Clinical Chemistry

2023/10/12
A93A01307EEN

ABX Pentra ALT CP

REF A11A01627
REAGENT 1 56 mL
REAGENT 2 14 mL

IVD CE

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

- Pentra C400

Diagnostic reagent for quantitative *in vitro* determination of Alanine AminoTransferase (ALT) in serum or plasma by colorimetry.

Application Release

Serum, plasma: ALT

1.xx

Intended Use

ABX Pentra ALT CP reagent is intended for the quantitative *in vitro* diagnostic determination of Alanine AminoTransferase (ALT) in serum or plasma by colorimetry.
Alanine amino transferase measurements are used in the diagnosis and treatment of certain liver diseases (e.g., viral hepatitis and cirrhosis) and heart diseases.

Clinical Interest (1, 2)

Alanine Aminotransferase (ALAT/ALT), formerly called Glutamic Pyruvic Transaminase (GPT) and Aspartate Aminotransferase (ASAT/AST), formerly called Glutamic Oxalacetic Transaminase (GOT) are the most important representatives of a group of enzymes, the aminotransferases or transaminases, which catalyze the conversion of α-keto acids into amino acids by transfer of amino groups. As a liver specific enzyme ALT is only significantly elevated in hepatobiliary diseases. Increased AST levels, however, can occur in connection with damages of heart or skeletal muscle as well as of liver parenchyma. Parallel measurement of ALT and AST is therefore applied to distinguish liver from heart or skeletal muscle damages. The AST/ALT ratio is used for differential diagnosis in liver diseases. While ratios < 1 indicate mild liver damage, ratios > 1 are associated with severe, often chronic liver diseases.

Method (3, 4)

Optimized UV-test according to IFCC (International Federation of Clinical Chemistry) modified method without pyridoxal phosphate.

$$\text{L-Alanine} + \text{2-Oxoglutarate} \xleftrightarrow{\text{ALT}} \text{L-Glutamate} + \text{Pyruvate}$$

$$\text{Pyruvate} + \text{NADH} + \text{H}^+ \xleftrightarrow{\text{LDH}} \text{D-Lactate} + \text{NAD}^+$$

(ALT = Alanine Aminotransferase, LDH = Lactate Dehydrogenase)

Reagents

ABX Pentra ALT CP is ready-to-use.

Reagent 1:	
TRIS pH 7.15	140 mmol/L
L-Alanine	700 mmol/L
LDH (lactate dehydrogenase)	≥ 2300 U/L
Sodium azide	< 1 g/L

Reagent 2:	
2-Oxoglutarate	85 mmol/L
NADH	1 mmol/L
Sodium azide	< 1 g/L

ABX Pentra ALT CP should be used according to this notice. The manufacturer cannot guarantee its performance if used otherwise.

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Handling

1. Remove both caps of the cassette.
2. If present, remove foam by using a plastic pipette.
3. Place the cassette into the refrigerated Pentra C400 reagent compartment.

Calibrator

For calibration, use:
ABX Pentra Multical (A11A01652) (not included)
10 x 3 mL (lyophilisate)

Control [a]

For internal quality control, use:

- **ABX Pentra N MultiControl** (1300054414) (not included)
  10 x 5 mL (lyophilisate)
- **ABX Pentra P MultiControl** (1300054415) (not included)
  10 x 5 mL (lyophilisate)

Each control should be assayed daily and/or after a calibration.
The frequency of controls and the confidence intervals should correspond to laboratory guidelines and country-specific directives. You should follow federal, state and local guidelines for testing quality control materials. The results must be within the range of the defined confidence limits. Each laboratory should establish a procedure to follow if the results exceed these confidence limits.

Materials Required but not Provided [a]

- Automated clinical chemistry analyzer: Pentra C400
- Calibrator: **ABX Pentra Multical** (A11A01652)
- Controls:
  ABX Pentra N MultiControl (1300054414)
  ABX Pentra P MultiControl (1300054415)
- Standard laboratory equipment.

Specimen (5) [b]

This device intended testing population is general population.

Specimen types

- Serum.
- Plasma in lithium heparin.

Anticoagulants other than those listed have not been tested by HORIBA Medical and are therefore not recommended for use with this assay.

Stability

- At 20-25°C: 3 days
- At 4-8°C: 7 days
- At -20°C: 7 days

Reference Range (4) [c]

Each laboratory should establish its own reference ranges. The values given here are used as guidelines only.

Women: ≤ 34 U/L (37°C)
Men: ≤ 45 U/L (37°C)

Clinical sensitivity and specificity, positive predictive value and negative predictive value are not commonly reported for this analyte. This is largely attributed to the fact that this analyte is not sole indicator for the intended purpose and patient treatment decision making. To arrive at a diagnosis and a course of treatment, results from others routine clinical chemistry tests should be used in conjunction with other diagnostic information and the attending health-care professional's evaluation of the patient's condition.

