CE
In Vitro
Diagnostic

Behnk Elektronik

BE Trol 2 Plasma Level 2

Plasma for quality control during coagulation tests in human plasma

REF 773101: CON (6 x 1 mL)

PRINCIPLE

BE Trol 2 Plasma Level 2 is used for quality control of indicated methods with BE reagents listed in § MATERIAL REQUIRED BUT NOT PROVIDED.

REAGENTS

CON **Trol 2** Plasma Level 2

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

CON: 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 caped 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 771100, REF 771101 BE PT LI: Thromboplastin low ISI
REF 771150, REF 771151 BE PT HI: Thromboplastin high ISI
REF 771200, REF 771201 BE APTT K: APTT Kaolin + CaCl2
REF 771300, REF 771301 BE FIB: Thrombin Kaolin + Buffer (Fibrinogen)

Calibration plasmas:
REF 775100 BE Cal Ref: Calibration Reference Plasma
REF 775200 BE Cal Set: Calibration Plasma PT

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 Trol 2 values are **batch-specific**.
- The levels of Fibrinogen are traceable to their respective secondary standards of the corresponding primary International Standard for relevant parameters: SSC/ISTH Secondary Coagulation Standard NIBSC code: SSCLOT4
- PT values are traceable to RBT16 (WHO International Standard Thromboplastin, Rabbit plain).
- 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:

LOT **011801A1**	Unit	Target	Range
BE PT LI: PT	INR	1.8	1.6 – 2.1
	%	44	37 – 50
	sec	21.3	18.7 – 23.8
BE PT HI: PT	INR	2.0	1.7 – 2.4
	%	43	37 – 49
	sec	19.2	16.9 – 21.5
BE APTT K: APTT	sec	54	46 – 62
BE FIB: Fibrinogen	mg/dL	133	110 – 150

CALIBRATION

Refer to technical sheet of the reagent in use.

QUALITY CONTROL

Refer to technical sheet of the reagent in use.

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*

Manufacturer | Use by | IVD In Vitro Diagnostic | Temperature limitation | REF Catalogue number | See insert | LOT Batch number | Store away from light | Sufficient for | → Dilute with | H2O Demineralized water | Biological hazard

Manufactured by
BIOLABO S.A.S.
Les Hautes Rives
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Made in France

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