

# BE Trol 1 Plasma Level 1

Plasma for quality control during coagulation tests in human plasma

## INTENDED USE

This plasma is designated for professional use in laboratory (manual or automated method). BE Trol 1 Plasma Level 1 is used for quality control of indicated methods with Behnk reagents listed in § MATERIAL REQUIRED BUT NOT PROVIDED.

## REAGENTS

<b>CON</b>	<b>Trol 1</b>	Plasma Level 1	
Freeze-dried human plasma (citrated)			Human origin

## SAFETY CAUTIONS <sup>(1) (2)</sup>

- Refer to current Material Safety Data Sheet available on request or on [www.behnk.de](http://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 capped 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 capped 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:

<b>REF</b> 771100,	<b>REF</b> 771101	BE PT LI: Thromboplastin low ISI
<b>REF</b> 771150,	<b>REF</b> 771151	BE PT HI: Thromboplastin high ISI
<b>REF</b> 771200,	<b>REF</b> 771201	BE APTT K: APTT Kaolin + CaCl <sub>2</sub>
<b>REF</b> 771250,	<b>REF</b> 771251	BE APTT SL: APTT Silica + CaCl <sub>2</sub>
<b>REF</b> 771300,	<b>REF</b> 771301	BE FIB: Thrombin Kaolin + Buffer
<b>REF</b> 771400		BE TT: Thrombin Time
<b>REF</b> 771602		BE Factor II: Deficient plasma FII
<b>REF</b> 771605		BE Factor V: Deficient plasma FV
<b>REF</b> 771607		BE Factor VII: Deficient plasma FVII
<b>REF</b> 771608		BE Factor VIII: Deficient plasma FVIII
<b>REF</b> 771609		BE Factor IX: Deficient plasma FIX
<b>REF</b> 771610		BE Factor X: Deficient plasma FX
<b>REF</b> 771611		BE Factor XI: Deficient plasma FXI
<b>REF</b> 771612		BE Factor XII: Deficient plasma FXII
Calibration plasmas:		
<b>REF</b> 775100		BE Cal Ref: Reference Plasma
<b>REF</b> 775200		BE Cal Set: Calibration Plasma PT

**REF** 773100: CON (6 x 1 mL)

## 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 <sup>(3)</sup>

BE Trol 1 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:

<b>LOT</b>	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

- Occupational Safety and Health Standards; Bloodborne pathogens (29CFR1910.1030) Federal Register July 1, (1998) ; 6, p.267-280
- Directive du conseil de l'Europe (90/679/CEE) J. O. de la communauté européenne n°L374 du 31.12.1990, p.1-12
- Section 5.6 of ISO 17511- Measurements of quantities in biological samples- metrological traceability of values assigned to calibrators and controls

| = Significant modifications

IFU\_773100-EN\_V04\_20240730

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

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

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