RHEUMATIOD FACTORS
(RF)

PRINCIPLE OF THE METHOD

Rheumatoid factors (RE) cause agglutination of the latex pa'flbie.1 human gamma-globulin. The agglutination of the latex pa .5923 proportional to the RE concentration and can be measured by turbidimetrryl-3.

CONTENTS

	CA 15
A. Reagent	1 x 40 ml
B Reagent	1 x 10 ml
C Standard	for 1 x 1 ml

COMPOSITION

A.Reagent :Tris buffer 20 mmoi/L,sodium azide 0.95g/L,pH8. 2.

B. Reagent. Suspension of latex particles coated with human gamma-globulin, sodium azide 0.95 g/L.

S.RE Standard: Human sersm. RE concentration is stated on the vial label. Human serum used' In the preparation of the standard has been tested und found to be negative for the presence of antibodies anti-HI V and anti-HCV as well as for HB5 antigen. However, the standard should be handled cautiously as potentially Infectious

STORAGE

Store at28CC

Reagents and Standard 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: Presence of particulate material, turbidity, absorbance of the blank over 1 .400 at 650 nm.

-Standard: Presence of moisture.

REAGENT PREPARATION

RE Standard (5): Reconstitute with 3.0 mL of distilled water. Stable for l month at 2-8CC

Calibration curve: Prepare dilutions of the RE Standard using 9 g/L saline as diluent. Multiply the concentration of the RE Standard by the corresponding factor indicate below to obtain the RE concentration of the dilutions (Note 1).

Dilution	1	2	3	4	5
RF Standard Saline( )	10 70	20 60	40 40	60 20	80 -
Factor	0.125	0.25	0.5	0.75	1.0

ADDITIONAL EQUIPMENT

-Thermostatic water bath at 37°C

Analyzer, spectrophotometer or photometer thermostatable at 37°C able to read at 650+ 20 nm.

SAMPLES

Serum collected by standard procedures.

RE in serum is stable for 2 days at 2800.

GENERAIZED SYSTEM PARAMETERS

Reaction Type	Fixed Time with std or factor
Wave Length	650 nm
Incubation Team	0
Read Time	120 sec
No. of readings	1
Sample Volume	10 αL
Reagent Volume	1 .0 mL
Standard	As par value given in the vial
Units	mg/L

PROCEDURE

1. Bring the Reagents and the instrument to 37^0C
2. Zero the instrument with distilled water (Note2),
3. Pipette into a cuvette:

Reagent A	0.8 ml
Water (Blank) Standard (S) or sample	10 αL
Reagent B (Note 3)	0-2 ml

4. Mix and insert cuvette into the instrument. Start stop watch.

5.Read the absorbance at 650 nm after 2 minutes of the Reagent B addition.

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CALIBRATION

Calibration curve: Calculate the absorbance difference (Agiandam -AM) of each point of the calibration curve and plot the values found against the RE concentration. Rheumat0id factors concentration in the sample Is calculated by interpolation of its absorbance (ASamp,e-BB,ank) on the calibration curve.

A culibration is recommended at least every 2 months, after reagent lot change or as required by quality control procedures.

The concentration value of he RE Standard is traceable to the WHO Reference Material W1066 (International Laborutory for Biological Standards, Amsterdam).

REFERENCE VALUES

Serum, adults[4] : Up to 30 lU/mL

This range is given for orientation only; each laboratory should establish its own reference range.

QUALITY CONTROL

it is recommended to use-the Rheumatoid Control Serum level II (Cod. 31213) and it (Cod. 31214) to verify the performance of the measurement procedure.

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

METROLOGICAL CHARACTERISTICS

- ✓ Detection limit: 2 lU/mL
- ✓ Measurement interval: (approximate value dependent on the highest standard concentration): 2-160 lU/mL. Eor higher values dilute sample 1/5 with distilled water and repeat measurement (Note 4).

-Repeutibility (within run)

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

- ✓ Reproducibility (run to run):
- ✓ Mean Concentration

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

- ✓ 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.
- ✓ Zone effect: This method has not zone effect up to 800 lU/mL.
- ✓ interferences: Hemoglobin (10 IL), bilirubin (20 mg/dL) and lipemia (triglycerides 10 g/L) do not interfere. 0t er drugs and substances may interferes. These metrological characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure are used.

DIAGNOSTIC CHARACTERISTICS

Rheumatoid Eactors (RE) are a group of 1gM antibodies (although lgG and lgA have been also described) directed against the Ec fragment of the lgG molecules. RE is mainly present in the serum of patients with rheumatoid arthritis but other diseases may also produce RE: chronic inflammatory processes, infectious diseases such as subacute bacterial endocurdifis, malaria, syphilis, leprosy, leishmaniasis, tuberculosis and a variety of autoimmune diseases such as systemic lupus erythematosus6.

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

NOTES

1 The calibration curve is linear up to 120 lU/ML in some instruments. in these cases, calibration may be performed with a single point (40 lU/ mL). it better accuracy is required, it is recommended to use the multipoint calibration met 0 .

2 These reagents may be used in several automatic analysers. instructions for many of them are available on request.

3 Shake the Reagent B vial gent y before using.

4 The measurement interval depends on the sample to reagent ratio. The interval will be higher by decreasing the sample volume,

although the sensitivity of the test will be proportionally decreased.

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