ABX Pentra
Uric Acid CP

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

2007/07/02
A93A00282K EN

REF A11A01670

REAGENT 1 60 ml

REAGENT 2 15 ml

IVD CE

HORIBA ABX
BP 7290
34184 Montpellier- cedex 4 - France

Clinical Interest

Uric acid is a waste product resulting from hepatic synthesis. It also emerges from the degradation of nucleic acids of dietary and cellular origin. The kidney and the intestines assure its decomposition. Biologically, uric acid is not a constant value, and its level varies according to the diet.
Hyperuricaemia is present in the origin of the development of urate thesaurismosis, commonly known as gout, which causes articular inflammations following the precipitation of uratic microcrystals, as well as renal disorders.
Hyperuricaemias may be primitive, linked to enzymatic deficiencies innate to the metabolism (malnutrition, ethnic and inherited factors), or secondary, resulting from an excess of production or a defect of renal elimination (renal calculus, leukaemias, cancer treatment, nutritional defects, alcoholism).

Method

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

$$\text{Uric acid} + 2H_2O + O_2 \xrightarrow{\text{Uricase}} \text{Allantoin} + CO_2 + H_2O_2$$

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

(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	≥ 7,500 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 reagent notice. HORIBA ABX cannot guarantee its performance if used otherwise.

Handling

Remove the caps of the cassette, place in the refrigerated ABX Pentra 400 reagent compartment.
If present, remove foam by using a plastic pipette.

Calibrator

For calibration, use:
ABX Pentra MultiCal, Ref. A11A01652 (not included)
10 x 3 ml (lyophilisate)

Control

For internal quality control, use:
ABX Pentra N Control, Ref. A11A01653 (not included)
10 x 5 ml (lyophilisate)
ABX Pentra P Control, Ref. A11A01654 (not included)
10 x 5 ml (lyophilisate)
ABX Pentra Urine Control L/H, Ref. A11A01674 (not included)
1 x 10 ml + 1 x 10 ml

Each control should be assayed daily and/or after each calibration.
The frequency of controls and the confidence intervals should correspond to laboratory guidelines and country-specific directives. 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 analyser
- Standard laboratory equipment

Latest version documents on www.horiba-abx.com

ABX Pentra
Uric Acid CP

Specimen
- Serum
- Plasma in heparin
- Fresh centrifuged urine

Reference range(8)

Serum, plasma: **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: 250 - 750 mg/24h
1500 - 4500 µmol/24h

We recommended that each laboratory establishes its own reference range.

Storage and Stability
Reagents, in unopened cassettes, are stable up to the expiry date on the label if stored at 2-8° C and protected from light.
Stability after opening: refer to the paragraph "Performance on ABX Pentra 400".

Assay Procedure
Test instructions for automated systems other than ABX Pentra 400 are available on request.

Waste Management
1. Please refer to local legal requirements.
2. These reagents contain less than 0.1 % of sodium azide as a preservative. As sodium azide may react with lead and copper to form explosive metal azides, these reagents should be disposed of by flushing with copious amounts of water.

General Precautions
1. Reagent, for professional *in-vitro* diagnostic use only.
2. Gently agitate any turbid reagents before use.
3. The reagent cassettes are disposable and should be disposed of in accordance with the local legal requirements.
4. Please refer to the MSDS associated with the reagent.

Performance on ABX Pentra 400
The performance data listed below have been obtained on the ABX Pentra 400 analyser.

Serum, Plasma

Number of tests: 220 tests.

On board Reagent Stability:
Once opened, the reagent cassette placed in the refrigerated ABX Pentra 400 compartment is stable for 41 days.

Sample volume: 5 µl/test

Detection limit:
The detection limit is determined according to the Valtec protocol (4) and equals 11.4 µmol/l.

Accuracy and Precision:
- Repeatability (within-run precision)

3 specimens of low, medium and high concentration and 2 controls are tested 20 times according to the recommendations found in the Valtec protocol (4).

	Mean value µmol/l	CV %
Normal control	275	0.5
Pathological control	692	0.3
Specimen 1	150.5	1.2
Specimen 2	272.5	0.9
Specimen 3	427.8	1

- Reproducibility (run-to-run precision)

2 specimens of low and high levels and 2 controls are tested in duplicate for 20 days (2 series per day) according to the recommendations found in the NCCLS, EP5-A protocol (5).

