BIOLABO
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RF-LATEX

Latex agglutination slide test for qualitative and semi-quantitative determination of Rheumatoid Factor (RF) in human serum

REF 098100 (100 tests) **R1** 1 x 4,0 mL **R2** 1 x 0,5 mL **R3** 1 x 0,5 mL

TECHNICAL SUPPORT AND ORDERS
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CE

IVD IN VITRO DIAGNOSTIC USE

CLINICAL SIGNIFICANCE (1)

In most patient suffering from evolutive chronic polyarthritis it is detected the presence of a macroglobulin (Rheumatoid Factor) which is able to agglutinate inert particles sensitized with human gammaglobulin.

This agglutination latex test allows to distinguish between Rheumatoid Arthritis and the other diseases known as particular rheumatic fever, in which Rheumatoid Factor is not present.

PRINCIPLE (2) (3)

RF-LATEX is a sensitive, standardised preparation made with selected polystyrene latex particles that have been coated with human purified IgG globulins.
The RF protein behaves as if it were an IgM directed against determinants of IgG globulins.
When the latex reagent is mixed with a serum containing RF, an antigen-antibodies reaction takes place easily visualized through the latex agglutination.
The presence or absence of a visible agglutination indicates the presence or absence of RF in the specimen.

REAGENTS COMPOSITION

1. RF-LATEX is a suspension of polystyrene latex particles coated with gamma-globulins.
2. Positive RF control serum (human origin).
3. Negative RF control serum (human origin).

-- Reusable agglutination slide and disposable stirring pipettes.

REAGENTS PREPARATION

Reagents are ready for use.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Semi-quantitative test: micropipettes and test tubes.
2. Saline (0.9 % NaCl)

STABILITY AND STORAGE

Store at 2-8°C away from light

DO NOT FREEZE THE LATEX REAGENT.

- When free from contamination, stored in the original vial and used as described in this technical data sheet, reagents are stable until expiry date stated on the label of the kit.
- Discard any reagent if contaminated or do not demonstrate correct activity with controls.

SAFETY CAUTIONS

BIOLABO reagents are designated for professional, in vitro diagnostic use.

- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In case of contact with skin and eyes, thoroughly wash affected areas with plenty of water.
- Reagents contain sodium azide (concentration < 0.1%) which may react with copper and lead plumbing. Flush with plenty of water when disposing.
- Controls contain human serum. Human serum used have been tested and found to be negative for HIV, HCV and HbsAg. Because no known test method can offer complete assurance that infectious agents are absent, this material should be handled as potentially infectious.
- For further information, Material Safety Data Sheet is available upon request.
- Waste disposal : Respect legislation in force in the country.

All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

SPECIMEN COLLECTION AND HANDLING (4)

Use fresh serum obtained by centrifugation of clotted blood.
The specimen may be stored at 2-8° C for 24 hours before performing the test. For longer periods of time the serum must be frozen (once only).
Do not use plasma.
Haematic, lipaemic or contaminated serum must be discarded.

INTERFERENCES (7)

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-False negative results may be given by patients in the early or in sub-clinical chronic phases of the disease.
3-Bacterial contamination of controls or specimens as well as freezing and thawing of the antigen may lead to false positive results.
4-Traces of detergent in the test slides may give false positive results. Wash used cards first under tap water until all reactance removed and then with distilled water. Allow to dry in air , avoiding the use of organic solvents as they may impair the special finished of the slide.
5-Diagnosis should not be solely based on the results of latex method but also should be complemented with other clinical informations.
NB: 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.
Haemoglobin (10 g/L), bilirubin (20 mg/dL) and lipemia (10 g/L), do not interfere. Other substances may interfere.

QUALITY CONTROL

Positive and Negative RF control serum included in this kit.
External quality control program.
It is recommended to control in the following cases :

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.

If control is is not correct, apply following actions :

1. Repeat the test with the same control.
2. If control is still not correct, try again with a new vial of control(s).
3. If control is still not correct, try again with a new vial of reagent.
4. If control is still not correct, please contact BIOLABO technical support or your local Agent.