Storage and Stability [d]

Stability before opening:

Stable up to the expiry date on the label if stored at 2-8°C. Store protected from light.

Stability after opening:

Refer to the paragraph "Performance on Pentra C400".

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[a]Modification: control removed.
[b]Modification: modification of "Specimen".
[c]Modification: information added.
[d]Modification: modification of storage and stability.

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Do not freeze.

Waste Management

- Please refer to local legal requirements.
- This reagent 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 [e]

- This reagent 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.
- **Reagent 1 (R1):**
  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 (6).
- Do not pipette by mouth.
- Do not replenish the reagents.
- Do not swallow. Avoid contact with skin and mucous membranes.
- Observe the standard laboratory precautions for use.
- The reagent cassettes are disposable and should be disposed of in accordance with the local legal requirements.
- Please refer to the SDS associated with the reagent.
- 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 Medical representative before attempting to operate the device.
- It is the user's responsibility to verify that this document is applicable to the reagent 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.

Performance on Pentra C400

Lot to Lot Variability [f]

The recovery of samples (serum and plasma) done during QC release of three consecutive lots of reagent shows that the lot to lot variability is within specification: < 10%.

Serum, plasma

The performance data listed below are representative of performance on HORIBA Medical Systems.

Number of tests: 250 tests
If the number of tests requested is low and the Pentra C400 user intends to utilise the cassette to the maximum on board stability, it is the recommendation of HORIBA Medical, to utilise the consumable part XEC232 (Kit membrane) to achieve the number of tests stated in this notice.

On Board Reagent Stability

Once opened, the reagent cassette placed in the refrigerated Pentra C400 compartment is stable for 42 days.

Sample volume: 20 µL/test

Detection Limit [g]

The detection limit is determined according to CLSI (NCCLS), EP17-A2 protocol (7) and equals 3.20 U/L.

Limit of Quantitation [h]

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A2 protocol (7) and equals 4.00 U/L.

Accuracy and Precision [i]

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (8) with samples tested 20 times:

- 2 controls
- 3 specimens (low / medium / high levels)

[e]Modification: general precautions modification.
[f]Modification: chapter added.
[g]Modification: modification of detection limit.
[h]Modification: data added.
[i]Modification: modification of accuracy and precision.

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	Mean value U/L	CV %
Control specimen 1	39.7	1.00
Control specimen 2	126.1	1.19
Specimen 1	17.4	3.07
Specimen 2	28.4	2.28
Specimen 3	127.9	0.59

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A2 protocol (9) with samples tested in duplicate for 20 days (2 series per day):

- 2 controls
- 2 specimens (medium / high levels)

	Mean value U/L	CV %
Control specimen 1	39.79	2.5
Control specimen 2	124.91	1.8
Specimen 1	31.49	6.0
Specimen 2	87.64	2.5

Measuring Range

The assay confirmed a measuring range from 4 U/L to 600 U/L.
The measuring range is extended up to 1800 U/L with the automatic post-dilution.
The reagent linearity has been assessed up to 600 U/L according to the recommendations found in the CLSI (NCCLS), EP06-Ed2 protocol (10).

Correlation [j]

Patient samples: Serum
Number of patient samples: 100
Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (11).
Values ranged from 6.4 U/L to 366.6 U/L.
The equation for the allometric line obtained using Passing-Bablok regression procedure (12) is:
Y = 0.9987 X + 4.869 (U/L)
with a correlation coefficient r^2 = 0.996.

Interferences [k]

Haemoglobin: No significant influence is observed up to 195 µmol/L (336 mg/dL).
Triglycerides: No significant influence is observed up to a triglyceride concentration of 5.50 mmol/L (481 mg/dL).
Total Bilirubin: No significant influence is observed up to 344 µmol/L (20.1 mg/dL).
Direct Bilirubin: No significant influence is observed up to 890 µmol/L (52.1 mg/dL).
The presence of Sulfasalazine or Sulfapyridine in sample can cause false results.

Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (13, 14).

Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 8 days.
Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.

Reference

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3. Bergmeyer HU, Horder M, Rej R. International Federation of Clinical Chemistry (IFCC) Scientific Committee, Analytical section: approved recommendation (1985) on IFCC methods for the measurement of catalytic concentration of enzymes. Part 3. IFCC method for alanine aminotransferase (L-alanine: 2-oxoglutarate aminotransferase, EC 2.6.1.2). J. Clin. Chem. Clin. Biochem. (1986) **24**: 481-495.
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5. Guder WG, Zawta B. The Quality of Diagnostics Samples. Samples: From the Patient to the Laboratory. 1st Ed. Guder WG, Narayanan S, Zawta B. (WHILEY-VCH, Darmstadt, Germany) (2001): 14.

[j]Modification: modification of correlation.
[k]Modification: modification of interferences.

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13. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th Edition, Washington, DC, AACC Press (2000).
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