



PRINCIPLE

The RA Latex reagent antigen consists of polystyrene latex particles coated with specially purified human Gammaglobulin. When the latex reagent mixed with sample containing RF shows agglutination indicating Positive test result. Agglutination depends on concentrations of RF in serum that may be equal or greater than sensitivity mentioned as detectable by the slide test method.

CLINICAL SIGNIFICANCE

Rheumatoid Factors (RF) are a group of IgM antibodies directed against the Fc fragment of the IgG molecules. RF mainly present in the sample of the patients with Rheumatoid Arthritis(RA) but other diseases may also produce RF.

SAMPLE COLLECTION & STORAGE

- ✓ Fresh clear serum is preferred
- ✓ Store at 2-8 degrees temperature.
- ✓ Do not use Plasma / Hemolysed / Lipemic samples

PRECAUTIONS

- * Bring all reagents to room temperature before use
- * Do not freeze the Latex reagent or expose to extreme temperature ' Shake well the Latex reagent before use
- * Drying of the reagent and improper mixing of the reagent with sample leads to Erroneous results
- * Use of Positive and Negative controls provided enables greater proficiency of the results
- * Latex reagent should be completely released

from the dropper before capping to avoid drying and formation of flakes upon storage at 2-8°C

- * Do not read the results after 2 minutes

KIT CONTENTS & STORAGE	25T	2X50T
RA Latex Reagent	1Vial	2 vials
Positive Control	1 Vial	1Vial
Negative Control	1 Vial	1Vial
Glass Slide	1NO	1NO
Sample dropper with teat	25 Nos	100nos
Mixing Sticks	25 Nos	100nos

All reagents are to be stored at 2-8 °C and stable till expiry date mentioned.

REAGENT PREPARATION

All reagents are ready to use.

PROCEDURE

A)Qualitative Method

1. Place one drop of Serum Positive Negative Control in separate test Circle of the glass slide
2. After swirling the RA Latex antigen suspension , place one drop in each Circle
3. Mix well with the disposable mixing sticks provided
4. Rock the slide gently for 2 minutes and observe for agglutination & read results

RESULTS

No Agglutination : **NEGATIVE**
Agglutination within 2 minutes : **POSITIVE**

A) Semi quantitative Method

1. Dilute the specimen serially 1 :2, 1:4, 1:8, 1:16 using normal saline
2. Place one drop of each diluted Serum in separate test circle of the glass slide .
3. After swirling the RA Latex antigen suspension, place one drop in each circle
4. Mix well with the disposable Mixing stick provided
5. Rock the slide gently for 2 minutes and observe for agglutination

RESULTS

Agglutination in the highest specimen dilution with in 2 minutes corresponds to RA titre in the specimen.

The concentration of RA can be calculated as follows: $RA_{inIU/ml} = \frac{D \times S}{2}$

D = Highest dilution showing clear cut agglutination

S = Sensitivity of the test: 1 2 IU/ml

LIMITATIONS

Positive test results may also found in syphilis , lupus erythematosus: hyper gamma globulinemia , hepatitis . So final diagnosis should be followed after correlation of test results with other clinical symptoms and findings. Controls should be handled with proper care though the source material used in the manufacture of Positive & Negative controls is tested for HBsAg & HIV antibodies and is found to be Negative

Bibliography :

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