RF Turbidimetric 3a Gen

IVD

Quantitative determination of Rheumatoid Factors (RF) in human Serum or Plasma. Turbidimetric Immunoassay.

REF TB1023 R1: 2x25 mL + R2: 1x10 mL + R3: 1x1 mL (calibrator)

METHOD AND PRINCIPLE

The Rheumatoid Factor reacts with aggregated human IgG producing a turbidity photometrically measurable at 340 nm. The absorbance measurement is proportional to the concentration of the Rheumatoid Factor in the sample under examination. Using a known concentration calibration set, it is possible to calculate the amount of Rheumatoid Factor in unknown samples.

CLINICAL SIGNIFICANCE

The Rheumatoid Factor (RF) is an autoantibody, that is an IgM produced by the immune system able to recognize and attack the tissues of the organism to which it belongs because they are mistakenly recognized as strangers. Although the biological role of RF has not been well clarified, its presence is a useful indicator of inflammation and autoimmune activity. This test detects and measures the amount of RF in the bloodstream.

The RF test is a useful support for the diagnosis of rheumatoid arthritis (RA). About 80% of people with RA have high levels of RF. However, RF can also be detected in patients with other diseases, including various autoimmune disorders such as Sjögren's syndrome, persistent bacterial, viral or parasitic infections and, in small percentages (1-5%), it can also be detected in healthy people.

The measure of the RF may be required if a person shows signs and symptoms of AR. Symptoms include pain, sense of heat, swelling and morning stiffness of the joints, presence of subcutaneous nodules and, in the advanced stages of the disease, radiographic evidence of swelling of the joint capsules and loss of cartilage and bones. In the event that the RF test provides a negative result but the symptoms persist, the test should be repeated.

Finally, the RF can be used in conjunction with other tests related to various autoimmune diseases, such as the anti-nuclear antibody (ANA) test, or other inflammation markers, such as C Reactive Protein (CRP) and erythrocyte sedimentation (ESR), as well as the complete blood count, aimed at the evaluation of blood cells

REAGENT COMPOSITION

R 1 (Buffer):

Good's buffer (pH 7.4) 50 mmol/L

R 2 (Antiserum):

Heat aggregated human IgG < 0.5 mg/mL

R 3 (Calibrator):

RF See value on the label

REAGENT PREPARATION AND STABILITY

Liquid and ready to use reagents, stable until the expiry date shown, if stored as indicated on the label and avoid contamination, evaporation and prolonged exposure to direct light. Do not freeze the reagents.

Discard the reagent if signs of deterioration appear, such as the presence of particles and turbidity or failure to recover the values of certified control sera or Absorbance of Blank Reagent >0.300 at 340 nm in cuvette 1 cm against water. After opening the bottles, it is advisable to withdraw the necessary volume, to immediately close the bottles and store them in the fridge in order to avoid contamination, degradation from direct light and evaporation.

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SPECIMEN:

Serum, EDTA or Lithium Heparin Plasma.

Avoid hemolysate or lipemic samples. Separate the serum from the clot quickly. Perform a single defrost.

Stability: 8 days at 2 - 8° C, 3 days at 15 - 25° C, 3 months at -20 ° C.

PROCEDURE

Wavelength: 340 nm
Temperature: +37°C
Measurement: against distilled water

Pipette as follow:

Reagent (R1)	1000 µL
Sample / Calibrator /H_2O	50 µL

Mix and after 60" read Absorbance (Abs1). Then add:

Reagent (R2)	200 µL

Mix, after other 300" read Absorbance again (Abs 2).

Calculate ΔAbs (Abs2 – Abs1) for samples, calibrator and controls..

CALIBRATION

The assigned values of RF Calibrator have been made traceable to WHO.

The results depend on the accuracy of the calibration, on the correct setting of the test on the instrument, on the correct volumetric ratio of reagent / sample and on the correct analysis temperature.

Dilute RF Calibrator (R3)using NaCl 9 g/L as follow:

Dilution	1	2	3	4	5	6
RF-CAL (uL)	--	10	25	50	75	100
NaCl 9 g/L (uL)	100	90	75	50	25	--
Factor	0.0	0.1	0.25	0.5	0.75	1.0

Multiply the concentration of Calibrator by the corresponding factor to obtain the concentration of each dilution.

To avoid to dilute the Calibrator, it is possible to use:

RF CALIBRATION SET REF TUC1075 - 5 x 1 mL

a multipoint calibration curve in pre-filled vials, each with a specific concentration. The values are shown on the label of each vial.

CALCULATION

The analytical session can not be validated if the Δ Abs (Abs2 - Abs1) of the Blank Reagent is > 0.300 in a 1 cm cuvette of optical path at 340 nm.

