

REF A11A01971

REAGENT 90 mL

IVD **CE** Rx Only

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



ABX Pentra ISE Cleaner CP

- Pentra C200
- Pentra C400
- ABX Pentra 400

Cleaning solution used on the ISE module of the HORIBA Medical clinical chemistry analyzers.

Intended Use

ABX Pentra ISE Cleaner CP is a solution used to clean the electrodes of the ISE module of the HORIBA Medical clinical chemistry analyzers.
Clinical laboratories use.

Reagents

ABX Pentra ISE Cleaner CP is ready-to-use.

Reagent:

Organic buffer	< 5%
Proteolytic enzyme	< 1%
Preservative	< 1%

ABX Pentra ISE Cleaner CP should be used according to this notice. The manufacturer cannot guarantee its performance if used otherwise.

Handling

1. Remove the cap of the cassette.
2. Place **ABX Pentra ISE Cleaner CP** on the instrument:
 - For **Pentra C200**: Fill a tube with **ABX Pentra ISE Cleaner CP**. Place the tube in the sample tray.
 - For **Pentra C400**: Place the cassette in the instrument reagent compartment at room temperature position.
 - For **ABX Pentra 400**: Place the cassette in the instrument reagent compartment at room temperature position.
3. For **Pentra C200**: Discard the tube after use.

For further details, please refer to the maintenance procedures outlined in the User Manual for Pentra C200 or ABX Pentra 400 or Pentra C400 clinical chemistry analyzers.

Materials Required but not Provided

- Automated clinical chemistry analyzers.
- Standard laboratory equipment.

Storage and Stability

Stability before opening:

Stable up to the expiry date on the label if stored at 18-25°C.

Stability after opening:

Stable for 3 months at 18-25°C if closed immediately and contamination is avoided.

Waste Management

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

ABX Pentra ISE Cleaner CP

General Precautions ^a

- This reagent 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**
 - H317:** May cause an allergic skin reaction.
 - H412:** Harmful to aquatic life with long lasting effects.
 - P261:** Avoid breathing dust/fume/gas/mist/vapours/spray.
 - P280:** Wear protective gloves or clothing and eye or face protection.
 - P302 + P352:** IF ON SKIN: Wash with plenty of soap and water.
 - P333 + P313:** If skin irritation or rash occurs: Get medical advice/attention.
 - P501:** Dispose of contents and container in accordance with all local, regional, national and international regulations.
- Contains:** 2-methyl-(2H)-isothiazol-3-one
- Contains:** octhilinone (ISO)
- Do not swallow. Avoid contact with skin and mucous membranes.
- In the event of a malaise following skin contact, ingestion, or inhalation, consult a doctor.
- Observe the standard laboratory precautions for use.
- The reagent cassettes are disposable and should be disposed of in accordance with the local legal requirements.
- Please refer to the SDS associated with the reagent.
- 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 reagent 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.

^aModification: general precautions modification.