Alpha-2-Macroglobulin High Urinary Control

**REFERENCE**

<table>
<thead>
<tr>
<th>Protein</th>
<th>Lot #</th>
<th>Expiry date</th>
<th>Control date</th>
<th>Quality control report</th>
<th>Document prepared and signed by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha-2-Macroglobulin</td>
<td>16H12</td>
<td>12/2017</td>
<td>30/08/2016</td>
<td>DGM-QAC-REP-16119</td>
<td>L. Ginneberge</td>
</tr>
<tr>
<td>High Urinary Control</td>
<td>MGCU2-002</td>
<td>1 x 2 ml</td>
<td>2-8°C</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**SAMPLES AND REFERENCE VALUES**

See the corresponding reagents technical sheet.

**COMPOSITION**

The high urinary control is a human biological fluid diluted in HEPES pH 7.4 buffer containing stabilizers, sodium azide (< 1g/l) as preservative and the following human protein: alpha-2 macroglobulin.

**PRINCIPLE OF TEST**

The human proteins of control react upon a specific antibody for corresponding protein and the turbidity induced by the formation of immune complexes is recorded at appropriate wavelength. The turbidity measured is directly proportional to the antigen concentration of the control which can be used for the validation of the calibration curve and the stability during time of this curve in immunoturbidimetry.

**PRECAUTIONS**

For in vitro single diagnostic use. To be handled by entitled Personnel. Products from human source were tested and found free from HBsAg and antibodies to HCV and HIV but this material should be treated just as carefully as potentially infective.

Products containing sodium azide have to be handled with care; avoid ingestion and contact with skin and mucous membranes. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.

**ANALYTICAL PERFORMANCES**

See the corresponding reagents technical sheet.

**PREPARATION AND REAGENTS STABILITY**

The control is ready for use; once opened, it is stable until expiry date if stored stoppered in appropriate temperature conditions and without any contamination (avoid pipetting and decantation).

**METHOD OF ANALYSIS AND CALCULATION**

See the corresponding reagents technical sheet.

**QUALITY CONTROL**

Accuracy and reproducibility: analytical performances can be checked with the internal quality control serum of the laboratory or with the Liquichek™ (BIO-RAD) Control sera (see the values range obtained with DiAgam reagents and indicated on the accompanying BIO-RAD sheet).

**BIBLIOGRAPHY**


**Proteins: Control**

<table>
<thead>
<tr>
<th>Proteins:</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha-2 macroglobulin</td>
<td>53.4</td>
</tr>
</tbody>
</table>

Values given for information only, this control should be used as an un-assayed control

Values assigned from the reference ERM-DA470k/IFCC.