

**REF** A11A01619

**CAL** 4 x 1 mL

**IVD** 



**HORIBA ABX SAS**  
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FRANCE

# ABX Pentra Ferritin Cal

- Pentra C200
- Pentra C400
- ABX Pentra 400

## Calibrator for the measurement of ferritin by latex-enhanced immunoturbidimetric assay.

### Intended Use (not for use in the USA)

**ABX Pentra Ferritin Cal** is used for the calibration of methods on HORIBA Medical clinical chemistry analyzers with the following reagent(s):

- **ABX Pentra Ferritin 2 CP** (A11A01900)

### Characteristics <sup>a</sup>

- **ABX Pentra Ferritin Cal** is a liquid calibrator prepared by dissolving ferritin in a buffer solution containing 1% (w/v) of bovine serum albumin and by adjusting each concentration. Ferritin concentration is shown on each vial.
- **ABX Pentra Ferritin Cal** is ready-to-use. The kit is composed of 4 vials of 1 mL.
- **ABX Pentra Ferritin Cal** 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. 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 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.

### Materials Required but not Provided

- HORIBA Medical reagents and automated clinical chemistry analyzer.
- Standard laboratory equipment.

### Assigned Values

The assigned values are based on primary calibration with WHO International Laboratory for Biological Standard. 1<sup>st</sup> International Standard (1984). Please refer to the vial label for the exact concentration.

### 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 opening:

Stable for 4 months at 2-10°C if closed immediately and contamination is avoided. Store protected from light.

Do not freeze.

### Waste Management

- Please refer to local legal requirements.
- This calibrator contains less than 0.1% of sodium azide as a preservative. Sodium azide may react with lead and copper to form explosive metal azides.

<sup>a</sup>Modification: modification of characteristics.

# ABX Pentra Ferritin Cal

## General Precautions <sup>b</sup>

- **ABX Pentra Ferritin Cal** should be used only for the determination of the calibration curve.
- This calibrator 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 calibrators 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 calibrator 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 calibrator.
- 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 calibrator 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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<sup>b</sup>Modification: general precautions modification.