BIOLABO
www.biolabo.fr

MANUFACTURER:
BIOLABO SAS,
Les Hautes Rives
02160, Maizy, France

RF Standard Super High

For calibration of quantitative determination
of Rheumatoid Factor by Turbidimetric immunoassay

REF RF CALSH1	**R1**	1 x 1 mL

TECHNICAL SUPPORT AND ORDERS
Tel : (33) 03 23 25 15 50
Fax: (33) 03 23 256 256
support@biolabo.fr
Latest revision : www.biolabo.fr

IVD

Made in France

I: corresponds to significant modifications

INTENDED USE

Standard to be diluted for the calibration 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 Standard Super High — 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 CONT1or REF RF CONT5: RF Control

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 standard 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.

CALIBRATION VALUES (3)

- Standard value is based on WHO standardisation
- **Batch-specific** value is indicated on the label of the 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. Textbook 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