

## 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)

### PRINCIPLE

Citrated plasmas for the calibration during the determination of Prothrombin Time. Each level has an assigned value for PT (%) and INR (international normalized ratio).

### REAGENTS

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

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

- Behnk reagents are designated for professional in vitro diagnostic use.
- 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.

### 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.

Once opened and reconstituted:

- To be used within 3 hours at room temperature
- Do not freeze once reconstituted**

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

- 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
<b>LOT</b>		111722A1	111722A2	111722A3
<b>BE PT LI</b>	%	94	32	20
	INR	1.0	2.5	4.0
<b>BE PT HI</b>	%	100	36	23
	INR	1.0	2.5	4.1

### 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

