CE
In Vitro
Diagnostic

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

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

REAGENTS

CON **Trol 2** Plasma Level 2 — Human Origin

Freeze-dried human plasma (citrated)

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.

I 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 caped in the original vial at 2-8 °C, lyophilised plasmas are stable until the expiry date stated on the label.
I 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 2 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

(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*

I correspond to significant modifications

Manufacturer | Use by | IVD In Vitro Diagnostic | Temperature limitation | REF Catalogue number | See insert | LOT Batch number | Store away from light | Sufficient for | Dilute with | H2O Demineralized water | Biological hazard

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

Made in France

Distributed by
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