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

TRANSFERRIN Standard Set

For calibration of quantitative determination
of Transferrin by Turbidimetric immunoassay

REF TRF 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
Tel: (33) 03 23 25 15 50
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Latest revision: www.biolabo.fr

CE

IVD

Made in France

I: corresponds to significant modifications

I INTENDED USE

Standard Set for the preparation of reference curve for quantitative immunochemical determination of Transferrin (TRF) in human serum.
Suitable for professional use in clinical laboratory with manual procedure or automated instruments with BIOLABO reagents:
REF K1208, REF K2208, REF K4208, REF 92208

REAGENTS

R1	TRF1	Human origin
R2	TRF2	
R3	TRF3	
R4	TRF4	
R5	TRF5	

5 vials of TRF Standard solutions (5 different levels)
Defibrinated human plasma, liquid stabilized.
Contains Sodium azide (0,95g/L).

SAFETY CAUTIONS (1) (2)

- 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.

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 TIA CONT21: Control Set

QUALITY CONTROL

Verify the integrity of each vial 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 ERM/DA470k, a reference preparation for human serum proteins from International Federation of Clinical Chemistry (IFCC)
- **Batch-specific values** are indicated on the label of each vial

LIMITS

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