Clinical Chemistry

2025/07/25
A93A01323HEN

ABX Pentra Uric Acid CP

REF A11A01670
REAGENT 1 60 mL
REAGENT 2 15 mL

IVD CE 2797

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

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

Diagnostic reagent for quantitative *in vitro* determination of Uric Acid in serum, plasma and urine by colorimetry.

Application Release

Serum, plasma: [a]

Pentra C400: UA
1.xx
ABX Pentra 400: UA
World wide except the USA: 4.xx
For the USA only: 2.xx

Urine: [a]

Pentra C400: UA-U
1.xx
ABX Pentra 400: UA-U
World wide except the USA: 3.xx
For the USA only: 2.xx

Intended Use [b c d]

ABX Pentra Uric Acid CP reagent is intended for the quantitative *in vitro* diagnostic determination of uric acid in human serum, plasma and urine based on the enzymatic determination of uric acid using a chromogenic system in the presence of peroxidase and uricase (Trinder method).
Clinical laboratories use.
Uric Acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.
Assessing the physiologic and pathologic variations of Uric Acid concentration in human serum, plasma and urine is useful for screening or follow-up of these diseases.

Clinical Interest (1, 2)

Uric acid is the final product of endogenic and exogenic (food origin) purine catabolism (adenosine and guanidine). This transformation takes place mainly in the liver. Approximatively 75% of uric acid is eliminated by kidneys, the rest is released in the gastro-intestinal tractus where it will be degraded by the intestinal flora. Uric acid is not very soluble in water; uratic microcrystals can form in the urines when the concentration is abnormally high. This phenomenal can also occur in the plasma, the microcrystals break up preferentially in joints causing painful inflammations (commonly known as gout). The increase of uric acid in the serum can result of several causes as: increase of purine production, metabolism disorders (Lesch-Nyhan syndrome for example), dietary troubles, increase of nuclear acid turn-over, particulary during tumoral cellular proliferation, leukaemias, psoriasis, cytostatic treatment, renal disorders... Thus, the uric acid determination is used in the diagnosis of all these pathologies and more generally, in the monitoring of renal attacks and metabolism troubles, such as renal deficiency, gout.
Seric hypouricaemia is more unusual. This decrease can be observed in differents cases as: defect of renal elimination (Fanconi syndrome), Hodgkin disease for example.

[a]Modification: application release modification.
[b]Modification: modification of Intended Use chapter.
[c]Modification: modification of CE mark.
[d]Modification: new leaflet form.

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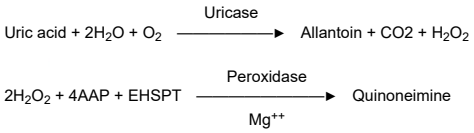
Method (3)

Enzymatic determination of uric acid using the following reactions (Trinder method):



(EHSPT = N-Ethyl-N-(2-Hydroxy-3-Sulfopropyl) n-Toluidine, 4 AAP = 4-aminoantipyrine)

Reagents

ABX Pentra Uric Acid CP is ready-to-use.

Reagent 1:	
Phosphate buffer pH 7.00	125 mmol/L
EHSPT	1.38 mmol/L
Ascorbate oxidase	≥ 1100 U/L
Bovine albumin	0.2%
Sodium azide	< 0.1%

Reagent 2:	
4-aminoantipyrine	1.8 mmol/L
Uricase	≥ 700 U/L
Peroxidase	≥ 7500 U/L
Ferrocyanide	250 µmol/L
Bovine albumin	0.2%
Sodium azide	< 0.1%

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

Handling

1. Remove both caps of the cassette.
2. If present, remove foam by using a plastic pipette.

Calibrator

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

Control

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)
- **Yumizen C Urine Level 1 Control** (1300023946) (not included)
  6 x 5 mL
- **Yumizen C Urine Level 2 Control** (1300023947) (not included)
  6 x 5 mL

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

- Automated clinical chemistry analyzer: ABX Pentra 400 / Pentra C400
- Calibrator: **ABX Pentra Multical** (A11A01652)
- Controls:
  ABX Pentra N MultiControl (1300054414)
  ABX Pentra P MultiControl (1300054415)
  Yumizen C Urine Level 1 Control (1300023946)
  Yumizen C Urine Level 2 Control (1300023947)
- Standard laboratory equipment.

