ISE S.r.l. CUSTOMISED SOLUTIONS FOR YOUR LABORATORY	EN	Rheumatoid Factor			Instruction For Use	CE IVD	Rev.D - 15-11-22
	REF	R3330000053	R1: 1x 14.0 mL	R2: 1x 3.0 mL			
		A-R1100004101	R1: 1x 25.0 mL	R2: 1x 5.0 mL			

Intended Use
Quantitative determination of Rheumatoid factor (RF) in human serum by turbidimetric immunoassay (Aggregated human IgG method).
For professional in vitro diagnostic use only.

Diagnostics Implications
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.

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

Reagents Provided
The same reagents are supplied in different volume formats depending on the I.S.E. S.r.l. analysers utilised and installed reagent support.

Supplied Volumes

	Product Code	
	R3330000053	*A-R1100004101*
Vial size	*18 / 18 mL*	*50 / 20 mL*
Reagent 1	1 x 14.0 mL	1x 25.0 mL
Reagent 2	1x 3.0 mL	1x 5.0 mL

Reagent format

Reagent	*Format*	*Code*
Reagent 1 – Buffer (liquid)	Ready to Use	100C03
Reagent 2 – Reagent (3rd Gen.) (liquid)	Ready to Use	100C02

Reagent Contents

Reagent 1:	*Conc.*	*U.M.*
Good's buffer	50	mmol/L
Sodium azide	0.95	g/L
Reagent 2:		
Heat-aggregated human IgG	≤ 0.5	mg/mL
Sodium azide	0.95	g/L

Stability and Storage
The reagents are stable until expiry date when kept at 2-8°C. Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

Reagents required but not supplied
1. Saline (9 g/L NaCl)
2. Calibrators and Controls

Key Reference	*Description*
R1300001901	RF Calibrator High, 1 mL
R1400000901	Immunology Control Low, 1 mL
R1400001001	Immunology Control High, 1 mL

Pooled human serum, liquid and stabilized. Contains 0.95 g/L sodium azide. Values are stated in the insert.

Sample collection and storage
Use fresh serum. If the test cannot 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.

General Assay Procedure
Application sheets are available upon request for use with I.S.E. S.r.l. automated systems. 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.
Wavelength λ=340nm.

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.

Quality control
It is 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.
If erratic results occur, please contact an authorised ISE representative.

Normal Ranges
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.

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

Measuring range: 0 - 500 IU/mL.
Detection Limit: 3 IU/mL
Hookeffect: No risk
Sensitivity: 0.000486 ABS units/concentration unit

Precision of the method

Condition	*U.M.*	*Low*	*Medium*	*High*
Intra-Run	CV%	3.65	2.69	1.54
Inter-Run	CV%	3.57	1.34	1.91

Accuracy of the method

Control	*U.M.*	*Assigned*	*Measured*
APTEC	IU/mL	101 (86-116)	105
Siemens	IU/mL	78.4 (62.7-94.1)	69.7
Biokit	IU/mL	60.5 (48.4-72.6)	67.4

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 2 - 8°C: at least 3 years after production

Precautions and Warnings
1. In vitro diagnostic use only.
2. Refer to the safety data sheets (SDS) and take the necessary precautions for the use of laboratory reagents.
3. Do not use after expiry date and do not interchange reagents from different lots.
4. Replace caps on reagents immediately after use. Do not switch caps.
5. Do not pipet by mouth. Do not smoke, eat, drink or use cosmetics during the use of the reagent. Do not swallow.
6. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains whit water thoroughly after disposing of fluids containing sodium azide.
7. 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. However, the material must be considered potentially hazardous and handled with the same care as samples taken from patients.
8. Cuts, abrasions, and other skin lesions should be properly protected with an appropriate waterproof dressing.
9. Take care to avoid self-inoculation, splashing of mucous membranes or generation of aerosols. Laboratory gloves should be worn while handling patients' samples or disposing of solid or liquid wastes.
10. 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 are 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.
11. All human samples must be handled and disposed of as potentially infectious materials.

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

Reporting of serious incidents
The user must report (through the distributor) any serious accident occurring in relation to the device to both the manufacturer and the competent authority of the European Union Member State in which the user and / or patient is established. For other jurisdictions, reports of serious incidents must be produced in accordance with regulatory requirements.

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Symbols on labels and packaging

IVD	In vitro diagnostic medical device
REF	Catalog Number
LOT	Lot number
	Manufacturer
	Expiry date
	Temperature limitation
	Consult Instructions for use
Rn	Reagent “n”

References

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)

Revision history		
Rev.D	15-11-2022	Revision of the document

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