Clinical Chemistry

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CONTROL P 10 x 5 mL

IVD CE

HORIBA ABX SAS
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ABX Pentra P MultiControl

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

Control serum for the quality control of HORIBA Medical methods.

Intended Use [a]

The **ABX Pentra P MultiControl** 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 MultiControl** 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 consists of 10 vials of 5 mL (after reconstitution).
- **ABX Pentra P MultiControl** 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.

Human serum with biological additives:

ALT (GPT)	Human, recombinant
AST (GOT)	Human, recombinant
Aldolase	Rabbit muscle
Alkaline phosphatase	Human placenta (recombinant)
Amylase (total)	Human saliva / porcine pancreas
Amylase (pancreatic)	Porcine pancreas
Creatine kinase	Human CK-MM / human CK-MB (recombinant)
CK-MB	Human CK-MB (recombinant)
γ-GT	Human, recombinant
GLDH	Bacterial, recombinant
LDH	Porcine heart
Lipase	Human pancreas (recombinant)
Acid phosphatase	Human prostate / Potato
ASLO	Sheep
CRP	Human
Transferrin	Human
Ferritin	Human

Handling

1. Reconstitute the content of one vial with 5 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 30 minutes.
3. Agitate the vial slowly, avoiding the formation of foam. Do not shake.
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 MultiControl** 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.

[a]Modification: leaflet reference modification.

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ABX Pentra P MultiControl

Materials Required but not Provided

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

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 ± 2 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 confidence interval are indicated in the enclosed annex.
These target values can also be downloaded from our web site www.horiba.com.

Storage and Stability

Stability before opening:

Stable up to the expiry date on the label if stored at 2-8°C. Store protected from light.

Stability after reconstitution:

- 12 hours at 15 - 25°C
- 5 days at 2 - 8°C
- 28 days at (-15) - (-25)°C

Freeze only once!

Stability of total bilirubin and direct bilirubin after reconstitution:

- 8 hours at 15 - 25°C
- 24 hours at 2 - 8°C
- 14 days at (-15) - (-25)°C

Freeze only once!

Store protected from light.

Stability of ALT after reconstitution:

- 12 hours at 15 - 25°C
- 5 days at 2 - 8°C
- 14 days at (-15) - (-25)°C

Freeze only once!

The possible appearance of a slight green coloration has no effect on the recovery of the values.

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 P MultiControl** should be used for quality control purpose only.
- This quality control 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.
- **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.

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ABX Pentra P MultiControl

- 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.
- 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.

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