Automated Procedure

MEDICHEM MIDDLE EAST
Clinical Chemistry Reagents
Liquid Stable Reagents

Cat. No. 30560	R1	2 x	15	ml
	R2	1 x	10	ml
Cat. No. 30561	R1	3 x	20	ml
	R2	1 x	20	ml

Rheumatoid Factor
RF-HA II

Quantitative turbid metric immunoassay

Liquid Reagents

Test Principle
When a sample is mixed with Reagent 1 and Reagent 2, 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 patients sample.

Concentrations in the test

Reagent R1		
Buffer pH = 7.4	50	mmol/L
Preservative		
Reagent R2		
Heat -aggregated human IgG	< 0.5	mg/mL
Preservative		

Stability of reagents
Reagent R1: *liquid, ready to use.*
Reagent R2: *liquid, ready to use.*
Reagents are stable up to expiry date given on the label when stored at + 2 ➔ + 8 °C. **Don't freeze.**

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

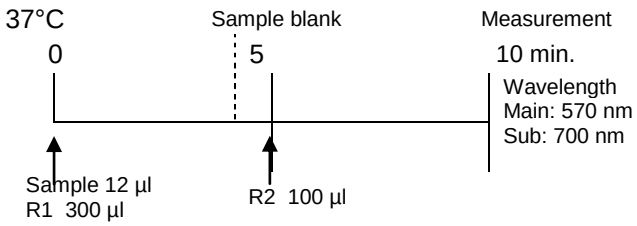
Specimen collection and handling
1. Fresh non-hemolyzed serum is recommended.
2. It is recommended to measure RF immediately after serum collection
3. The sample can be stored for 1 week at 2 – 8 °C, and for 6 months at – 20 °C.

Calibrator
RF calibrator Cat. No. 15061

Quality control
Rheumatoid control Level 1 Cat. No. 15241
Rheumatoid control Level 2 Cat. No. 15242
A quality control program is recommended for all clinical laboratories. The analysis of control sera in both the normal and abnormal ranges with each assay is recommended for monitoring the performance of the procedure. The values obtained for the controls should fall within the manufacturer's acceptable ranges. If values are to be established for unassayed control sera, the laboratory should assay each serum a sufficient number of times to generate a valid mean and acceptable range.

Procedure
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.

Assay



Note:
Applications on various instruments are available upon request.

Linearity
Up to 500 U/ml.
If the result exceeds 500 U/mL, repeat the test using diluted sample (1+1) with sodium chloride solution (0.9 %) and multiply the result by 2.
An antigen excess will not occur up to 7300 U/ml RF (In the case of using standard procedure)

Interferences
1. Ascorbic acid, bilirubin and hemolysis do not have a significant effect on the assay.
2. 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.

Performance
Sensitivity:
- When purified water is used as a sample, the absorbance is 0.050 or less.
- When a control serum (100 U/ml RF) is used as a sample, the absorbance should be within 0.020 - 0.100.

Specificity:
When a sample of known concentration is assayed, the measured value is within plus minus 15 % of the known concentration.

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 U/ml RF or more).

Measurable range:
10 - 500 U/ml RF (In the case of using standard procedure), in the case of using the multi-point assay with 500 U/ml as the highest concentration.

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Precautions

1. Don't use the reagents described above in any procedures other than those descried herein. Performance cannot be guaranteed if the reagents are used in other procedures or for other purposes.
2. Operate the instruments according to operator's manuals under appropriate conditions. Consult the instrument manufacturer for details.
3. Don't use reagents which were frozen in error. Such reagents may give false results.
4. After opening the reagents, it is recommended to use them immediately. When the opened reagents are stored, cap the bottles and keep them under the specified conditions.
5. Reagents contain sodium azide. Don't swallow. Avoid any contact with eye, skin or mucous membranes. If contact occures wash off immediately with a large amount of water. sodium azide may react with lead or copper plumbing to form explosive compounds. Drains should be flushed well with a large amount of water, when disposing of the reagents.

Reference range

Lower than 20 U/ml.

Note:

Reagent with Cat. No. 13561 suitable for Hitachi 717 / 902
Reagent with Cat. No. 13562 suitable for Hitachi 704 / 911

References

1. Mukaida.N, and Kawai.T, : Japanese Journal of Medical Technology, 31, 603 - 609 (1987). (Japanese)
2. Ezaki, I. and Nobunaga.M, : Japanese Journal of Medical Technology, 26, 205 - 207(1984). (Japanese)
3. Japanese Journal of Clinical Medicine, vol.53, Supplemental Issue, vol. 2, 422 - 426
4. (1995) (Japanese).
5. Mierau, H. and Genth. H.. Autoantibodies in rheumatoid Arthritis, pp. 810 - 813 in: Thomas, L. Clinical Laboratory Diagnostics TH Books Frankfurt (1998).
6. Anderson SG, Bentzon MW, Houba V, Krag P. International reference preparation of rheumatoid arthritis serum. Bull World Health Organ 1970, 42: 311 - 8.