RF-Turbilatex

INTENDED USE

Vitro RF-Turbilatex is a quantitative turbidimetric test for the measurement of Rheumatoid Factors (RF) in human serum or plasma on both manual and automated systems.

METHOD

Highly sensitive immunoturbidimetric assay.

CLINICAL SIGNIFICANCE

Sometimes autoantibodies are produced by the human body against self antigens. The precise role that this aberrant immunity plays in the pathogenesis of certain rheumatic diseases is unknown. However the presence of these autoantibodies serves as credible marker of the disease. In rheumatoid arthritis, diagnostically useful autoantibodies termed as "Rheumatoid factors" (RF) can be detected which are immunoglobulins of the class IgM, IgG, IgA and IgE. Practically, IgM class RF with specificity to human IgG (Fc) is the most useful prognostic marker of RA. The clinical significance of RF determinations consists in differentiation between rheumatoid arthritis, in which RF of modified IgM class have been demonstrated in the serum of approximately 80% of the cases examined and rheumatic fever, in which RF are almost always absent. The agglutination test is most frequently used because of its greater sensitivity and simplicity.

ASSAY PRINCIPLE

Vitro RF-Turbilatex is a quantitative turbidimetric test for the measurement of RF in human serum or plasma.
Latex particles coated with human gammaglobulin are agglutinated when mixed with samples containing RF. The agglutination causes an absorbance change, dependent upon the RF contents of sample that can be quantified by comparison from a calibrator of known RF concentration.

EXPECTED VALUES

Normal values up to 20 IU/mL

Each laboratory should establish its own reference range.

REAGENTS

Diluent (R1)	Tris buffer 20 mmol/L, pH 8.2. Preservative.
Latex (R2)	Latex particles coated with human gammaglobulin, pH 7.4. Preservative.
RF-CAL	Calibrator. Human serum. RF concentration is stated on the vial label.

- **Reagent Preparation & Stability**

RF Calibrator: Reconstitute with 2.0 mL of distilled water. Mix gently and incubate 10 minutes at room temperature before use.

Calibration Curve: Prepare the following RF calibrator dilutions in NaCl 9 g/L. Multiply the concentration of the RF calibrator by the corresponding factor stated in table bellow to obtain the RF concentration of each dilution.

Calibrator dilution	1	2	3	4	5	6
Calibrator RF (µL)	--	25	50	100	200	400
NaCl 9 g/L (µL)	400	375	350	300	200	-
Factor	0	0,0625	0,125	0,25	0,5	1,0

Precautions

Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However, handle cautiously as potentially infectious.

Storage and Stability

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not use reagents over the expiration date.

Reagent deterioration: Presence of particles and turbidity.

RF Calibrator: Stable for 1 month at 2-8ºC or 3 months at –20ºC.

Do not freeze; frozen Latex or Diluent could change the functionality of the test.

SPECIMEN

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

The samples with presence of fibrin should be centrifuged before testing.

Do not use highly hemolyzed or lipemic samples.

PROCEDURE

Wavelength	600 - 650 nm (650 nm)
Cuvette	1 cm light path
Temperature	37 ^{0}C
Zero adjustment	against distilled water
Specimen	Serum

	Blank
Diluent (R1)	400 µl
Latex R2	100 µl

- Mix and read the absorbance (Blank reagent).
- Add the sample/ calibrator.

	Blank	Calibrator	Specimen
NaCl 9 g/L	4 µl	100 µl	100 µl
Calibrator	……	4 µl	……
Specimen	……	……	4 µl

Mix and read the absorbance after 2 minutes (A2) of the sample addition.

CALCULATION

Calculate the absorbance difference (A_2-$A_{\text{blank reagent}}$) 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-$A_{\text{blank reagent}}$) in the calibration curve.

QUALITY CONTROL

It is recommended that controls (normal and abnormal) be included in:

- Each set of assays, or
- At least once a shift, or
- When a new bottle of reagent is used, or
- After preventive maintenance is performed or a clinical component is replaced.

Commercially available control material with established RF values may be routinely used for quality control.
Failure to obtain the proper range of values in the assay of control material may indicate:

- Reagent deterioration,
- Instrument malfunction, or
- Procedure errors.

The following corrective actions are recommended in such situations:

- Repeat the same controls.
- If repeated control results are outside the limits, prepare fresh control serum and repeat the test.
- If results on fresh control material still remain outside the limits, then repeat the test with fresh reagent.
- If results are still out of control, contact Vitro Technical Services.

PERFORMANCE CHARACTERISTICS

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EC REP **Medical Device Safety Services**
MDSS GmbH, Burckhardtstr. 1
30163 Hannover, Germany.

1. **Detection limit:** Values less than 6 IU/mL give non-reproducible results.
2. **Measurement range** (calibration curve): 6-160 IU/mL, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 in NaCl 9 g/L and retested again. The linearity limit and measurement range depends on the sample to 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. **Prozone effect:** No prozone effect was detected upon 800 IU/mL.
4. **Sensitivity:** Δ 3.34 mA. IU/mL.
5. **Precision:** The reagent has been tested for 20 days, using three different FR

EP5	CV (%)		
IU/mL	35.8	78.05	123.26
Total	4.5%	4.1%	5.9%
Within Run	3.3%	2.6%	3.2%
Between	1.7%	2.3%	3.4%
Between	2.5%	2.1%	3.6%

6. **Accuracy:** Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 41 samples of different concentrations of FR were assayed. The correlation coefficient (r) was 0.91 and the regression equation y = 1.2042x +3.1344.

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

REF	SIZE
70301	100 TEST

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ISO 13485:2016 CE

INTERFERING SUBSTANCES

Bilirrubin (20 mg/dL), lipemia (10 g/L) do not interfere.
Hemoglobin (≥ 10 g/L), interferes.
Other substances may interfere[7].

BIBLIOGRAPHY

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SYMBOL DECLARATION

	Manufacturer
	Consult instructions for use
LOT	Batch code (Lot #)
REF	Catalog number
	Temperature limitation
IVD	In vitro diagnostic medical device
	Use by
	Caution. Consult instructions
	Keep away from light

ORDERING INFORMATION

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