



## SLIDE TEST FOR RHEUMATOID FACTORS

### 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.

RHELAX<sup>®</sup>-RF is a latex agglutination slide test for detection of rheumatoid factors of the IgM class.

### PRESENTATION

REF	REF	10410005	10410025	10410035	10410050	10410070	10410100
Latex/ Tests	▽	5 ml	25 Tests	35 Tests	50 Tests	70 Tests	100 Tests
Control	+	-	0.4 ml	0.4 ml	0.4 ml	0.4 ml	0.4 ml
Control	-	-	0.4 ml	0.4 ml	0.4 ml	0.4 ml	0.4 ml
Six circle black plastic slide		-	1	1	1	1	1
Sample droppers		-	25	35	50	70	100
Mixing stick ladder		-	1	2	2	3	4
Rubber teat		-	1	1	1	2	2
Pack insert		1	1	1	1	1	1

### REAGENTS

1. RHELAX<sup>®</sup>-RF reagent (latex): A uniform suspension of polystyrene latex particles coated with suitably modified Fc fraction of IgG (agglutinating sera). The reagent is standardised to detect  $\approx 10$  IU/ml of RF or more. The standardization of detection limit of RHELAX<sup>®</sup>-RF is traceable to the W.H.O., 1st International Reference Preparation of Rheumatoid Arthritis Serum.
2. Positive control, reactive with the RHELAX<sup>®</sup>-RF reagent.
3. Negative control, non-reactive with the RHELAX<sup>®</sup>-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

1. Store the reagent at 2-8°C. DO NOT FREEZE.
2. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label.

### PRINCIPLE

RHELAX<sup>®</sup>-RF slide test for detection of rheumatoid factors is based on the principle of agglutination. The test specimen (serum) is mixed with RHELAX<sup>®</sup>-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.

### NOTE

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 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 RHELAX<sup>®</sup>-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.

#### **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 up to a week. Do not use hemolysed serum.

#### **MATERIAL PROVIDED WITH THE KIT**

Reagent

RHELAX®-RF latex reagent, Positive control, Negative control.

Accessories

Slide with six reaction circles, Sample dispensing pipettes, Mixing sticks, Rubber teat.

#### **ADDITIONAL MATERIAL REQUIRED**

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

#### **TEST PROCEDURE**

1. Bring reagent and test specimen (serum) to room temperature before use.
2. Tighten the cap of each; Latex reagent bottle, positive control and negative control bottles respectively in the clockwise direction to pierce the bottle nozzle.

#### **Qualitative Method**

1. Pipette one drop of test specimen (serum) onto the slide using disposable pipette provided with the kit.
2. Add one drop of RHELAX®-RF latex reagent to the drop of test specimen (serum) on the slide by holding the latex reagent vial vertically. Do not let the dropper tip touch the liquid on the slide.
3. Using a mixing stick, mix the test specimen (serum) and the RHELAX®-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 test specimen (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 test specimen (serum) sample onto separate reaction circles.
3. Add one drop of RHELAX®-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 test specimen (serum) 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 presence of rheumatoid factors in the test specimen (serum).

No agglutination is a negative test result and indicates absence of rheumatoid factors in the test specimen (serum).

##### **Semi Quantitative Method**

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

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**

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 RHELAX®-RF reagent is free from prozone effect at RF levels between 10 IU/ml to 2300 IU/ml of RF concentration.
7. RHELAX®-RF reagent is sensitive to the presence of IgM RF with heterogenous specificity.
8. Cap the reagent vial tightly after use to avoid spilling of reagent inside the cap.
9. Always keep the reagent vial in upright position during storage.

**PERFORMANCE CHARACTERISTICS**

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

	Total	RHELAX®-RF	
		+ VE	- VE
RF + Ve samples	16	16	0
RF - Ve samples	70	0	70
	86	16	70

Sensitivity: 100%

Specificity: 100%

Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of RF negative and RF positive serum 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**

1. Amy. M. Wasserman et.al, Diagnosis and Management of Rheumatoid Arthritis, American Family Physician , Vol 84, No. 11, Dec 1, 2011 , pgs 1245-1252.
2. Clinical Laboratory by Lothar Thomas , M.D., 1st edition, 1988, TH-Books, Verlagsgesellschaft mbH, Frankfurt, Germany, pgs 810-813
3. Data on file: Tulip Diagnostics (P) Ltd.

### SYMBOL KEYS

	Temperature limitation		Manufacturer		Contains sufficient for <n> tests
	Use by		Consult Instructions for use	<b>CONTROL +</b>	Positive control
	Date of Manufacture	<b>REF</b>	Catalogue Number	<b>CONTROL -</b>	Negative control
<b>LOT</b>	Batch Number/ Lot Number	<b>IVD</b>	<i>In vitro</i> Diagnostic Medical Device	<b>REAGENT</b>	Description of reagent
	This side up	<b>EC REP</b>	Authorised Representative in the European Community		



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**EC REP**

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