Clinical Chemistry

2013/03/04
A98A00021DUS

REF A11A01678

CAL 2 x 1 mL

IVD CE

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

ABX Pentra LDL Cal

- **Pentra C200**
- **Pentra C400**
- **ABX Pentra 400**

Calibrator for the measurement of low density lipoprotein cholesterol (LDL-C) by colorimetry.

Intended Use [a]

ABX Pentra LDL Cal is used to calibrate **ABX Pentra LDL Direct CP**, Ref. A11A01638.

Characteristics

- **ABX Pentra LDL Cal** is a lyophilized calibrator. It is a preparation of lyophilized human serum containing lipoproteins from the various lipoprotein classes including low-density lipoproteins.
- The kit is composed of 2 vials of calibrator (lyophilizate for 1 mL).

Note: The LDL cholesterol value is traceable to the Reference Method for the determination of LDL cholesterol (Beta quantification and Abell-Kendall cholesterol analysis; the value is confirmed by a CDC laboratory using Beta quantification).

- **ABX Pentra LDL Cal** should be used according to this calibrator 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. Reconstitute the content of one vial with 1 mL of distilled or deionised water.
   Be careful when opening the rubber cap as some lyophilized material may be lost.
2. Allow the vial to stand at room temperature for at least 5 minutes.
3. Agitate the vial slowly, avoiding the formation of foam. Do not shake.
4. Remove the cap of the vial, use a pipette to transfer the required volume into a sample cup.
5. 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.

Materials Required but not Provided

- HORIBA Medical reagents and automated clinical chemistry analyzer.
- Standard laboratory equipment.
- Distilled or deionised water.

Assigned Values

Assigned value has been determined by procedures traceable to the National Reference System for Cholesterol (NRS/CHOL). Calibration materials have concentrations around the medical decision level.
The concentration of the constituent(s) is lot specific.
Assigned value is indicated in the enclosed annex, Ref.04710801.

[a] Modification from index C to D: available on Pentra C400.
[b] Modification: Pentra C400 handling added.

ABX Pentra LDL Cal

Storage and Stability [c]

Calibrators, in unopened vials, are stable up to the expiry date written on the label if stored at 2-8°C.

Once reconstituted, **ABX Pentra LDL Cal** is stable for 2 weeks at 2-8°C.
Reconstitution stability of the calibrator may be extended by aliquoting and freezing the reconstituted calibrator preparation at less than -80°C for up to 4 weeks.
This stability is obtained when vials are tightly recapped immediately after use and if contamination is avoided.

Packaging spoiling

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

Waste Management

- Please refer to local legal requirements.
- This calibrator contains a small amount of sodium azide as a preservative. Sodium azide may react with lead and copper to form explosive metal azides.

General Precautions

- **ABX Pentra LDL Cal** should be used only for the determination of the calibration curve.
- This calibrator is for professional *in vitro* diagnostic use only.
- **Warning:** Due to sodium azide presence.
  Xn: harmful.
  R22: harmful if swallowed.
  R52/53: harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
  S45: in case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
  S61: avoid release to the environment. Refer to special instructions/safety data sheets.
- Observe the standard laboratory precautions for use.
- Do not pipette by mouth.
- **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).
- The calibrator 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 calibrator.
- 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 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.

[c] Modification: additional data on storage and stability.