Plot the different ΔAbs (Abs2-Abs1) absorbances against the concentration of each calibrator dilution. The concentration of the sample is calculated by interpolation of its ΔAbs (Abs2-Abs1) value on the calibration curve. For automatic calculation, use the SPLINE curve but other mathematical method can be used (Point-Point; Logit-Log 4P, etc..).

QUALITY CONTROL

Normal and abnormal control sera of known concentration should be analysed routinely with each group of unknown samples utilizing **MTD Diagnostics** Quality Control Material:

Plasma Protein Control Level 1 REF: TUC1040 (3 x 1 mL)
Plasma Protein Control Level 2 REF: TUC1050 (3 x 1 mL)

The range of the values of the controls must be evaluated as a guideline, since it can be determined by the application of the method or by the user's manual skills or by other factors. The values obtained must be used for the evaluation of the Precision of the method (Repeatability). For the evaluation of the Accuracy of the method (Reproducibility) it is necessary to adhere to a program of External Quality Assessment (EQA) managed by certified bodies.

EXPECTED VALUES

Adults: Up to 20 IU/mL (WHO)

Each laboratory should establish a range of expected values based on its patient population and, if necessary, determine its own reference interval. For diagnostic purposes, results should always be assessed together with the patient's medical history, clinical examination and other results.

NOTES

1. This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meet the performance characteristics of the method. It is recommended to validate periodically the instrument. Contact your distributor for any question on the application method.
2. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

PERFORMANCE

PRECISION:
Low Level: Samples (n) = 20; Average = 27.1; S.D. = 0.57; CV = 2.10%
High Level: Samples (n) = 20; Average = 65.1; S.D. = 1.17; CV = 1.79%
ACCURACY (CORRELATION): A comparison between this method (x) and a certified method of trade (y) gave the following correlation:

y = 1.002 x – 0.71 r = 0.999

SENSITIVITY: 3.0 UI/mL
LINEARITY: 3 – 500 UI/mL

SPECIFICITY / INTERFERENCES

Bilirubin up to 20 mg/dL, Haemoglobin up to 400 mg/dL do not interfere. Other substances may interfere.

PRECAUTIONS

R1 and R2 contain TRIS BUFFER 100 mmol/L – pH 7.5 - CAS 1185-53-1

H315: Causes skin irritation
H319: Causes serious eye damage
H335: May cause respiratory irritation

The human serum in the preparation (R3 calibrator) was tested by CE and FDA approved methods and found to be negative for the presence of hepatitis B virus surface antigen (HBsAg), human immunodeficiency virus (HIV) 1&2 and hepatitis C virus (HCV). However, because no test method can provide complete assurance that infectious agents are absent, this product should be handled as a potentially biohazardous material in accordance with Universal/Standard Precautions.

The antibody present in the preparation are of animal origin and are not capable of transmitting infectious diseases to humans. However, since there are no methods to ensure the total absence of such infectious agents, this product must be handled as if it were risky and potentially capable of transmitting infectious diseases of any kind, in accordance with Good Laboratory Practice standards.
The products do not contain other dangerous substances or mixtures, according to the EC Regulation n ° 1272/2008 or their concentrations are such as not to be considered persistent, bioaccumulative or toxic (PBT). The product is classified and labeled in accordance with EC directives or respective national laws. Sodium azide, less than 0.1%.
However, in compliance with the normal prudential rules that everyone has to keep managing any chemical or laboratory reagent, in case of contact of reagents with the operator, you must apply the following first aid:
S26 (P305 – P351 – P338): In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 (P302–P352): After contact with skin, wash immediately with plenty of water.
S36/37/39 (P280): Wear suitable protective clothing, gloves and eye/face protection.
S46 (P301 – P310): If swallowed, seek medical advice immediately and show container or label. If victim is conscious and alert, wash out mouth with water.
S56 (P273): Dispose of this material and its container at hazardous or special waste collection point.
S63 (P304 – P340): In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, give oxygen and get medical aid.

All samples, calibrators and controls should be treated as potentially infectious material capable of transmitting HIV and hepatitis.

FOR MORE INFORMATION, REQUEST SAFETY DATA SHEET FOR REAGENT (MSDS) AT THE MANUFACTURER.

SIMBOLOGY

CE	CE Mark (EC Directive 98/79)		
IVD	In Vitro Diagnostic		Temperature Limitation
	Consult instructions for use		Contains sufficient for <n> test
REF	Catalog Number		Use By
LOT	Batch Code		Manufacturer

BIBLIOGRAPHY

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