

REF 1300036421

CLEANER 1 x 0.1 L

IVD CE


 HORIBA ABX SAS
 Parc Euromédecine
 Rue du Caducée
 BP 7290
 34184 Montpellier Cedex 4
 FRANCE

Yumizen G Clean SYS

- Yumizen G800
- Yumizen G1500/G1550

Washing solution.

Intended Use ^{a b}

Yumizen G Clean SYS is a hypochlorite washing solution used for daily maintenance and cleaning of Yumizen G Line fully automated coagulation analyzers during the maintenance process.

For *in vitro* diagnostic use only.

Reagents ^c

Yumizen G Clean SYS is ready-to-use.

It is a washing solution that effectively cleans out cell debris, proteins and triglycerides by oxidative digestion.

Sodium hypochlorite < 1.0%

Sodium hydroxide < 0.8%

Yumizen G Clean SYS should be used according to this notice.

The manufacturer cannot guarantee its performance if used otherwise.

Handling ^d

1. Allow the vials to stand for at least 24 h (room temperature).

2. **For automated analyzers only:** place the reagent in the instrument without cap as follows:

Holder type	Container type	Reagent volume
Auxiliary holder	1 x empty vial	5 mL
STAT holder	1 x empty tube	5 mL

3. Refer to the maintenance chapter of the instrument user manual for more information.

Care should be taken not to interchange the caps with others products.

Materials Required but not Provided ^e

- Hemostasis analyzer
- HORIBA Medical analyzers (Yumizen G Line) are recommended.
- Standard laboratory equipment

Storage and Stability

Stability before opening

Stable up to the expiry date on the label if stored at 15 - 35°C.

Stability after opening

	15 - 35°C
Yumizen G Clean SYS	60 days

^aModification: § "Intended Use" changed.

^bModification: new leaflet form.

^cModification: § "Reagents" changed.

^dModification: § "Handling" changed.

^eModification: § "Material Required but not Provided" changed.

Yumizen G Clean SYS

Do not freeze.

Waste Management ^f

Please refer to local legal requirements.

General Precautions ^g

- This product is for professional *in vitro* diagnostic use only.
For laboratory use.
- For prescription use only.
- This reagent is classified as hazardous in compliance with regulation (EC) N°.1272/2008.
- **Danger**
 - H314:** Causes severe skin burns and eye damage.
 - H290:** May be corrosive to metals.
 - H400:** Very toxic to aquatic life.
 - H411:** Toxic to aquatic life with long lasting effects.
 - P234:** Keep only in original container.
 - P260:** Do not breathe dust/fume/gas/mist/vapours/spray.
 - P264:** Wash hands thoroughly after handling.
 - P273:** Avoid release to the environment.
 - P280:** Wear protective gloves/protective clothing/eye protection/face protection.
 - P310:** Immediately call a POISON CENTER or doctor/physician.
 - P321:** Specific treatment (see [***] on this label).
 - P390:** Absorb spillage to prevent material damage.
 - P405:** Store locked up.
 - P501:** Dispose of contents and container in accordance with all local, regional, national and international regulations.
 - P304 + P340:** IF INHALED: Remove person to fresh air and keep comfortable for breathing.
 - 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].
 - P305 + P351 + P338:** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 - P303 + P361 + P353:** IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- **EUH031:** Contact with acids liberates toxic gas.
- Do not pipette by mouth.
- Do not replenish the products.

- Do not swallow. Avoid contact with skin and mucous membranes.
- Observe the standard laboratory precautions for use.
- The product vials should be discarded after use. Disposal of all waste material should be in accordance with local guidelines.
- Please refer to the SDS associated with the product.
- Do not use the product if there is visible evidence of biological, chemical or physical deterioration.
- Do not use the product if the recommended storage conditions, including temperature, are not followed.
- User must be trained by a HORIBA Medical representative before attempting to operate the device.
- It is the user's responsibility to verify that this document is applicable to the product used.
- For technical assistance, you can call +33 (0)4 67 14 15 16.
- 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.
- Using of third-party hemostasis analyzers may cause a risk of system un-harmonization.
- It is the user's responsibility to evaluate the risk of using a third-party hemostasis analyzers.

^fModification: chapter added.

^gModification: § "General Precautions" changed.