Clinical Chemistry

2026/02/23
A98A00021HUS

REF A11A01678

CAL 2 x 1 mL

IVD CE 2797

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

ABX Pentra LDL Cal

- **Pentra C200**
- **Pentra C400**
- **ABX Pentra 400**
- **Yumizen C230**
- **Yumizen C240**
- **Yumizen C560**

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

Intended Use [a] [b] [c] [d]

ABX Pentra LDL Cal is used for calibration of *in vitro* diagnostic quantitative HORIBA methods with the following parameter(s):
Low-Density Lipoprotein Cholesterol (LDL-C)
Clinical laboratories use.

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

Handling [d]

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 for at least 5 minutes (room temperature).
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.
   - For **Yumizen C230/C240/C560**: Place the sample cup in the correct position on the instrument sample tray.

Materials Required but not Provided

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

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

ABX Pentra LDL Cal

Assigned Values [e]

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.
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.
The concentration of the constituent(s) is lot specific.
Assigned values are indicated in the enclosed annex.
The annex can also be downloaded from our web site www.horiba.com.

Storage and Stability [f]

Stability before opening:

Stable up to the expiry date on the label if stored at 2-8°C.

Stability after reconstitution:

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.

Waste Management [g]

- Please refer to local legal requirements.
- This calibrator contains less than 0.1% of sodium azide as a preservative.

General Precautions [h]

- **ABX Pentra LDL Cal** should be used only for the determination of the calibration curve.
  For laboratory use.
- This calibrator is for professional *in vitro* diagnostic use only.
- For prescription use only.
- This reagent is classified as hazardous in compliance with regulation (EC) N°.1272/2008.
- **Warning**
  H302: Harmful if swallowed.
  H412: Harmful to aquatic life with long lasting effects.
- **P264**: Wash hands thoroughly after handling.
  P270: Do not eat, drink or smoke when using this product.
  P273: Avoid release to the environment.
  P301 + P312: IF SWALLOWED: Call a POISON CENTER or physician if you feel unwell.
  P330: Rinse mouth.
  P501: Dispose of contents and container in accordance with all local, regional, national and international regulations.
- 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 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.

Reference

1. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR 1910. 1030). Federal Register July 1, 1998; **6**: 267-280.

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[e]Modification: information added.
[f]Modification: modification of storage and stability.
[g]Modification: modification of waste management.
[h]Modification: general precautions modification.

ABX Pentra LDL Cal

2. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.