

REF A11A01619

CAL 4 x 1 mL

IVD  2797



HORIBA ABX SAS
Parc Euromédecine
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FRANCE

ABX Pentra Ferritin Cal

- Pentra C200
- Pentra C400
- ABX Pentra 400
- Yumizen C230
- Yumizen C240
- Yumizen C560

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

Intended Use (not for use in the USA) ^{a b c}

ABX Pentra Ferritin Cal is used for calibration of *in vitro* diagnostic quantitative HORIBA methods with the following parameter(s):

Ferritin

Clinical laboratories use.

Characteristics

- **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 ^d

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.
- For **Yumizen C230/C240/C560**: Place the sample cup in the correct position on the instrument sample tray.

Materials Required but not Provided

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

Assigned Values ^e

Application: FERR2

On ABX Pentra 400 / Pentra C400 / Pentra C200:

The assigned values are based on primary calibration with WHO International Laboratory for Biological Standard. 1st International Standard (1984).

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 is not lot specific and the exact concentration is: 500 ng/mL.

^aModification: modification of Intended Use chapter.

^bModification: modification of CE mark.

^cModification: instrument added.

^dModification: § handling changed.

^eModification: information added.

ABX Pentra Ferritin Cal

Application: FERR3

On ABX Pentra 400 / Pentra C400 / Pentra C200 / Yumizen C230 / Yumizen C240 / Yumizen C560:

The assigned values are based on fourth calibration with WHO International Laboratory for Biological Standard. 4th International Standard (19/118).

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 is not lot specific and the exact concentration is: 650 ng/mL.

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 ^f

- Please refer to local legal requirements.
- This calibrator contains less than 0.1% of sodium azide as a preservative.

General Precautions

- **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 laboratory use.
- 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 SDS associated with the calibrator.
- Do not use the product if there is visible evidence of biological, chemical or physical deterioration.
- Do not use the product if the recommended storage conditions, including temperature, are not followed.
- User must be trained by a HORIBA representative before attempting to operate the device.
- It is the user's responsibility to verify that this document is applicable to the calibrator used.
- For technical assistance, you can call +33 (0)4 67 14 15 16.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the country in which the user and/or the patient is established.

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.

^fModification: modification of waste management.