ISE S.r.l.
CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

Rheumatoid Factor– Instructions for use

IVD

R1: 1x 14,5 mL REF R3330000053
R2: 1x 3,1 mL

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SUMMARY AND EXPLANATION OF THE TEST

The diagnosis of rheumatoid arthritis (RA) is based largely on clinical examination, but laboratory tests (e.g. RF Test) are useful to support the clinical diagnosis and to evaluate the severity and course of the disease in the individual patient.
RF is a term used to describe a variety of antibodies (in most cases of the IgM type) that will react with modified human IgG (e.g. IgG in circulating immune complexes, IgG adsorbed to latex, etc.) and IgG of animal origin.
RF is highly associated with rheumatoid arthritis, as high as 90 % of patients with RA have RF titers of more than 20 IU/mL.

PRINCIPLE OF THE TEST

Measurement of antigen-antibody reaction by the end-point method.

Rheumatoid Factor (RF) Reagent Kit
Code R3330000052
Reagent 1 (R1) - Buffer - 1 x 14,5 mL/vial
Reagent 2 (R2) - 1 x 3,1 mL/vial
Each vial is ready to use and contains:

Reagent 1:	**Conc.**	**U.M.**
Good Buffer (pH 7.4)	50	mmol/L
Sodium azide	0,95	g/L
Reagent 2:	**Conc.**	**U.M.**
Heat-aggregated human IgG	≤ 0.5	mg/mL
Sodium azide	0,95	g/L

Reagent Preparation:
Liquids reagents ready for use.

Storage and Stability:
If stored at 2 - 8°C avoiding direct light, the reactants remain stable until the expiration date printed on the label.
Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.
Do not freeze the reagents.

EQUIPMENT / ACCESSORIES REQUIRED AND NOT SUPPLIED

General laboratory equipment
Saline (9 g/L)
Calibrators and/or Control
(Pooled human serum, liquid and stabilized. Contains 0.95 g/L sodium azide. Value is stated in the insert)

PRECAUTIONS AND LIMITATIONS

For *in vitro* diagnostic use.
Only experienced laboratory personnel should use this test and handling should be in agreement with Good Laboratory Practice (GLP).
Reagents from different lots must not be interchanged.

Safety Precautions

1. Each donor unit used in the preparation of the reagents, standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA
2. Do not pipet by mouth.
3. Do not smoke, eat or apply cosmetics in areas in which patients' samples or kit reagents are handled.
4. Cuts, abrasions, and other skin lesions should be properly protected with an appropriate waterproof dressing.
5. Take care to avoid self-inoculation, splashing of mucous membranes or generation of aerosols.
6. Laboratory gloves should be worn while handling patients' samples or disposing of solid or liquid wastes.
7. In addition to the eventual risk indications regarding the active components, the reagents contain inactive components such as preservatives (e.g. sodium azide or others) and detergents. The total concentrations of these components is lower than the limits reported by the current directive sand following modification and amendments. However, it is recommended to handle reagents carefully, to avoid ingestion and contact with eyes, skin and mucus membranes and to use laboratory reagents according to good laboratory practice.
8. All human samples must be handled and disposed of as potentially infectious materials.
9. For information about safe handling, read carefully the Material Safety Data Sheet (MSDS).

Disposal of Reagents
Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

SPECIMEN COLLECTION AND STORAGE

Use fresh serum.
If the test can not be carried out on the same day, the serum may be stored at 2 - 8°C for 48 hours.
If stored for a longer period, the sample should be frozen.

ASSAY PROCEDURE

Allow reagents to reach working temperature before using.

Quality control
It's necessary, each time the kit is used, to perform the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Automation
All applications not explicitly approved by I.S.E. S.r.l. cannot be guaranteed in terms of performance, and must therefore be established by the operator.

Procedures
Sample/Control/Standard: Ready for use.
Reference curve: generate a reference curve by diluting the standard high level **Ref R1300001901** 1:1, 1:2, 1:4, 1:8, 1:16 in saline 9 g/L. Use saline 9 g/L as zero point.

EXPECTED VALUES

0 - 20 IU/mL (WHO)
Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

PERFORMANCE CHARACTERISTICS

The performance characteristics for the CRP reagents were measured on a clinical chemistry analyzer.

Measuring Range: 0 - 500 IU/mL
Detection Limit: 3.0 IU/mL
Hookeffect: No Risk
Sensitivity: 0.00027 ABS units/concentration unit

Precision: [%CV]		Low	Medium	High
	Intra-Run	2.68	1.38	1.55
	Inter-Run	3.07	1.40	1.78
Accuracy: [mg/dL]	Control	Assigned	Measured	
	Bio-Rad 1	19.6 (16.6 - 22.5)	18.0	
	Bio-Rad 2	39.8 (33.8 - 46.2)	39.7	

Specificity: Monospecific
Interferences: No interference for:
Hemoglobin (500 mg/dL), Bilirubin (50 mg/dL), Ascorbic acid (50 mg/dL), Intrafat (3%)
Limitations: None
Comparison with Roche reagents: y = 0.9486x - 0.2587, r = 0.9900
Stability at 4°C: at least 3 years after production

BIBLIOGRAPHY

1. Waaler, e., Acta Path. Microb. Scan., 17 (1940)
2. Bandilla, K. I., and Mc Duffie, F. C., Arthritis Rheum., 12, 74 (1969)
3. Müller, W., The Serology of Rheumatoid Arthritis. Berlin - Göttingen - Heidelberg 97 (1962)

Numero lotto / Lot numer


Consultare la metodica operativa / consult instructions for use

Per uso diagnostico in-vitro / For in-vitro diagnostic use


Prodotto da / manufactured by


Data di scadenza / expiry date


Temp. Di Conservazione / storage temperature

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