RF-HA II

Turbidimetric Immunoassay

For the quantitative determination of Rheumatoid Factor in Serum

Read this instruction sheet thoroughly before use.

CE

419-70757
0108 D1

Intended use

RF-HA II is an *in vitro* assay for the quantitative determination of rheumatoid factor (RF) activity in serum.

Summary and explanation of the test

Rheumatoid factor (RF) is contained in the serum of rheumatoid arthritis patients. Because of its high degree of specificity, the detection of RF by serologic test has proved to be useful in the clinical diagnosis and prognosis of rheumatoid arthritis.[1] RF is an autoantibody of human immunoglobulin G (IgG). The most conventional serologic test for RF is the method dependent upon the agglutination of particles (e.g., latex and erythrocytes) which have been sensitized with human gamma-globulin.[1] Assays for RF have been improved and more quantitative RF test have been reported (e.g., nephelometric immunoassay and turbidimetric immunoassay). Turbidimetric immunoassay method (TIA) has the advantages of ease of use, accurate quantitation, and it is applicable to automated analyzers.
The Wako RF-HA II test is a highly specific reagent based on turbidimetric immunoassay.

Principle of the method

When a sample is mixed with R1 and R2, rheumatoid factor in the sample combines specifically with the heat-aggregated human IgG in the reagents to yield an insoluble aggregate which causes increased turbidity in the solution. The degree of turbidity of solution can be measured optically and is proportional to the activity of rheumatoid factor in the patient's sample.

Reagents

Contents and storage conditions

R1:	Buffer	Store at 2 - 10°C
R2:	RF Reagent	Store at 2 - 10°C

Ingredients

R1: Buffer	Good's Buffer (pH 7.4)	50 mmol/L
	Sodium Azide	0.09%
R2: RF Reagent	Heat-aggregated human IgG	≤ 0.5 mg/mL
	Sodium Azide	0.09%

Reagent preparation

R1: Use as supplied.
After opening the bottle, this solution is stable for one month at 2 - 10°C.
R2: Use as supplied.
After opening the bottle, this solution is stable for one month at 2 - 10°C.

Specimen collection and preparation

Serum can be used as a specimen.
It is recommended to measure RF immediately after collection.

Physical or chemical indications of instability

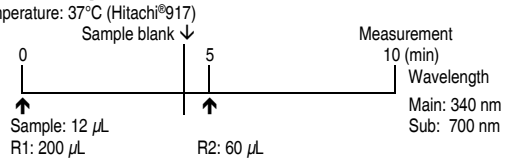
The presence of precipitates in the reagents or values of control sera outside the manufacturer's acceptable range may be an indication of reagent instability.

Instruments

The reagent is designed to be used on commercially available automated analyzers. Refer to the operating manual for a description of instrument operation and specifications.
A validation by the user in practice at the customer's site in the form of measurements of adequate control or patient sera in sufficient number is indispensable.

Standard procedure

Temperature: 37°C (Hitachi®917)



Calibrator: Wako RF-TIA Calibrator Set (Available separately.)

Calculation of RF concentration

Calculate RF concentration from the calibration curve which was created from absorbance of calibrator.

Application to the various automatic analyzers

Input the parameters according to the instructions of instruments to perform the measurement. Instrument applications are available upon request.

Results

The final results are automatically calculated and printed in concentration. The results are given in IU/mL.
The measuring signal of the RF-HA II test is converted by a non-linear mathematical function into the final concentration. The mathematical model used for the curve fitting and its arithmetic approximation depend on the type of the analyzer used. The validation of the suitability of the used mathematical function lies in the responsibility of the user.

Expected values[2]

Serum: 20 IU/mL or lower.

Performance characteristics

(1) Accuracy
When a sample of known concentration is assayed, the measured value is within ±15% of the known concentration.

(2) **Sensitivity**
a) When purified water is used as a sample, the absorbance is 0.050 or less.
b) When a control serum (100 IU/mL RF) is used as a sample, the absorbance is 0.020 - 0.100.

(3) Precision
When a sample is assayed 5 times or more in a run, CV is within 10%.
(In the case of a sample of 30 IU/mL RF or more)

(4) Measurable range
10 - 500 IU/mL RF (In the case of using standard procedure).
In the case of using the multi-point assay with 500 IU/mL as the highest concentration.

(5) Correlation

Specimen	Serum
Correlation coefficient	r = 0.993 (n = 92)
Regression equation	y = 0.91 x - 11.7
y	Wako RF-HA II (TIA) / IU/mL
x	Product of Company A (TIA) / IU/mL

Interfering substances

Hemolysis, ascorbic acid and bilirubin do not have significant effects on the assay.

Warnings and precautions

- For *in vitro* diagnostic use.
- The usage and application of this test is reserved for professional use only. Please refer to respective national and local regulations and legislation.
- Not to be used internally in humans or animals.
- Store the reagents under the specified conditions. Do not use reagents past the expiration date stated on each reagent container label.
- Performance cannot be guaranteed if the reagents are used in other procedures or for other purposes.
- Do not use the reagents described above for any purpose other than described here in.
- Do not use reagents which were frozen by mistake. Such reagents may give false results.
- Do not use the containers and other materials in the package for any purposes other than those described herein.
- After opening the reagent, it is not recommended to store it for a long period of time. When the opened reagent is stored, cap the bottle and keep it at the specified temperature.
- An antigen excess will not occur up to 7,300 IU/mL RF (In the case of using the standard procedure).
- When RF in a sample exceeds 500 IU/mL, dilute the sample with saline, repeat assay and multiply the result by the dilution factor.
- In some instances, falsely high or low results occur due to non-specific turbidity. If a result is questionable, inspect the reaction course or dilute the sample and repeat analysis.
- If the reagents come in contact with mouth, eyes or skin, wash off immediately with a large amount of water. Consult a physician if necessary.
- R2 (RF Reagent) is prepared from human sera which were found to be negative for HBsAg, anti-HIV1&2 antibodies and anti-HCV antibody. Because no test can offer complete assurance that products derived from human blood will not transmit infectious agents, it is recommended that RF-HA II reagent should be handled with the same precautions used for patient specimens.
- R1 and R2 contain 0.09% of sodium azide as a stabilizer. Sodium azide may react with copper or lead plumbing to form explosive compounds. Even though the reagents contain minute quantities of sodium azide, drains should be flushed well with a large amount of water, when discarding the reagents.
- When discarding the reagents, dispose of them according to local or national regulations.

Quality control

A quality control program is recommended for all clinical laboratories.

References

1. Mierau, R., and Genth, H., Autoantibodies in rheumatoid Arthritis, pp. 810 - 811 in: Thomas, L. Clinical Laboratory Diagnostics TH Books Frankfurt (1998).
2. Hahn, J.-M.:Checkliste Innere Medizin, 5. vollst. überarb. Aufl. S. 239 (2006).

Ordering information

Code No.	Products	Package
419-70757	RF-HA II	R1: 2 x 50 mL
		R2: 2 x 15 mL
419-77902	RF-TIA Calibrator Set	CAL: 5 conc. x for 1 mL

GB.DE.FR.ES.GR

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