RF-AGGLUTINATION SLIDE TEST

INTENDED USE
Kit for qualitative and semi-quantitative detection of Rheumatoid factors (RF) in human serum.

TEST PRINCIPLE
The latex particles are coated with Human Immunoglobulin (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 negative test result.

MATERIALS PROVIDED
1. Reagent 1 Latex Reagent
2. Reagent 2 Positive Control
3. Reagent 3 Negative Control
4. Glass slide with drawn circles
5. Disposable sample droppers
6. Disposable Mixing Sticks

MATERIALS REQUIRED BUT NOT PROVIDED
1. Vortex mixer
2. Normal saline
3. Micropipettes
4. Tissue paper

WARNING AND PRECAUTIONS
1. Firmly shake the latex reagent vial properly to get the homogenous latex particles before testing.
2. Do not freeze the latex reagent.
3. Cap the vial properly after use to avoid drying of the latex reagent.
4. Drying of the samples and latex reagent mixture at the periphery of the circle could lead to erroneous results.
5. Positive & negative controls are ready to use & should not be diluted while using in test procedure.
6. As with all diagnostic tests, the final diagnosis should be based on a correlation of test results with other clinical symptoms & findings.
7. In addition to Rheumatoid Arthritis, positive result may also be found in Syphilis, Systemic Lupus Erythematosus, Hepatitis, Hypergammaglobulinemia etc.
8. This package insert must be read completely before performing the test, Failure to follow the insert may give inaccurate test results.
9. Do not use expired test kit.
10. Bring all components to room temperature (15°C-30°C) before use.
11. Do not use the components of any other type of test kit as a substitute for the components in this kit.
12. Apply standard biosafety precautions for handling and disposal of potentially infective material:
    - Handle all specimens as potentially infectious.
    - Wear gloves while handling specimens and performing the test.
    - Avoid splashing and aerosol formation.
    - Clean up spills thoroughly using an appropriate disinfectant.
13. Do not use if the product has been exposed to excessive heat.
14. Do not smoke, drink or eat in areas where specimens or kit is being handled.
15. Dispose off all specimens and materials used to perform the test as biohazardous waste.

STORAGE AND EXPIRATION
Please refer to the outer box for details.

The kit components are stable up to expiry date indicated on the component label.

SPECIMEN COLLECTION AND HANDLING
Fresh serum is the preferred specimen.
Plasma or hemolysed / lipaemic serum should not be used.

TEST PROCEDURE
A. QUALITATIVE TEST
1. Bring all the reagents and specimens to room temperature before use. Shake the latex reagent gently to ensure homogenous suspension.
2. Place one drop (Approximately 35-40 µl) each of specimen, positive control & negative control into separate circles of glass slide using a separate disposable sample dropper provided in the kit.
3. Add one drop latex reagent in each of these circles.
4. Mix the contents of each circle separately by the disposable mixing sticks provided with the kit and spread it in the entire circle.
5. Move the slide gently to & fro for two minutes and look for agglutination.
6. Results should be read at a normal reading distance in good light. Do not examine for agglutination after 2 min. Do not use magnifying lens.

Interpretation of Results
- Agglutination with Positive Control and no agglutination with Negative Control validates test results.
- Distinct agglutination within 2 minutes indicates RF concentration of more than 8 IU/ml.
- Sera with positive results should be retested in the semi-quantitative test.
- No agglutination up to two minutes is a negative test and indicates RF concentration is below 8 IU/ml in the test specimen.

● DO NOT INTERPRET RESULTS AFTER 2 MINUTES

B. SEMI QUANTITATIVE TEST
1. Dilute the specimen serially 1:2, 1:4, ... 1:64 using normal saline.
2. Place one drop each of diluted serum sample using sample droppers in each circle of glass slide & proceed further as in Qualitative Test (A) (proceed from step 3).

Interpretation Of Results
The highest dilution which shows clear agglutination within two minutes indicates the RF titre. The approximate RF concentration can be obtained by multiplying titre by sensitivity of the test.

RF in IU/ml=DXS
D = Highest dilution showing clear agglutination.
S = Sensitivity of the test - 8 IU/ml

INTERFERENCES
Bilirubin (20 mg/dl), hemoglobin (10 g/L) and lipids (10 g/L) do not interfere. Other substances may interfere.

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

PERFORMANCE CHARACTERISTICS
Analytical sensitivity: 8 IU/ml
Prozone effect: No prozone effect was detected up to 1500IU/ml. Any prozone phenomena can be excluded up to 1500IU/ml.
Diagnostic sensitivity: 100%
Diagnostic specificity: 100%

REFERENCES

1. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.
2. Frederick Wolfe et al. Arthritis and Rheumatism 1991; 34: 951-960
3. Robert H Shmerling et al. The American Journal of Medicine 1991; 261: 363-368.

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, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative in the use of this product.

Symbol	Explanation	Symbol	Explanation
	Manufactured by	IVD	In vitro diagnostic medical device
Σ	No. of Tests		See instructions for use
LOT	Lot No.		Temperature Limitation
	Manufacturing Date	REF	Catalogue Number
	Expiry Date		Do not reuse
CE	Conformité Européenne	EC REP	Authorized representative in European Conformity

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