Clinical Chemistry

2025/06/11
A98A00017EUS

REF A11A01616

CAL 5 x 1 mL

IVD CE 2797

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

ABX Pentra CRP Cal

- **Pentra C200**
- **Pentra C400**
- **ABX Pentra 400**
- **Yumizen C1200**

Calibrator for the measurement of C-Reactive Protein (CRP) by latex-enhanced immunoturbidimetric assay.

Intended Use [a] [b] [c]

ABX Pentra CRP Cal is used for calibration of *in vitro* diagnostic quantitative HORIBA methods with the following parameter(s):
C-Reactive Protein (CRP)
Clinical laboratories use.

Characteristics

- **ABX Pentra CRP Cal** is a liquid calibrator prepared by diluting C-reactive protein (CRP) with normal human serum at various concentrations.
- **ABX Pentra CRP Cal** is ready-to-use. The kit is composed of 5 vials of 1 mL. Each one has a different concentration (shown on each vial): 2.5, 10, 40, 80 and 160 mg/L. As the color of caps varies according to the CRP level in the vial, care should be taken not to interchange the caps.
- **ABX Pentra CRP Cal** 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 each vial, use a pipette to transfer the required volume into a sample cup.
2. Place the sample cups on the instrument:
   - For **Pentra C200**: Place each sample cup in the correct position on the instrument sample tray.
   - For **Pentra C400**: Place the sample cups on the appropriate rack of the instrument.
   - For **ABX Pentra 400**: Place the sample cups on the appropriate rack of the instrument.
   - For **Yumizen C1200**: Place the sample cups on the appropriate rack of the instrument.

Please, refer to the reagent notice for further explanations concerning the use of this calibrator on the instrument.

Materials Required but not Provided

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

Assigned Values [d]

The assigned values are based on primary calibration with IRMM/ERM-DA472/IFCC.
Results must be within the range of the defined confidence limits. Each laboratory must establish the procedure to be followed in case the results are outside of the confidence interval given.
Please refer to the vial label for the exact concentration.

[a] Modification: modification of Intended Use chapter.
[b] Modification: modification of CE mark.
[c] Modification: new leaflet form.
[d] Modification: information added.

ABX Pentra CRP Cal

Storage and Stability

Stability before opening:

Stable up to the expiry date on the label if stored at 2-10°C. Store protected from light.

Stability after opening:

Stable for 3 months at 2-10°C if closed immediately and contamination is avoided. Store protected from light.

Do not freeze.

Waste Management [e]

- Please refer to local legal requirements.
- This calibrator contains less than 0.1% of sodium azide as a preservative. Do not bring ABX Pentra CRP Cal in contact with lead or copper as sodium azide may react with lead and copper to form explosive metal azides.

General Precautions [f]

- **ABX Pentra CRP Cal** should be used only for the determination of the calibration curve.
- This calibrator is for professional *in vitro* diagnostic use only.
  For laboratory use.
- For prescription use only.
- This reagent is classified as non-hazardous in compliance with regulation (EC) N°.1272/2008.
- **Warning:** Human source material. Treat as potentially infectious. Each plasma donor unit used in the preparation of this product has been tested by an FDA approved method and found negative for the presence of HBsAg, HCV and antibody to HIV1/2. Because no known test method can offer complete assurance that hepatitis B virus, Human Immunodeficiency Virus (HIV) or other infectious agents are absent, the calibrators should be treated like patient specimens as potentially infectious and handled with appropriate cautions in accordance with good laboratory practices (1, 2).
- Do not pipette by mouth.
- Do not swallow. Avoid contact with skin and mucous membranes.
- Observe the standard laboratory precautions for use.
- The calibrator 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 calibrator.
- 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 representative before attempting to operate the device.
- It is the user's responsibility to verify that this document is applicable to the calibrator 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.
- The Summary of Safety and Performance (SSP) of the product is available in Eudamed (https://ec.europa.eu/tools/eudamed).

Reference

1. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR 1910. 1030). Federal Register July 1, 1998; **6**: 267-280.
2. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.

[e]Modification: modification of waste management.
[f]Modification: general precautions modification.