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# Rheumatoid Factor Turbidimetric Immunoassay

Reagent for quantitative determination
of Rheumatoid Factor (RF) in human serum

REF K4RF1 **R1** 1 x 50 mL **R2** 1 x 10 mL **R3** 2 x 50mL

CE

IVD

Made in France

I: corresponds to significant modifications

## INTENDED USE

This reagent is designated for professional use in laboratory (manual or automated method).
It allows to detect and measure rheumatoid factors in human serum to assess the status of rheumatoid factors in the body.

## GENERALITIES (2) (4) (5)

RF is found in Rheumatoid Arthritis (RA), Sjogren's syndrome, scleroderma, sarcoidosis and other pathologies.

RF consists in a variety of antibodies that are usually of IgM class and will react with modified human IgG or IgG of animal origin.

About 75% of patients with RA have detectable RF of IgM class. The highest titres are seen in severe active chronic disease with vasculitis, and subcutaneous nodules.
80-90% of patients with Sjogren's syndrome will have high titre of RF.

## PRINCIPLE (3)

Turbidimetric Immunoassay (TIA): Photometric measurement of antigen-antibody reaction between aggregated human IgG and RF, by the end-point method at 340 nm.

## REAGENTS

| | | |
|---|---|---|
| **R1** | **RF TIA** | Buffer |
| Good's buffer (pH 7,4) | 50 | mM |
| Sodium azide | 0.95 | g/L |

| | | |
|---|---|---|
| **R2** | **RF TIA** | Anti-RF |
| Heat-aggregated human IgG | (≤ 0,5 mg/mL) | |
| Sodium azide | 0.95 | g/L |

According to 1272/2008 regulation, Reagent R1 and R2 are not classified as dangerous.

**R3** **RF TIA** Cleaning Solution
Classification due to sodium hydroxide
Met. Corr. 1: H290 - May be corrosive to metals.
Skin Corr. 1B: H314 - Causes severe skin burns and eye damage.
P280: Wear protective gloves/protective clothing/eye protection/face protection. P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310: Immediately call a poison center/doctor.

## SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

## REAGENTS PREPARATION

Liquid Reagents, ready for use.

## STABILITY AND STORAGE

**Stored away from light, well cap in the original vial at 2-8°C, reagent is stable when stored and used as described in the insert:**

Unopened,
- Until the expiry date stated on the label of the Kit.

Once opened:
- When free from contamination, Reagents R1 and R2 are stable for:
  - 3 months at 2-8° C

## SPECIMEN COLLECTION AND HANDLING (1) (2)

Use fresh serum.

If the test cannot be carried out on the same day, the serum may be stored at 2-8°C for 24 hours.

If stored for a longer period, the sample should be frozen at -20°C.

## LIMITS (6)

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

## MATERIAL REQUIRED BUT NOT PROVIDED

1. Medical analysis laboratory equipment.
2. Biochemistry Clinical Analyzer KENZA One, KENZA 240TX/ISE or KENZA 450TX/ISE
3. Saline (NaCl 9 g/L)
4. REF CO4000: Cleaning Solution

| | | | | | |
|---|---|---|---|---|---|
| Manufacturer | Expiry date | In vitro diagnostic | Storage temperature | Dematerialized water | Biological risk |
| Product Reference | See Insert | Batch number | Store away from light | Sufficient for | Dilute with |

## I CALIBRATION

- REF RF CALSET51: RF Standard Set (WHO Standardization)
- Batch specific value is indicated in the certificate of analysis and on the label of each vial.
- Use saline as zero point.
- Batch specific value are indicated in the certificate of analysis and on the label of each vial.
- Construct Standard curve as indicated in the application of KENZA analyser used

The calibration frequency depends on proper instrument functions and on the preservation of the reagent.

## REFERENCE INTERVALS (1)

WHO Values: < 20 IU/mL

This range is given as a guide only.

Each laboratory should establish its own normal ranges for the population that it serves.

## I PERFORMANCES

On a clinical chemistry analyser Selectra PRO M, 340 nm , at 37°C

Detection limit: 3 IU/mL

Linearity range**:** from 15 (LOQ) to 500 IU/mL.

Above 500 IU/mL, dilute the specimen with saline and re-assay considering the dilution factor to calculate the result. Linearity limit depends on specimen/reagent ratio.

Precision:

| *Within-run N = 20* | *Low level* | *Normal level* | *High level* |
|---|---|---|---|
| Mean (IU/mL) | 29.2 | 105.7 | 204 |
| S.D. IU/mL | 1.06 | 2.85 | 3.13 |
| C.V. % | 3.7% | 2.7% | 1.5% |

| *Between run N = 20* | *Low level* | *Normal level* | *High level* |
|---|---|---|---|
| Mean (IU/mL) | 24.6 | 102.2 | 190.2 |
| S.D. IU/mL | 0.88 | 1.37 | 3.63 |
| C.V. % | 3.6% | 1.3% | 1.9% |

Sensitivity: 0.00021 Abs/concentration unit

Specificity: Monospecific

Hook effect: No Risk

Comparison study with Nephelometry:

y = 0.6026x + 32.5 r = 0.8776

Interferences:

No interference for: Haemoglobin (500 mg/dL), Ascorbic acid (50 mg/dL), Bilirubin (50 mg/dL), Intralipid (3%)

Other substances may interfere (see § Limitations)

On-board stability:

Reagents R1 and R2 are stable 30 days.

Calibration Frequency:

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations

## QUALITY CONTROL

- REF RF CONT1: RF Control
- External quality control program.

It is recommended to control in the following cases:

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test.
2. If control is still out of range, use a new vial of calibrator or a fresh calibrator and repeat the test.
3. If control is still out of range, repeat the tests with a new vial of reagent.

If control is still out of range, please contact BIOLABO technical support or your local Agent.

## I PROCEDURE

Refer to specific applications of KENZA Analyzer used.

Minimal Software revision required :

- KENZA 240TX/ISE : from 6.13
- KENZA 450TX/ISE : from 2.20
- KENZA ONE : from 2.04

Contact support@biolabo.fr for more details

## CALCULATION

The analyser provides directly final result (IU/mL).
Refer to User's manual of analyzer used.

## REFERENCES


*(1) TIETZ N.W. Textbook of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p.1833.*

*(2) Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p.958-961.*

*(3) Klauss K., Bandilla M. D., and Mc Duffie M. D., Arthritis and Rheumatism, vol.12, n°2, p.74-81 (1969)*

*(4) Waaler E., Acta Path. Microb. Scan., 17 (1940)*

*(5) Müller W., The serology of Rheumatoid Arthritis. Berlin-Göttingen-Heidelberg 97 (1962)*

(6) YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p. 3-511 to 3-512