TRUEchemie Rheumatoid Factor (RF) Test Kit (Immunoturbidimetry)

for direct quantitative turbidimetric test for the measurement of RF in human serum

INTENDED USE

The TRUEchemie Rheumatoid Factor (RF) Test Kit (Immunoturbidimetry) is a quantitative turbidimetric test for the measurement of RF in human serum.

PRINCIPLE

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 sample that can be quantified by comparison from a calibrator of known RF concentration.

INTRODUCTION

Rheumatoid factors are a group of 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 Sjogren'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). A study of the "American College of Rheumatology" shows that the 80.4% of RA patients were RF positive.

PACK SIZE

Kit size	**50 ml**
Cat. no.	**ADX922**
Kit contents	
1) RF Diluent (R1)	1x 40 mL
2) RF Latex (R2)	1 x 10 mL
3) RF Calibrator	1 x0.5 mL

REAGENTS COMPOSITION

RF Diluent (R1) Tris buffer 20 mmol/L, pH 8.2. Preservative

RF Latex (R2) Latex particles coated with human gamma globulin, pH 7.4. Preservative

RF Calibrator Human serum. The RF concentration is stated on the vial label.

REAGENT PREPARATION

Ready to use reagents.

TRUEchemie RF calibrator – To be serially diluted.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use. To be handled by entitled and professionally educated person. Reagents of the kit are not classified as dangerous but contain less than 0.1% sodium azide.
2. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.
3. Components from human origin used in the preparation of standard are negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies. However, handle cautiously as potentially infectious.

CALIBRATION

Use TRUEchemie RF Calibrators, which are ready to use.
Re-calibrate when control result is out of specified tolerances, when using different lot of reagents and when the instrument is adjusted.

REAGENT STORAGE & STABILITY

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2-8°C. Do not use reagents over the expiration date.
Reagent deterioration: Do not freeze the reagents, frozen Latex or Diluent could change the functionality of the test.
Calibrator: Calibrator stored at 2-8 °C and are stable till the expiry date mentioned on the label.

SPECIMEN COLLECTION AND STORAGE

Serum collected according to the standard procedures. RF in serum is stable for 2 days at +2/+8ºC. The samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipettes to accurately measure required volumes.
2. Test tubes/rack
3. Timer
4. 37°C heating block or water bath
5. Photometer capable of measuring absorbance at 660 nm

TEST PROCEDURE FOR PREPARATION OF CALIBRATION CURVE

Calibration curve: Prepare the following RF Calibrator dilutions in normal saline. Multiply the concentration (stated on the vial) of the RF Calibrator by the corresponding factor stated in table below to obtain the concentration of each dilution

Dilution	1	2	3	4	5	6
Calibrator (µl)	-	50	50	50	50	100
Saline (µl)	100	50	50	50	50	-
Factor	0	0.0625	0.125	0.25	0.50	1.00

TEST PROCEDURE

Wavelength: 660 nm
Temperature: 37ºC
Cuvette light path: 1 cm
Prewarm the reagents to reaction temperature

Reagent	**Cal -1**	**Cal -2**	**Cal -3**	**Cal -4**	**Cal -5**	**Cal - 6**	**Test**
RF Diluent (R1) (µL)	800	800	800	800	800	800	800
RF Latex (R2) (µL)	200	200	200	200	200	200	200
Saline (µL)	10	-	-	-	-	-	-
Calibrator (µL)	-	10	10	10	10	10	-
Sample (µL)	-	-	-	-	-	-	10

Mix well and read absorbance of calibrator and sample against distilled water at 660 nm as follows:
Initial absorbance A0 – Exactly after 10 sec.
Final absorbance A1 – Exactly after 120 sec.
Determine Δ A for Calibrator(C) and Sample(S)

Δ AC = Δ AC1 - Δ AC0
Δ AS = Δ AS1 - Δ AS0

Calculations:
The RF concentration of unknown samples is derived from a calibration curve using an appropriate mathematical model such as spline.

QUALITY CONTROL

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

EXPECTED VALUE

Up to 20 IU/ mL.
Each laboratory should establish its own reference range. It is recommended that results of the test should be correlated with clinical findings to arrive at the final diagnosis.

PERFORMANCE CHARACTERISTICS

Sensitivity: 5 IU/mL
Linearity: 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. The linearity limit and measurement range depend on the sample to reagent/ratio, as well as the analyser used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
Prozone effect: No prozone effect was detected upon 800 IU/mL.

PRECISION:

Intra-assay precision within run (n=20)	**Mean (IU/mL)**	**SD (IU/mL)**	**CV (%)**
Low	22.6	0.4	1.7
High	61.8	0.6	0.9

Inter-assay precision Run to run (n=20)	**Mean (IU/mL)**	**SD (IU/mL)**	**CV (%)**
Low	29.0	0.5	1.6
High	61.0	0.5	0.8

The reagent was tested for 20 days, using three different RF concentrations. The coefficient of variation was <5%.

AUTOMATED PROCEDURE

Appropriate program sheet is available for different analyzers upon request.

METHOD COMPARISON

Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 80 samples of different concentrations of TRUEchemie RF were assayed. The correlation coefficient (r) was 0.996 and the regression equation was y = 0.979x + 0.997. The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

No significant interactions were observed for hemoglobin, conjugated bilirubin, lipemia up to the interferent concentration given: Hemoglobin: ≤ 10 g/L; Bilirubin : ≤ 20 mg/dL;Lipemia : ≤ 10 g/L

WASTE MANAGEMENT

Please refer to local regulation requirements.

SYSTEMS PARAMETERS

Mode	:	Fixed kinetic
Calibrator	:	Stated in the vial
Wavelength	:	660 nm
Units	:	IU/mL
Flow cell Temp	:	37°C
Reagent volume	:	R1: 800 µl & R2: 200 µl
Sample volume	:	10 µl
Delay time	:	10 sec.
Read time	:	120 sec. (2min.)
Normal range	:	up to 20
Sensitivity	:	5
Linearity	:	up to 160
Reaction Slope	:	Increasing

REFERENCES

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. ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

Index of Symbols

Consult instructions for use	REF Catalogue number	Caution
IVD *In vitro* diagnostic medical device	LOT Batch code	Non-sterile
2°C 8°C Temperature limit 2-8°C	Do not re-use	Use-by date
Manufacturer	Date of manufacture	Keep dry

Do not use if package is damaged — Keep away from sunlight

Athenese-Dx Pvt. Ltd.
Module No. 407 & 408, 4th Floor,
TICEL Bio Park II, No. 5, CSIR Road.
Taramani, Chennai-600113, India
Tel: +91-44-22541131
E-mail: info@athenesedx.com
Website: www.athenesedx.com

PI-ADX92 Rev. F
Effective date: 28.12.2023
English version