Clinical Chemistry

2023/12/15
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ABX Pentra Immuno I Control L/H

REF A11A01621
CONTROL L 1 x 3 mL
CONTROL H 1 x 3 mL

IVD CE

HORIBA ABX SAS
Parc Euromédecine
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FRANCE

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

Multiparametric control for the measurement of serum specific proteins by immunoturbidimetry.

Intended Use [a] [b]

The **ABX Pentra Immuno I Control L/H** is for use in quality control by monitoring accuracy and precision of HORIBA Medical methods (by immunoturbidimetry) on HORIBA Medical clinical chemistry analyzers with the following reagents:

- **ABX Pentra RF CP** (A11A01613)

Characteristics

- **ABX Pentra Immuno I Control L/H** is a lyophilized control obtained from pooled human sera.
- This kit is composed of 2 vials:
  - 1 vial of Low control (lyophilizate for 3 mL)
  - 1 vial of High control (lyophilizate for 3 mL)
- **ABX Pentra Immuno I Control L/H** 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

1. Reconstitute the content of one vial with 3 mL of distilled or deionised water.
   Be careful when opening the rubber cap as some lyophilized material may be lost.
2. Allow the vial to stand for at least 20 minutes (room temperature).
3. Agitate the vial slowly, avoiding the formation of foam. Do not shake.
4. Remove the cap of each vial, use a pipette to transfer the required volume into a sample cup.
5. Place the sample cups on the instrument:
   - For **Pentra C200**: Place the sample cups 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.
6. Once reconstituted, treat the **ABX Pentra Immuno I Control L/H** as a patient specimen.

An analysis of the control serum must be carried out on a daily basis at the same time as the patient samples, including each time a calibration is carried out. The frequency of the controls depends on the laboratory requirements. Each laboratory must establish the quality assurance procedures to be followed. These must conform to the current accreditation requirements and pertinent regulations.

Materials Required but not Provided

- HORIBA Medical reagents and automated clinical chemistry analyzer.
- Distilled or deionised water.
- Standard laboratory equipment.

Assigned Values [c]

Assigned values were determined by calculating the mean value obtained from multiple determinations.

[a] Modification: modification of Intended Use chapter.
[b] Modification: reagent removed.
[c] Modification: information added.

ABX Pentra Immuno I Control L/H

Determinations were performed under strictly standardized conditions on HORIBA Medical analyzers using HORIBA Medical reagents and HORIBA Medical master calibrator.
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 and confidence interval are indicated in the enclosed annex.

Storage and Stability

Stability before opening:

Stable up to the expiry date on the label if stored at 2-10°C. Store protected from light.

Stability after reconstitution:

Stable for:

- 2 weeks at 2-10°C
- 3 months at -20°C

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

Waste Management [d]

Please refer to local legal requirements.

General Precautions [e]

- **ABX Pentra Immuno I Control L/H** should be used for quality control purpose only.
- This quality control 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:** 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 control should be treated like patient specimens as potentially infectious and handled with appropriate cautions in accordance with good laboratory practices (1, 2).
- **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 (2).
- Do not pipette by mouth.
- Do not swallow. Avoid contact with skin and mucous membranes.
- Observe the standard laboratory precautions for use.
- The quality control 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 control.
- 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 control 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. 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.

[d]Modification: modification of waste management.
[e]Modification: general precautions modification.