CE
In Vitro
Diagnostic

Behnk Elektronik

BE Cal Ref Reference Plasma

Plasma for calibration of coagulation tests

REF 775100: CAL (6 x 1 mL)

INTENDED USE

I This reagent is designated for professional use in laboratory (manual or automated method).
The Reference Plasma is used for calibration of indicated methods with BE reagents listed in § MATERIAL REQUIRED BUT NOT PROVIDED

REAGENTS

CAL	**Cal Ref**	Reference Plasma	Human Origin

Freeze-dried, human plasma (citrated)

SAFETY CAUTIONS [1] [2]

- 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

CAL: 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:

- 4 hours at 2-25 °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
Demineralised water

Behnk Reagents as follows:

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

Control plasma:

REF 773100 BE Trol 1
REF 773101 BE Trol 2

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 Cal Ref values are **batch-specific**.
- The level of Fibrinogen and Factors II, V, VII, VIII, IX, X, XI are determined against its secondary standards of the corresponding primary International Standard for relevant parameters: SSC/ISTH Secondary Coagulation Standard NIBSC code: SSCLOT4
- This value is 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	Calibration values
Fibrinogen	mg/dL	
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*

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.
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