EXPECTED VALUES

Healthy peoples do not have RF levels detected by this method (less than 5 % of positive results can be expected).

The number of positives reported using various types of latex test reagent range from 70% to over 90% with case of clinically defined rheumatoid arthritis.

False positive results also occur in various pathological conditions including lupus erythematosus, hepatitis, cirrhosis of the liver, lymphomas, scleroderma, and various other infections.

The frequency of false positive results is not high even in these conditions but the possibility must be borne in mind when interpreting results.

PERFORMANCES CHARACTERISTICS

Analytical Sensitivity: 8 (6-16 IU/mL)
Prozone effect: No effect detected up to 800 IU/mL
Diagnostic Sensitivity: 100%
Diagnostic Specificity: 98.8%

MANUAL PROCEDURE

QUALITATIVE METHOD

1. Allow each component to reach room temperature before use.
2. Place one drop of the Negative RF Control onto a circle of the agglutination slide.
3. Place one drop of the Positive RF Control onto an adjacent circle of the agglutination slide.
4. Using the pipette-stirrers provided, place one drop of serum specimen(s) onto the remaining circle(s) of the agglutination slide.
5. Shake and re-suspend the RF latex reagent. Add one drop to each of the test circles of the agglutination slide.
6. Stir with individual pipette-stirrers and spread mixture over entire area of the test circle.
7. Gently rock the agglutination test slide for two minutes and observe the test circles for agglutination. Interpret results at two minutes. Extended incubation may result in evaporation and erroneous results.
8. At the end of the test rinse the slide with distilled water and dry on air.

SEMI-QUANTITATIVE DETERMINATION

The semi-quantitative test can be performed in the same way as the qualitative test using dilutions of the specimen in saline as follows:

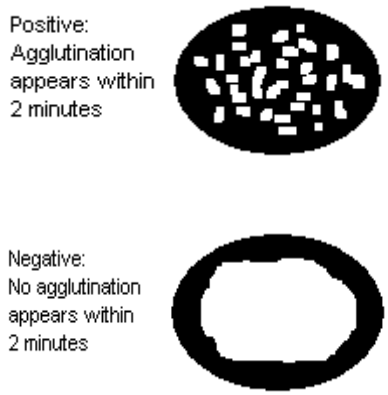
Prepare dilutions in test tubes :

Dilutions	1/2	1/4	1/8	1/16
Saline	100 µL	100 µL	100 µL	100 µL
Specimen	100 µL	-	-	-
	→	100 µL →	100 µL →	100 µL →
Transfer onto a circle of a test slide :				
Diluted Specimen	50 µL	50 µL	50 µL	50 µL
Reagent (vial R1)	50 µL	50 µL	50 µL	50 µL
Calculate the result as follows :				
8 x N° of dilution	8 x 2	8 x 4	8 x 8	8 x 16
Results : IU/mL	16	32	64	128

INTERPRETATIONS OF RESULTS

QUALITATIVE METHOD

Agglutination indicates a level of RF equal or > 8 IU/mL.



No agglutination indicates a level of RF equal or < 8 IU/mL.

SEMI-QUANTITATIVE METHOD

The titre is expressed as the product of the analytical sensitivity by the reciprocal of the highest dilution showing macroscopic agglutination:

e.g. if this occurs in dilution 1/4, the titre is 4 x 8 = 32 IU/mL.

REFERENCES

(1) *TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p.215, p.1224-1225.*
(2) *Singer J.M., Plotz, C.M. Amer. J. Med. 21:888-895 (1956)*
(3) *Singer J.M., Plotz C.M. Amer. J. Med. Assoc. 168:180 (1958)*
(4) *Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 958-961*
(5) *Dorner R.W. et al. Clinica Chimica Acta. 1987: 167: 1-21*
(6) *Wolfe F. et al. Arthritis and Rheumatism 1991; 34: 951-960*
(7) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995*

Manufacturer | Use by | IVD In vitro diagnostic | Temperature limitation | REF Catalogue number | See insert | LOT Batch number | Store away from light | sufficient for | → dilute with