



BIOLABO
www.biolabo.fr

MANUFACTURER:
BIOLABO SAS,

Les Hautes Rives
02160, Maizy, France

BIO-CAL Reference Plasma

For use as calibration plasma during Haemostasis Assays

REF 13970 R1 6 x 1 mL



Made In France

TECHNICAL SUPPORT AND ORDERS

Tel: (33) 03 23 25 15 50

support@biolabo.fr

Latest revision: www.biolabo.fr

I: corresponds to significant modifications

INTENDED USE

| This plasma is designated for professional use in laboratory (manual or automated method).

BIO-CAL is a reference plasma for calibration of the following coagulation parameters:

Parameter	Reference	Name
Fibrinogen	REF 13450, 13451	BIO-FIBRI
Factor II	REF 13302	Factor II Deficient plasma
Factor V	REF 13305	Factor V Deficient plasma
Factor VII	REF 13307	Factor VII Deficient plasma
Factor VIII	REF 13308	Factor VIII Deficient plasma
Factor IX	REF 13309	Factor IX Deficient plasma
Factor X	REF 13310	Factor X Deficient plasma
Factor XI	REF 13311	Factor XI Deficient plasma
Factor XII	REF 13312	Factor XII Deficient plasma

REAGENTS

REF 13970: **BIO-CAL** Reference plasma



Freeze-dried, human citrated plasmas

Human Origin

SAFETY CAUTIONS

- 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.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment
2. Control Plasmas REF 13961, REF 13962 and REF 13963
3. Control Plasmas REF 13971, REF 13972 with Deficient Factors

PERFORMANCES

Calibration Values were determined against respective SRM and may slightly vary from batch to batch. See § CALIBRATION VALUES

LIMITES

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

REAGENTS PREPARATION

- Open the vial carefully and add exactly the volume of demineralised water stated on the label
 - Wait for 15 minutes at room temperature
 - Gently agitate before use (avoid the formation of foam).
- WARNING: DO NOT SHAKE. STORE AWAY FROM LIGHT

STABILITY AND STORAGE

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

Unopened:

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

Once opened:

- plasma must be reconstituted immediately,
- Once reconstituted, plasma is stable: 4 hours at 2-25°C
Don't use reconstituted plasma after expiry date stated on the label

PROCEDURE

Run in accordance with the IFU of the reagent used with the calibrator § CALIBRATION of reagent used with calibrator.

I CALIBRATION VALUES (3)

The levels of Fibrinogen and Factors II, V, VII, VIII, IX, X, XI are determined against their respective secondary standards of the corresponding primary International Standard for relevant parameters: SSC/ISTH Secondary Coagulation Standard NIBSC code: SSCLOT4

Make sure that the batch number stated on the label of the vial corresponds to the batch number indicated here above:

LOT XXXXXX	Calibration values Semi-automated and full-automated methods, including: BIOLABO SOLEA 100, BEHNK THROMBOLYZER Series
Fibrinogen (mg/dL)	
Factor II (%)	
Factor V (%)	
Factor VII (%)	
Factor VIII (%)	
Factor IX (%)	
Factor X (%)	
Factor XI (%)	
Factor XII (%)	

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) Section 5.6 of ISO 17511- Measurements of quantities in biological samples- metrological traceability of values assigned to calibrators and controls

Manufacturer REF	Expiry date See Insert	In vitro diagnostic LOT	Storage temperature Store away from light	Dematerialized water Sufficient for	Biological risk Dilute with
---------------------	---------------------------	----------------------------	--	--	--------------------------------