

BE Trol 1 Plasma Level 1

Plasma for quality control during coagulation tests in human plasma

REF 773100: CON (6 x 1 mL)

INTENDED USE

This reagent 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 BE reagents listed in § MATERIAL REQUIRED BUT NOT PROVIDED.

REAGENTS

CON Trol 1 Plasma Level 1



Human Origin

Freeze-dried human plasma (citrate)

SAFETY CAUTIONS ^{(1) (2)}

- Refer to current Material Safety datasheet (MSDS) is available upon request.
 - Use adequate protections (overall, gloves, glasses).
 - Each individual donation of plasma was tested with approved tests and found negative for HBsAg, anti-HCV and anti-HIV I and II.
 - However, as absence of infectious agents can never be proven, this plasma and all specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions.
 - In the event of exposure, the directive of the responsible health authorities should be followed.
 - Dispose of waste in accordance with the local regulations.
- 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

CON: Open the vial carefully and add exactly 1.0 mL of demineralised water, reconstitute without delay.

Recap 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

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
Automatic or semi-automatic 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

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 1 values are **batch specific**.
- The levels of Fibrinogen and Factors II, V, VII, VIII, IX, X, XI are traceable to their respective secondary standards of the corresponding primary International Standard for relevant parameters: SSC/ISTH Secondary Coagulation Standard NIBSC code: SSCLOT4,
- PT values are traceable to RBT16 (WHO International Standard Thromboplastin, Rabbit plain).
- These values are useable with Behnk Reagents on Thrombotimer 1, 2 and 4, Thrombostat 1 and 2 semi-automated analyzer, automatic analyzers as Behnk Thrombolyzer Series.
- 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	%		

CALIBRATION

Refer to technical sheet of the reagent in use.

QUALITY CONTROL

Refer to technical sheet of the reagent in use.

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

I correspond to significant modifications

