

Yumizen G SORB

- Yumizen G800
- Yumizen G1500/G1550

REF 1300036418

CLEANER 12 x 15 mL

IVD CE



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

Washing solution.

Intended Use ^a

Yumizen G SORB is a hypochlorite washing solution used for daily maintenance and cleaning of Yumizen G Line fully automated coagulation analyzers during diagnostic measurements.

For *in vitro* diagnostic use only.

Reagents ^b

Yumizen G SORB is ready-to-use.

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

Sodium hypochlorite	< 1.0%
Potassium hydroxide	< 1.0%
Detergent	< 1.0%

Yumizen G SORB should be used according to this notice.

The manufacturer cannot guarantee its performance if used otherwise.

Handling

1. Wait until the reagents reach the working temperature.
2. **For automated analyzers only:** place the reagent in the instrument without cap as follows:

Holder type	Container type
Reagent holder	1 x original vial
Auxiliary holder	1 x original vial

For optimal performance remove the reagent from the instrument after use, close the vial and store at 2 - 8°C.

^aModification: new leaflet form.

^bModification: § "Reagents" changed.

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

Materials Required but not Provided

- 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 2 - 8°C.

Stability after opening

	20 - 25°C
Yumizen G SORB	21 days

Stability on board

Automated Analyzers

	20 - 25°C	15 - 19°C
Yumizen G SORB	21 days	21 days

Waste Management

Please refer to local legal requirements.

Yumizen G SORB

General Precautions °

- 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.
- **Warning**
 - H315:** Causes skin irritation.
 - H319:** Cause serious eye irritation.
 - H290:** May be corrosive to metals.
 - H412:** Harmful to aquatic life with long lasting effects.
 - P234:** Keep only in original packaging.
 - P280:** Wear protective gloves/protective clothing/eye protection/face protection.
 - P390:** Absorb spillage to prevent material damage.
 - P406:** Store in corrosive resistant container with a resistant inner liner.
 - P501:** Dispose of contents and container in accordance with all local, regional, national and international regulations.
 - P305 + P351 + P338:** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 - P302 + P352:** IF ON SKIN: Wash with plenty of soap and water.
 - P332 + P313:** If skin irritation occurs: Get medical advice/attention.
 - P337 + P313:** If eye irritation persists: Get medical advice/attention.
- 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.

°Modification: § "General Precautions" changed.