Lifescreen™ - RA

(Latex Agglutination Method)

CLINICAL SIGNIFICANCE:

Autoantibodies produced during Rheumatoid arthritis (RA), termed as Rheumatoid Factors (RF) can be detected which are immunoglobulins, belonging to the class of IgG, IgM, IgA, and IgE. Immunoglobulin M class RF with specificity to human IgG Fc is the most useful prognostic marker for RA. These Rheumatoid factors are diagnostically useful tools for detecting Rheumatoid arthritis.

RF plays a role in perpetuating the rheumatoid inflammatory process and the severity of joint damage could be predicted according to the strength of RF reactivity. A significant decline of RF with the remission of disease activity has also been demonstrated as seen with quantified serial determinations of RF, hence, making it more meaningful to the diagnosis , prognosis and assessment of therapeutic efficacy of rheumatoid arthritis.

Measurement of rheumatoid factor is used for differentiating rheumatoid arthritis from other chronic inflammatory arthritis and is important in the progress and therapeutic management of the disease.Rheumatoid factor has been associated with some bacterial and viral infections (eg. Hepatitis, infectious Mononucleosis) and some chronic infections (e.g. Tuberculosis, Parasiti diseases, Subacute Bacterial Endocarditis) and Cancer.

TEST PRINCIPLE:

The latex Reagent is coated with human Gammaglobulin (IgG). The specimen containing RF, on mixing with Latex Reagent, agglutinates, showing the positive test result. If RF is absent there will be no agglutination which is the negative test result.

KIT CONTENTS:	**Code No. KRA1 25 T**	**Code No. KRA2 50T**
Reagent 1. Latex Reagent	25 T	50 T
Reagent 2. Positive Control	0.25 ml	0.25 ml
Reagent 3. Negative Control	0.25 ml	0.25 ml

ACCESSORIES:

Black glass slide with 4-circles, glass dropper for Latex reagent, capillary droppers & mixing sticks.

SPECIMEN:

Fresh serum collected by approved techniques. In case of a delay in testing, store at 2-8^{0}C (stable upto a week). Hemolysed , lipaemic or icteric serum samples should not be used.

STORAGE & STABILITY :

All the reagents are ready-to-use and are Stable at 2-8^{0}C till the expiry date mentioned on the labels.

PROCEDURE:

QUALITATIVE TEST:

1. Place one drop each of specimen, positive control and negative control in separate circles of the slide using the capillary droppers provided.
2. Add one drop of Latex Reagent in each of these circles.
3. Mix the content of each circle separately ,spreading it within the circle.
4. Rock the slide gently for 2 minutes and look for agglutination.

SEMI QUANTITATIVE TEST:

1. Dilute the specimen serially 1:2, 1:4, 1:8, 1:16, 1:32, 1:64 using normal saline.
2. Place one drop each of the serially diluted serum sample using the capillary droppers, in each circle of the slide. Now, proceed testing further as in the Qualitative Test method.

INTERPRETATION OF RESULTS:

QUALITATIVE TEST :

1. To validate test results , check agglutination with Positive Control and no agglutination with Negative Control .
2. Agglutination within 2 minutes is a positive test and indicates presence of RA in the test specimen.
3. No agglutination up to 2 minutes is a negative test and indicates absence of RA in the test specimen.

DO NOT OBSERVE RESULTS BEYOND 2 MINUTES

SEMI QUANTITATIVE TEST:

1. The highest dilution, which shows a visible agglutination within 2 minutes, indicates the RF titre.
2. The approximate RF concentration can be obtained by multiplying titre by sensitivity of the test.

RF in IU/ml = D x S
D = Highest dilution showing clear cut agglutination.
S= Sensitivity of the test – 12 IU/ml

NOTES:

1. Bring all the reagents and samples to RT before use.
2. Do not freeze the Latex Reagent.
3. Positive and Negative Controls are ready to use and should not be diluted while using in test procedure
4. The reagents can be damaged on exposure to extreme temperatures.
5. It is recommended that the performance of the reagents be verified using the positive control provided
6. Use of plasma rather than serum can lead to erroneous RA values.
7. Improper mixing and drying of reagents may lead to erroneous results Markedly lipaemic, hemolysed, and contaminated serum could produce non-specific RA values.
8. Do not use hemolysed or turbid specimen.
9. Shake the Latex Reagent (1) well prior to use, to ensure a homogeneous latex suspension.
10. Contaminated sera and a longer reaction time may lead to false positive results
11. All material derived from human source have been tested for HBsAg & HIV antibodies and found to be non reactive. However, for better safety, handle this material with proper care.
12. Hold the glass dropper vertically while dispensing Latex Reagent, to ensure uniform drop size.
13. Results should be read at a normal reading distance in good light. DO NOT USE A MAGNIFYING LENS.
14. In addition to Rheumatoid arthritis, positive results may also be found in Syphilis, Systemic Lupus Erythematosus, Hepatitis, and Hypergammaglobulinemia.
15. As with all diagnostic procedure, the physician should evaluate data obtained by the use of this kit in light with other clinical information.

BIBLIOGRAPHY:

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