TurbiMAX RA

(Turbilatex / Immunoturbidometric)

ORDERING INFORMATION

Ref. No.	Pack Size	Presentation
AVRFT - 50	50 ml	Two Liquid Reagents with Calibrator
AVRFT - 100	100 ml	

INTENDED USE:

TurbiMAX RA is an in-vitro diagnostic kit for the Quantitative determination of Rheumatoid Factors (RF) in human serum.

PRODUCT FEATURES :

1. Quantitative Immunotur bidometric Assay
2. Two liquid stable reagents(Turbilatex and Buffer).
3. Linearity range 2-280 IU/mL
4. Calibrator provided.
5. No Prozone effect was detected upon 800 IU/mL
6. Can be automated to semi and fully auto analyzers.

CLINICAL SIGNIFICANCE

Rheumatoid factors are a group of antibodies directed to determinants in the Fc portion of the immunoglobulin G molecules. Although rheumatoid factors are found in a number of rheumatoid disorders, such as systemic lupus erythematosus (SLE) and Sjogren's syndrome, as well as in non rheumatoid conditions, its central role in clinic lies utility as an aid in the diagnosis of rheumatoid arthritis (RA). A study of the "American College] of Rheumatology" shows that the 80.4% of RA patients were RF positive.

PRINCIPLE

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

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the labels when stored at 2-8ºC and the contaminations is prevented during their use. Do not freeze the latex and diluent.

KIT COMPONENTS

1. Buffer Reagent R1
2. Turbi Latex Reagent R2
3. RA Calibrators : Concentration as stated on the label

COMPOSITION

Buffer (R1)	Tris buffer 20 mmol/L, ph 8.2. Sodium azide 0.95g/L.
Latex (R2	Latex particles coated with human gammaglobulin, ph 7.4. Sodium azide 0.95g/L.
RF-CAL	Liquid stable calibrator.

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard reagent if blank reagent absorbance exceeds 1.3 at 630 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN COLLECTION & STORAGE

Fresh serum

Stable for 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 hemolized or lipemic samples.

System Parameters

Mode	Fixed Time/Two point Kinetic
Reaction	Increasing
Wavelength	630nm (600-650nm)
Blank	Distilled water
Sample volume	10 µL
Reagent volume	1000 µL
Delay time	10 (Sec.)
Read time	120 (Sec.)
Calibrator Conc.	stated on the vial
Linearity	280 IU/ml
Unit	IU/ml

TEST PROCEDURE

Pipette into test tubes labeled Calibrator (C) and Test (T).

Reagent	(C)	(T)
Buffer Reagent R1	800 µl	800 µl
RA Calibrator	10 µl	-
Sample	-	10 µl
Latex Reagent R2	200 µl	200 µl

Reaction temperature : 37°C

Mix well and read absorbances of Calibrator (C) and Test (T) against distilled water at 630 nm (600-650 nm) as follows:

Initial absorbance A1 -exactly after 10 sec.

Final absorbance A2 - exactly 120 sec. after A1

Determine ΔA for Calibrator (C) and Test (T)

CALCULATIONS :

$$\text{RA Conc.: (IU/ml)} = \frac{\text{(A2-A1) Sample}}{\text{(A2-A1) Calibrator}} \times \text{Calibrator Concentration (Printed on the Vial)}$$

EXPECTED VALUES

Normal values up to 20 IU/ml. Each laboratory should establish its own reference range.

QUALITY CONTROL & CALIBRATION

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.

PERFORMANCE CHARACTERESTICS:

1. Linearity

Linearity : 280 IU/ml

2. Sensitivity/ Limit of Detection (LOD)

The lower limit of detection is 1 IU/mL

3.Interferences:

Hemoglobin (10 g/l), bilirubin (20 mg/dl) and lipemia (10 g/l) do not interfere.

4. Precision: The reagent has been tested for 20 days, using two levels of serum in a EP5-based study (NCCLS).

Intra-Assay

N=10	Mean (mg/dl)	SD (mg/dl)	CV%
Control serum 1	14.9	0.38	2.55
Control serum 2	45.8	1.36	2.96

Inter-Assay

N=10	Mean (mg/dl)	SD (mg/dl)	CV%
Control serum 1	15.3	0.43	2.81
Control serum 2	46.2	1.53	3.31

5. Method Comparison:
Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 86 samples ranging from 2 to 280 IU/mL of RF were assayed. The correlation coefficient (r) was 0.95 and the regression equation y = 0.797x -1.075.

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

LIMITATIONS

(Calibration curve): 2-280 IU/ml, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 in saline (10 parts serum sample + 40 parts normal saline ex: 10µl serum sample+40 µl saline) and retested again and the results should be multiplied by 5. 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.

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

NOTES

1. Multipoint calibration gives more accurate results than one point calibration.
2. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

REFERENCE

1. Frederick Wolfe et al. Arthritis and Rheumatism 1991; 34: 951- 960.
2. Robert W Dorner et al. Clinica Chimica Acta 1987; 167: 1-21.
3. Robert H Shmerling et al. The American Journal of Medicine 1991; 91: 528 – 534.
4. Vladimir Muié et al. Scand J Rheumatology 1972; 1: 181 – 187.
5. Paul R et al. Clin Chem 1979; 25/11: 1909 – 1914.
6. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		

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5 Schedule MDR 2017

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