Clinical Chemistry

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CAL 10 x 3 mL

IVD CE

HORIBA ABX SAS
Parc Euromédecine
Rue du Caducée
BP 7290
34184 Montpellier Cedex 4
FRANCE

ABX Pentra Multical

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

Calibrator for the measurement of HORIBA methods.

Intended Use [a] [b]

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

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 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
Alkaline phosphatase	Placenta (human, recombinant)
Amylase (total)	Porcine pancreas
Cholesterol	Bovine plasma
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 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 for at least 30 minutes (room temperature).
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.
   - 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.
- Distilled or deionised water.
- Standard laboratory equipment.

[a]Modification: new leaflet form.
[b]Modification: instrument added.

ABX Pentra Multical

Assigned Values [c]

The calibrator values were determined using the method mentioned in the enclosed annex.
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.
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.
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
AST	ERM-AD457 /IFCC
Albumin	ERM-DA470k
Amylase	IRMM/IFCC-456
Total Bilirubin	SRM916a
Total Protein	SRM927d
Calcium	SRM909c
Cholesterol	SRM909c Abell-Kendall
CK-NAC	ERM-AD455/IFCC
Creatinine	SRM967a
GGT	ERM-AD452/IFCC
Glucose PAP	SRM965b
Glucose HK	SRM965b
Iron	SRM909c
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
Direct Bilirubin	Primary reference material (weighed in purified material) Bilirubin ditaurate
Lactate	Primary reference material (weighed in purified material)
LDH	HORIBA Reagent/manual measurement; Epsilon of NADH
Lipase	HORIBA Reagent/manual measurement; Epsilon of methylresorufin
Phosphorus	Primary reference material (weighed in purified material) NERL

Storage and Stability

Stability before opening:

Stable up to the expiry date on the label if stored at 2-8°C.
Criterion for the stability data: Recovery within ±5% of initial value.

Stability after reconstitution:

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.

Waste Management

Please refer to local legal requirements.

[c]Modification: § assigned values changed.

ABX Pentra Multical

General Precautions [d]

- **ABX Pentra Multical** 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.
- 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.

[d]Modification: general precautions modification.