

# BE Cal Ref Reference Plasma

Plasma for calibration of coagulation tests

REF 775100: CAL (6 x 1 mL)

### INTENDED USE

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

### REAGENTS

<b>CAL</b>	<b>Cal Ref</b>	Reference Plasma	
		Freeze-dried human plasma (citratd)	Human origin

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

- Refer to current Material Safety Data Sheet available on request or on [www.behnk.de](http://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 vial carefully and add exactly the volume of demineralised water stated on the label. Cap the vial 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, 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 771300, REF 771301 BE FIB: Thrombin Kaolin + Buffer
  - 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 Tro1
- REF 773101 BE Tro2

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

- BE Cal Ref values are batch specific.
- Fibrinogen and Factors II, V, VII, VIII, IX, X, XI are determined using secondary Standards traceable to International Standards as follows: SSC/ISTH Secondary Coagulation Standard NIBSC code: SSCLOT4
  - 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	Calibration values
BE FIB: 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

- 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\_775100-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

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

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