in circles 2 to 5 of an RPR card.
d) Using a safety pipetting device with disposable tip place 50 µL of the 1:16 dilution of the test specimen in circle 1 and 50 µL in circle 2.
e) Using the same pipette and tip, make two fold dilutions.
f) After gently mixing RPR antigen suspension place one drop (15 to 20 µL) by antigen dropper in each diluted sample drop.
g) Mix well and spread out the liquid on entire area of circle by using disposable mixing stick.
h) Rock the slide gently for 6 minutes and observe under good light source for appearance of carbon particle clumping.
i) Use a clean tip for each specimen tested. Prepare higher dilutions if necessary in 1:50 non reactive serum diluent.

10. The end point is the highest dilution showing visible black clumps.

## INTERPRETATION OF RESULT :

**Screening test :**

Read the results under strong source of light with a hand lens. Test results showing slight but definite clumping is reported as reactive or positive.
No Flocculation indicate negative reaction.

**Semi quantitative :**

Report the results in terms of highest dilution that has given a reactive result Including a minimally reactive result, as follows:

| Undiluted (1:1) | Serum Dilutions | | | | REPORT |
|---|---|---|---|---|---|
| | 1:2 | 1:4 | 1:8 | 1:16 | |
| Rm | N | N | N | N | Reactive, Undiluted 1:1 |
| R | R | N | N | N | Reactive, 1:2 dilution |
| R | R | R | N | N | Reactive, 1:4 dilution |
| R | R | R | Rm | N | Reactive, 1:8 dilution |

R = Reactive, Rm = Minimally reactive, N = Non-reactive

## LIMITATIONS :

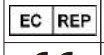
The cardiolipin antigens used in RPR test may tend to give Biological False Positive (BFP) reaction in the conditions like malaria, lepromatous leprosy, collagen disease, rheumatoid arthritis, Infectious mononucleosis, rubella, mumps, measles leptospirosis, relapsing fever, ratbite fever etc. In such a condition a positive reaction should be confirmed by other treponemal tests like TPI (Treponema Pallidium Immobilisation), FTA (Fluorescent Treponemal Antibody) test and Rpcf ( Reiter protein compliment fixation ).

## TO REMEMBER :

1. Bring all reagents to room temperature.
2. Drying of reagent on the slide may lead to erroneous result.
3. Discard haemolysed or contaminated sample.
4. Do not use an excess of anti-coaggulants, such as Potassium oxalate or Sodium fluoride which can lead to unreliable results.
5. RPR Test results should be read immediately after rotation of slide under a high intensity lamp or strong day light.
6. Avoid performing the test directly under the fan.

## SYMBOL LEGENDS

| Symbol | Explanation of Symbol |
|---|---|
|  | Consult instruction for use |
|  | In Vitro diagnostic device |
|  | Fragile |
|  | Store at 2°C to 8°C |
|  | Keep away from sunlight |
|  | Keep dry |
|  | Do not reuse |

| Symbol | Explanation of Symbol |
|---|---|
|  | Batch code no. |
|  | Manufacturer |
|  | Date of manufacture |
|  | Use by (date or month of expiry) |
|  | Authorized Representative |
|  | European Conformity |

## REFERENCES :


1. Pertnoy J.(1963), Modification of the Rapid Plasma Reagin (RPR) card test for use in large scale testing, Am. J. Clin., Path., 40, 473-479.
2. Herweg. J. C. Haffmann, F. D. and Reed, C. A. (1967), Pediatric use of Rapid Plasma Reagin (circle) card test 40 : 440-43.
3. N. C.Dey. Medical Bacteriology 6th edition (1970) P. 390-396.



BEA/24/URP/SE/IFU-00