Precision in Hemostasis



BE Clean Cleaning solution

For needle cleaning on Behnk Thrombolyzer systems

| INTENDED USE

This reagent is designated for professional use in laboratory (automated method). It allows the cleaning of sampling needle of BEHNK Thrombolyzer system.

This solution cleans the sampling needle after every pipetting action which prevents carryover 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.

CL Clean Acid solution

Cleaning solution

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

| STABILITY AND STORAGE

Unopened vials, stored away from light at 2-25 °C are stable until the expiry date stated on the label.

Once opened:

- On board Stability (OBS)* 6 days
- * 15-25 °C, original opened vial
- Discard the remaining volume when the analyser indicates "empty volume".
- Discard any cloudy reagent.
- Do not use any reagent after expiry date.

REF 771800: CL (16 x 15 mL)

MATERIAL REQUIRED BUT NOT PROVIDED

Behnk Thrombolyzer: Automated coagulation analyzer BE Reagents, calibrators and controls

QUALITY CONTROL

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

PROCEDURE

- Open the vial.
- Note the opening date.
- 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 Thrombolyzer system.

- 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

I = Significant modifications

X 淤 Ω Πi IVD REF LOT Expiry date In Vitro Temperature Catalogue number Store away Diagnostic limitation from light

Sufficient for

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Dilute with

₩ Demineralized Biological hazard

FU 771800-EN V02 20230927

H2O

water