2024/10/01
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REF 1300036385

BUFFER 12 x 15 mL

IVD CE

Yumizen G IMIDAZOL

- **Yumizen G200**
- **Yumizen G400/ G400DDi/G405**
- **Yumizen G800/G800h/G850h**
- **Yumizen G1500/G1550/G1500h/G1550h**

Imidazol buffer solution for coagulation tests.

Intended Use [a]

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

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

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 [b]

- 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)
  Factor II deficient plasma (38005 / 1300113497)
  Factor V deficient plasma (38105 / 1300113499)
  Factor VII deficient plasma (38205 / 1300113520)
  Factor VIII deficient plasma (38305 / 1300113523)
  Factor IX deficient plasma (38405 / 1300113524)
  Factor X deficient plasma (38505 / 1300113522)
  Factor XI deficient plasma (38605 / 1300113525)
  Factor XII deficient plasma (38705 / 1300113526)
- 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	20 - 25°C*
Yumizen G IMIDAZOL	5 days	14 days

*: if the reagent is stored at 2 - 8°C after the working day.

[a]Modification: new leaflet form.
[b]Modification: § "Material Required but not Provided" changed.

Yumizen G IMIDAZOL

Waste Management

- 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

- 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.