Clinical Chemistry

2012/12/05
A98A00022EEN

REF A11A01652

CAL 10 x 3 mL

IVD CE

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

ABX Pentra MultiCal

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

Calibrator for the measurement of HORIBA Medical methods.

Intended Use [a]

ABX Pentra Multical is used for the calibration of quantitative HORIBA Medical methods, listed in the annex, on HORIBA Medical clinical chemistry analysers.

Characteristics

- **ABX Pentra Multical** is a lyophilized calibrator based on human serum.
- The kit is composed of 10 vials of calibrator (lyophilizate for 3 mL).
  The concentrations and activities have been adjusted to ensure optimum calibration of the appropriate HORIBA Medical methods on clinical chemistry analysers.

The origin of the biological additives is as follows:

ALT (GPT)	Porcine heart
AST (GOT)	Human recombinant
Albumin	Bovine plasma
Aldolase	Rabbit muscle
Alkaline phosphatase	Placenta (human, recombinant)
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 pancreas (recombinant)
Acid phosphatase	Human prostate / Potato
Triglycerides	Chicken egg yolk

- *Reactive components*: human serum with chemical additives and tissue extracts of human and animal origin.

- *Non-Reactive components*: stabilizers.

- **ABX Pentra Multical** 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. Reconstitute the content of one vial with 3 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.

Materials Required but not Provided

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

[a] Modification: available on Pentra C400.
[b] Modification: Pentra C400 handling added.

ABX Pentra MultiCal

Assigned Values

The calibrator values were determined using the method mentioned 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 calibration values were obtained via multiple assays performed in different analysers in several independent series. The calibration value specified is the median of the values obtained.
The concentration of the constituent(s) is lot specific.
Assigned values are indicated in the enclosed annex, Ref.04710797.
These target values can also be downloaded from our web site www.horiba.com.

Traceability of the assigned values are given in the tables below.

List of parameters standardized by the calibrator comparison method:

Parameter	Reference material
ALT	ERM-AD454 /IFCC
Albumin	ERM-DA470k
Amylase	IRMM/IFCC-456
Total Bilirubin	SRM916a
Total Protein	SRM927d
Calcium	SRM956c
Cholesterol	SRM909c Abell-Kendall
CK-NAC	ERM-AD455/IFCC
Creatinine	SRM967a
GGT	ERM-AD452/IFCC
Glucose PAP	SRM965b
Glucose HK	SRM965b
Iron	SRM937
LDH ifcc	ERM-AD453/IFCC
Magnesium	SRM956c
Urea / BUN	SRM909c
Uric Acid	SRM909c
Triglycerides	SRM909c

List of parameters standardized by comparison of methods with “pools” of human serum:

Parameter	Reference method
ALP	IFCC Reference Measurement Procedure (37°C) for ALP
AST	IFCC Reference Measurement Procedure (37°C) for AST
Direct Bilirubin	Primary reference material (weighed in purified material) Bilirubin ditaurate
Lactate	Primary reference material (weighed in purified material)
LDH	HORIBA Medical Reagent/manual measurement; Epsilon of NADH
Lipase	HORIBA Medical Reagent/manual measurement; Epsilon of methylresorufin
Phosphorus	Primary reference material (weighed in purified material) NERL

Storage and Stability

Calibrators, 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 ±5% of initial value.

Stability of components* after the reconstitution of **ABX Pentra Multical** :
8 hours at 15°C to 25°C
2 days at 2°C to 8°C
2 weeks at -25°C to -15°C (only one freezing session)
*Exceptions : see below.

Stability of direct bilirubin after reconstitution (when stored protected from light):
3 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)

Stability of total bilirubin after reconstitution (when stored protected from light):
6 hours at 15°C to 25°C
1 day at 2°C to 8°C
2 weeks at -25°C to -15°C (only one freezing session)

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

Packaging spoiling

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

ABX Pentra MultiCal

Waste Management

Please refer to local legal requirements.

General Precautions

- **ABX Pentra Multical** 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.