ORDER INFORMATION

CODE : DL4201: 25 Test
DL4202: 50 Test
DL4203: 100 Test

DELTA
RHEUMATOID FACTOR
Latex Method

This diagnostic reagent kit is used for "in-vitro" determination of Rheumatoid Factor (RF) in serum by qualitative and semi quantitative latex slide method..

PRINCIPLE OF THE METHOD :

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 stabilized 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. Slide tests 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 sometimes produces auto antibodies against the host antigen. The role which this aberrant immunity plays in certain as rheumatic disease is unknown but their presence serves 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.

REAGENTS :

Reagent 1: RF Antigen
Reagent 2: Positive Control
Reagent 3: Negative Control

STORAGE AND STABILITY :

RF Antigen, Positive and Negative control are ready to use.

All the components of the kit are stable until the expiration date mentioned on the individual label when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not use reagents over the expiration date.

Do not freeze. Frozen latex and diluent could change the functionality of the test.

SAMPLES:

No special preparation of the patient is required Prior to sample collection.

Serum must be used since fibrinogen in plasma may give nonspecific agglutination of the latex gammaglobutin present in reagent.

Lipemic, haemolysed and contaminated serum could produce non-specific results.

The serum samples should be stored at 2° to 8°C after collection. It can be stored best at -20° C if prolonged storage is desired.

Inactivation of the serum is not necessary. However inactivated serum can also be used for the test.

PROCEDURE FOR 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 plastic slide provided in the kit.
2. Shake the Latex reagent well. 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.

RESULT INTERPRETATION FOR QUALITATIVE SLIDE TEST:

The following conclusion may be drawn depending upon the observation.

Observation	Conclusion
(i) **Coarse agglutination** (usually occurring within one minute)	**Strongly Positive**
(ii) **Finer agglutination** (usually taking full 2 minutes)	**Weakly Positive**
(iii) **Smooth suspension**	**Negative**

PROCEDURE FOR SEMI QUANTITATIVE TEST:

1. Dilute the specimen serially in the ratio of 1:2, 1:4, 1:8, 1:16, 1:32 and 1:64 using Normal Saline.
2. Place one drop of diluted sample using plastic droppers in each circle of the plastic slide.
3. Shake the Latex reagent well. Add one drop of RF 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.

RESULT CALCULATIONS FOR SEMI QUANTITATIVE TEST:

Concentration of Rheumatoid Factor (RF) can be determined as follows:

RF (IU/ml) = RF Sensitivity (IU/ml) x Titre

Where RF Sensitivity = 8 IU/ml
Titre = Highest dilution showing clear agglutination.

LIMITATIONS:

The Latex agglutination test for Rheumatoid Factor has occasionally been found positive with same sera of patients with hepatitis, sarcoidosis, cirrhosis of liver, syphilis, systemic lupus erythematosus (SLE), hypergammaglobulinemia, scieroderma, 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 therefore it should be used only in connection with complete clinical evaluation.

PRECAUTIONS:

1. Contaminated sera and longer reaction time will lead to false Positive results.
2. Improper mixing and drying of reagents will lead to erroneous results.
3. Do not perform the test directly under the air flow.
4. Do not interchange the dropper of bottles.
5. Care should be taken to empty the dropper after every use.
6. 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.
7. Specimen bottles or tubes and the test slides must be free from detergents.
8. Use positive and negative controls for greater proficiency of result interpretation.

NOTES :

Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

BIBLIOGRAPHY :

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