Clinical Chemistry

2024/01/02
A98A00091CEN

REF 1300032565

CAL 5 x 1 mL

IVD CE

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

ABX Pentra Micro ALB 2 Cal

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

Calibrator for the measurement of µ-Albumin (µ-ALB) in urine by immunoturbidimetric assay.

Intended Use [a] [b]

ABX Pentra Micro ALB 2 Cal is used for calibration of *in vitro* diagnostic quantitative HORIBA Medical methods with the following reagent(s):

- **ABX Pentra Micro ALBUMIN 2 CP** (1300032563)

Clinical laboratories use.

Characteristics

- **ABX Pentra Micro ALB 2 Cal** is a liquid calibrator containing human blood material (plasma).
- **ABX Pentra Micro ALB 2 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.
- **ABX Pentra Micro ALB 2 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

Remove the cap of each vial, use a pipette to transfer the required volume into a sample cup.

Materials Required but not Provided

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

Assigned Values [c]

Assigned value is based on primary calibration with ERM-DA470k/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.
The concentration of the constituent(s) is lot specific.
Assigned values are indicated in the enclosed annex.
These target values can also be downloaded from our web site www.horiba.com.

Storage and Stability

Stability before opening:

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

Stability after opening:

Stable for 45 days at 2-8°C if closed immediately and contamination is avoided.

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

ABX Pentra Micro ALB 2 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 [d]

- **ABX Pentra Micro ALB 2 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:** This reagent is obtained from substances of animal origin. Consequently, it should be treated as potentially infectious and handled with the appropriate cautions in accordance with good laboratory practices (1).
- 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 Medical 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. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.

[d]Modification: general precautions modification.