



BIOLABO
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MANUFACTURER:
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RF Control

Serum for quality control of quantitative determination of Rheumatoid Factor by Turbidimetric immunoassay

| | | |
|---------------------|-----------|----------|
| REF RF CONT1 | R1 | 1 x 1 mL |
| REF RF CONT5 | R1 | 1 x 5 mL |



Made in France

I: corresponds to significant modifications

TECHNICAL SUPPORT AND ORDERS

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Latest revision : www.biolabo.fr

INTENDED USE

Titred Control serum for the quality control of quantitative immunochemical determination of Rheumatoid Factor (RF) in human serum.

Suitable for manual procedure or automated instruments with BIOLABO reagents **REF** RF050E, **REF** RF520E.

REAGENTS

R1 RF Control 
 Human origin

Liquid stabilized plasma supplemented with RF.

SAFETY CAUTIONS (1) (2)

- BIOLABO reagents are designated for professional use in laboratory.
- Material Safety Data Sheet is available upon request.
 - Each donor unit used to manufacture this product was tested and found non-reactive for HbsAg, antibody to Hepatitis C and antibody to HIV-1/HIV-2.
 - However, no test method can offer complete assurance that infectious agents are absent. All specimens or reagents from biological origin should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions.
 - Waste disposal: Respect legislation in force in the country.

I 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

Ready for use

MATERIAL REQUIRED BUT NOT PROVIDED

1. BIOLABO Reagents (§ Intended Use).
2. **REF** RF CALSH1: RF Standard Super High (to be diluted)
3. **REF** RF CALSET51: RF Standard Set

QUALITY CONTROL

Verify the integrity of the vial and batch-specific value before use
 Run in accordance with the IFU of the reagent used.



STABILITY AND STORAGE

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

Unopened,

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

Once opened:

- Transfer requested quantity, well recap vials and store at 2-8°C.
- Well recapped in the original vial, at least for 6 weeks when free from contamination.

Do not freeze

PROCEDURE

Run in accordance with the IFU of the reagent used.

CONTROL VALUES (3)

- The value is based on WHO Standardisation.
- **Batch-specific value** is indicated on the label of the vial













It is recommended that each laboratory validate each new batch-specific value before use. For an optimal use, laboratories should establish their own targets and ranges. These target values have to be periodically retested.

LIMITATIONS

Factors which may influence results are bacterial contamination, accuracy of reconstitution volume, respect of automated instrument procedure, temperature...

REFERENCES

- (1) *Occupational Safety and Health Standards ; Bloodborne pathogens (29CFR1910.1030) Federal Register July 1, (1998) ; 6, p.267-280*
- (2) *Directive du conseil de l'Europe (90/679/CEE) J. O. de la communauté européenne n°L374 du 31.12.1990,p.1-12*
- (3) *TIETZ N.W. Textbook of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p.520*

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|--|--|--|--|---|--|
|  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 |