

BE Cal Ref Reference Plasma


For use during the determination of Fibrinogen

REF 775100: CAL (6 x 1 mL)

PRINCIPLE

Citrated plasma for the calibration during the quantitative determination of Fibrinogen.

REAGENTS

CAL	Cal Ref	Reference Plasma	 Human Origin
Freeze-dried, human plasma (citrated)			

SAFETY CAUTIONS ^{(1) (2)}

- 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

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 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
Automatic or semi-automatic Coagulation analyzer
Demineralised water

Behnk Reagents as follows:

REF 771300, REF 771301 BE FIB: Thrombin Kaolin + Buffer

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 is 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
111747A1		
Fibrinogen	mg/dL	228

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*

 Manufacturer	 Use by	 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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