RF

Latex turbidimetry

Product information

24RF01-UN	**Meditest RF**	**4x24 mL 2x12 mL**
24RF01-AU	**Meditest RF**	**4x24 mL 2x12 mL**
24RF01-AB	**Meditest RF**	**4x24 mL 2x12 mL**
24RF01-ER	**Meditest RF**	**4x24 mL 2x12 mL**
24RF01-AR	**Meditest RF**	**4x24 mL 2x12 mL**

Purpose

In vitro assay for quantitative determination of rheumatoid factor in human serum and plasma. Measurements can be used as an aid in the diagnosis of rheumatoid arthritis.

Summary

Rheumatoid factors are a group of antibodies to markers in the Fc portion of the immunoglobulin G molecule. Although rheumatoid factors are found in a number of rheumatic diseases such as systemic lupus erythematosus (SLE) and Sjogren's syndrome and non-rheumatic conditions, its central role in the clinic is its use as an aid in the diagnosis of rheumatoid arthritis (RA). A study by the "American College of Rheumatology" shows that 80.4% of RA patients are RF positive.

Test principle

RF-Turbilatex is a quantitative turbidimetric assay for the measurement of RF in human serum or plasma. Latex particles coated with human gamma globulin become agglutinated when mixed with RF-containing samples. Agglutination causes an absorbance change depending on the RF content of the sample, which can be measured by comparing it to a calibrator with a known RF concentration.

Reagents - working solutions

R 1 Diluent	Tris buffer Sodium chloride Sodium azide	<20 mmol/L <150 mmol/L <0.95 g/L
R 2 Latex	Latex particles coated with human gammaglobulin Sodium azide	<0.95 g/L

Precautions warnings

It is intended for in vitro diagnostic use by healthcare professionals. Follow the normal precautions necessary in handling all laboratory reagents.
Infectious or microbial waste:
Warning: handle waste as potentially biohazardous. Dispose of waste according to accepted laboratory instructions and procedures.
Environmental hazards: Follow all relevant local disposal regulations to determine that it has been disposed of safely. If requested, a safety data sheet can be provided to professional users.

Inhibit foam formation in all reagents and sample types (sample, calibrator and control).

If there is any damage on the package, do not use it Read the user manual carefully before use, do not use the expired assay kit Do not mix different lot reagents.

All samples should be considered epidemic material, please dispose of them in accordance with the laboratory working standard of infectious diseases.
Take the necessary protective measures to prevent users from becoming infected during operation.

Use of reagents

Ready to use.

Storage and stability

All components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC, protected from light and contamination is avoided during their use.
Do not use reagents after the expiration date. Signs of reactive deterioration: Presence of particles and turbidity.

Sample collection and preparation

Fresh serum or plasma. It is stable for 7 days at 2-8ºC or 3 months at -20ºC. Fibrin-containing specimens should be centrifuged prior to testing. Do not use highly hemolyzed or lipemic specimens.

Required Materials (not included in the kit)

1. Cat# 24RF01-DC Meditest Diachem RF Calibrator
2. Cat# 24PRO01-DQ Meditest Diacheck Protein Control L1
3. Cat# 24PRO01-DQ Meditest Diacheck Protein Control L2
4. General laboratory equipment
5. Distilled or deionized water

Working Procedure

If you are using a spectrophotometer to perform this test, work with the following procedure. Ask your representative for the application data for fully automatic devices.

1.Test Conditions:
Wavelength: . 650 nm
Cuvette: . . . . . 1 cm light path
Temperature: .
2.Set the appliance to zero with distilled water.
3.Place the pipettes in a cuvette.

R (mL)	0.8
Sample (µL)	20

4. Stir and read the absorbance (Empty reagent).
5. Add the sample/calibrator.

	Blank	Calibrator /Sample
NaCl 9 g/L (µL)	7	--
Calibrator or sample (µL)	--	7

6. Stir and read the absorbance (A2) 2 minutes after sample addition.

Calculation
Calculate the absorbance difference (A2-Ablank) of each point of the calibration curve and plot the obtained values against the RF concentration of each calibrator dilution. The concentration of rheumatoid factor in the sample is calculated by interpolating its value on the calibration curve (A2-Ablank).

Expected values
<20 IU/mL

It is recommended that each laboratory establish its own normal range. The reference range was validated using the CLSI EP28-A3c protocol.

Limitations
Hemoglobin (10 g/L), bilirrubin (20 mg/dL) and lipemia (10 g/L) do not interact. Other substances may mix[6].

Performance characteristics
Measuring range 6-160 IU/mL
Samples with higher concentrations should be diluted in 9 g/L NaCl by 1/5 and retested. The result is multiplied by 5.
The linearity limit and measurement range depend on the reagent/ratio sample as well as the analyzer used. Although the sensitivity of the test will decrease proportionally, it will be higher as the sample volume decreases.
Prozone effect: No Prozone effect has been detected above 800 IU/mL

Precision

	Intra-assay			Inter-assay		
	Mean (%)	%CV	N	Mean (%)	%CV	n
Low	15	0.7	20	15	3.9	20
High	45	1.4	20	45	5.7	20

Sensitivity: 1 IU/mL = 3.34 ΔA/min
Accuracy: The results obtained using this reagent (y) were compared with the results obtained using a commercial reagent (x) with similar properties. 41 FR samples with different concentrations were analyzed.
Correlation coefficient (r)²: 0.91
Regression equation y= 1.2042x + 3.1344

The results of the performance characteristics depend on the analyzer used.

References

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3. M, Fasani et al. Eur J Lab Med 1994; vol2.nº1: 67.
4. Todd E W. J Exp Med 1932; 55: 267 - 280.
5. Klein, GC. Applied Microbiology 1970; 19:60-61.
6. Klein GC. Applied Microbiology 1971; 21: 999-1001.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995

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