Clinical Chemistry

2023/10/16
A93A01306DEN

REF A11A01626
REAGENT 1 26 mL
REAGENT 2 6.5 mL

IVD CE

HORIBA ABX SAS
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FRANCE

ABX Pentra ALP CP

Use in reagent rack

- **Pentra C400**

Diagnostic reagent for quantitative *in vitro* determination of Alkaline Phosphatase (ALP) in serum or plasma by colorimetry.

Application Release

Serum, plasma: ALP_R
1.xx

Intended Use

ABX Pentra ALP CP reagent is intended for the quantitative *in vitro* diagnostic determination of alkaline phosphatase in human serum and plasma based on a kinetic photometric test using p-Nitrophenylphosphate. Measurements of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

Clinical Interest (1, 2)

Alkaline phosphatase (ALP), an hydrolytic enzyme acting optimally at alkaline pH, exists in blood in numerous distinct forms which originate mainly from bone and liver, but also from other tissues as kidney, placenta, intestine, testes, thymus, lung and tumors. Physiological increases are found during bone growth in childhood and in pregnancy, while pathological increases are largely associated with hepatobiliary and bone diseases. In hepatobiliary disease they indicate obstruction of the bile ducts as in cholestasis caused by gall stones, tumors or inflammation. Elevated activities are also observed in infectious hepatitis. In bone diseases elevated ALP activities originate from increased osteoblastic activity as in Paget's disease, osteomalacia (rickets), bone metastases and hyperparathyroidism.

Method (3)

Kinetic photometric test, according to the International Federation of Clinical Chemistry (IFCC).

(ALP = Alkaline Phosphatase)

Reagents

ABX Pentra ALP CP is ready-to-use.

Reagent 1:	
2-Amino-2-methyl-1-propanol pH 10.4	440 mmol/L
Magnesium sulphate	2.0 mmol/L
Zinc sulphate	1.25 mmol/L
HEDTA	2.5 mmol/L
Sodium azide	< 1 g/L
Reagent 2:	
p-Nitrophenylphosphate	80 mmol/L
Sodium azide	< 1 g/L

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

Handling

1. Transfer the necessary volume of reagent R1 for a daily workload into a 15, 10 or 4 mL reagent vial.

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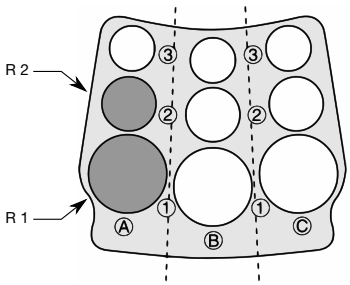
2. Transfer the necessary volume of reagent R2 for a daily workload into a 10 or 4 mL reagent vial.
   Reagent R1 and R2 should be placed on the same reagent rack sector A, B or C (see diagram below, sector A is taken as example).



3. Place reagent R1 in position 1 of one available sector.
   Please use one of the following:
   - a 15 mL reagent vial
   - a 10 mL reagent vial + a specific adaptor
   - a 4 mL reagent vial + a specific adaptor
4. Place reagent R2 in position 2 of the same selected sector.
   Please use one of the following:
   - a 10 mL reagent vial + a specific adaptor
   - a 4 mL reagent vial + a specific adaptor
5. If present, remove foam by using a plastic pipette.
6. Place the reagent rack into the refrigerated Pentra C400 reagent compartment.

Important note: Discard the remaining reagent at the end of the day.

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 [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 (4)

- At 20°C: loss of activity after 3 days: 3%
- At 4-8°C: 1 week

Reference Range [c]

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

Adults (37°C): (5)

Women 20 - 50 years	[U/L]	42 - 98
Men 20 - 50 years	[U/L]	53 - 128

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

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Women > 60 years	[U/L]	53 - 141
Men > 60 years	[U/L]	56 - 119

Children (37°C): (6)

		Female	Male
1 - 30 days	[U/L]	48 - 406	75 - 319
1 month - 1 year	[U/L]	124 - 341	82 - 383
1 - 3 year(s)	[U/L]	108 - 317	104 - 345
4 - 6 years	[U/L]	96 - 297	93 - 309
7 - 9 years	[U/L]	69 - 325	86 - 315
10 - 12 years	[U/L]	51 - 332	42 - 362
13 - 15 years	[U/L]	50 - 162	74 - 390
16 - 18 years	[U/L]	47 - 119	52 - 171

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

Stability before opening:

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

Stability after opening:

Refer to the paragraph "Performance on Pentra C400".

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 [d]

- 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.
- Do not swallow. Avoid contact with skin and mucous membranes.
- During reaction p-nitrophenol is produced which is poisonous when inhaled, swallowed or absorbed through skin. If the reaction mixture comes in contact with skin or mucous membranes wash copiously with water.
- 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 [e]

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: approximately 125 tests

[d]Modification: general precautions modification.
[e]Modification: chapter added.

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On Board Reagent Stability

Use fresh reagent each day. Discard the remaining reagent in container after use.
Once opened, the reagent cassette is stable for 29 days if closed immediately.

Sample volume: 4.0 µL/test

Detection Limit [f]

The detection limit is determined according to CLSI (NCCLS), EP17-A2 protocol (7) and equals 9.49 U/L.

Limit of Quantitation [g]

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A2 protocol (7) and equals 10 U/L.

Accuracy and Precision [h]

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)

	Mean value U/L	CV %
Control specimen 1	90.79	1.27
Control specimen 2	252.68	0.62
Specimen 1	28.05	3.98
Specimen 2	54.88	2.42
Specimen 3	430.87	0.84

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	90.79	3.6
Control specimen 2	254.38	2.4

	Mean value U/L	CV %
Specimen 1	64.11	4.4
Specimen 2	190.44	2.7

Measuring Range [i]

The assay confirmed a measuring range from 10 U/L to 1500 U/L.
The measuring range is extended up to 6000 U/L with the automatic post-dilution.
The reagent linearity has been assessed up to 1500 U/L according to the recommendations found in the CLSI (NCCLS), EP06-Ed2 protocol (10).

Correlation [j]

Patient samples: Serum
Number of patient samples: 129
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 10.3 U/L to 1477.2 U/L.
The equation for the allometric line obtained using Passing-Bablok regression procedure (12) is:
$Y = 1.085\ X - 6.816$ (U/L)
with a correlation coefficient $r^2 = 0.998$.

Interferences [k]

Haemoglobin: No significant influence is observed up to 195 µmol/L (314.15 mg/dL).
Triglycerides: No significant influence is observed up to a triglyceride concentration of 6.29 mmol/L (550.38 mg/dL).
Total Bilirubin: No significant influence is observed up to 470 µmol/L (27.5 mg/dL).
Direct Bilirubin: No significant influence is observed up to 254 µmol/L (14.9 mg/dL).

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 7 hours.

[f]Modification: modification of detection limit.
[g]Modification: data added.
[h]Modification: modification of accuracy and precision.
[i]Modification: modification of measuring range.
[j]Modification: modification of correlation.
[k]Modification: modification of interferences.

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Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.

Reference

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