	Mean value µmol/l	CV %
Normal control	275.9	2.78
Pathological control	698.1	1.38
Specimen 1	277.6	2.63
Specimen 2	400.9	2.49

Linearity and Measuring Range:
The reagent linearity is determined according to the recommendations found in the NCCLS, EP6-P protocol (6).
Low linearity: 11.4 µmol/l
High linearity: 1480 µmol/l, with automatic post-dilution: 4440 µmol/l.

Correlation:
100 patient samples are correlated with a commercial reagent taken as reference according to the recommendations found in the NCCLS, EP9-A2 protocol (7).
The equation for the allometric line obtained is:
Y = 1.07 x - 21.6 with a correlation coefficient r = 0.998.

Interferences:

Haemoglobin: No significant influence is observed up to 290 µmol/l
Triglycerides: No significant influence is observed up to 7 mmol/l
Total Bilirubin: No significant influence is observed up to 616 µmol/l
Direct Bilirubin: No significant influence is observed up to 513 µmol/l

Conversion factor:
µmol/l x 0.168 = mg/l
µmol/l x 0.0168 = mg/dl

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

The calibration stability is at least 15 days.

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

Application release[a]: 4.xx

Urine

Number of tests: 220 tests.

On board Reagent Stability:
Once opened, the reagent cassette placed in the refrigerated ABX Pentra 400 compartment is stable for 41 days.

Sample volume: 5 µl/test

Detection limit:
The detection limit is determined according to the Valtec protocol (4) and equals 113 µmol/l.

Accuracy and Precision:
• Repeatability (within-run precision)
3 specimens of low, medium and high concentration and 1 control are tested 20 times according to the recommendations found in the Valtec protocol (4).

	Mean value µmol/l	**CV %**
Normal control	712	2.4
Pathological control	484	3.0
Specimen 1	486	3.3
Specimen 2	1517	2.2
Specimen 3	3660	0.8

• Reproducibility (run-to-run precision)
2 specimens of low and high levels and 1 control are tested in duplicate for 20 days (2 series per day) according to the recommendations found in the NCCLS, EP5-A protocol (5).

	Mean value µmol/l	**CV %**
Normal control	724	4.13
Pathological control	530	4.36
Specimen 1	1565	2.84
Specimen 2	3804	2.41

Linearity and Measuring Range:
The reagent linearity is determined according to the recommendations found in the NCCLS, EP6-P protocol (6).
Low linearity: 113 µmol/l
High linearity: 14875 µmol/l, with automatic post-dilution: 44625 µmol/l.

a.Modification from index J to K: suppression of minor index.

Correlation:
100 patient samples are correlated with a commercial reagent taken as reference according to the recommendations found in the NCCLS, EP9-A2 protocol (7).
The equation for the allometric line obtained is:
Y = 0.97 x + 37.2 with a correlation coefficient r = 0.999.

Conversion factor:
µmol/l x 0.168 = mg/l
µmol/l x 0.0168 = mg/dl

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

The calibration stability is at least 15 days.

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

Application release[b]: 3.xx

Warning
It is the user's responsibility to verify that this document is applicable to the reagent used.

Reference
1. Mazières B., Physiopathologie des hyperuricémies, Rev. Prat., **33**, 43, (1983), 2231-2241.
2. Fossati,P., Prencipe,L. et Berti, G. Use of 3,5-dichloro-2-hydroxy-benzenesulfonic acid 4-aminophenazone chromogenic system in direct enzymatic assay of uric acid in serum and urine. Clin.Chem. 1980,**26**,227.
3. Tietz. Fundamentals of Clinical Chemistry.Chap.22.425-426(2001).
4. Vassault A., Grafmeyer D. Naudin C. et al., Protocole de validation de techniques (document B), Ann. Biol. Clin., 1986, **44**, 686-745.
5. Evaluation of Precision Performance of Clinical Chemistry Devices, Approved Guideline, NCCLS document EP5-A, Vol. 19, No. 2, february 1999.
6. Evaluation of the Linearity of Quantitative Analytical Methods, Proposed Guideline, NCCLS document EP6-P, Vol. 6, No. 18, september 1986.
7. Method Comparison and Bias Estimation Using Patient Samples, Approved Guideline, 2nd ed., NCCLS document EP9-A2, Vol. 22, No. 19, 2002.
8. Tietz, N.W. Clinical guide to laboratory tests, 3rd Ed, (W.B. Saunders eds. Philadelphia USA), (1995), 624.

b.Modification from index J to K: suppression of minor index.

ABX Pentra

Uric Acid CP