Clinical Chemistry

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REF 1300141449
REAGENT 1 2 x 37 mL
REAGENT 2 2 x 11 mL

IVD CE 2797

HORIBA ABX SAS
Parc Euromédecine
Rue du Caducée
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FRANCE

# Yumizen C Uric Acid

- **Yumizen C230**
- **Yumizen C240**

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

## Intended Use

**Yumizen C Uric Acid** 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):

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

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

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

## Reagents

**Yumizen C Uric Acid** 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 |

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| **Reagent 2:** | |
|---|---|
| Peroxidase | ≥ 7500 U/L |
| Ferrocyanide | 250 µmol/L |
| Bovine albumin | 0.2% |
| Sodium azide | < 0.1% |

**Yumizen C Uric Acid** should be used according to this notice. The manufacturer cannot guarantee its performance if used otherwise.

## Handling

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

## 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: Yumizen C230/C240
- 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.

### 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 |

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**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 Yumizen C230/C240".

## Waste Management

- 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.
- 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 Yumizen C230/C240

***Serum, plasma***

The performance data listed below have been obtained on the Yumizen C230/C240 analyzer.

**Number of tests:** approximately 2 x 238 tests

# Yumizen C Uric Acid

### On Board Reagent Stability

Once opened, the reagent cassette placed in the refrigerated Yumizen C230/C240 compartment is stable for 48 days.

**Sample volume:** 5 µL/test

### Lowest Detectable Level

The lowest detectable level represents the lowest measurable level of analyte that can be distinguished from zero. It is calculated as the absolute mean plus three standard deviations of 20 replicates of an analyte free sample. The lowest detectable level is estimated at 1.05 µmol/L (0.02 mg/dL).

### Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A2 protocol (9) and equals 10 µmol/L (0.2 mg/dL).

### Accuracy and Precision

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

Repeatability according to the recommendations found in the CLSI (NCCLS), EP05-A3 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 | 326.50 | 5.49 | 0.8 |
| Control specimen 2 | 638.83 | 10.73 | 0.7 |
| Specimen 1 | 154.34 | 2.59 | 0.7 |
| Specimen 2 | 289.77 | 4.87 | 0.7 |
| Specimen 3 | 450.60 | 7.57 | 0.6 |

#### *Reproducibility (total precision)*

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP05-A3 protocol (10) 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 | 336.71 | 5.66 | 1.8 |
| Control specimen 2 | 658.11 | 11.06 | 1.6 |
| Specimen 1 | 158.89 | 2.67 | 1.6 |
| Specimen 2 | 301.12 | 5.06 | 1.6 |
| Specimen 3 | 461.62 | 7.76 | 1.6 |

### Measuring Range

The assay confirmed a measuring range from 10 µmol/L (0.2 mg/dL) to 1300 µmol/L (21.8 mg/dL).
The measuring range is extended up to 5200 µmol/L (87.4 mg/dL) with the automatic post-dilution.
The reagent linearity has been assessed up to 1300 µmol/L (21.8 mg/dL) according to the recommendations found in the CLSI (NCCLS), EP06-Ed2 protocol (11).

### Correlation

Patient samples: Serum
Number of patient samples: 106
Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (12).
Values ranged from 21 µmol/L (0.4 mg/dL) to 1278 µmol/L (21.5 mg/dL).
The equation for the allometric line obtained using Passing-Bablok regression procedure (13) is:
Y = 0.9858 X + 6.129 (µmol/L)
Y = 0.9858 X + 0.103 (mg/dL)
with a correlation coefficient $r^2$ = 0.998.

### Interferences

Haemoglobin: No significant influence is observed up to 579 µmol/L (1000 mg/dL).
Triglycerides: No significant influence is observed up to a triglyceride concentration of 23.93 mmol/L (2093.88 mg/dL).
Total Bilirubin: No significant influence is observed up to 297.25 µmol/L (17.39 mg/L).
Direct Bilirubin: No significant influence is observed up to 175.23 µmol/L (10.25 mg/dL).

*Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (14, 15).*

### Calibration Stability

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

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The calibration stability is 24 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 Yumizen C230/C240 analyzer.

**Number of tests:** approximately 2 x 238 test

### On Board Reagent Stability

Once opened, the reagent cassette placed in the refrigerated Yumizen C230/C240 compartment is stable for 48 days.

**Sample volume:** 5 µL/test

### Lowest Detectable Level

The lowest detectable level represents the lowest measurable level of analyte that can be distinguished from zero. It is calculated as the absolute mean plus three standard deviations of 20 replicates of an analyte free sample. The lowest detectable level is estimated at 14.00 µmol/L (0.24 mg/dL).

### Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A2 protocol (9) and equals 100 µmol/L (1.7 mg/dL).

### Accuracy and Precision

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

Repeatability according to the recommendations found in the CLSI (NCCLS), EP05-A3 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 | 474.11 | 7.97 | 1.2 |
| Control specimen 2 | 868.00 | 14.58 | 1.1 |

| | Mean value µmol/L | Mean value mg/dL | CV % |
|---|---|---|---|
| Specimen 1 | 534.91 | 8.99 | 1.2 |
| Specimen 2 | 1562.75 | 26.25 | 1.0 |
| Specimen 3 | 4121.71 | 69.24 | 1.0 |

#### *Reproducibility (total precision)*

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP05-A3 protocol (10) 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 | 506.10 | 8.50 | 2.0 |
| Control specimen 2 | 912.45 | 15.33 | 2.1 |
| Specimen 1 | 528.01 | 8.87 | 2.8 |
| Specimen 2 | 1663.64 | 27.95 | 2.2 |
| Specimen 3 | 3970.44 | 66.70 | 1.7 |

### Measuring Range

The assay confirmed a measuring range from 100 µmol/L (1.7 mg/dL) to 15000 µmol/L (252.0 mg/dL).
The measuring range is extended up to 60000 µmol/L (1008 mg/dL) with the automatic post-dilution.
The reagent linearity has been assessed up to 15000 µmol/L (252.0 mg/dL) according to the recommendations found in the CLSI (NCCLS), EP06-Ed2 protocol (11).

### Correlation

Patient samples: urine
Number of patient samples: 112
Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (12).
Values ranged from 140 µmol/L (2.4 mg/dL) to 13472 µmol/L (226.3 mg/dL).
The equation for the allometric line obtained using Passing-Bablok regression procedure (13) is:
Y = 1.003 X + 17.45 (µmol/L)
Y = 1.003 X + 0.29 (mg/dL)
with a correlation coefficient $r^2$ = 0.997.

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**Interferences**

| | |
|---|---|
| Haemoglobin: | No significant influence is observed up to 579 µmol/L (1000 mg/dL). |
| Triglycerides: | No significant influence is observed up to a triglyceride concentration of 21.95 mmol/L (1920.63 mg/dL). |
| Direct Bilirubin: | No significant influence is observed up to 660.70 µmol/L (38.65 mg/dL). |

*Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (14, 15).*

**Calibration Stability**

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 24 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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