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Rheumatoid Factor (RF)

Diagnostic reagent set **(Slide latex tests)** for the in-vitro qualitative screening and semi-quantitative determination of Rheumatoid Factor present in infected human serum manually.

REF: BS.1/RFC1.050.0050	50 test	REF: BS.1/RFC1.100.0100	100 test
REF: BS.1/RF01.050.0050	50 test	REF: BS.1/RF01.100.0100	100 test

CLINICAL SIGNIFICANCE

Rheumatoid factors are immunoglobulins which are directed against the Fc portion of IgG. Rheumatoid arthritis is a chronic systemic disease of unknown etiology. Its diagnosis is based on combined clinical and radiographic analysis. The determination of RF is the laboratory test that is most commonly used not only for the diagnosis of rheumatoid arthritis but also assists in the prognosis of the disease and in the monitoring of therapeutic response.

METHOD PRINCIPLE [2]

BioScien RF latex reagent is a suspension of polystyrene particles sensitized with human gamma globulin. When the latex reagent is mixed with a serum containing rheumatoid factor, visible agglutination occurs. The latex reagent has been produced so that agglutination will take place only when the level of RF is greater than 10 IU/ml.

REAGENT COMPOSITION

Reagents:	Composition
Latex Reagent	A suspension of polystyrene latex particles in glycine-saline buffer pH: 8.6 ± 0.1, coated with human gamma globulin.
Positive Control * * Only with REF: BS.1/RFC1.050.0050 BS.1/RFC1.100.0100	Is prepared from a stabilized human serum pool containing RF.

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person. Do not ingest or inhale as reagent (R) contains sodium azide which is classified as dangerous substance for environment.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.
  S56: dispose of this material and its container at hazardous or special waste collection point.
  S57: use appropriate container to avoid environmental contamination.
  S61: avoid release in environment.

For further information, refer to the RF reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

BioScien RF reagent is ready-to-use and is stable until expiration date stated on label when properly stored in an upright position and refrigerated at 2-8°C (do not freeze).

Deterioration

The ***BioScien*** RF reagent can be damaged due to microbial contamination or on exposure to extreme temperatures. It is recommended that the performance of the reagent be verified with the positive controls.

SPECIMEN COLLECTION AND PRESERVATION [2]

Clean and dry glassware free from detergents must be used for sample collection, freshly collected serum is preferable. Specimen should be free of turbidity and hemolysis. Fresh, uncontaminated serum samples may be stored at 2-8°C in case of delay in testing up to 72 hours.

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes
- Centrifuge
- Stop watch
- Variable Micropipettes
- Physiological saline (as negative control)

ASSAY PROCEDURE

Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures. Shake and mix antigens well before dispensing

Qualitative procedure

1. Identify each reaction circle of the slide test to make one positive control, one negative control and the desired number of samples respectively.
2. Place one drop of positive control reagents, 50 µl of physiological saline and one drop of patient's serum to be tested onto each reaction circles.
3. Add one drop of RF to the reaction circles containing positive controls, physiological saline and patient's serum.
4. Mix contents of each circle uniformly over the entire circle with separate mixing sticks.
5. Rock the slide gently back and forth, and observe for agglutination macroscopically at 2 minutes.

Semi-quantitative method

1. Serum to be titrated is serially diluted (1:2, 1:4, 1:8 etc.) in 9 g/L saline solution.
2. Place one drop of latex reagent on each slide.
   (**NB**.: Do not attempt to dilute the RF latex reagent or positive control for comparative or other purposes).
3. Place 50 ml of each serum dilution individually in successive circles on the slide and proceed as in screening methodology.

Note: This method is recommended for obtaining quick approximate titers only.

READING AND INTERPRETATION

Qualitative procedure	
Positive	Agglutination as indication for the presence of corresponding antibody in the patient's serum.
Negative	No agglutination as indication for the RF level in the patient's serum within the normal range.
Semi-Quantitative procedure	
Titer	The titer of the patient serum corresponds to the visible agglutination in the test circle with the smallest amount of serum sample.

RF Titer (IU/ml) = Highest dilution with positive reaction x Reagent sensitivity (10 IU/ml).
e.g., if the agglutination is present up to a titer 1:8, the approximate serum RF level is 8 x 10 = 80 IU/ml.

QUALITY CONTROL

The positive controls have been included with the test kit to monitor the performance of the reagent. Good physiological saline may be used as a negative control, if the expected results have not been observed; the reagent should not be used. For more information, please contact ***BioScien*** technical support.

PERFORMANCE CHARACTERISTICS

Precision (reproducibility and repeatability): Precision of RF suspensions is 100% (+/- one double dilution).

Analytical sensitivity: Accurate titer determination of the reference material, under the described assay conditions.

Prozone effect: No prozone effect was detected up to titers 1/160.

Diagnostic sensitivity: 100 %.

Diagnostic specificity: 99 %.

LIMITATIONS OF PROCEDURE

1. The results of this test ***should not*** be used as a single diagnostic tool to make a clinical diagnosis. Instead, the test results must be evaluated together with other clinical findings and observed symptoms to aid in the final diagnosis.
2. Temperature of the reagents and specimens is critical to test outcome.
3. The negative control should show no agglutination.
4. RF suspensions are not from human sources hence contamination due to HBsAg and HIV is practically excluded.
5. Accessories provided with the kit only must be used for optimum results.
6. Do not use damaged or leaking reagents.
7. TAB vaccinated patients may show a high titer of antibodies to each of the antigens. Similarly, an amnestic response to other vaccines and unrelated fevers in case of patients who have had prior infection or immunization may give a false result.
8. Agglutinins usually appear by the end of the first week of infection, blood sample taken earlier may give a negative result.
9. A rising titer is more significant than a single high titer. It is therefore necessary to evaluate two or more serum samples taken at 4- 6 days intervals after the onset of the disease.
10. False positive results are likely if the test is read more than two minutes after mixing on the slide test.
11. Use a separate disposable tip for each sample to prevent cross contamination.
12. After usage the antigen suspension should be immediately recapped and replaced at 2-8 °C.

REFERENCES

1. Ball J. et al. Ann Rheum. Die 1963; 22: 311-314.
2. Halbert, SP. Ann. N.Y. Acad. Sci., 103, 1027:1051; 1963.
3. Klein GL, Applied Microbiology, 21:999, 1971.
4. Klein GC: Manual of Clinical Immunology ASM 264-273:1976.
5. Rantz LD, DiCapri JM, Randall E. Am. J. Med. Sci., 24,1952.

SYMBOLS IN PRODUCT LABELLING

IVD	For in-vitro diagnostic use	Σ	Number of <n> test in the pack
LOT	Batch Code/Lot number		Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		

EC REP

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