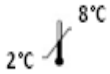
Atlas Medical

Quantitative determination of Rheumatoid Factors (RF)

IVD *For In-Vitro diagnostic and professional use only*



Store at 2-8ºC

CE

Principle

The latex particles coated with human gammaglobulin are agglutinated when they react with samples that contain RF. The latex particles agglutination is proportional to the concentration of the RF in the sample and can be measured by turbidimetry.

Clinical Significance

Rheumatoid factors are a group of IgM antibodies directed to determinants in the Fc portion of the immunoglobulin G molecule. Although rheumatoid factors are found in a number of rheumatoid disorders, such as systemic lupus Erythematosus (SLE) and Sjögren's syndrome, as well as in non-rheumatic conditions, its central role in clinic lies its utility as an aid in the diagnosis of rheumatoid arthritis (RA). The Rheumatoid factors are found in 70-100% of cases of definite rheumatoid arthritis depending on the test procedure used to detect them.

Reagents

Diluent (R1)	Tris buffer 20 mmol/L, pH 8.2. Sodium azide 0.95 g/L. **Ready to use.**
Latex (R2)	Latex particles coated with human gammaglobulin, pH 8.2. Sodium azide 0.95 g/L. **Ready to use. Mix gently the vial by inversion before use (See Note 4).**
RF-CAL	Human serum. RF concentration is stated on the label vial and it is traceable to the (Rheumatoid Arthritis Serum). **Ready to use.**

Additional Equipment

- Thermostatic bath at 37ºC.
- Spectrophotometer or photometer thermostatable at 37ºC with a 650 ± 20 nm filters.

Storage and Stability

1. The reagents will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not use the reagents after the expiration date.
2. Reagent deterioration: presence of particles, turbidity and increment of blank reagent.

Precautions

- The reagents contain sodium azide 0.95 g/l. Avoid any contact with skin or mucous.
- The reagents from human donors have been given negative results to anti-HIV 1\2, HBsAg and anti-HCV. Handle cautiously is recommended.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.

Calibration Curve

Prepare dilution of the Calibrator using NaCl 9 g/L as a diluent. Multiply the concentration of the RF calibrator by the corresponding factor stated in table below to obtain the RF concentration of each point of the curve.

Calibrator dilution	**1**	**2**	**3**	**4**	**5**	**6**
RF-Cal(µl)	--	10	20	40	60	80
NaCl 9 g/l (µl)	80	70	60	40	20	--
Factor	0.0	0.125	0.25	0.5	0.75	1.0

Samples

Fresh serum. Stable 7 days at 2-8ºC or 3 months at -20ºC.

Samples with presence of fibrin should be centrifuged before testing.

Homolyzed or contaminated samples are not suitable for testing.

Procedure

Preliminary Procedure

1. Pre-warm the reagents and photometer (cuvette holder) to 37ºC **(Critical step).**

Analytical Procedure

1. Using distilled water zero the instrument at 650 nm.
2. Pipette into a Cuvette:

Diluent (R1)	0.8 mL
Calibrator or sample or Water (Blank)	7.0 µL
Latex (R2)	0.2 mL

3. Mix well and record the absorbance after 2 minutes (A2) of the reagent R2 addition.

Calculation

Calculate the absorbance difference (A_2-A_{blank}) of each point of the calibration curve and plot the values obtained against the RF concentration of each calibrator dilution.

Rheumatoid factor concentration in the sample is calculated by interpolation of its (A_2-A_{blank}) in the calibration curve.

Quality control

- Control Sera are recommended to monitor the performance of manual and automated assay procedures.
- Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

Reference Values

Adults: up to 30 IU/mL.

Each laboratory should establish its own reference range.

Performance Characteristics

- **Linearity limit:**

  Up to 160 IU/mL, under the described assay conditions. Samples with higher concentrations, should be diluted 1/5 in NaCl 9 g/L and retested again.
- **Detection limit:**
  Values less than 5 IU/mL give non-reproducible results.
- **Analytical Sensitivity:**
  3.0 mA/IU /mL.
- **Prozone effect:**
  Up to 800 IU/mL
- **Precision:**

	Intra-assay (n=10)		Inter-assay (n=10)	
Mean (IU/mL)	27.1	65.1	27.1	65.1
CV %	5.5	3.8	7.7	6.7

- **Accuracy:**

Results obtained with these reagents did not show systematic differences when compared commercial reagents of similar characteristics. Details of comparison are available on request.

Interferences

Bilirubin (40 mg/dL), hemoglobin (4 g/L), Lipemia (5g/L) do not interfere. Other substances may interfere.

Notes

1. This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meets the performance characteristics of the method .It is recommended to validate periodically the instrument. Contact to the distributor for any question on the application method.
2. The linearity limit depends on the sample/reagent ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
3. Clinical diagnosis should not be made findings of a single test result, but should integrate both clinical and laboratory data.
4. For automatic instruments, avoid the presence of bubbles in the reagents that may interfere with the assay results.

Bibliography

1. Dorner RW,Alexander RL, Moore TL. Clinica Acta 167:1 (1987).
2. Soltys AJ, Axford JS, Suttan BJ. Annals of Rheumatic Diseases. 56: 75 (1993).
3. Moore TL, Dorner RW .Clinical Biochem 26:75 (1993).
4. Shmerling RH,Delbanco TL. The American Journal of medicine. 91:528 (1991).
5. Young DS. Effects of drugs on clinical laboratory test, 3th ed. AACC Press (1997).
6. Cook L, Agnello V. Manual of clinical Lab Immunol. Chap 112 NR Rose 1992 4th ed ASM Washington DC.

ATLAS Medical
Ludwig-Erhard Ring 3
15827 Blankenfelde-Mahlow
Germany
Tel: +49 - 33708 – 3550 30
Email: Info@atlas-medical.com

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry