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CONTROL PLASMA Level 3

For Internal Quality Control in Haemostasis

REF 13963 **R1** 6 x 1 mL

CE

IVD

Made In France

I: corresponds to significant modifications

I VALUES AND RANGES (3)

CONTROL PLASMA Level 3 LOT _____

Make sure that the batch number stated on the label of the vial corresponds to the batch number indicated here above.
Fibrinogen is determined against secondary standard of SSC/ISTH Secondary Coagulation Standard NIBSC Code: SSCLOT4

	Semi-automated and full-automated methods, including: BIOLABO SOLEA 100, BEHNK THROMBOLYZER Series	
	Target value	Confidence Interval
BIO -TP LI: INR **Low ISI** Prothrombin level or PT (%) Prothrombin Time (seconds) Reagent batch XXXX, ISI: XXX		
BIO-TP: INR **High ISI** Prothrombin level or PT (%) Prothrombin Time (seconds) Reagent batch XXXX, ISI: XXX		
BIO-CK: Activated Partial Thromboplastin Time (sec)		
BIO-SIL: Activated Partial Thromboplastin Time (sec)		
BIO-TT : Thrombin Time or TT (sec)		
BIO-FIBRI: Fibrinogen (mg/dL)		

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 and 13712 : BIO-TP LI
REF 13885, 13880 and 13881 : BIO-TP
REF 13980 : BIO-TT
REF 13560 and 13570 : BIO-CK
REF 13660 and 13670 : BIO-SIL
REF 13450 and 13451: BIO-FIBRI

I REAGENTS

R1 **CONTROL PLASMA** Level 3

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 13961, REF 13962
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 caped 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	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