Specimen (4, 5)

This device intended testing population is general population.

Specimen types

- Serum.
- Plasma in lithium heparin.
- Fresh centrifuged urine.

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

Stability

Serum, plasma (4)

- At room temperature: 3 days

Urine (5)

- At 20-25°C: 4 days if pH > 8.0

Reference Range (6, 7)

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

Serum, plasma (6)

Women

26 - 60 mg/L

2.6 - 6 mg/dL

155 - 357 µmol/L

Men

35 - 72 mg/L

3.5 - 7.2 mg/dL

208 - 428 µmol/L

***Urine* (average diet)** (7)

250 - 750 mg/24h

1480 - 4430 µmol/24h

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 ABX Pentra 400 / Pentra C400".

Waste Management [e]

- Please refer to local legal requirements.
- This reagent contains less than 0.1% of sodium azide as a preservative.

General Precautions

- 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 and 2 (R1 and R2):**
  Danger
  H360FD: May damage fertility. May damage the unborn child.
  P280: Wear protective gloves/protective clothing/eye protection/face protection.
  P202: Do not handle until all safety precautions have been read and understood.
  P308 + P313: IF exposed or concerned: Get medical advice/attention.
  Reagent 1 (R1):
  Contains: decahydrate dissodium tetraborate
  Reagent 2 (R2):
  Contains: boric acid
- **Reagent 1 and 2 (R1 and R2):**
  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 (8).
- Do not replenish the reagents.
- Do not swallow. Avoid contact with skin and mucous membranes.
- Observe the standard laboratory precautions for use.

[e]Modification: modification of waste management.

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- 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.
- It is the user's responsibility to verify that this document is applicable to the reagent used.
- 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.
- 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 ABX Pentra 400 / Pentra C400

Lot to Lot Variability

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: < 8%.

Serum, plasma

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

Number of tests: 220 tests
If the number of tests requested is low and the ABX Pentra 400 / Pentra C400 user intends to utilise the cassette to the maximum on board stability, it is the recommendation of HORIBA, 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 ABX Pentra 400 / Pentra C400 compartment is stable for 41 days.

Sample volume: 5.0 µL/test

Detection Limit

The detection limit is determined according to CLSI (NCCLS), EP17-A2 protocol (9) and equals 9.07 µmol/L (0.15 mg/dL).

Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A2 protocol (9) and equals 17.13 µmol/L (0.29 mg/dL).

Accuracy and Precision

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (10) with samples tested 20 times:

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

	Mean value µmol/L	Mean value mg/dL	CV %
Control specimen 1	274.7	4.62	0.45
Control specimen 2	692.1	11.63	0.34
Specimen 1	150.8	2.53	1.24
Specimen 2	272.8	4.58	0.91
Specimen 3	428.2	7.19	1.02

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A2 protocol (11) with samples tested in duplicate for 20 days (2 series per day):

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

	Mean value µmol/L	Mean value mg/dL	CV %
Control specimen 1	276.0	4.64	2.8
Control specimen 2	698.4	11.73	1.4
Specimen 1	277.7	4.67	2.6
Specimen 2	401.0	6.74	2.5

Measuring Range

The assay confirmed a measuring range from 18 µmol/L (0.30 mg/dL) to 1487 µmol/L (25.0 mg/dL).
The measuring range is extended up to 4461 µmol/L (75.0 mg/dL) with the automatic post-dilution.
The reagent linearity has been assessed up to 1487 µmol/L (25 mg/dL) according to the recommendations found in the CLSI (NCCLS), EP06-Ed2 protocol (12).

