

BE Cal Set Calibration Plasma PT


For use during the determination of Prothrombin Time (%), INR)

REF 775200: CAL1 (4 x 0.5 mL), CAL2 (4 x 0.5 mL)
CAL3 (4 x 0.5 mL)

INTENDED USE

I This reagent is designated for professional use in laboratory (manual or automated method).
Citratd plasmas for the calibration during the determination of Prothrombin Time.
Each level has an assigned value for PT (%) and INR (international normalized ratio).

REAGENTS

CAL Cal1, Cal2, Cal3 Calibration plasma PT  Human Origin
Freeze-dried, citrated plasmas (3 different levels)

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

Cal1, Cal2 and Cal3: Open the vial carefully and add exactly 0.5 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.
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
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

Control plasma:

REF 773100 BE Trol 1
REF 773101 BE Trol 2

PROCEDURE

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

ASSIGNED VALUES ⁽³⁾

- Cal 1, Cal 2, Cal 3 values are **batch-specific**.
- BE Cal Set values are traceable to WHO INTERNATIONAL STANDARD THROMBOPLASTIN, RABBIT, PLAIN (RBT) from NIBSC
- 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:

		CAL 1	CAL 2	CAL 3
LOT				
BE PT LI	%			
	INR			
BE PT HI	%			
	INR			

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

| correspond to significant modifications

