

REF 1300032565

CAL 5 x 1 mL

IVD 



HORIBA ABX SAS
Parc Euromédecine - Rue du Caducée
B.P. 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

ABX Pentra Micro ALB 2 Cal is used to calibrate ABX Pentra Micro ALBUMIN 2 CP, Ref. 1300032563.

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 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. 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.

Materials Required but not Provided

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

Assigned Values

Assigned value is based on primary calibration with ERM-DA470k/IFCC.

The concentration of the constituent(s) is lot specific. Assigned values are indicated in the enclosed annex.

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 Micro ALB 2 Cal is stable for 45 days at 2-8°C.

This stability is obtained when vials are tightly recapped immediately after use and if contamination is avoided.

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.

ABX Pentra Micro ALB 2 Cal

General Precautions

- **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 prescription use only.
- This reagent is classified as non-hazardous in compliance with regulation (EC) N°.1272/2008.
- 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 (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.
- 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.