Clinical Chemistry

2017/06/23
A98A00009GUS

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

IVD CE

HORIBA ABX SAS
Parc Euromédecine - Rue du Caducée
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FRANCE

ABX Pentra Immuno I Control L/H

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

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

Intended Use [a]

ABX Pentra Immuno I Control L/H is a quality control used to monitor by turbidimetry the performance of:

- **ABX Pentra ASO 2 CP**, Ref.1300022598
- **ABX Pentra CRP CP**, Ref.A11A01611
- **ABX Pentra RF CP**, Ref.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 control 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 at room temperature for at least 20 minutes.
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.
- Standard laboratory equipment.
- Distilled or deionised water.

Assigned Values

Assigned values were determined by calculating the mean value obtained from multiple determinations.
The concentration of the constituent(s) is lot specific.
Assigned values and confidence interval are indicated in the enclosed annex.

[a]Modification: modification of Intended Use chapter.

ABX Pentra Immuno I Control L/H

Storage and Stability

Controls, in unopened vials, are stable up to the expiry date written on the label if stored at 2-10°C and protected from light.

Once reconstituted, **ABX Pentra Immuno I Control L/H** is 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

- Please refer to local legal requirements.
- This control 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 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 prescription use only.
- 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 control should be treated like patient specimens as potentially infectious and handled with appropriate cautions in accordance with good laboratory practices (1, 2).
- 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 MSDS associated with the control.
- 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 control 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.