RHEUMATOID FACTOR

En

REF DMT120	1.125	Tests
REF 8A120	5.357	Tests
REF 8A121	3.488	Tests
REF BY120	5.973	Tests
REF BY121	3.913	Tests
REF At120	1.314	Tests

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

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 and plasma
Linearity	: 5 IU/mL-150 IU/mL

REAGENT COMPOSITION

Reagent 1:
Tris buffer ≤ 25mmol/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.

REAGENT PREPARATION

Reagents are ready to use, liquid.

REAGENT STABILITY AND STORAGE

Store at +2/+8°C.
Reagents are stable till the expiration date stated on the label which is only for closed and uncontaminated vials.
On board stability:
Once the vials are open they are stable at least 30 days at +2/+8°C in optimum conditions.
Once opened vials are stable 30 days at +2/+8°C at optimum conditions. There is a strong relation between on board stability and auto analyzer's cooling specification and the carry-over percentage.

Indications of deterioration:
Instability or deterioration sould be suspected if there are the absorbance of the blank over ≥0,99 at 650 nm and controls do not meet the appropriate criteria.

SAMPLE

Serum and plasma:
Sample is collected by standard procedures.
RF in serum is stable for 2 days at +2/+8°C,
Samples should preferably be analyzed on the day of collection.

PROCEDURE

Materials provided

Rheumatoid Factor,
DMT120 (for Dimension),
8A120 or 8A121 (for Advia 1800),
BY120 or BY121 (for Advia 2400),
At120 (for Atellica).

Materials required but not provided

RF Calibrator: REF: TA121S

REFERENCE INTERVALS (NORMAL VALUES) (Based on CLSI EP28A3/Transference) [19]

Serum Adults: 0 - 30 IU/mL
Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges

QUALITY CONTROL

Commercially available control material with established values determined by the same method of Archem ASO Turbidimetric. We highly recommend:

Specific Protein Control Level I	**REF: RCN01**
Specific Protein Control Level II	**REF: RCN05**

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

CALIBRATION

Use RF calibrator. We recommend:

RF Calibrator (Standard): REF: TA121S

Calibration Stability: Calibration stability is 30 days. Calibration is not recommended if QC values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Sensitivity (LoD): 4 IU/mL
Low Linearity (LoQ) (Values are based on LoQ CV% values ≤ 20%): 5 IU/mL RF

High Linearity: The test is linear up to 150 IU/mL
For higher concentrations over linearity range dilute sample 1/5 with distilled water or dilute with analyser predefined automated dilution mode and repeat measurement.

Precision Studies (Based on CLSI EP05A3):

Repeatability (within run) (intra-assay):
Within-run reproducibility was established by assaying two levels of control serum 40 runs.

Mean conc.	SD	CV	N
24.3 IU/mL	0.44	1.8%	40
64.6 IU/mL	0.50	0.8%	40

Repeatability (day to day) (inter-assay): Run-to-run reproducibility was established by assaying two levels of control serum for 40 runs.

Mean conc.	SD	CV	N
24.4 IU/mL	0.53	2.2%	40
63.8 IU/mL	0.88	1.4%	40

Method Comparison and Correlation:
Correlation with a comparative method is: r=0.980
(Between 10 IU/mL to 140 IU/mL)
Regression analysis according to Passing-Bablok Fit:
Slope: 1,031 Intercept: -2,46

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

Interferences:
The acceptable interference limit is set 10% below the highest interferent concentration that is within ±10% recovery of the target.
No significant interaction was observed for hemoglobin, conjugated bilirubin, lipemia up to the interferant concentration given in the table. Other drugs and substances may interfere.
Reference observed results in the table below.

Interferent and Concentration	RF Direct Target IU/mL	N	Observed Recovery %
Bilirubin (Conjugated) 6.1 mg/dL	32.4	3	109
Bilirubin (Conjugated) 6.1 mg/dL	53.8	3	109
Triglycerides 850 mg/dL	32.7	3	96
Triglycerides 850 mg/dL	53.5	3	98
Hemoglobin 1080 mg/dL	33.3	3	98
Hemoglobin 1080 mg/dL	51.4	3	96

The effect of interfering substances has only been evaluated for those listed in this table.
A biochemistry analyzer has been used to obtain these performance characteristics. Usage of different biochemistry auto analyzers or manual procedure may cause the variance in results.
Intralipid has been used for Triglycerides interferences studies.

NOTES

1. For in vitro diagnostic use only. Mouth pipetting is prohibited. Avoid contact with skin and mucous membranes.
2. All the calibrators and controls must be considered as human or animal-sourced substances and thus they are potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet (SDS) will be provided upon request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. Caps of the reagents bottles cannot 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.

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 GLP guidelines.
R32: Contact with acids liberates very toxic gas.
EUH032: Contact with acids liberates very toxic gas.
H300: Fatal if swallowed
H400: Very toxic to aquatic life
H410: Very toxic to aquatic life with long lasting effects.
Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
IU : International Unit
mL : milliliter
QC : Quality Control
NCEP : National Cholesterol Education Program
mg : milligram

L : liter
g : gram
dL :deciliter

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SYMBOLS

IVD	In Vitro Diagnostic Medical Device
LOT	Lot number
R1	Reagent 1
R2	Reagent 2
GTIN	Global Trade Item Number
REF	Reference Number
GLP	Good Laboratory Practices
FOR USE WITH	Identifies products to be used together
PRODUCT OF TURKEY	Product of Turkey
	Manufacturer
	Expiration date
	Temperature limitation
	Consult instructions for use
	Caution
	Sufficient for

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