

ABX Pentra RF Cal

- Pentra C200
- Pentra C400
- ABX Pentra 400

REF A11A01618

CAL 5 x 1 mL

IVD 



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

Calibrator for the measurement of rheumatoid factor (RF) by latex-enhanced immunoturbidimetric assay.

Intended Use (not for use in the USA) ^a

ABX Pentra RF Cal is used to calibrate ABX Pentra RF CP, Ref. A11A01613.

Characteristics

- **ABX Pentra RF Cal** is a liquid calibrator prepared by diluting RF positive human sera with buffer solution containing 1 % w/v bovine serum albumin at various concentrations.
- **ABX Pentra RF Cal** is ready-to-use. The kit is composed of 5 vials of 1 mL. Each one has a different concentration (shown on each vial): 10, 20, 40, 80 and 120 IU/mL. As the color of caps varies according to the RF levels in the vial, care should be taken not to interchange the caps.
- **ABX Pentra RF Cal** should be used according to this calibrator notice and as specified in the respective instructions for use of the reagent. The manufacturer cannot guarantee its performance if used otherwise.

Handling ^b

1. Remove the cap of each vial, use a pipette to transfer the required volume into a sample cup.
2. Place the sample cups on the instrument:
 - For **Pentra C200**: Place each sample cup in the correct position on the instrument sample tray.
 - For **Pentra C400**: Place the sample cups on the appropriate rack of the instrument.
 - For **ABX Pentra 400**: Place the sample cups 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 material 64/2. 1st International Standard (1970). Please refer to the vial label for the exact concentration.

Storage and Stability

Calibrators, 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 RF Cal** is stable for 5 weeks at 2-10°C.

This stability is obtained when vials are tightly recapped immediately after use and if contamination is avoided.

Do not freeze.

Packaging spoiling

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

^a Modification from index A to B: available on Pentra C400.

^b Modification from index A to B: Pentra C400 handling added.

ABX Pentra RF Cal

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.

General Precautions

- **ABX Pentra RF Cal** should be used only for the determination of the calibration curve.
- This calibrator is for professional *in vitro* diagnostic 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 calibrators should be treated like patient specimens as potentially infectious and handled with appropriate cautions in accordance with good laboratory practices (1, 2).
- 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.

Warning

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.

[°] Modification from index A to B: modification of waste management.