

BE Cal Set Calibration Plasma PT

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

- REF 775200: CAL 1 (4 x 0.5 mL)
- CAL 2 (4 x 0.5 mL)
- CAL 3 (4 x 0.5 mL)

INTENDED USE

These plasmas are designated for professional use in laboratory (manual or automated method).

| There are used for the calibration during the determination of Prothrombin Time (% INR) with Behnk reagents:

REF 771100, REF 771101 BE PT LI: Thromboplastin low ISI

REF 771150, REF 771151 BE PT HI: Thromboplastin high ISI

INR values may be used as assistance in verifying that the environmental conditions are equivalent to those during the determination of ISI of the reagent used.

REAGENTS

CAL Cal 1, Cal 2, Cal 3 Calibration Plasma PT

Freeze-dried human plasma (citrated), 3 different levels Human origin

| SAFETY CAUTIONS ^{(1) (2)}

- Refer to current Material Safety Data Sheet available on request or on www.behnk.de
 - Each donor unit used to manufacture this product was tested and found non-reactive for HbsAg, antibody to Hepatitis C and antibody to HIV-1/HIV-2.
 - However, no test method can offer complete assurance that infectious agents are absent. All specimens or reagents from biological origin should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions.
 - Waste disposal: Respect legislation in force in the country.
- 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

Open the vials carefully and add exactly the volume of demineralised water stated on the label.

Cap the vials 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, plasmas are 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.
- Each level has an assigned value for PT (%) and INR (international normalized ratio).
- These values are useable for semi-automated (manual) and automated methods with Behnk Reagents on Behnk Thrombolyzer series and semi-automated systems.

Make sure that the batch number stated on the label of the vial corresponds to the batch number indicated here above:

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

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

| = Significant modifications

IFU_775200-EN_V04_20240730

Manufacturer	Expiry date	In Vitro Diagnostic	Temperature limitation	Catalogue number	See insert	Batch number	Store away from light	Sufficient for	Dilute with	Demineralized water	Biological hazard
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