ImmunoScience INDIA

ImmunoSlide

RF

Slide agglutination test for Rheumatoid Factors

For *In-Vitro* Diagnostic Use Only **Store at 2°C to 8°C**

OVERVIEW

A B Garrod in 1858 named the disease rheumatoid arthritis replacing the old terms arthritis deformans and rheumatic gout.

Rheumatoid arthritis, or RA, is an autoimmune and inflammatory disease, which means that your immune system attacks healthy cells in your body by mistake, causing inflammation (painful swelling) in the affected parts of the body. RA mainly attacks the joints, usually many joints at once.

Arthritis" literally means joint inflammation. Joints are places where two bones meet, such as your elbow or knee. There are many different types of arthritis with different causes and treatments. In some types, other organs, such as your eyes, heart, or skin, can also be affected.

INTENDED USE

Qualitative determination of Rheumatoid Factors (RF) in human serum/plasma.

This test is for in vitro diagnostic use only.

PRINCIPLE

The RF-latex is a slide agglutination test for the qualitative detection of RF in human serum/Plasma. Latex particles coated with human gamma globulin are provided in the latex reagent kit. When a drop of serum/plasma is mixed with reagent on slide, RF is attached to gamma globulin to form agglutination. Absence of Agglutination defines absence of RF in the sample

CONTENTS OF KIT

1. Reagent 1: RF Latex Reagent
2. Reagent 2: Positive Control
3. Reagent 3: Negative Control
4. PVC Slides
5. Mixing Sticks
6. Sample droppers
7. Pack inserts

OPTIONAL MATERIAL REQUIRED

1. PPEs (Disposable Gloves, Mask, Safety Goggles, Apron)
2. Biohazard Dust Bin.
3. Micropipettes (optional)

PRECAUTIONS /KIT STORAGE AND STABILITY

1. Please read all the information in this package insert before performing the test.
2. Do not use after the expiration date.
3. Store in between temperature 2°C to 8°C.
4. Do not use if damaged or leaked.
5. Do not open until you are ready to start the test.
6. Keep out of the reach of children.

WARNINGS

1. Do not reuse the tested reagent.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose the leftover and used reagents and samples hygienically in biohazard waste.
5. Treat samples and reagent reaction volume as potentially infectious. Avoid contact with skin.
6. For in vitro diagnostic use. Not to be taken internally.
7. Do not mix the specimen sample or interchange the different specimen.
8. Do not use the reagents of other lots in combination with the kit.
9. Discard the remaining reagent in the kit.
10. The manufacturer and distributor of this product shall not be liable for any loses, liability, claims, costs or damages whether director cons sequential rising out for related to an incorrect diagnosis.

SPECIMEN COLLECTION

1. Fresh serum or plasma shall be used.
2. Serum shall be separated from freshly collected blood in plain tube or clot activator tube.
3. Freshly collected EDTA blood can be used to separate plasma for testing.
4. The samples stored at 2-8ºC for 2 to 3 days can also be used.
5. Do not use highly haemolized or lipemic samples.

TEST PROCEDURE

1. Bring the kit components samples and controls to room temperature (20 to 30 ºC) before testing.
2. Take a PVC Slide and keep on horizontal surface.
3. Put 1 drop (40 to 50 µl) of Latex reagent (R1) inside the circle of slide.
4. Put 1 drop (40 to 50 µl) of sample or control to be tested inside the circle of slide without touching the drop of sample.
5. Take a mixing stick and mix the sample and latex in circular motion slowly for 30 seconds to one minute. Allow the sample to be spread but not outside of the circle.
6. Now, observe the presence or absence agglutination. Observation of agglutination after 5 minutes shall be considered as invalid.

INTERPRETATION OF RESULTS

1. **Positive (Reactive):** If the agglutination is observed in the reaction.
2. **Negative (Non-Reactive):** If the agglutination is not observed in the reaction.

LIMITATIONS

1. As with all diagnostic tests, the test result must always be correlated with clinical findings.
2. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context. When it seems indicated, reference correlation should be considered.
3. Any modification to the above procedure and / or uses of other reagents will invalidate the test procedure.

QUALITY CONTROL

Positive and Negative controls are recommended to monitor the performance of test procedure, as well as a comparative pattern for a better results interpretation.

REFERENCE VALUE

Positive: greater than 8 IU/mL.

Negative: Less than 8 IU/mL.

Each laboratory should establish its own reference range.

DISCLAIMER

The all precautions shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results.

REFERENCES

1. Clinical Laboratory by Lothar Thomas, M.D., 1st edition, 1988, TH-Books, Verlagsgesellschaft mbH, Frankfurt, Germany, page no. 810-813.
2. Waaler. E., Acta Path. Micr. Scand., 17,1 & 2 (40). Bandila, K.L., & Mc Duffie, F.c., Arthritis Rheum. 12 (1969) 74.

	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
	Lot Number
	Store at 4°C to 30°C
	Single Use
	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
	Read package insert before use

MANUFACTURED BY

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