CE IVD

Precision in Hemostasis

Behnk Elektronik

BE Owren Buffer Owren Koller Buffer

Diluent for human plasmas during coagulation tests

REF 771700: BU (16 x 15 mL)

| INTENDED USE

Buffered solution intended for use *in vitro* as a diluent for human plasmas during coagulation tests. Suitable for use with manual procedure on semi automated coagulometer, or on automated coagulation analyzer, using BEHNK Reagents.
For clinical laboratory use by healthcare professionals.

PRINCIPLE

When determining the individual Factors (FII, FV, FVII, FVIII, FIX, FX, FXI, FXII) with deficient plasma, it is necessary to dilute the plasma to achieve the Factor to be detected in a presentable range.

GENERALITIES

Refer to technical sheet of the reagent in use.

| REAGENTS

BU	**Owren BU**	Owren Koller Buffer
Barbital buffer		pH 7.35 (20°C)
Preservative		

According to (EC) 1272/2008 regulation, this reagent is not classified as dangerous.

SAFETY CAUTIONS [1] [2]

- Refer to Safety Data Sheet (SDS) available on request or on www.behnk.de
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. 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

BU: Ready for use.

STABILITY AND STORAGE

Unopened vials, stored away from light at 2-8 °C are stable until the expiry date stated on the label.
Once opened, well capped in the original vial, stored and used as indicated upper, vials are stable:

- Until expiry date stated on the label.
- Discard any cloudy reagent.

SAMPLES COLLECTION AND HANDLING

Refer to technical sheet of the reagent in use.

LIMITS

Refer to technical sheet of the reagent in use.

MATERIAL REQUIRED BUT NOT PROVIDED

Basic medical analysis laboratory equipment
Precision pipettes
Automated or semi-automated coagulation analyzer
Demineralized water

Behnk Reagents as follows:

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

REFERENCE RANGE

Refer to technical sheet of the reagent in use.

QUALITY CONTROL

Refer to technical sheet of the reagent in use.

PROCEDURE

Dilute plasma as described in the technical sheet of the reagent in use.

CALIBRATION

Refer to technical sheet of the reagent in use.

CALCULATION

Refer to technical sheet of the reagent in use.

PERFORMANCES

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*

| = Significant modifications

IFU_771700-EN_V03_20260902

Table of symbols

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

Made in France

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