Clinical Chemistry

2015/11/18
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CAL 4 x 1 mL

IVD CE

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

ABX Pentra Protein Cal

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

Calibrator for the measurement of specific serum proteins by immunoturbidimetry.

Intended Use (not for use in the USA)

ABX Pentra Protein Cal is used to calibrate specific serum protein assays on clinical chemistry analysers.

Characteristics

- **ABX Pentra Protein Cal** is a liquid pool of 30 human sera proceeding from healthy donors. The human serum has been purified by precipitation to eliminate unstable compounds such as lipoproteins (including HDL).
- **ABX Pentra Protein Cal** is ready-to-use.
- **ABX Pentra Protein 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, allow to come 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 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.

Materials Required but not Provided

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

Assigned Values

The protein concentrations are determined by turbidimetry using a very precise, specially elaborated transfer protocol.
This protocol and the procedure are the same as those used for setting the precipitation values of the international reference preparation for serum proteins (A).
The analytical values are based on 140 determinations per protein.

The reference solutions used are listed below:

- BCR reference material. Human serum proteins. CRM 470 - CAP/ IFCC lot 91/06 19. International reference preparations for the immunological determination of 14 serum proteins, certified June 1993.
- The values for kappa and lambda have been calculated using the concentrations of IgG, IgA and IgM and applying the following formulae (1):
  $C_{kappa} = C_{IgG} \times 0.1983 + C_{IgA} \times 0.171 + C_{IgM} \times 0.0975$
  $C_{lambda} = C_{IgG} \times 0.1054 + C_{IgA} \times 0.1206 + C_{IgM} \times 0.0305$
- The total protein concentration has been determined by refractometry.

Assigned values are indicated in the enclosed annex, Ref.04710788.

S.A.S. au capital de 23.859.980 € - RCS Montpellier 328 031 042 - SIRET 328 031 042 000 42 - APE 332 B

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ABX Pentra Protein Cal

List of parameters:

Proteins	Reference material
Albumin	CRM470
Haptoglobin	CRM470
Kappa	CRM470
Lambda	CRM470
Orosomucoid	CRM470
Prealbumin	CRM470

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 Protein Cal** is stable for 3 months at 2-8°C.
This stability is obtained when vials are tightly recapped immediately after use and if contamination is avoided.

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 [b]

- **ABX Pentra Protein 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 (2, 3).
- 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. Lievens MM. Medical and technical usefulness of measurement of kappa and lambda immunoglobulin light chains in serum with an M-component. J. Clin. Chem. Clin. Biochem. (1989) **27**: 519-523.
2. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR 1910. 1030). Federal Register July 1, 1998; **6**: 267-280.
3. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.

[a]Modification: modification of waste management.
[b]Modification: general precautions modification.

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