**INTENDED USE**

This reagent is designated for professional use in laboratory (manual or automated method).

It allows the quantification of uric acid in human serum and plasma or urines.

**GENERALITIES** (1) (2)

In humans, uric acid is the major product of the catabolism of the purine nucleosides, adenosine and guanosine.

**PRINCIPLE** (1) (3)

Uricase acts on uric acid to produce allantoin, carbon dioxide and hydrogen peroxide. Hydrogen peroxide in the presence of peroxidase reacts with a chromogen (amino-antipyrine and dichloro-hydroxybenzene sulfonate) to yield quinonimine, a red coloured complex.

| The absorbance measured at 505 nm (495-505) is proportional to the amount of uric acid in the specimen. |

**REAGENTS**

| **R1** | **URIC ACID** | Enzymes

Potassium hexacyanoferrate (II) | 42 µmol/L

Peroxidase | ≥ 450 U/L

Amino-antipyrine | 0.150 mmol/L

Uricase | ≥ 120 U/L

According to 1272/2008 regulation, this reagent is not classified as dangerous |

| **R2** | **URIC ACID** | Buffer

Dichloro-hydroxybenzene Sulfonate | 2 mmol/L

Tris pH 8.0 at 25°C | 50 mmol/L

Preservative

According to 1272/2008 regulation, this reagent is not classified as dangerous |

| **R3** | **URIC ACID** | Standard

Uric acid 10 mg/dL (595 µmol/L)

**ATTENTION:** Flam. Liq.1: H226 Flammable liquid and vapor


Classification due to: Ethanol 10 - < 25%

For more details, see Safety Data Sheet (SDS)

**SAFETY CAUTIONS**

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.
- Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

**REAGENTS PREPARATION**

Use a non-sharp instrument to remove aluminium cap.

Add promptly the contents of vial R1 into vial R2.

Mix gently until complete dissolution.

Vial R3: Ready for use

**STABILITY AND STORAGE**

Stored away from light, well cap in the original vial at 2-8°C, reagents are stable when stored and used as described in the insert:

Unopened,

- Until the expiry date stated on the label of the Kit.

Once opened:

- Reconstitute immediately substrate (vial R1)

Once reconstituted:

- Transfer requested quantity and store in the original vial at 2-8°C.

- Working reagent is stable at least 1 month.

- Discard any reagent if cloudy or if absorbance at 505 nm > 0.100.

- Don’t use working reagent after expiry date stated on the label.

**SPECIMEN COLLECTION AND HANDLING** (4)

Unhemolysed serum or plasma (Heparin or EDTA).

Urines: diluted (1+9) in demineralised water before assay.

Uric acid is stable in the specimen for:

- 3 days at room temperature.

- 1 week at 2-8°C.

- 6 months when freeze at – 20°C.

Add NaOH to keep urine alkaline and to prevent uric acid precipitation.

**LIMITS** (3) (5)

Patient under vitamin C therapy: In order to reduce acid ascorbic interference, let stand specimen 2 hours at room temperature before performing the assay.

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

**MATERIAL REQUIRED BUT NOT PROVIDED**

1. Basic medical analysis laboratory equipment.
   2. Spectrophotometer or Biochemistry Clinical Analyzer
QUALITY CONTROL

- 95010 EXATROL-N Level I
- 95011 EXATROL-P Level II
- External quality control program
It is recommended to control in the following cases:
- At least once a run.
- At least once between 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.
If control is out of range, apply following actions:
1. Prepare a fresh control serum and repeat the test.
2. If control is still out of range, use a new vial of calibrator or a fresh calibrator and repeat the test.
3. If control is still out of range, repeat the tests with a new vial of reagent.
If control is still out of range, please contact BIOLABO technical support or your local Agent.

EXPECTED VALUES (4)

<table>
<thead>
<tr>
<th>Serum or plasma</th>
<th>mg/dL</th>
<th>[µmol/L]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child(∗)</td>
<td>2.0-5.5</td>
<td>[119-327]</td>
</tr>
<tr>
<td>Men</td>
<td>3.5-7.2</td>
<td>[208-428]</td>
</tr>
<tr>
<td>Women(∗∗)</td>
<td>2.6-6.0</td>
<td>[155-357]</td>
</tr>
<tr>
<td>Urines</td>
<td>250-750 mg/24h</td>
<td>[1.48-4.43 mmol/24 h]</td>
</tr>
</tbody>
</table>

(∗) Higher value in newborn.
(∗∗) Lower during pregnancy.
Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES

On Kenza 240TX, 37°C, 505 nm
Detection limit: approx. 0.03 mg/dL

Precision:

<table>
<thead>
<tr>
<th>Within run</th>
<th>Normal level</th>
<th>High level</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 20</td>
<td>Mean mg/dL</td>
<td>S.D. mg/dL</td>
</tr>
<tr>
<td></td>
<td>3.24</td>
<td>0.003</td>
</tr>
<tr>
<td></td>
<td>9.05</td>
<td>0.007</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Between run</th>
<th>Normal level</th>
<th>High level</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 20</td>
<td>Mean mg/dL</td>
<td>S.D. mg/dL</td>
</tr>
<tr>
<td></td>
<td>6.84</td>
<td>0.076</td>
</tr>
<tr>
<td></td>
<td>9.4</td>
<td>0.172</td>
</tr>
</tbody>
</table>

On Cobas Mira, 37°C, 505 nm
Measurement interval: between 0.3 mg/dL and 20.0 mg/dL
Comparison study with commercially available reagent:
With n=98 specimens between 2.0 and 200 mg/dL
y = 0.9953 x – 0.025
r = 0.9923

Interferences:

<table>
<thead>
<tr>
<th>Turbidity</th>
<th>Positive from 0.060 abs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total bilirubin</td>
<td>Positive interference from 500 µmol/L</td>
</tr>
<tr>
<td>Ascorbic acid</td>
<td>Negative interference from 0.5 mg/dL</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>No interference up to 115 µmol/L</td>
</tr>
<tr>
<td>Glucose</td>
<td>No interference up to 1010 mg/dL</td>
</tr>
</tbody>
</table>

Other substances may interfere (see § Limits)

CALIBRATION

- 95015 Multicalibrator traceable to SRM 913
Or
- Standard (vial R3)
The calibration frequency depends on proper instrument functions and on the preservation of reagent.
Make a new calibration when changing reagent batch, if quality control results are found out of the range and after maintenance operations

PROCEDURE

Manual method
Let stand reagent and specimens at room temperature.

<table>
<thead>
<tr>
<th>Reagent</th>
<th>1000 µL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard / Control or Specimen</td>
<td>25 µL</td>
</tr>
</tbody>
</table>

Mix. Let stands for 5 minutes at 25°C.
Record absorbance at 505 (495-505) nm against reagent blank.
Colour is stable for 30 minutes.

Notes:
1. Serum, plasma, or urines diluted (1+9) with demineralised water.
2. Performances with manual procedure should be validated by user.
3. Kenza applications and other applications proposal are available on request.

CALCULATION

Serum or plasma:

Result = Abs (Assay) × Standard concentration
Abs (Standard)

Diluted urines (1+9): Multiply the above result by dilution factor 10.

REFERENCES

(2) Bernard S. Biochimie clinique - Instruments et techniques de laboratoire - Diagnostiques médicaux chirurgicaux.2nd ed.1989 p153-156 Ed. MALVINE PARIS.
(6) SRM: Standard Reference Material®