SPECTRUM

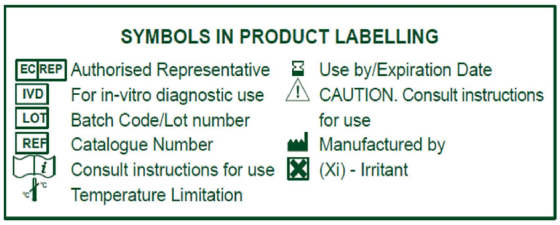
The Creative Approach to Bioscience

Rheumatoid Factor (RF)

REF: 518 001 50 test (Complete Kit)
REF: 518 002 100 test (Complete Kit)

REF: 518 003 50 test (latex with positive control)
REF: 518 004 100 test (latex with positive control)

REF: 518 005 50 test (latex only)
REF: 518 006 100 test (latex only)



Intended Use

Rapid latex agglutination test for the qualitative screening and semi-quantitative determination of rheumatoid factor (RF) in human serum.

Background

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.

Test Principle

Spectrum 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 .

Reagents

Spectrum RF latex kit contains the following reagents:

Latex Reagent (bottle with green cap):
A suspension of polystyrene latex particles in glycine-saline buffer pH: 8.6 ± 0.1, coated with human gama globulin.

Positive Control Serum (bottle with red cap):
Is prepared from a stabilized human serum pool containing RF. Both reagents contain 0.9 g/L Sodium azide as a preservative.

Negative Control Serum (bottle with white cap):
Reagent contain 0.9 g/L Na azide as a preservative.

Slides and Stirrers

Storage and Stability

The reagents are stable up to the expiration date specified when stored at 2 – 8^{O}C.Open vials are stable for 6 months if contamination is avoided.

Precautions and Warnings

All human blood components used to prepare controls have been tested for Hepatitis B surface antigen (HBsAg) and HTLV-III antibodies by FDA approved procedure and found to be non-reactive.No known test method for HBsAg or HTLV-III antibodies offers total assurance that a human derived product will not transmit hepatitis or HTLV-III virus. The user is therefore cautioned to handle reagents as if being capable of transmitting these diseases.

Specimen Collection and Preservation

Use only serum specimens, plasma samples are not suitable for the test . Serum samples can be stored for 24 hrs at 2 - 8 ^{O}C , for longer storage it is recommended to store the samples at -20 ^{O}C.

Procedure

Qualitative Test (Screening)

1. Bring all reagents and specimens to room temperature.
2. Place one drop (50 µl) of the positive control and 50 µl of the patient serum into separate circles on the glass slide.
3. Shake the RF latex reagent gently and add one drop (45 µl) on each circle next to the sample to be tested and control.
4. Mix well using disposable stirrer spreading the mixture over the whole test area and tilt the slide gently. Agitate for about 2 minutes with rotator or by hand and observe for the presence or abscence of agglutination.

Results and Interpretation

Negative result: No agglutination of the latex particles suspension within two minutes.

Positive result: An agglutination of the latex particles suspension will occur within two minutes, indicating an RF level of more than 10 IU/ml.

Semi-Quantitative Test

1. Serum to be titrated is serially diluted (1:2, 1:4, 1:8 etc) in 0.9 g/L saline solution.
2. Place one drop of positive control on slide. Do not attempt to dilute the RF positive control serum for comparative or other purposes as no correlation exists between actual titre of the control and titre of unknown sera.
3. Place 50 µl of each serum dilution individually in successive circles on the slide and proceed as in screening methodology.

Results and Interpretation

The serum RF titre can be defined as the highest dilution showing a positive result. The approximate RF level (IU/ml) present in the sample can be optained by the following formula:

RF Titre (IU/ml) = Highest dilution with positive reaction x Reagent sensitivity (10 IU/ml)

e.g. if the agglutination is present up to a titre 1:8, the approximate serum RF level is 8 x 10 = 80 IU/ml.

Expected Value

Not clearly specified . However, it has been found that the existence of significantly high titre (more than 30 IU/ml) are present in more than 70 % of patients with rheumatoid arthritis.

Performance characteristics

1.Analytical sensitivity: 8 (6-16) IU/mL, under the described assay conditions
2.Prozone effect: No prozone effect was detected up to 1500 IU/mL.
3. Diagnostic sensitivity: 100%.
4. Diagnostic specificity: 100%.
The diagnostic sensitivity and specificity have been obtained using 139 samples compared with the same method of a competitor.

Interferences

Lipids (10g/L), hemoglobin (10g/L) and Bilirubin (20mg/dL) do not interfere.

Limitations of the Procedure

Occasional agglutinations observed after 4 minutes have no diagnostic significance. Highly haemolyzed and lipemic serum as well as plasma interfere with the test.

Waste Disposal

Reagents are to be disposed according to the local regulations and guide lines.

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.

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
518 001	50 test
518 002	100 test
518 003	50 test
518 004	100 test
518 005	50 test
518 006	100 test

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