100423106BEN
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INSTRUCTION FOR USE

Diaclean-SYS

WASHING SOLUTION

IVD CE

REF	REAGENT 1 [d]
h23106	1 x 1,0 L
h23126	1 x 0,1 L
h23136	1 x 0,05 L

INTENDED USE

Diaclean-SYS is a hypochlorite washing solution used for daily maintenance and cleaning of hematology analysers, urine analysers and Coag Line fully automated coagulation analysers, during the maintenance process. For In Vitro Diagnostic use only.

Hematology and urine diagnostics:

Diaclean-SYS solution is used for daily maintenance and cleaning of SYSMEX K-800 (8 parameter), K-800 (18 parameter), K-1000, K-4500, E-2500, E-4000, E-5000, SF-3000, KX-21, XT-1800, XT-2000, XS-1000i, XE-2100 hematology analysers and SYSMEX UF-50, UF-100 urine analyser.

Hemostasis diagnostics:

Diaclean-SYS solution is used for daily maintenance and cleaning of DIAGON Coag Line fully automated coagulation analysers (Coag M, Coag L / Coag L CP, Coag XL / Coag XL CP).

METHOD PRINCIPLE

Diaclean-SYS effectively cleans out cell debris, proteins and triglycerides by oxidative digestion from tubes and liquid reservoirs.

REAGENT COMPONENTS

Diaclean-SYS:

Reagent 1:

- Sodium Hypochlorite <16%

PREPARATION AND HANDLING

Diaclean-SYS solution should be used according to this notice. The manufacturer cannot guarantee its performance if used otherwise.

1. Diaclean-SYS solution is ready for use.
2. Leave the solution at working temperature (15-35°C) for at least 24 hours.
3. Wait until the solution reaches the working temperature.
4. Loosen and remove the cap on the solution bottle.

MATERIALS REQUIRED BUT NOT PROVIDED [d]

Hematology and urine diagnostics:

- Cell Counter (Sysmex K-800 (8 parameter), K-800 (18 parameter), K-1000, K-4500, E-2500, E-4000, E-5000, SF-3000, KX-21, XT-1800, XT-2000, XS-1000i, XE-2100, UF-50 and UF-100).
- Diluent, Lyse, Stain, Cleaner reagents for the above mentioned Cell Counters. Please enquire at your local distributor or directly from the manufacturer.

Hemostasis diagnostics:

- Coagulation reagents
- DIAGON Coag Line fully automated coagulation analyser for measuring.

TEST PROCEDURE

Hematology and urine diagnostics:

- Diaclean-SYS is not an on-board reagent only required for maintenance. For proper application of Diaclean-SYS solution, please follow the instructions of the user manual of the instrument.

Hemostasis diagnostics:

- Fill 5 mL Diaclean-SYS solution into an empty blood collecting tube (5mL) and into an empty reagent vial (5mL).
- For proper application of Diaclean-SYS solution, please follow the instructions of the user manual of the instrument.
- Wipe all needles with a clean tissue.

STORAGE AND STABILITY

Diaclean-SYS solution in intact bottle is stable until the expiration date given on the label, when stored at 15-35℃. Stability after opening in the original bottle is shown in below table:

T (°C)	15-35
Day	60

Precautions of storage:

- Do not use solution once frozen!

PRECAUTIONS [d]

- This reagent is for professional in vitro diagnostic use only.
- For laboratory use and for prescription use only.
- This reagent is classified in compliance with regulation (EC) N°.1272/2008:
  - Corrosive to metals, Category 1
  - Skin Corrosion, Category 1B
  - Serious Eye Damage, Category 1
  - Acute Aquatic Hazard, Category 1
  - Chronic Aquatic Hazard, Category 2
  - GHS pictogram:



  - Signal word: Danger
  - H290: May be corrosive to metals.
  - H314: Causes severe skin burns and eye damage.
  - H400: Very toxic to aquatic life.
  - H411: Toxic to aquatic life with long lasting effects.
  - EUH031: Contact with acids liberates toxic gas.

[a] Modification: updated leaflet form
[b] Modification: updated CE mark
[c] Modification: restructured chapter
[d] Modification: information added
[e] Modification: chapter added

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- P260: Do not breathe dust/fume/gas/mist/ vapours/spray.
- P273: Avoid release to the environment.
- P280: Wear protective gloves/protective clothing /eye protection/face protection.
- P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- 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 or doctor/physician.
- P390: Absorb spillage to prevent material damage.

- Avoid to inhale, swallow or contact with skin and eye.
- Observe the standard laboratory precautions for use.
- The reagent vials are disposable and should be disposed of in accordance with the local legal requirements.
- Please refer to the safety document associated with the reagent.
- Do not use the product if there is visible evidence of biological, chemical or physical deterioration.
- It is the user's responsibility to verify that this document is applicable to the reagent used.
- For technical assistance, you can call +(36 1) 369 6500.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the country in which the user and/or the patient is established.

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SYMBOLS			
	Manufacturer		Use-by date
LOT	Batch code	REF	Catalogue number
	Keep away from sunlight	35 °C 15 °C	Temperature limit
IVD	*In vitro* diagnostic medical device		Consult instruction for use
CE	CE mark		

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