TRUEchemie Rheumatoid Factor (RF) Test Kit (Slide Agglutination)

for the qualitative and semi-quantitative determination of Rheumatoid Factor (RF) in serum

INTENDED USE

The TRUEchemie Rheumatoid Factor (RF) Test Kit (Slide Agglutination) is used for the qualitative and semi-quantitative determination of Rheumatoid Factor (RF) in serum.

INTRODUCTION

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) Some Chronic infections (e.g.Tuberculosis, Parasitic diseases, Sub acute Bacterial Endocarditis) and Cancer.

PRINCIPLE

The latex Reagent coated with human gamma globulin (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.

PACK SIZE

Kit Size	25 T	100 T
Cat. No.	ADX821	ADX823
Kit Contents		
1) RF/RA Latex	1 x 1 ml	2 x 2 ml
2) RF/RA Positive Control	1 x 0.250 ml	1 x 0.250 ml
3) RF/RA Negative Control	1 x 0.250 ml	1 x 0.250 ml
Accessories Reusable Plastic Slides Disposable Plastic Droppers Disposable Plastic Sticks Rubber Teat		

REAGENT COMPOSITION

RF/RA Latex : Disodium hydrogen phosphate 8.00gm/L, sodium chloride 10.50gm/L, sodium azide 1gm/L, Glycine 4.65gm/L,
RF/RA Positive Control : Disodium hydrogen phosphate 35gm/L and Glycine 2gm/L.
RF/RA Negative Control : Tris hydrochloride 12gm/L, Sodium chloride 14 gm/L, Sodium azide 3 gm/L and BSA 4.65gm/L

REAGENT PREPARATION

Ready to use reagents.

WARNINGS AND PRECAUTIONS

1. Do not freeze the Latex Reagent.
2. Release the Latex Reagent completely from the dropper before capping
3. Cap the vial properly after use to avoid drying up of the latex reagent
4. Drying of the mixture at the periphery of the circle could lead to erroneous results.
5. The disposal of the residues has to be done as per local legal regulations.

REAGENT STORAGE AND STABILITY

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2-8°C. Do not use reagents over the expiration date.

SPECIMEN COLLECTION AND STORAGE

Fresh serum to be used
Plasma or hemolyzed /lipemic serum should not be used.

TEST PROCEDURE

(A) QUALITATIVE TEST:

1. Bring the Latex Reagent, Controls and specimens to room temperature before use. Shake the latex Reagent gently to ensure uniform suspension.

2. Place one drop (40 µL) each of Specimen, Positive Control & Negative Control in separate circles of the slide using separate plastic droppers for each.

3. Add one drop (35 µL) Latex Reagent in each of the se circles.

4. Mix the contents of each circle separately and spread it in the entire circle.

5. Rock the slide gently for **two minutes,** and look for agglutination**.**

Results should be read at a normal reading distance in good light. DO NOT USE A MAGNIFYING LENS.

INTERPRETATION OF RESULTS:

Agglutination with Positive Control and no agglutination with Negative Control validates test result.
Distinct agglutination indicates RF content of more than 12 IU/mL. Sera with Positive results should be retested in the semi quantitative test.
Agglutination within **two minutes** is a positive test and indicates presence of RF in the test specimen. No agglutination up to **two minutes** is a negative test, and indicates absence of RF in the test specimen.

DO NOT OBSERVE RESULTS BEYOND 2 MINUTES

(B) SEMI QUANTITATIVE TEST:

1. Dilute the specimen serially 1:2, 1:4, ----- up to 1:64 using normal saline.

2. Place one drop of each of diluted serum sample using plastic droppers in each circle of slide and proceeds further as in qualitative test (A).

INTERPRETATION OF RESULTS:

The highest dilution which shows clear cut agglutination within **two minutes** indicate the RF titre, 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

QUALITY CONTROLS

Positive & Negative Controls are used to validate the kit performance.

INTERFERENCES

Increased levels of RF may be found in some diseases other than rheumatoid arthritis such as infectious mononucleosis, sarcoidosis, lupus erythematosus, Sjogren's syndrome. Certain patients with rheumatoid arthritis will not have the RF present in their serum.

NOTES

1. Positive & Negative controls are ready-to-use & should not be diluted while using in test procedure.
2. As with all diagnostic tests, the final diagnosis should be based on a correlation of test results with other clinical symptoms & findings.
3. The source material used in the manufacture of Positive & Negative controls is tested for HBsAg & HIV antibodies, and is found to be negative. However, for better safety, these controls should be handled with proper care.

REFERENCES

1. Sanger, J.M., (1956) ; Am. J.Med.21,888
2. ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

Index of symbols

Consult instructions for use	REF Catalogue number	Caution
In vitro diagnostic medical device	LOT Batch code	Non-sterile
Temperature limit 2-8 °C	Do not re-use	Use-by date
Manufacturer	Date of manufacture	Keep dry
		Keep away from sunlight
Do not use if package is damaged	Contains sufficient for <n> tests	

Athenese-Dx Pvt. Ltd.
Module No. 407 & 408, 4th Floor,
TICEL Bio Park II, No. 5, CSIR Road.
Taramani, Chennai-600113, India
Tel: +91-44-22541131
E-mail: info@athenesedx.com
Website: www.athenesedx.com

PI-ADX82 Rev. D
Effective date: 28.12.2023
English version