BIOLABO
www.biolabo.fr
MANUFACTURER:
BIOLABO SAS,
Les Hautes Rives
02160, Maizy, France

RF Standard Set

For calibration of quantitative determination
of Rheumatoid Factor by Turbidimetric immunoassay

REF RF CALSET51
R1 1x 1 mL, **R2** 1x 1 mL, **R3** 1x 1 mL, **R4** 1x 1 mL, **R5** 1x 1 mL

TECHNICAL SUPPORT AND ORDERS
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CE

IVD

Made in France

I: corresponds to significant modifications

INTENDED USE

Standard Set for the preparation of reference curve for quantitative immunochemical determination of RF in human serum.
Suitable for manual procedure or automated instruments with BIOLABO reagents REF RF050E, REF RF520E

REAGENTS

R1	RF1	
R2	RF2	
R3	RF3	Human origin
R4	RF4	
R5	RF5	

5 vials of RF Standards (5 different levels)

Liquid stabilized plasmas supplemented with RF and diluted in saline

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 CONT1 or REF RF CONT5: RF Control

QUALITY CONTROL

Verify the integrity of each vials and batch-specific values 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, standards are 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.

CALIBRATION VALUES (3)

- Values are traceable to a reference material (WHO Standardisation)
- **Batch-specific values** are indicated on the label of each vial

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. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p.520*

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