2014/07/21
A98A00011BEN

REF A11A01731

CONTROL 4 x 1 mL

IVD CE

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

ABX Pentra Low CRP Control

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

Control for the measurement of CRP at low concentration by latex-enhanced immunoturbidimetric assay.

Intended Use [a]

ABX Pentra Low CRP Control is a quality control used to monitor the performance of **ABX Pentra CRP CP (High sensitive method)**, Ref.A11A01611 determination at low concentration by latex-enhanced immunoturbidimetric assay.

Characteristics

- **ABX Pentra Low CRP Control** is liquid control prepared by diluting C-reactive protein (CRP) with normal human serum at low concentration.
- **ABX Pentra Low CRP Control** is ready-to-use. The kit is composed fo 4 vials of 1 mL.
- **ABX Pentra Low CRP Control** 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. Remove the cap of the vial, use a pipette to transfer the required volume into a sample cup.
2. 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.
3. Treat the **ABX Pentra Low CRP Control** 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.

Assigned Values [b]

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, Ref.04710786.

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 opened, **ABX Pentra Low CRP Control** is stable for 4 weeks at 2-10°C.
This stability is obtained when vials are tightly recapped immediately after use and if contamination is avoided.

[a]Modification: modification of Intended Use chapter.
[b]Modification: traceability removed.

ABX Pentra Low CRP Control

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 [c]

- **ABX Pentra Low CRP Control** 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.

[c]Modification: general precautions modification.