Clinical Chemistry

2025/07/01
A93A01233HEN

# 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
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34184 Montpellier Cedex 4
FRANCE

- Pentra C200

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

## Application Release

**Serum, plasma: UA**

01.xx

**Urine: UA**

01.xx

## Intended Use [a] [b] [c]

**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.

## Method (3)

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

$$\text{Uric acid} + 2H_2O + O_2 \xrightarrow{\text{Uricase}} \text{Allantoin} + CO2 + H_2O_2$$

$$2H_2O_2 + 4AAP + EHSPT \xrightarrow[Mg^{++}]{\text{Peroxidase}} \text{Quinoneimine}$$

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

# ABX Pentra Uric Acid CP

(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: Pentra C200
- 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.

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

# ABX Pentra Uric Acid CP

**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 Pentra C200".

## Waste Management [d]

- 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.
- 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.

[d]Modification: modification of waste management.

# ABX Pentra Uric Acid CP

- 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 Pentra C200

### 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 have been obtained on the Pentra C200 analyzer.

**Number of tests:** approximately 271 tests

### On Board Reagent Stability

Once opened, the reagent cassette placed in the refrigerated Pentra C200 compartment is stable for 48 days.

**Sample volume:** 5 µL/test

### Detection Limit

The detection limit is determined according to CLSI (NCCLS), EP17-A protocol (9) and equals 3.71 µmol/L (0.06 mg/dL).

### Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A2 protocol (10) and equals 18 µmol/L (0.30 mg/dL).

### Accuracy and Precision

#### *Repeatability (within-run precision)*

Repeatability according to the recommendations found in the Valtec protocol (11) 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 | 296.7 | 4.98 | 0.71 |
| Control specimen 2 | 664.5 | 11.16 | 0.52 |
| Specimen 1 | 153.8 | 2.58 | 0.54 |
| Specimen 2 | 305.5 | 5.13 | 0.72 |
| Specimen 3 | 448.1 | 7.53 | 0.66 |

#### *Reproducibility (total precision)*

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A2 protocol (12) with samples tested in duplicate for 20 days (2 series per day):

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

| | Mean value µmol/L | Mean value mg/dL | CV % |
|---|---|---|---|
| Control specimen 1 | 298.6 | 5.02 | 1.1 |
| Control specimen 2 | 662.1 | 11.12 | 2.8 |
| Specimen 1 | 151.6 | 2.55 | 1.6 |
| Specimen 2 | 302.0 | 5.07 | 1.3 |
| Specimen 3 | 444.2 | 7.46 | 1.7 |

### Measuring Range

The assay confirmed a measuring range from 18 µmol/L (0.30 mg/dL) to 1400 µmol/L (23.52 mg/dL).
The measuring range is extended up to 4200 µmol/L (70.56 mg/dL) with the automatic post-dilution.
The reagent linearity has been assessed up to 1400 µmol/L (23.52 mg/dL) according to the recommendations found in the CLSI (NCCLS), EP06-Ed2 protocol (13).

### Correlation

Patient samples: Serum
Number of patient samples: 123
Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (14).
Values ranged from 48.21 µmol/L (0.81 mg/dL) to 1394.08 µmol/L (23.42 mg/dL).
The equation for the allometric line obtained using Passing-Bablok regression procedure (15) is:
Y = 0.9807 x + 5.455 (µmol/L)
Y = 0.9807 x + 0.091 (mg/dL)
with a correlation coefficient $r^2$ = 0.998.

# ABX Pentra Uric Acid CP

### Interferences

| | |
|---|---|
| Haemoglobin: | No significant influence is observed up to 300 µmol/L (517 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 250 µmol/L (14.6 mg/L). |
| Direct Bilirubin: | No significant influence is observed up to 70 µmol/L (4.1 mg/dL). |
| N-Acetylcysteine (NAC): | 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 (16, 17).*

### Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 25 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 have been obtained on the Pentra C200 analyzer.

**Number of tests:** approximately 271 tests

### On Board Reagent Stability

Once opened, the reagent cassette placed in the refrigerated Pentra C200 compartment is stable for 48 days.

**Sample volume:** 5 µL/test

### Detection Limit

The detection limit is determined according to CLSI (NCCLS), EP17-A protocol (9) and equals 44.85 µmol/L (0.75 mg/dL).

### Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A protocol (9) and equals 323 µmol/L (5.43 mg/dL).

### Accuracy and Precision

#### *Repeatability (within-run precision)*

Repeatability according to the recommendations found in the Valtec protocol (11) 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 | 537 | 9.02 | 2.60 |
| Control specimen 2 | 1022 | 17.16 | 2.29 |
| Specimen 1 | 563 | 9.45 | 2.74 |
| Specimen 2 | 1471 | 24.71 | 2.06 |
| Specimen 3 | 3950 | 66.37 | 1.84 |

#### *Reproducibility (total precision)*

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A2 protocol (12) with samples tested in duplicate for 20 days (2 series per day):

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

| | Mean value µmol/L | Mean value mg/dL | CV % |
|---|---|---|---|
| Control specimen 1 | 557 | 9.4 | 3.6 |
| Control specimen 2 | 1031 | 17.3 | 3.1 |
| Specimen 1 | 557 | 9.4 | 3.2 |
| Specimen 2 | 1485 | 24.9 | 5.0 |
| Specimen 3 | 3951 | 66.4 | 3.9 |

### Measuring Range

The assay confirmed a measuring range from 323 µmol/L (5.43 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 (13).

### Correlation

Patient samples: urine
Number of patient samples: 105

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Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (14).
Values ranged from 343 µmol/L (5.76 mg/dL) to 13184 µmol/L (221.49 mg/dL).
The equation for the allometric line obtained using Passing-Bablok regression procedure (15) is:
Y = 0.992 x + 27.04 (µmol/L)
Y = 0.992 x + 0.454 (mg/dL)
with a correlation coefficient $r^2$ = 0.989.

**Interferences**

| | |
|---|---|
| Haemoglobin: | No significant influence is observed up to 400 µmol/L (690 mg/dL). |
| Direct Bilirubin: | No significant influence is observed up to 395 µmol/L (23.1 mg/dL). |
| Ascorbic Acid: | No significant influence is observed up to 3.40 mmol/L (59.9 mg/dL). |
| pH: | Acidification or alcalinisation do not interfere with this test. |

*Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (16, 17).*

**Calibration Stability**

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 25 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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