RF IMMUNOTURBIDIMETRY
RHEUMATOID FACTORS

Test for the quantitative immunological determination of Rheumatoid factors in human serum and plasma.
Liquid. Dual reagents. Store at 2°C - 8°C. Do not freeze. For in Vitro Diagnostic Use.

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
TA120	5X100 ML	DMT120	840 Tests	NAB120	880 Tests	SAB121	1309 Tests
TA121	5X50 ML	TAB120	3474 Tests	NAB121	440 Tests	BY120	6136 Tests
TA122	5X25 ML	TAB121	1795 Tests	MAB120	2512 Tests	BY121	4091 Tests
TA123	5X10 ML	RAB120	2344 Tests	MAB121	1675 Tests	KAB120	2927 Tests
LAB120	3409 Tests	RAB121	781 Tests	SAB120	2727 Tests	KAB121	1951 Tests
LAB121	1818 Tests						

INTENDED USE

Rheumatoid Factors (RF) are a group of IgM antibodies (although IgG and IgA have been also described) directed against the Fc fragment of the IgG molecules.

RF is mainly present in the serum of patients with rheumatoid arthritis but other diseases may also produce RF: chronic inflammatory processes, infectious diseases such as subacute bacterial endocarditis, malaria, syphilis, leprosy, leishmaniasis, tuberculosis and a variety of autoimmune diseases such as systemic lupus erythematosus.

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

TEST PRINCIPLE

Rheumatoid factors (RF) cause agglutination of the latex particles coated with human gamma- globulin. The agglutination of the latex particles is proportional to the RF concentration and can be measured by turbidimetry.

TEST PARAMETERS

Method	: Immunoturbidimetric
Wavelength	: 660 nm
Temperature	: 2-8°C
Sample	: Serum, plasma
Linearity	: 150 IU/ML

REAGENT COMPOSITION

Reagent 1:

Tris buffer	≤	25 mmol/L
Sodium azide	≤	0.99 g/L, pH 8.2.

Reagent 2:
Suspension of latex particles coated with suspension of latex particles coated with human gamma-globulin, sodium azide <0.99 g/L.
Once opened vials, R1and R2 are stable 30 days minimum at 2-8ºC. On board stability is strongly related of analyzers specifications.

RF Calibrator (Standard): Human serum. RF concentration is stated on the vial label. Concentration value is traceable to the WHO Reference Material W1066 (International Laboratory for Biological Standards, Amsterdam).

Human serum used in the preparation of the standard has been tested and found to be negative for the presence of antibodies anti-HIV and anti-HCV, as well as for HBs antigen. However, the standard should be handled cautiously as potentially infectious.

REAGENT PREPARATION

The reagent is ready for use.
Working Reagent:
Reagent volumes can be prepared by mixing: 1 mL of Reagent 2 + 4 mL of Reagent 1. Gently mix the Reagent 2 vial before pipetting.

RF Calibrator (Standard): Reconstitute with 3.00 mL of distilled water. Stable for 3 days at 2-8ºC. After reconstitution; freezed samples are stable at least 1 month. Calibration curve: Prepare dilutions of the RF Standard using 9 g/L saline as diluent. Multiply the concentration of the RF Standard by the corresponding factor indicated below to obtain the RF concentration of the dilutions (Note 1).

DILUTION	1	2	3	4	5
RF Standard (µL) Saline (µL)	10 70	20 60	40 40	60 20	80 0
Factor	0,1 25	0,2 5	0,5	0,7 5	1.0

For manual working procedures; if working reagent will be used; shake the Reagent 2 vial gently before pouring its contents into the Reagent 1 bottle. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

REAGENT STABILITY AND STORAGE

Store at 2-8ºC.
Reagents are stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during their use.

Indications of deterioration:
Reagents: absorbance of the blank over 1.400 at 650 nm.
Calibrator: Presence of moisture.

SAMPLE

Serum collected by standard procedures.
Rheumatoid factors in serum are stable for 2 days at 2-8ºC.

TEST PROCEDURE

Sample Start
There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

Substrate Start

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATIONS

Calibration curve: Calculate the absorbance difference (AStandard − ABlank) of each point of the calibration curve and plot the values found against the RF concentration. Rheumatoid factors concentration in the sample is calculated by interpolation of its absorbance (ASample − ABlank) on the calibration curve.

For linear Calibration: The Rheumatoid factors concentration in the sample is calculated using the following general formula:

$$\frac{A2 - A1\ \text{Sample}}{A2 - A1\ \text{Standard}} \times C\ \text{Standard} = C\ \text{Sample}$$

REFERANCE INTERVALS (NORMAL VALUES) (Based on Rules CLSI C28-P Document)*

Serum Adults: Up to 30 IU/ML
*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

It is recommended to use the Rheumatoid Control Serum level I (Ref No: RCN01) and II (Ref No: RCN05) to verify the performance of the measurement procedure. Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

Calibrator: We recommend: ARCHEM Calibrator (Standard) Ref.No. TA120S.
*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 30 days in general.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

PERFORMANCE CHARACTERISTICS

Low Linearity: Detection limit is 2 IU/mL

High Linearity: (approximate value dependent on the highest standard concentration): 2-160 IU/mL. For higher values dilute sample 1/5 with distilled water and repeat measurement.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatability (within run) (intra-assay):

Mean concentration	CV	n
24 IU/ML	5.3 %	20
39 IU/ML	5.6 %	20

Reproducibility (run to run) (inter-assay):

Mean concentration	CV	n
24 IU/ML	6.6 %	25
39 IU/ML	6.1 %	25

Sensitivity (LOD) (Based on CLSI EP17 document): 2 IU/mL
Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Prozone effect: This method has not prozone effect up to 800 IU/mL.

Interferences: Hemoglobin (10 g/L), bilirubin (20 mg/dL) and lipemia (triglycerides10 g/L) do not interfere. Other drugs and substances may interfere.

These metrological characteristics have been obtained using an analyzer. Results may vary if a different instrument or manual procedure is used.

NOTES

1. For *in vitro* diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human&animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles can not be used between two different kind of reagent and between R1&R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The reagents contain sodium azide (< 0.1%) as a preservative.
8. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general “Good Laboratory Practice” (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CV%	: Coefficient of Variation Percentage
GLP	: Good Laboratory Practice
IU	: International Unit
mA	: miliabsorbance
mL	: mililiter
QC	: Quality Control
RF	: Rheumatoid factors

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SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
R2	Reagent 2
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog Number)
SN	Serial Number


Expiration date


Storage temperature interval


Read the directions


Biological risk

CE

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