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REF A11A01654

CONTROL P 10 x 5 mL

IVD CE

HORIBA ABX SAS
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FRANCE

ABX Pentra P Control

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

Control serum for the quality control of HORIBA Medical methods.

Intended Use [a]

The **ABX Pentra P Control** is for use in quality control by monitoring accuracy and precision of HORIBA Medical methods, listed in the annex, on HORIBA Medical clinical chemistry analyzers.

Characteristics

- **ABX Pentra P Control** is a lyophilized control based on human serum. The adjusted concentrations and activities of the control components are usually in the pathological range.
- The kit is composed of 10 vials of control (lyophilizate for 5 mL).
  ABX Pentra P Control is composed of human serum to which chemical substances and extracts from human - or animal - derived tissue have been added.

Origin of biological substances:

ALT (GPT)	Porcine heart
AST (GOT)	Human recombinant
Albumin	Bovine plasma
Aldolase	Rabbit muscle
Alkaline phosphatase	Human recombinant placenta alkaline phosphatase
Amylase (total)	Porcine pancreas
Amylase (pancreatic)	Porcine pancreas
Cholesterol	Bovine plasma
Cholinesterase	Human serum
Creatine kinase	Rabbit muscle
γ-GT	Human recombinant
GLDH	Bacterium, recombinant
LD (LDH)	Porcine heart
Lipase	Human recombinant pancreas lipase
Acid phosphatase	Human prostate / Potato
Triglycerides	Chicken egg yolk

- **ABX Pentra P 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. Reconstitute the content of one vial with 5 mL of distilled water or deionised water.
   Be careful when opening the rubber cap as some lyophilized material may be lost. Close the vial carrefully.
2. Allow the vial to stand at room temperature for at least 30 minutes.
3. Agitate the vial slowly, avoiding the formation of foam. Do not shake.
   Important: The determination of enzyme activity may be carried out immediately in the case of all enzymes except for alkaline phosphatase. To reactivate alkaline phosphatase, incubate the reconstituted control serum for one hour at 25°C.
4. Remove the cap of the vial, use a pipette to transfer the required volume into a sample cup.
5. Place the sample cup on the instrument:
   - For **Pentra C200**: Place the sample cup in the correct position on the instrument sample tray.
   - 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.
6. Once reconstituted, treat the **ABX Pentra P Control** as a patient specimen.

[a]Modification: available on Pentra C400.

ABX Pentra P Control

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

The assigned values were determined using the methods stated in the enclosed annex.
Determinations were performed under strictly standardized conditions on HORIBA Medical analyzers using HORIBA Medical reagents and HORIBA Medical master calibrator.
The target value is the median of all values obtained. The corresponding control range is calculated as the target value ± 3 standard deviations (with the standard deviation being the value obtained from several target value determination).

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 precise confidence interval are indicated in the enclosed annex, Ref.04710796.
These target values can also be downloaded from our web site www.horiba.com.
The traceability of the target values is given in the instructions for use of the calibrator, **ABX Pentra Multical**, Ref. A11A01652.

Storage and Stability

Controls, in unopened vials, are stable up to the expiry date written on the label if stored at 2-8°C.
Criterion for the stability data: Recovery within ±10% of initial value.

Stability of parameters* after the reconstitution of ABX Pentra P Control:

- 12 hours at 15°C to 25°C
- 5 days at 2°C to 8°C
- 1 month at -25°C to -15°C (only one freezing session)

*Exceptions: see below.

Stability of total bilirubin following reconstitution (when stored protected from light):

- 8 hours at 15°C to 25°C
- 24 hours at 2°C to 8°C
- 2 weeks at -25°C to -15°C (only one freezing session)

Stability of direct bilirubin following reconstitution (when stored protected from light):

- 4 hours at 15°C to 25°C
- 8 hours at 2°C to 8°C
- 2 weeks at -25°C to -15°C (only one freezing session)

A slight green coloration of the control serum does not in any way affect theoretical values.
This stability is obtained when vials are tightly recapped immediately after use and if contamination is avoided.
Store controls protected from light when not in use.

Packaging spoiling

In case of protective packaging spoiling, do not use the control if the damages might have an effect on the product performance.

Waste Management

Please refer to local legal requirements.

General Precautions

- **ABX Pentra P Control** should be used for quality control purpose only.
- This control is for professional *in vitro* diagnostic use only.
- Observe the standard laboratory precautions for use.

ABX Pentra P Control

- **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 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 reagent.
- 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 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.