ASTAM DIAGNOSTICS

PRODUCT INSERT

REF RAFS

PRATHAM®
RF Test (Latex)

INTENDED USE

PRATHAM® RF Test (Latex) is a latex slide agglutination test intended used for the qualitative and semi-quantitative detection of Rhematoid factor (RF) in human serum.

INTRODUCTION

Rheumatoid factors are antibodies directed against sites in the FC fragment of human and animal IgG. Their frequent occurrence in rheumatoid arthritis makes them useful for diagnosis and monitoring of the disease.
One method used for rheumatoid factor detection is based on the ability of rheumatoid arthritis sera to agglutinate sensitized res cells. A more sensitive reagent consisting of biologically inert latex beads coated with human gamma globulin was later described. The RF kit is based on the principle of latex agglutination assay. The major advantage of this method is rapid performance and lack of heterophile antibody interference.

TEST PRINCIPAL

PRATHAM® RF Test (Latex) slide test for qualitative and semi-quantitative detection of Rheumatoid factors (RF) in human serum. Latex particles coated with goat IgG anti-human RF are agglutinated when mixed with samples contacting RF.

KIT COMPONENTS

1. Latex Reagent
2. Positive Control
3. Negative Control
4. Test Slide
5. Mixing Sticks
6. Sample Droppers
7. Product Insert

MATERIAL REQUIRED BUT NOT PROVIDED

Micro pipettes, Vortex mixer, Tissue paper, Normal saline, Test Tube, Centrifuge Marker, Timer, Specimen Collection Device.

STORAGE AND STABILITY

PRATHAM® RF Test (Latex) slide test components are stable up to expiry date indicated on the component label/box label. RF kit needs to be stored at 2-8º C.

SPECIMEN COLLECTION AND STORAGE

1. Use fresh serum collected by centrifuging clotted blood.
2. If the test cannot be carried out on the same day, the serum may be stored between 2-8º C for no longer than 48 hours after collection. For longer periods the sample must be frozen.
3. As in all serological tests, hemolytic or contaminated serum must not be used.
4. Do not use plasma.

WARNING AND PRECAUTION

- Cap the vial properly after use to avoid drying of the latex reagent. Do not freeze the latex reagent.
- Positive & negative controls are ready to use & should not be diluted while using in test procedure.
- As with all diagnostic tests, the final diagnosis should be based on a correlation of test results with other clinical symptoms & findings.
- Drying of the specimen and latex reagent mixture at the periphery of the circle could lead to erroneous results.
- In addition to Rheumatoid Arthritis, positive result may also be found in Syphilis, Systemic Lupus, Erythematosus, Hepatitis, Hypergammaglobulinema etc.

- This package insert must be read completely before performing the test. Failure to follow the insert may give inaccurate test results.
- Do not use expired test kit.
- Bring all components to room temperature (15º C-30º C) before use.
- Do not use the components of any other type of test kit as for the components in this kit.
- Apply standard bio-safety precautions for handling and disposal of potentially infective material.
- Do not smoke, drink or eat in areas where specimens or kit is being handled.
- Handle all specimen as potentially infections.
- Wear gloves while handling specimens and performing the test.
- Avoid splashing and aerosol formation.
- Clean up spills throughly using an appropriate disinfectand.
- Do not use if the product has been exposed to excessive heat.
- Dispose off all specimens and materials used to perform the test as bio- hazardous waste.
- Firmly shake the latex reagent vial properly to get the homogenous latex particles before testing.

TEST PROCEDURE

A. QUALITATIVE TEST:

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperature.
2. Place 1 drop of the sample with the help of specimen dropper and one drop of each positive and negative controls into separate circle on the test slide.
3. Mix the RF-latex reagent vigorously or on a vortex mixer before using and add one drop to each test circle.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Gently rock the slide for two (2) minutes and read agglutination reaction if any immediately under direct light.

B. SEMI-QUANTITATIVE TEST:

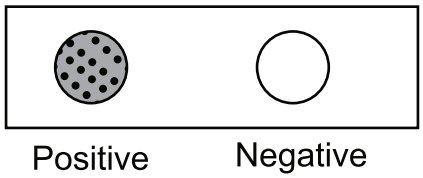
1. Make serial two fold dilutions of the sample in normal saline solution (9 g/L).
2. Proceed for each dilution as in qualitative method.

INTERPRETATION OF RESULTS

A. QUALITATIVE TEST:

A negative reaction is indicated by a uniform milky suspension with no agglutination as observed and compose with the RF Negative Control.

A positive reaction is indicated by any observable agglutination in the reaction mixture. The specimen reaction should be compared to the RF Negative Control.



B. SEMI-QUANTITATIVE TEST:

The titer of the test is equal to the highest dilution, which shows a visible agglutination. To determine the mg/L, multiply the titer with the conversion factor (8):

IU/ml of sample = Factor of 8 x Reciprocal of Last dilution

Dilution	Conc of Serum (mg/dL)
1:2	16
1:4	32
1:8	64
1:16	128

INTERNAL QUALITY CONTROL

1. Positive and negative controls should be included in each test batch.
2. Acceptable performance is indicated when a uniform milky suspension with no agglutination in observed with the ASO Negative Control and agglutination with large aggregates is observed with the RF Positive Control.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity: 8(6-16) IU/ml, under the described assay conditions.
PROZONE EFFECT: No prozone effect was detected up to 1500 IU/ml.
SENSITIVITY 98%.
SPECIFICITY 97%.

LIMITATION OF THE TEST

1. The incidence of false positive results is about 3-5%. Individuals suffering from infectious mononucleosis, hepatitis, syphilis as well as elderly people may give positive results.
2. Diagnosis should not be solely based on the results of latex method but also should be complemented with a Waaler Rose test along with the clinical examination.

NOTES:

Results obtained with a latex method do not compare with those obtained with Waaler Rose test. Differences in the results between methods do not reflect differences in the ability to detect rheumatoid factors.

DISPOSAL

Consider all test run with human specimen as potentially infectious and discard using standard biosafety practices.

DISCLAIMER:

Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product the product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by environmental factors and / or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

The manufacturer and distributors of this product shall not be liable for any losses, liability, claims, coasts or damages whether direct or indirect or consequential out of or related to an incorrect diagnosis, whether positive or negative in the use of this product.

REFERENCES

1. Robert W Dorner et al. Clinica Chimica Acta 1987; 167:1-21.
2. Frederick Wolfe et al. Arthritis and Rheumatism 1991; 34:951-960.
3. Robert H Shmerling et al. The American Journal of Medicine 1991;91: 528-534.
4. Adalbert F S et al. The New England Journal of Medicine 1959;261:363-368. ARVAN 3108 BAN DOIS WR A

SYMBOLS

	See instruction for use		Storage temeprature	IVD	For in-vitro diagnostic use
	Expiry date	REF	Catalogue number		Manufactured by
	Keep away from sunlight		Manufacturing date		No. of tests

Manufactured By:
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