COD 13922

MOLDOVA EUROPEANĂ

BioSystems

RHEUMATOID FACTORS (RF)
LATEX

INTENDED USE

Reagent for the quantitative measurement of rheumatoid factors (RF) concentration in human serum for the monitoring of inflammatory disorders and risc of rheumatoid arthritis in adult population

This reagent is for use in the BioSystems A15 and A25 analyzers. For *in vitro* professional use only in the clinical laboratory.

CLINICAL BENEFIT

RF is mainly present in the serum of patients with rheumatoid arthritis but other diseases may also present RF: chronic inflammatory processes, infectious diseases such as subacute bacterial endocarditis, malaria, syphilis, leprosy, leishmaniasis, tuberculosis and a variety of autoimmune diseases such as systemic lupus erythematosus[1].

Based on clinical guidelines and textbooks, and when used in conjunction with other diagnostic technologies and options, this medical information is useful for the assessment of rheumatoid factors variations. Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

PRINCIPLE OF THE METHOD

Rheumatoid factors (RF) cause agglutination of the latex particles coated with human gamma-globulin. The agglutination of the latex particles is proportional to the RF concentration and can be measured by turbidimetry[2-4].

CONTENTS AND COMPOSITION

A. Reagent: 1 x 40 mL. Tris buffer 100 mmol/L, sodium azide 0.95 g/L, pH 8.
B. Reagent: 1 x 10 mL. Suspension of latex particles coated with human gamma-globulin, sodium azide 0.95 g/L (Note 1).

STORAGE AND STABILITY

Store at 2-8ºC.

Components are stable once opened until the expiry date marked in the label if they are kept at the recomended storage temperature, well closed and care is taken to prevent contamination during their use.

On board stability: The reagents opened and stored in the refrigerated compartment of the analyzer are stable for 2 months.

Indications of deterioration: Absorbance of the blank over the limit indicated in the parameterization of the analyzer.

WARNINGS AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents. Safety data sheet available for professional user on request. Disposal of all waste material should be in accordance with local guidelines. Any serious incident that might occur in relation to the device shall be reported to BioSystems S.A.

ADDITIONAL MATERIALS REQUIRED (NOT PROVIDED)

S. RF Standard: 1 x 3 mL (BioSystems Cod. 31116). Human serum. RF concentration is stated on the vial label. The concentration value is traceable to the WHO Reference Material W1066 (National Institute for Biological Standards and Control, NIBSC) (Note 2).

Human serum used in the preparation of the standard has been tested and found to be negative for the presence of antibodies anti-HIV and anti-HCV, as well as for HBs antigen. However, the standard should be handled cautiously as potentially infectious.

Reconstitute with 3.0 mL of distilled water. Stable for 30 days at 2-8°C.

REAGENT PREPARATION

Calibration curve: Prepare dilutions of the RF Standard using 9 g/L saline as diluent. Multiply the concentration of the RF Standard by the corresponding factor indicated below to obtain the RF concentration of the dilutions.

DILUTION	1	2	3	4	5
RF Standard (µL)	24	36	72	144	240
Saline (µL)	296	204	168	96	—
Factor	0.075	0.15	0.3	0.6	1.0

Reagents are provided ready to use. R1: use Reagent A, R2: use Reagent B.

SAMPLES

Serum collected by standard procedures.

RF in serum is stable for 7 days at 2-8°C.

CALIBRATION

A reagent blank should be done every day and a calibration at least every 2 months, after reagent lot change or as required by quality control procedures. It is recommended to use the calibrators mentioned in the paragraph on Additional Materials Required.

QUALITY CONTROL

It is recommended to use the Rheumatoid Control Serum level I (Cod. 31213) and II (Cod. 31214) to verify the accuracy of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if control results are not within the acceptable limits.

REFERENCE VALUES

Serum, adults[5]: Up to 14 IU/mL.

This range is given for orientation only; each laboratory should establish its own reference range.

ANALYTICAL AND CLINICAL PERFORMANCE

The metrological characteristics described below have been obtained using a A25 analyzer and following the guidelines of the Clinical & Laboratory Standars Institute (CLSI). Results are similar with A15. Details on evaluation data are available on request.

– Detection limit: 1.0 IU/mL

– Measurement interval: (approximate value dependent on the highest standard concentration): 1.0-175 IU/mL. For higher values dilute sample 1/5 with distilled water and repeat measurement.

– Precision:

Mean	Repeatability (CV)%	Within-laboratory (CV)%
40 IU/mL	1.8	4.2
79 IU/mL	2.2	3.2

– Trueness: Results obtained with this procedure did not show systematic differences when compared with a reference procedure. Details of the comparison experiments are available on request.

LIMITATIONS OF THE PROCEDURE

- Interferences: bilirubin (up to 30 mg/dL) and hemolysis (hemoglobin up to 500 mg/dL) and lipemia (triglycerides up to 1000 mg/dL) do not interfere. Other drugs and substances may interfere[6].
- Zone effect: This method has not zone effect up to 800 IU/mL.

NOTES

1. Shake the Reagent B vial gently before using.
2. The presence of turbidity that can be observed in some lots does not affect the functionality of the standard.

BIBLIOGRAPHY

1. Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press, 2001.
2. Melamies LM, Ruutsalo MH, Nissilä H. Evaluation of a quantitative immunoturbidimetric assay for rheumatoid factors. *Clin Chem* 1986; 32: 1890-1894.
3. Winkles JW, Lunec J, Gray L. Automated enhanced latex agglutination assay for rheumatoid factors in serum. *Clin Chem* 1989; 35: 303-307.
4. Muic V, Dezelié G, Dezelié N, Richter B. A photometric latex test for rheumatoid factors. *Scand J Rheumatol* 1972; 1: 181-187.
5. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 6th ed. Rifai N, Horvath AR, Wittwer CT. WB Saunders Co, 2018.
6. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.

TEST PARAMETERS

		A25	A15
GENERAL	Test name	RF	RF
	Analysis mode	Differential bir.	Differential bir.
	Sample type	SER	SER
	Units	IU/mL	IU/mL
	Reaction type	increasing	increasing
	Turbidimetry test	yes	yes
	Active Mixing	yes	yes
	Decimals	0	0
	No. of replicates	1	1
	Test name in patient report	-	-
PROCEDURE	Reading	monoch.	monoch.
Volumes	Sample	3	3
	Reagent 1	240	240
	Reagent 2	60	60
	Washing	1.2	1.2
	Predilution factor	-	-
	Postdilution factor	2	2
Filters	Main	535	535
	Reference	-	-
Times	Reading 1 (cycle)	4	3
	Reading 2 (cycle)	25	17
	Reagent 2 (cycle)	5	4
CALIBRATION	Calibration type	specific	specific
	No. of calibrators	5	5
	Calibrator replicates	3	3
	Blank replicates	3	3
	Calibration curve	increasing polygonal	increasing polygonal
OPTIONS	Blank absorbance limit	0.600	0.600
	Kinetic blank limit	-	-
	Linearity limit	-	-

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