CE IVD

Precision in Hemostasis

Behnk Elektronik

BE Trol 2 Plasma Level 2

Plasma for quality control during coagulation tests in human plasma

REF 773101: CON (6 x 1 mL)

INTENDED USE

This plasma is designated for professional use in laboratory (manual or automated method). BE Trol 2 Plasma Level 2 is used for quality control of indicated methods with Behnk reagents listed in § MATERIAL REQUIRED BUT NOT PROVIDED.

REAGENTS

CON	Trol 2	Plasma Level 2	
Freeze-dried human plasma (citrated)			Human origin

| SAFETY CAUTIONS [1] [2]

- Refer to current Material Safety Data Sheet available on request or on www.behnk.de
- 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.

PREPARATION OF REAGENTS

Open the vial carefully and add exactly the volume of demineralised water stated on the label.
Cap the vial and let stand for 15 minutes at room temperature.
Mix gently by swirling and inverting before use, to homogenise the content.

WARNING: DO NOT SHAKE. STORE AWAY FROM LIGHT.

STABILITY AND STORAGE

Before reconstitution:
Stored away from light, well caped in the original vial at 2-8 °C, lyophilised plasmas are stable until the expiry date stated on the label.
Once opened and reconstituted, plasma is stable:

- 10 hours at 2-25 °C
- 5 days at -20°C (If quickly frozen, well caped in the original vial)

LIMITS

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

MATERIAL REQUIRED BUT NOT PROVIDED

Basic medical analysis laboratory equipment
Precision pipettes
Automated or semi-automated coagulation analyzer
Demineralised water
Behnk Reagents as follows:

REF 771100, REF 771101 BE PT LI: Thromboplastin low ISI
REF 771150, REF 771151 BE PT HI: Thromboplastin high ISI
REF 771200, REF 771201 BE APTT K: APTT Kaolin + CaCl2
REF 771250, REF 771251 BE APTT SL: APTT Silica + CaCl2
REF 771300, REF 771301 BE FIB: Thrombin Kaolin + Buffer
REF 771400 BE TT: Thrombin Time
REF 771602 BE Factor II: Deficient plasma FII
REF 771605 BE Factor V: Deficient plasma FV
REF 771607 BE Factor VII: Deficient plasma FVII
REF 771608 BE Factor VIII: Deficient plasma FVIII
REF 771609 BE Factor IX: Deficient plasma FIX
REF 771610 BE Factor X: Deficient plasma FX
REF 771611 BE Factor XI: Deficient plasma FXI
REF 771612 BE Factor XII: Deficient plasma FXII

Calibration plasmas:
REF 775100 BE Cal Ref: Reference Plasma
REF 775200 BE Cal Set: Calibration Plasma PT

CALIBRATION

Refer to technical sheet of the reagent in use.

PROCEDURE

This plasma should be used as described in the technical data sheet of the BE reagents listed in § MATERIAL REQUIRED BUT NOT PROVIDED.

| ASSIGNED VALUES [3]

BE Trol 2 values are batch specific.

- 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 NIBSC code: SSCLOT5
- These values are useable for semi-automated (manual) and automated methods with Behnk Reagents on Behnk Thrombolyzer series and semi-automated systems.

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

LOT	Unit	Target	Range
BE PT LI: PT	INR		
	%		
	sec		
BE PT HI: PT	INR		
	%		
	sec		
BE APTT K: APTT	sec		
BE APTT SL: APTT	sec		
BE FIB: Fibrinogen	mg/dL		
BE TT: Thrombin Time	sec		
BE Factor II: FII	%		
BE Factor V: FV	%		
BE Factor VII: FVII	%		
BE Factor VIII: FVIII	%		
BE Factor IX: FIX	%		
BE Factor X: FX	%		
BE Factor XI: FXI	%		
BE Factor XII: FXII	%		

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*

| = Significant modifications

Manufacturer	Expiry date	In Vitro Diagnostic	Temperature limitation	Catalogue number	See insert	Batch number	Store away from light	Sufficient for	Dilute with	Demineralized water	Biological hazard

IFU_773101-EN_V04_20240730

Manufactured by
BIOLABO S.A.S.
Les Hautes Rives
02160 Maizy, France

Made in France

Distributed by
Kommanditgesellschaft Behnk Elektronik GmbH & Co.
Hans-Böckler-Ring 27
22851 Norderstedt, Germany

T. +49 (0)40-529 861 0
F. +49 (0)40-529 861 99
info@behnk.de

Latest revision: www.behnk.de