

ABX Pentra CO₂ Control

- Pentra C200
- Pentra C400
- ABX Pentra 400

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

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

Intended Use ^a

ABX Pentra CO₂ Control is a control used to monitor the performance of **ABX Pentra CO₂ RTU**, Ref.A11A01645 determination by colorimetry.

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 control notice and as specified in the respective instructions for use of the reagent. The manufacturer cannot guarantee its performance if used otherwise.

Handling ^b

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, including each time a calibration is carried out. The frequency of the controls depends on the laboratory

^a Modification from index B to C: available on Pentra C400.

^b Modification from index B to C: Pentra C400 handling added.

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

The traceability of the target values is given in the instructions for use of the calibrator.

The concentration of the constituent(s) is lot specific. Assigned values and precise confidence interval are indicated in the enclosed annex, Ref.04710802.

Storage and Stability

Controls, in unopened vials, are stable up to the expiry date written on the label if stored at 2-25°C.

Once opened, **ABX Pentra CO₂ Control** is stable for 3 months at 2-25°C.

This stability is obtained when vials are tightly recapped immediately after use and if contamination is avoided.

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Packaging spoiling

In case of protective packaging spoiling, do not use the control if the damages might have an effect on the product performance.

Waste Management

Please refer to local legal requirements.

General Precautions

- **ABX Pentra CO₂ Control** should be used for quality control purpose only.
- This control is for professional *in vitro* diagnostic use only.
- Observe the standard laboratory precautions for use.
- The 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.

Warning

It is the user's responsibility to verify that this document is applicable to the control used.