SBio RF

Slide Test for Rheumatoid Factors

REF	90410050	90410100
Σ	50 T	100 T

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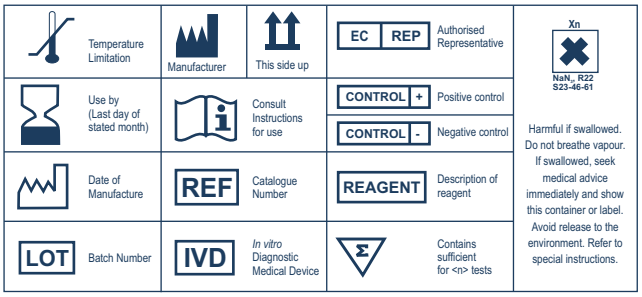

SUMMARY

Sometimes autoantibodies are produced by the human body against self antigens. The precise role that this aberrant immunity plays in the pathogenesis of certain rheumatic diseases is unknown. However the presence of these autoantibodies serves as credible marker of the disease.

In rheumatoid arthritis, diagnostically useful autoantibodies termed as "Rheumatoid factors" (RF) can be detected which are immunoglobulins of the class IgM, IgG, IgA and IgE. Practically, IgM class RF with specificity to human IgG (Fc) is the most useful prognostic marker of RA. The clinical significance of RF determinations consists in differentiation between rheumatoid arthritis, in which RF of modified IgM class have been demonstrated in the serum of approximately 80% of the cases examined and rheumatic fever, in which RF are almost always absent. The agglutination test is most frequently used because of its greater sensitivity and simplicity.

SBio RF is a latex agglutination slide test for detection of rheumatoid factors of the IgM class.

REAGENTS

1. SBio RF reagent (latex): A uniform suspension of polystyrene latex particles coated with suitably modified Fc fraction of IgG. The reagent is standardized to detect ≈10 IU/ml of RF or more. The standardization of detection limit of SBio RF is traceable to the W.H.O.,1st International Reference Preparation of Rheumatoid Arthritis Serum.
2. Positive control, reactive with the SBio RF reagent.
3. Negative control, non-reactive with the SBio RF reagent.

Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity and performance.

REAGENT STORAGE AND STABILITY

a) Store the reagents at 2-8°C. DO NOT FREEZE.
b) The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label. Do not use reagents after the expiry date.

PRINCIPLE

SBio RF slide test for detection of rheumatoid factors is based on the principle of agglutination. The test specimen is mixed with SBio RF latex reagent and allowed to react. If RF is present within detectable levels then a visible agglutination is observed. If RF is absent or below detectable levels then no agglutination is observed.

NOTE

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. The reagents that are derived from human source have been tested for HBsAg and Anti-HIV antibodies and are found to be non-reactive. However handle the material as if infectious.
3. Reagent contains 0.1% Sodium Azide as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
4. The reagent can be damaged due to microbial contamination or on exposure to extreme temperatures. It is recommended that the performance of the reagent be verified with the positive and negative controls provided with the kit.
5. Shake the SBio RF latex reagent well before use to disperse the latex particles uniformly and improve test readability.
6. Only a clean and dry slide must be used. Clean the slide with distilled water and wipe dry.
7. Accessories provided with the kit only must be used for optimum results.
8. Do not use damaged or leaking reagents.

SPECIMEN COLLECTION AND PREPARATION

No special preparation of the patient is required prior to specimen collection by approved techniques. Only serum must be used for testing. Should a delay in testing occur, store the sample at 2-8°C. Samples can be stored for upto a week. Do not use hemolysed serum.

ADDITIONAL MATERIAL REQUIRED

Stop watch, Test tubes, A high intensity direct light source, Isotonic saline.

TEST PROCEDURE

Bring reagent and samples to room temperature before use.

Qualitative Method

1. Pipette one drop (40µl) of serum onto the slide using the disposable pipette provided with kit.
2. Add one drop of SBio RF latex reagent to the drop of serum on the slide. Do not let the dropper tip touch the liquid on the slide.
3. Using a mixing stick, mix the serum and SBio RF latex reagent uniformly over the entire circle.
4. Immediately start a stopwatch. Rock the slide gently, back and forth, observing for agglutination macroscopically at **two minutes**.

Semi Quantitative Method

1. Using isotonic saline prepare serial dilutions of the serum sample positive in the qualitative method 1:2, 1:4, 1:8, 1:16, 1:32, 1:64 and so on.
2. Pipette one drop (40µl) of each dilution of the serum sample onto separate reaction circles.
3. Add one drop of SBio RF latex reagent to each drop of the diluted serum sample on the slide. Do not let the dropper tip touch the

liquid on the slide.
4. Using a mixing stick, mix the sample and the latex reagent uniformly over the entire circle.
5. Immediately start a stopwatch. Rock the slide gently, back and forth, observing for agglutination macroscopically at **two minutes**.

INTERPRETATION OF RESULTS

Qualitative Method

Agglutination is a positive test result and indicates the presence of rheumatoid factors in the test specimen.
No agglutination is a negative test result and indicates the absence of rheumatoid factors in the test specimen.

Semi Quantitative Method

Agglutination in the highest serum dilution corresponds to the approximate amount of rheumatoid factors in IU/ml present in the test specimen.

To calculate the RF in IU/ml, use the following formula.
RF (IU/ml) = S x D
Where, S = Sensitivity of the reagent i.e. 10 IU/ml.
D = Highest dilution of serum showing agglutination.

REMARKS

1. Markedly lipemic, hemolysed and contaminated serum samples could produce non-specific results.
2. Use of plasma rather than serum can lead to false positive results.
3. Do not read results beyond two minutes.
4. Rheumatoid factors are not exclusively found in rheumatoid arthritis but sometimes in syphilis, systemic lupus erythematosus, hepatitis, hypergammaglobulinemia also.
5. It is recommended that results of the test should be correlated with clinical findings to arrive at the final diagnosis.
6. The SBio RF reagent is free from prozone effect at RF levels between 10 IU/ml to 2300 IU/ml of RF concentration.
7. SBio RF reagent is sensitive to the presence of IgM RF with heterogenous specificity.

PERFORMANCE CHARACTERISTICS

1. The performance characteristics of SBio RF were evaluated using known positive and negative samples. The known samples were validated using other commercial manufacturers latex slide test reagent having similar performance characteristics.

	Total	SBio RF	
		Positive	Negative
RF +ve samples	16	16	0
RF -ve samples	70	0	70
	86	16	70

Sensitivity: 100% Specificity: 100%

2. Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of RF negative and RF positive samples. No variations were found in the outcome of different tests.

WARRANTY

This product is designed to perform as described on the label and the package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

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Manufactured by:

TULIP DIAGNOSTICS (P) LTD.

Plot Nos. 92/96, Phase II C, Verna Industrial Estate,
Verna, Goa - 403 722, INDIA.
Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh,
Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.

Manufactured for:

Singapore SB Biosciences PTE Ltd.
11 Yishun Street 51, #04-23,
The Criterion, Singapore 767971

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EC REP

CMC Medical Devices & Drugs S.L., C/ Horacio Lengo No. 18, CP 29006, Malaga, Spain