



BIOLABO
www.biolabo.fr

MANUFACTURER:
BIOLABO SAS,

Les Hautes Rives
02160, Maizy, France

COATROL 2 Level 2

For Internal Quality Control in haemostasis

REF 13972 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

]: corresponds to significant modifications

I INTENDED USE

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

It is used to monitor the reproducibility and accuracy of following analysis performed with BIOLABO Reagents:

- REF 13702, 13704, 13712: BIO-TP LI
- REF 13885, 13880 and 13881: BIO – TP
- REF 13560 and 13570 : BIO-CK
- REF 13660 and 13670 : BIO-SIL
- REF 13450 and 13451: BIO-FIBRI
- REF 13980: BIO-TT
- REF 13302: Factor II
- REF 13305: Factor V
- REF 13307: Factor VII
- REF 13308: Factor VIII
- REF 13309: Factor IX
- REF 13310: Factor X
- REF 13311: Factor XI
- REF 13312: Factor XII

I REAGENTS

R1	COATROL 2	Level 2	
Freeze-dried, human citrated plasmas			Human origin

I SAFETY CAUTIONS (1) (2)

- Safety Data Sheet is available on request or on www.biolabo.fr.
- 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.
- As 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.
- 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 13971
3. Reference plasma REF 13970 or TP CAL SET REF 13965

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:

- R1 must be reconstituted immediately,

Once reconstituted, plasma is stable:

- 10 hours at 2 – 8°C and 15 - 25°C, 5 days at -20°C

Don't use reconstituted plasma after expiry date stated on the label

I PROCEDURE

- Refer to the technical sheet of reagent used.

LIMITS

Factors which may interfere with the result are:

- Bacterial contamination.
- The volume measured to reconstitute the plasma.
- The setting of the instrument.
- Temperatures

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
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VALUES AND RANGES (3)

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

Fibrinogen and Factors II, V, VII, VIII, IX, X, XI are determined using secondary Standards traceable to International Standards as follows:
SSC/ISTH Secondary Coagulation Standard Lot #4 NIBSC code: SSCLOT4

LOT _____	Semi-automated and full-automated methods, including: BIOLABO SOLEA 100, BEHNK THROMBOLYZER Series	
	Assigned Values	Ranges
BIO - TP LI : INR (Low ISI) (%) Prothrombin level or PT (sec) Prothrombin time Reagent batch XXXX, ISI: XXX		
BIO - TP : INR (High ISI) (%) Prothrombin level or PT (sec) Prothrombin time Reagent batch XXXX, ISI: XXX		
BIO - CK : Activated partial thromboplastin time (sec) or APTT (Kaolin)		
BIO - SIL : Activated partial thromboplastin time (sec) or APTT (Silica)		
BIO-FIBRI : Fibrinogen (mg/dL)		
BIO-TT : Thrombin Time (sec)		
Factor II- Deficient plasma (%)		
Factor V - Deficient plasma (%)		
Factor VII - Deficient plasma (%)		
Factor VIII - Deficient plasma (%)		
Factor IX - Deficient plasma (%)		
Factor X - Deficient plasma (%)		
Factor XI - Deficient plasma (%)		
Factor XII - Deficient plasma (%)		