RHEUMATOID FACTOR LATEX TEST KIT
(R.A. TEST KIT)

INTENDED USE :
This diagnostic reagent kit is used for “in vitro” detection of Rheumatoid factor in patient serum.

PRINCIPLE :
R.A. Test antigen consists of polystyrene latex particles coated with specially purified human gammaglobulin. The suspension of coated latex particles agglutinate visibly when mixed with a serum containing Rheumatoid Factor in concentration equal to or greater than the sensitivity mentioned as detectable by slide test methods. The idea of using inert particles coated with gammaglobulin to detect Rheumatoid Factor was developed from the sheep cell agglutination tests like Rose-Waaler test. Uniformly stabilised polystyrene latex particles as well as bentonite particles coated with Gammaglobulin have been used. Several techniques have employed polystyrene latex particles. Most of these are based on the original technique of singer and plotz. A slide test as well as a tube titration technique are available. The bentonit test based on similar principles has largely been abandoned because of technical complexities.

CLINICAL SIGNIFICANCE :
The human body some times produces auto antibodies against the host antigen. The role which this aberrant immunity plays in certain as rheumatic disease is unknown but their presence serve as credible marker of the disease. The immunoglobulins of the class IgG, IgM, IgA or IgE. Auto antibodies are diagnostically important for Rheumatoid arthritis, which are termed as Rheumatoid Factors (RF.) In almost 80% of the patient suffering from Rheumatoid arthritis the RF Test gives positive results where as in case of rheumatic fever RF will yield negative results.

Contents :
Reagent 1 : R.F. Antigen (Gamma Globulin)
Reagent 2 : Positive Control
Reagent 3 : Negative Control

SAMPLE :
No special preparation of the patient is required Prior to sample collection. Serum must be used beacuse fibrinogen in plasma may give nonspecific agglutination of the latex gammaglobulin present in reagent. The serum samples should be stored at 2º-8ºC after collection. It can be stored best at -20º C if prolonged storage is desired. Inactivation of the serum is not neccessary. However inactivated serum can also be used for the test.

STORAGE AND STABILITY :
All Reagents are stable at 2º-8ºC till the expiry date mentioned on the individual labels. Do not Freeze.

PROCEDURE :
Qualitative Slide Test :
Allow all reagents as well as the sample to reach room temperature.
1. Using disposable plastic dropper place one drop of test specimen in circled area of the glass slide provided in the kit.
2. Add one drop of Latex Gammaglobulin Reagent to the above drop and mix well with disposable applicator stick.
3. Rock the slide gently back and forth for two minutes and examine for agglutination. Do not examine beyond two minutes. For Positive & Negative Controls follow the same Procedure as mentioned above by taking control serum from respective vials.

TEST RESULTS :
The following conclusion may be drawn depending upon the observation.

Observation | Conclusion
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(i) Coarse agglutination (usually occuring within one minute) | Strongly positive
(ii) Finer agglutination (usually taking full 2 minutes) | Weakly positive
(iii) Smooth suspension | Negative

SEMI QUANTITATIVE TEST :
1. Dilute the specimen serially in the ratio of 1:2, 1:4, 1:8, 1:16, 1:32, 1:64 using Normal Saline.
2. Place one drop of diluted sample using plastic droppers in each circle of the glass slide.
3. Add one drop of latex reagent in each of these circle. Mix well with applicator stick.
4. Rock the slide gently back and forth for two minutes and examine for agglutination.

CALCULATIONS :
Concentration of Rheumatoid Factor (RF) can be determined as follows :
RF IU/ml = Sensitivity x Titre
Where : Sensitivity = 8 IU/ml
Titre = Highest dilution showing clear cut agglutination.

LIMITATIONS :
The Latex agglutination test for Rheumatoid Factor has occasionally been found positive with same sera of patients with hepatities, sarcoidosis, cirrhosis of liver, syphilis, systemic lupus erythematosus (SLE), hypergammaglobulinemia, scleroderma, siogren's syndrome, as well as acute bacterial and viral infections. It is almost always absent in case of Rheumatic fever. The latex agglutination test does not provide definite diagnosis of Rheumatoid Arthritis and therefor it should be used only in connection with complete clinical evaluation.

TO REMEMBER :
1. Positive and Negative controls are ready to use.
2. Contaminated sera and longer reaction time will lead to false Positive results.
3. Improper mixing and drying of reagents will lead to erroneous results.
4. Do not perform the test directly under the fan.
5. Do not interchange the dropper of bottles.
6. Care should be taken to empty the dropper after every use.
7. The Latex Gammaglobulin Reagent vial should be properly closed to avoid drying and formation of flakes when stored at 2-8. Do not freeze it or leave it at room temperature for long period.
8. Specimen bottles or tubes and the test slides must be free from detergents.
9. Use positive and negative controls for greater proficiency of result interpretation.

REFERENCES :

Code No. | Pack Size |
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J79 | 25 T |
J79A | 50 T |
J79B | 100 T |