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Correlation

Patient samples: Serum
Number of patient samples: 131
Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (13).
Values ranged from 25 µmol/L (0.42 mg/dL) to 1426 µmol/L (23.96 mg/dL).
The equation for the allometric line obtained using Passing-Bablok regression procedure (14) is:
Y = 0.9644 x + 3.333 (µmol/L)
Y = 0.9644 x + 0.056 (mg/dL)
with a correlation coefficient r^2 = 0.996.

Interferences

Haemoglobin:	No significant influence is observed up to 290 µmol/L (500 mg/dL).
Triglycerides:	Do not use lipemic samples.
Total Bilirubin:	No significant influence is observed up to 615 µmol/L (36.0 mg/L).
Direct Bilirubin:	No significant influence is observed up to 513 µmol/L (30.0 mg/dL).
N-Acetylcysteine (NAC):	No significant influence is observed up to 275 mg/L (0.28 mg/mL). Patients treated with N-Acetylcysteine (NAC) for Paracetamol overdose may generate a false low result.

The presence of N-Acetylbenzoquinoneimine (NAPQI) in serum/plasma can cause false results.

Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (15, 16).

Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 14 days.
Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.

Conversion Factor

µmol/L x 0.168 = mg/L
µmol/L x 0.0168 = mg/dL

Urine

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

Number of tests: 220 tests

If the number of tests requested is low and the ABX Pentra 400 / Pentra C400 user intends to utilise the cassette to the maximum on board stability, it is the recommendation of HORIBA, 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 ABX Pentra 400 / Pentra C400 compartment is stable for 41 days.

Sample volume: 5.0 µL/test

Detection Limit

The detection limit is determined according to CLSI (NCCLS), EP17-A protocol (17) and equals 207.56 µmol/L (3.49 mg/dL).

Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A protocol (17) and equals 310 µmol/L (5.2 mg/dL).

Accuracy and Precision

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (10) with samples tested 20 times:

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

	Mean value µmol/L	Mean value mg/dL	CV %
Control specimen 1	712	11.96	2.45
Control specimen 2	484	8.13	3.01
Specimen 1	486	8.16	3.26
Specimen 2	1520	25.53	2.19
Specimen 3	3662	61.52	0.78

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A2 protocol (11) with samples tested in duplicate for 20 days (2 series per day):

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

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	Mean value µmol/L	Mean value mg/dL	CV %
Control specimen 1	724	12.17	4.1
Control specimen 2	530	8.91	4.4
Specimen 1	1565	26.29	2.8
Specimen 2	3806	63.94	2.4

Measuring Range

The assay confirmed a measuring range from 310 µmol/L (5.20 mg/dL) to 15000 µmol/L (252 mg/dL).
The measuring range is extended up to 45000 µmol/L (756 mg/dL) with the automatic post-dilution.
The reagent linearity has been assessed up to 15000 µmol/L (252 mg/dL) according to the recommendations found in the CLSI (NCCLS), EP06-Ed2 protocol (12).

Correlation

Patient samples: urine
Number of patient samples: 113
Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (13).
Values ranged from 314 µmol/L (5.28 mg/dL) to 14808 µmol/L (248.77 mg/dL).
The equation for the allometric line obtained using Passing-Bablok regression procedure (14) is:
Y = 1.004 x + 11.03 (µmol/L)
Y = 1.004 x + 0.185 (mg/dL)
with a correlation coefficient r^2 = 0.996.

Interferences

Haemoglobin: No significant influence is observed up to 290 µmol/L (500 mg/dL).
Direct Bilirubin: No significant influence is observed up to 576 µmol/L (33.7 mg/dL).
Ascorbic Acid: No significant influence is observed up to 350 µmol/L (6.16 mg/dL).
Specific gravity: In the range of 1.005 to 1.035, no significant influence is observed.

Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (15, 16).

Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 14 days.
Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.

Conversion Factor:

µmol/L x 0.168 = mg/L
µmol/L x 0.0168 = mg/dL

Reference

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17. Protocols for determination of limits of detection and limits of quantitation. Approved Guideline, CLSI (NCCLS) document EP17-A (2004) **24** (34).