

REF A11A01755

REAGENT 30 mL

IVD CE



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

ABX Pentra Clean-Chem CP

- Pentra C200
- Pentra C400
- ABX Pentra 400

Cleaning solution used on HORIBA Medical clinical chemistry analyzers.

Intended Use ^{a b}

ABX Pentra Clean-Chem CP is a cleaning solution used on HORIBA Medical clinical chemistry analyzers. Clinical laboratories use.

Reagents

ABX Pentra Clean-Chem CP is ready-to-use. This reagent contains sodium hydroxide (< 2%).

The pH of the solution is greater than 12.

ABX Pentra Clean-Chem CP should be used according to this notice. The manufacturer cannot guarantee its performance if used otherwise.

Handling on Pentra C200

1. Remove the cap of the cassette, transfer the required volume of **ABX Pentra Clean-Chem CP** in the two DET. W bottles: probe and mixer.
2. Change the solution of the DET. W bottles every week.

Handling on ABX Pentra 400 and Pentra C400

Remove the cap of the cassette, place the cassette in the refrigerated reagent compartment of the instrument.

Materials required but not provided

- Automated clinical chemistry analyzer.
- Standard laboratory equipment.

^aModification: modification of Intended Use chapter.

^bModification: new leaflet form.

^cModification: modification of classification.

Storage and Stability

Stability before opening:

Stable up to the expiry date on the label if stored at 2-8°C.

Stability after opening:

Once opened, **ABX Pentra Clean-Chem CP** is stable for 45 days at 2-8°C or installed on the refrigerated compartment of the ABX Pentra 400 or Pentra C400 clinical chemistry analyzer.

Waste Management

Please refer to local legal requirements.

General Precautions ^c

- 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.

ABX Pentra Clean-Chem CP

■ Warning

H290: May be corrosive to metals.

H315: Causes skin irritation.

H319: Causes serious eye irritation.

P234: Keep only in original container.

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.

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.

P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

- Do not swallow. Avoid contact with skin and mucous membranes.
- 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.