

REF 1300036385

BUFFER 12 x 15 mL

IVD CE



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

# Yumizen G IMIDAZOL

- Yumizen G200
- Yumizen G400/G400 DDi
- Yumizen G800
- Yumizen G1500/G1550

## Imidazol buffer solution for coagulation tests.

### Intended Use <sup>a b</sup>

**Yumizen G IMIDAZOL** is dilution buffer used as diluting control, calibrator and human sample when performing coagulation tests in decalcified plasma on coagulometry assay, for all human populations.  
For *in vitro* diagnostic use only.

### Reagents <sup>c</sup>

**Yumizen G IMIDAZOL** is ready-to-use.  
It is a buffered solution with stabilizer.

Imidazole	< 4 g/L
Sodium azide	< 1 g/L

**Yumizen G IMIDAZOL** should be used according to this notice.  
The manufacturer cannot guarantee its performance if used otherwise.

### Handling <sup>d</sup>

1. Wait until the reagent reaches the working temperature.
2. **For automated analyzers only:** place the vial in the auxiliary holder without cap.

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

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

### Materials Required but not Provided <sup>e</sup>

- Hemostasis analyzer
- HORIBA Medical analyzers (Yumizen G Line) are recommended.
- **Yumizen G IMIDAZOL** is recommended with the following reagents:
  - Yumizen G FIB 2 (1300036383)
  - Yumizen G FIB 5 (1300036384)
  - Yumizen G DDi 2 (1300036391)
- 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	2 - 8°C
Yumizen G IMIDAZOL	2 weeks	8 weeks

#### Stability on board

##### Automated Analyzers

	20 - 25°C
Yumizen G IMIDAZOL	2 weeks

<sup>a</sup>Modification: § "Intended Use" changed.

<sup>b</sup>Modification: new leaflet form.

<sup>c</sup>Modification: § "Reagents" changed.

<sup>d</sup>Modification: chapter added.

<sup>e</sup>Modification: § "Material Required but not Provided" changed.

# Yumizen G IMIDAZOL

## Waste Management <sup>d</sup>

- Please refer to local legal requirements.
- This product contains less than 0.1% of sodium azide as a preservative. Sodium azide may react with lead and copper to form explosive metal azides.

## General Precautions <sup>f</sup>

- 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**  
**H360:** May damage fertility or the unborn child.  
**P201:** Obtain special instructions before use.  
**P202:** Do not handle until all safety precautions have been read and understood.  
**P280:** Wear protective gloves/protective clothing/eye protection/face protection.  
**P308 + P313:** IF exposed or concerned: Get medical advice/attention.  
**P405:** Store locked up.  
**P501:** Dispose of contents and container in accordance with all local, regional, national and international regulations.
- 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.

<sup>d</sup>Modification: chapter added.

<sup>f</sup>Modification: § "General Precautions" changed.