CE IVD

Precision in Hemostasis

Behnk Elektronik

BE Clean Pro Cleaning solution

For cleaning the sampling needle of automated Behnk coagulation and aggregation analyzers

REF 050951: CL (16 x 15 mL)

| INTENDED PURPOSE

BE Clean Pro (ref. 050951) is a cleaning solution intended for use with the fully automated Thrombolyzer and Thrombomate Series in vitro diagnostic instruments to clean the needle. It is designed for exclusive use by trained healthcare professionals in clinical laboratories and hospital settings.

PRINCIPLE

This solution cleans the sampling needle after every pipetting action which prevents carry-over between tests.
The cleaning solution dissolves any residues of plasma and reagent that may adhere to the needle. The dissolved residues and cleaning solution are rinsed out during a subsequent rinse with fresh water. This cleaning process is carried out automatically during the routine operation of the unit.

GENERALITIES

The needle is connected via the pipetting tube to the syringe. The needle aspirate and dispense fluids when the plunger of the syringe moves up or down. Only the tip of the needle is in contact with the liquids and is washed in the wash station. From the wash station, the cleaning water flows to a liquid waste container.

REAGENTS

CL **Clean Pro** Cleaning solution

Sodium hydroxide solution (NaOH), 1 mol/L



Danger
H290, H314

According to 1272/2008 regulation, this reagent is classified as dangerous:
H290*: May be corrosive to metals*
H314*: Causes severe skin burns and eye damage*

Precautionary statements:
P280: Wear protective gloves/protective clothing/eye protection.
P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310: Immediately call a poison center/doctor.
Substances that contribute to the classification: Sodium hydroxide

SAFETY CAUTIONS (1) (2)

- Refer to current Material Safety Data Sheet 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

CL: Ready for use.

For aggregometry (BE LTA on Thrombomate), close the opened bottle with the silicone cap. See § MATERIAL REQUIRED BUT NOT PROVIDED.

STABILITY AND STORAGE

Unopened vials, stored away from light at 2-30°C are stable until the expiry date stated on the label.
Once opened, stored and used as indicated upper, vials are stable:

- Until expiry date stated on the label.

Once opened for aggregometry (BE LTA on Thrombomate), use and store the cleaning solution as indicated upper; closed with the silicone cap, in the original bottle, vials are stable:

- Until expiry date stated on the label.

- Do not refill.
- Discard the remaining volume when the analyser indicates “empty volume”.
- Discard any cloudy reagent.
- Do not use any reagent after expiry date.

MATERIAL REQUIRED BUT NOT PROVIDED

Behnk Analyzer: Fully automated analyzer for coagulation or aggregometry

Coagulation: BE Reagents, calibrator and controls
Aggregometry: BE LTA Reagents

REF 050705: Silicone Cap á 25, for Thrombomate

QUALITY CONTROL

- Verify the integrity of vials before use.
- Discard any cloudy reagent.

PROCEDURE

- Note the opening date.
- Open the vial.
- Only for Behnk Thrombomate: Lock the BE Clean Pro bottle with a silicone cap.
- Place it directly at dedicated position in the analyzer.
- To be used as indicated in the Behnk analyser User’s manual.

PERFORMANCES

No cross contamination detected using this Cleaning Solution if used as indicated in the User’s manual of BEHNK automated systems.

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

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
		IVD		REF		LOT			→	H_2O	

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