

REF A11A01650
CONTROL 3 x 3 mL



IVD **CE**

HORIBA ABX SAS
Parc Euromédecine - Rue du Caducée
B.P. 7290
34184 MONTPELLIER Cedex 4
FRANCE

ABX Pentra CO₂ Control

- Pentra C200
- Pentra C400
- ABX Pentra 400

Control for the measurement of bicarbonate / total CO₂ by colorimetry.

Intended Use

The **ABX Pentra CO₂ Control** is for use in quality control by monitoring accuracy and precision of HORIBA Medical methods (by colorimetry) on HORIBA Medical clinical chemistry analyzers with the following reagents:

- **ABX Pentra CO₂ RTU** (A11A01645)

Characteristics

- **ABX Pentra CO₂ Control** is a liquid control.
- **ABX Pentra CO₂ Control** is ready-to-use. The kit is composed of 3 vials of 3 mL.
- **ABX Pentra CO₂ Control** should be used according to this notice and as specified in the respective instructions for use of the reagent. The manufacturer cannot guarantee its performance if used otherwise.

Handling

1. Remove the cap of the vial, use a pipette to transfer the required volume into a sample cup.
2. Place the sample cup on the instrument:
 - For **Pentra C200**: Place the sample cup in the correct position on the instrument sample tray.
 - For **Pentra C400**: Place the sample cup on the appropriate rack of the instrument.
 - For **ABX Pentra 400**: Place the sample cup on the appropriate rack of the instrument.
3. Treat the **ABX Pentra CO₂ Control** as a patient specimen.

An analysis of the control serum must be carried out on a daily basis at the same time as the patient samples,

^aModification: traceability removed.

^bModification: annex reference removed.

including each time a calibration is carried out. The frequency of the controls depends on the laboratory requirements. Each laboratory must establish the quality assurance procedures to be followed. These must conform to the current accreditation requirements and pertinent regulations.

Materials Required but not Provided

- HORIBA Medical reagents and automated clinical chemistry analyzer.
- Standard laboratory equipment.

Assigned Values ^{a b}

The concentration of the constituent(s) is lot specific. Assigned values and confidence interval are indicated in the enclosed annex.

Storage and Stability

Stability before opening:

Stable up to the expiry date on the label if stored at 2-25°C.

Stability after opening:

Stable for 3 months at 2-25°C if closed immediately and contamination is avoided.

ABX Pentra CO₂ Control

Waste Management ^c

- Please refer to local legal requirements.
- This control 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 ^d

- **ABX Pentra CO₂ Control** should be used for quality control purpose only.
- This quality control is for professional *in vitro* diagnostic use only.
- For prescription use only.
- This reagent is classified as non-hazardous in compliance with regulation (EC) N°.1272/2008.
- Do not pipette by mouth.
- Do not swallow. Avoid contact with skin and mucous membranes.
- Observe the standard laboratory precautions for use.
- The quality control vials should be discarded after use. Disposal of all waste material should be in accordance with local guidelines.
- Please refer to the MSDS associated with the control.
- Do not use the product if there is visible evidence of biological, chemical or physical deterioration.
- It is the user's responsibility to verify that this document is applicable to the control used.

^cModification: modification of waste management.

^dModification: general precautions modification.