



BIOLABO
www.biolabo.fr

MANUFACTURER:
BIOLABO SAS,
02160, Maizy, France

TP-CALSET Standard Set

For use during the determination of Prothrombin Time (%, INR)

REF 13965 R1 4 x 0.5 mL R2 4 x 0.5 mL R3 4 x 0.5 mL



Made In France

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

I: corresponds to significant modifications



INTENDED USE

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

It is used for the calibration during the determination of Prothrombin Time (%, INR) with BIOLABO Reagents:

REF 13880, 13885 ou 13881 : BIO-TP

REF 13702, 13704 or 13712: BIO-TP LI (Low ISI)

INR values are assistance in verifying that the environmental conditions are equivalent to those during the determination of ISI of the reagent used.

REAGENTS

R1 TP-CAL1, R2 TP-CAL2, R3 TP-CAL3



Freeze-dried, citrated plasmas

Human Origin

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.

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:

- plasmas 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 § CALIBRATION

CALIBRATION VALUES (3)

TP-CAL SET values are traceable to WHO INTERNATIONAL STANDARD THROMBOPLASTIN, RABBIT, PLAIN (RBT) from NIBSC.

- Each level has an assigned value for PT (%) and INR (international normalized ratio).
- CAL1, CAL2 and CAL3 values are **batch-specific**
- These values are useable with BIO SOLEA2 and 4 semi-automated analyzer, automatic analyzers as SOLEA100 or BEHNK THROMBOLYZER Series
- Make sure that the batch number stated on the label of the vial corresponds to the batch number indicated here above:

		TP-CAL1	TP-CAL2	TP-CAL3
LOT		XXXXX	XXXXX	XXXXX
BIO-TP LI	%	XXX%	XXX%	XXX%
	INR			
BIO-TP	%	XXX%	XXX%	XXX%
	INR			

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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