Clinical Chemistry

2020/07/30
A98A00017DUS

REF **A11A01616**

CAL 5 x 1 mL

IVD CE Rx Only

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]

ABX Pentra CRP Cal is used for the calibration of methods on clinical chemistry analyzers with the following reagent(s):

- **ABX Pentra CRP CP** (A11A01611)
- **Yumizen C1200 CRP** (1300023877)

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 [b]

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

Assigned Values

The assigned values are based on primary calibration with IRMM/ERM-DA472/IFCC.
Please refer to the vial label for the exact concentration.

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.

[a]Modification: modification of Intended Use chapter.
[b]Modification: § handling changed.

ABX Pentra CRP Cal

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

- Please refer to local legal requirements.
- This calibrator 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

- **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 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.
- It is the user's responsibility to verify that this document is applicable to the calibrator used.

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.