

REF A11A01898

CAL 3 x 3 mL

IVD 



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

ABX Pentra TPU Cal

- Pentra C200
- ABX Pentra 400

Calibrator for the measurement of urinary proteins by colorimetry.

Intended Use

ABX Pentra TPU Cal is used to calibrate **ABX Pentra Urinary Proteins CP**, Ref. A11A01642.

Characteristics

- **ABX Pentra TPU Cal** is a liquid ready-to-use calibrator based on an aqueous solution containing human serum.
- The kit is composed of 3 vials of 3 mL.
- **ABX Pentra TPU 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 vial, leave at room temperature then gently agitate before use, avoiding the formation of foam. Do not shake.
2. Remove the cap of the vial, use a pipette to transfer the required volume into a sample cup.
3. Place the sample cup on the instrument:
 - For **Pentra C200**: Place the sample cup in the correct position on the instrument sample tray.
 - 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.

^a Modification from index A to B: modification of waste management.

Assigned Values

The calibrator value is traceable with SRM927. Please refer to the vial label for the exact concentration: 1.30 g/L (1300 mg/L).

Storage and Stability

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

Once opened, **ABX Pentra TPU Cal** is stable for 9 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.

Waste Management ^a

- 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

- **ABX Pentra TPU Cal** should be used only for the determination of the calibration curve.
- This calibrator is for professional *in vitro* diagnostic use only.

ABX Pentra TPU Cal

- Observe the standard laboratory precautions for use.
- **Warning:** Human source material. Treat as potentially infectious. All products derived from blood are prepared exclusively from blood of donors tested individually and shown by approved methods to be free from HBsAg and antibodies to HCV and HIV. 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.