Clinical Chemistry

2010/11/15
A98A00037BEN

REF A11A01927

CAL 5 x 1 mL

IVD CE

HORIBA ABX SAS
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FRANCE

ABX Pentra SP Cal

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

Calibrator for the measurement of specific serum proteins by immunoturbidimetry.

Intended Use [a]

ABX Pentra SP Cal is used to calibrate **ABX Pentra IgA CP**, Ref. A11A01923, **ABX Pentra IgG CP**, Ref. A11A01924, **ABX Pentra IgM CP**, Ref. A11A01925 and **ABX Pentra Transferrin CP**, Ref. A11A01926 on HORIBA Medical clinical chemistry analysers.

Characteristics

- **ABX Pentra SP Cal** is a liquid calibrator based on human plasma.
- **ABX Pentra SP Cal** is ready-to-use. The kit is composed of 5 vials of 1 mL. Each one has a different concentration specified in the enclosed annex, Ref.04710818.
- **ABX Pentra SP 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

1. Before opening the vials, leave at room temperature then gently agitate before use, avoiding the formation of foam. Do not shake.
2. Remove the cap of each vial, use a pipette to transfer the required volume into a sample cup.
3. Place the sample cups on the instrument:
   - For **Pentra C200**: Place each sample cup in the correct position on the instrument sample tray.
   - For **ABX Pentra 400**: Place the sample cups on the appropriate rack of the instrument.

Materials Required but not Provided

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

Assigned Values (1, 2)

The assigned values have been made traceable to the IFCC/BCR/CAP Reference Material for 15 Plasma Proteins CRM 470 using established protocols.

Assigned values are indicated in the enclosed annex, Ref.04710818.
The annex can also be downloaded from our web site www.horiba.com.

Storage and Stability

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

Once opened, **ABX Pentra SP Cal** is stable for 12 weeks at 2-8°C.
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.

[a] Modification from index A to B: available on ABX Pentra 400.

ABX Pentra SP Cal

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 (3) [b]

- **ABX Pentra SP Cal** should be used only for the determination of the calibration curve.
- This calibrator is for professional *in vitro* diagnostic use only.
- Observe the standard laboratory precautions for use.
- **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 (4, 5).
- 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. Stenman UH. Standardization of immunoassays. In: Price CP, Newman DJ, editors. Principles and practice of immunoassay. New York: Stockton Press (1997): 243-68.
2. Dati F. Reference materials and guidelines for standardization of methods in laboratory medecine. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgeselischaft (1998): 1393-1401.
3. Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington (1993). HHS Publication No. CDC 93-8395.
4. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR 1910. 1030). Federal Register July 1, 1998; **6**: 267-280.
5. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.

[b] Modification from index A to B: addition of reference.