

INSTRUCTION FOR USE

Diaclean-SYS WASHING SOLUTION



PRODUCT NAME

Diaclean-SYS washing solution.

INTENDED USE

(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 hematological analysers and SYSMEX UF-50, UF-100 urine analysers.

• Hemostasis diagnostics:

Diaclean-SYS solution is used for daily maintenance and cleaning of DIAGON Coag Line automated coagulation analysers.

SUMMARY AND EXPLANATIONS

Diaclean-SYS solution is a hypochlorite washing solution, that effectively cleans out cell debris, proteins and triglycerides by oxidative digestion.

ACTIVE INGREDIENTS

Diaclean-SYS solution contains sodium hypochlorite (<16,0%).

PRECAUTIONS

- Hazardous symbol, category, hazard and precautionary statements by the latest CLP regulation:
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 - Metal Corrosive, Category 1
 - Skin Corrosive, Category 1B
 - Eye Damage, Category 1
 - Aquatic Acute, Category 1
 - Aquatic Chronic, Category 2
 - 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
 - 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.
- Person installing the Diaclean-SYS solution must be a trained laboratory professional!
- All solutions, waste and utilized disposable laboratory equipment should be considered as hazardous waste! Their handling and disposal should be done according to the valid hazardous material processing regulation.
- Do not use the solution beyond the expiration date printed on the label!

PREPARATION

Diaclean-SYS solution is ready to use. Leave the solution at working temperature (15-35°C) for at least 24 hours and wait until the solution reaches the working temperature!

Loosen and remove the cap on the solution bottle.

TEST PROCEDURE

• Hematology and urine diagnostics:

- Attach the aspiration assembly to the bottle. Tighten the cap.
- Connect the other reagents to the instrument similarly (see below).
- Prime the reagents through the instrument thoroughly to wash out third party reagents, traces of which may cause erroneous results. Refer to the instrument Operator's Manual for further information.
- Generally a recalibration of the instrument is not required. However it is advised that you check that the instrument performance is within specification. A control measurement is suggested with a control as specified in your Operator's Manual.

• 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 daily and weekly cleaning procedures with Diaclean-SYS solution, please follow the Maintenance instructions of the instrument's manual.
- Wipe both needles with a clean tissue.





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STORAGE AND STABILITY

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

| T (°C) | 15-35 | |
|--------|-------|--|
| Day | 60 | |

Do not use solution once frozen!

EXPECTED RESULTS

Diaclean-SYS solution will effectively clean the tubes and liquid reservoirs in the instrument used on daily basis and keeping background and carryover values within specification.

MATERIALS REQUIRED BUT NOT PROVIDED

• 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, UF-100)
- Diluent, Lyse reagents for the above mentioned Cell Counter. Please enquire at your local distributor or directly from the manufacturer.

• Hemostasis diagnostics:

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

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