SLIDE TEST FOR RHEUMATOID FACTORS

BACKGROUND

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.

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

ASSAY PRINCIPLE

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

REAGENTS

1. Vitro RF reagent: A ~~sion of polystyrene latex~~ particles coated with suitably modified Fc faction of IgG. The reagent is standardised to detect » 10 IU/ml of RF or more.
2. Positive control, reactive with the Vitro RF reagent.
3. Negative control, non-reactive with the Vitro 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.

SPECIMEN

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.

PROCEDURE

Bring reagent and samples to room temperature before use.

Qualitative Method

1. Pipette one drop of serum onto the glass slide using the disposable pipette provided with kit.
2. Add one drop of Vitro RF latex reagent to the drop of test specimen on the slide. Do not let the dropper tip touch the liquid on the slide.
3. Using a mixing stick, mix the serum and Vitro 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 each dilution of the serum sample onto separate reaction circles.
3. Add one drop of Vitro 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.

To calculate the RF in IU/ml, use the following formula:

$$RF\ (IU/ml) = S \times D$$

Where, S = sensitivity of the reagent i.e.10 IU/ml

D = Highest dilution of serum showing agglutination.

REMARKS

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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 Vitro RF reagent is free from prozone effect at RF levels between 10 IU/ml to 2300 IU/ml of RF concentration.
7. Vitro RF reagent is sensitive to the presence of IgM RF with heterogeneous specificity.

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.

NOTES

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. All the reagents 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 a 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 supplied with the kit.
5. Shake the Vitro RF latex reagent well before use to disperse the latex particles uniformly and improve test readability.
6. Only a clean and dry glass 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.

BIBLIOGRAPHY

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2. **Heller G., Jacobson S.A., Koloday M. H., Kammerer M. H.,** J. Immunol., 72:66 (1954).
3. **Singer J. M., Bull.** Rheum. Dis., 24: 762 (1974).
4. **Clinical Laboratory Diagnosis, Edited by Lothar Thomas, M.D**., 1st Ed., 1998, TH-Books Verlagsgesellschaft GmbH, Frankfurt, Germany.
5. **Data on file**: Vitro Diagnostics.

SYMBOL DECLARATION

	Manufacturer
	Consult instructions for use
LOT	Batch code (Lot #)
REF	Catalog number
	Temperature limitation
IVD	In vitro diagnostic medical device
	Use by
	Caution. Consult instructions
	Keep away from light

ORDERING INFORMATION

REF	SIZE
4051	100 TEST
4052	50 TEST

*All kit sizes are available with or without accessories which include:

- Positive Control.
- Negative Control.
- Slide.
- Mixing Staws.

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