INTENDED USE
Reagent for quantitative in vitro determination of albumin in biological fluids.

SUMMARY OF TEST
Plasma levels of albumin, because they depend on protein intake, are frequently used to assess nutritional status. Moderate to large changes in plasma concentration of albumin have significant effects on the relative amounts of the bound and free concentrations of the ligands it carries, as a consequence on the metabolism of endogenous substances such as calcium, bilirubin, and fatty acids and on the effects of drugs and hormones.

PRINCIPLE OF THE METHOD
Albumin and BCG are followed to bind at pH 4.2, and absorption of the BCG-albumin complex is determined spectrophotometrically at 628 nm. At pH 4.2, albumin acts as a cation to bind the anionic dye.

KIT COMPONENTS
For in vitro diagnostic use only.
The components of the kit are stable until expiration date on the label.

Store all components at 2-8°C.

STABILITY
Stability since first opening of vials: preferably within 60 days at 2-8°C.

Stability: up to expiration date on labels at 2-8°C.

Use reagent ready to use.

MATERIALS REQUIRED BUT NOT SUPPLIED

REAGENT PREPARATION
Use reagent ready to use.

Stability: up to expiration date on labels at 2-8°C.

Stability since first opening of vials: preferably within 60 days at 2-8°C.

PRECAUTIONS

SPECMEN
Serum (preferred), plasma (heparinated or EDTA).

Venostasis should be avoided in specimen collection because hemococoncentration increases the apparent concentrations of albumin and other plasma proteins.

TEST PROCEDURE

Wavelength: 628 nm (allowed 580 - 630 nm)
Lightpath: 1 cm
Temperature: 25, 30 or 37°C

Dispense: blank standard sample
Reagent: 3 ml 3 ml 3 ml
Water: 20 μl - -
Standard: 20 μl
Sample: - - 20 μl

Mix, incubate at 25, 30 or 37°C for 2 minutes. Read absorbances of standard (As) and samples (Ax) against reagent blank.

RESULTS CALCULATION

```
<table>
<thead>
<tr>
<th>Serum/plasma sample</th>
<th>albumin g/dl</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ax/As x 4</td>
</tr>
</tbody>
</table>
```

EXPECTED VALUES

<table>
<thead>
<tr>
<th>Sex</th>
<th>Albumin (g/dl)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>4.2 - 5.5</td>
</tr>
<tr>
<td>Women</td>
<td>3.7 - 5.3</td>
</tr>
</tbody>
</table>

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:

QUANTINORM CHEMA
with normal or close to normal control values
QUANTITPATH CHEMA
with pathological control values.

If required, a multiparametric, human based calibrator is available: AUTOCAL H

Please contact Customer Care for further information.

TEST PERFORMANCE

Linearity: the method is linear up to 6 g/dl.

If the limit value is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

Sensitivity/limit of detection (LOD)
the limit of detection is 0.01 g/dl.

Interferences
no interference was observed by the presence of:
- Hemoglobin ≤ 350 mg/dl
- Bilirubin ≤ 27 mg/dl
- Lipid ≤ 850 mg/dl

Precision

<table>
<thead>
<tr>
<th></th>
<th>intra-assay (n=10) mean (g/dl)</th>
<th>SD (g/dl)</th>
<th>CV%</th>
</tr>
</thead>
<tbody>
<tr>
<td>sample 1</td>
<td>3.37</td>
<td>0.04</td>
<td>1.10</td>
</tr>
<tr>
<td>sample 2</td>
<td>3.34</td>
<td>0.04</td>
<td>1.30</td>
</tr>
</tbody>
</table>

Methods comparison
A comparison between Chema and a commercially available product gave the following results:

```
<table>
<thead>
<tr>
<th>Albumin Chema</th>
<th>Albumin competitor</th>
</tr>
</thead>
<tbody>
<tr>
<td>x</td>
<td>y</td>
</tr>
<tr>
<td>n = 73</td>
<td></td>
</tr>
<tr>
<td>y = 1.009x - 0.195 g/dl</td>
<td>r² = 0.956</td>
</tr>
</tbody>
</table>
```

Waste Disposal

This product is made to be used in professional laboratories.
P501: Dispose of contents according to national/international regulations.

REFERENCES


MANUFACTURER

Chema Diagnostica
Via Campania 2/4
60030 Monsano (AN) - ITALY - EU
phone +39 0731 213360
fax +39 0731 213361
E-mail: mail@chema.com
Website: http://www.chema.com

SYMBOLS

```
[VD]  in vitro diagnostic medical device
[LOT] batch code
[REF] catalogue number
                              temperature limit
ina use by date
[CAUTION] caution
[INSTRUCTIONS] consult instructions for use
```