**ALBUMIN**

**INTENDED USE**

Vitro albumin reagent is intended for the in vitro quantitative determination of albumin in serum or plasma on both automated and manual systems.

**BACKGROUND**

Albumin is a carbohydrate-free protein, representing 55 – 65% of the total plasma proteins. It is synthesized in the liver and is noted for its ability of configuration changes. It maintains the plasma colloidal osmotic pressure, transports and stores a wide variety of ligands and serves as a source of endogenous amino acids. Albumin binds and solubilizes a variety of compounds amongst which are bilirubin, calcium, and long-chain fatty acids. Albumin also binds toxic heavy metal ions and many drugs, which is why a decrease in albumin in the blood can have important pharmacokinetic consequences.

**METHOD**

Colorimetric endpoint method according to modified bromcresol green binding assay (BCG) (Doumas et al)

**ASSAY PRINCIPLE**

For a number of years the standard method for albumin determination was measurement of protein remaining in solution following salt precipitation of globulin on both automated and manual systems.

**EXPECTED VALUES**

<table>
<thead>
<tr>
<th>Group</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td></td>
</tr>
<tr>
<td>18 – 60 years</td>
<td>3.5 – 5.0 g/dl</td>
</tr>
<tr>
<td>&gt; 60 years</td>
<td>3.4 – 4.8 g/dl</td>
</tr>
<tr>
<td>Children</td>
<td></td>
</tr>
<tr>
<td>14 – 18 years</td>
<td>3.2 – 4.5 g/dl</td>
</tr>
<tr>
<td>4 days - 14 years</td>
<td>3.8 – 5.4 g/dl</td>
</tr>
<tr>
<td>Newborns</td>
<td></td>
</tr>
<tr>
<td>&lt; 4 days</td>
<td>2.8 – 4.4 g/dl</td>
</tr>
</tbody>
</table>

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference range. For diagnostic purposes, the albumin results should always be assessed in conjunction with the patient’s medical history, clinical examination, and other findings.

**REAGENTS**

<table>
<thead>
<tr>
<th>Component</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>R₁ Albumin standard</td>
<td>4.0 g/dl</td>
</tr>
<tr>
<td>R₂ Succinate buffer, pH 4.2</td>
<td>75.0 mmol/l</td>
</tr>
<tr>
<td>Bromcresol green</td>
<td>0.26 mmol/l</td>
</tr>
</tbody>
</table>

**PROCEDURE**

- **Manual Procedure**
  - Wavelength: 580 - 630 nm
  - Cuvette: 1 cm light path
  - Temperature: 20 - 25 °C
  - Zero adjustment: against reagent blank
  - Specimen: Serum or plasma

<table>
<thead>
<tr>
<th>Component</th>
<th>Blank</th>
<th>Standard</th>
<th>Specimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>R₂</td>
<td>2.0 ml</td>
<td>2.0 ml</td>
<td>2.0 ml</td>
</tr>
<tr>
<td>Standard</td>
<td>......</td>
<td>10 µl</td>
<td>......</td>
</tr>
<tr>
<td>Specimen</td>
<td>......</td>
<td>......</td>
<td>10 µl</td>
</tr>
</tbody>
</table>

Mix, and Incubate for 5 minutes at room temperature. Measure the absorbance of specimen \(A_{\text{specimen}}\) and standard \(A_{\text{standard}}\) against reagent blank.

The color is stable for 30 minutes.

- **Automated Procedure**
  - User defined parameters for different auto analyzers are available upon request

**CALCULATION**

Calculate the albumin concentration in serum by using the following formulae:

\[
\text{Serum albumin Concentration} = \frac{\text{Absorbance of Specimen}}{\text{Absorbance of Standard}} \times \text{X Standard value}
\]

- **Unit conversion**
  - g/dl x 1.45 = µmol/l

Expression of results in mol/l is only used for binding albumin.
It is recommended that controls (normal and abnormal) be included in:

- Each set of assays, or
- At least once a shift, or
- When a new bottle of reagent is used, or
- After preventive maintenance is performed or a clinical component is replaced.

Commerciaally available control material with established albumin values may be routinely used for quality control.

Failure to obtain the proper range of values in the assay of control material may indicate:

- Reagent deterioration,
- Instrument malfunction, or
- Procedure errors.

The following corrective actions are recommended in such situations:

- Repeat the same controls.
- If repeated control results are outside the limits, prepare fresh control serum and repeat the test.
- If results on fresh control material still remain outside the limits, then repeat the test with fresh reagent.
- If results are still out of control, contact Vitro Technical Services.

**QUALITY CONTROL**

**INTERFERING SUBSTANCES**

- **Anticoagulants:** Heparin and EDTA are the only accepted anticoagulants.
- **Bilirubin:** No significant interference from free or conjugated bilirubin up to a level of 60 mg/dl.
- **Drugs:** Young (1990) has published a comprehensive list of drugs and substances which may interfere with this assay.
- **Haemoglobin:** Haemoglobin levels higher than 3.0 g/dl increase the apparent albumin concentration significantly.
- **Lipemia:** Intralipid levels higher than 1.0 g/dl increase the apparent albumin concentration significantly.

**WARNING & PRECAUTION**

Vitro albumin reagent is for in vitro diagnostic use only. Normal precautions exercised in handling laboratory reagents should be followed.

- The reagents should be brought to room temperature before use.
- The reagent and sample volumes may be altered proportionally to accommodate different spectrophotometer requirements.
- Valid results depend on an accurate calibrated instrument, timing, and temperature control.
- Don’t use the reagent if it is turbid.

**PERFORMANCE CHARACTERISTICS**

**Imprecision**

Reproducibility was determined using an internal protocol. The following results were obtained:

<table>
<thead>
<tr>
<th>Within Run</th>
<th>Between Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>Level I</td>
</tr>
<tr>
<td>Number of samples</td>
<td>40</td>
</tr>
<tr>
<td>Mean (g/dl)</td>
<td>2.8</td>
</tr>
<tr>
<td>SD (g/dl)</td>
<td>0.47</td>
</tr>
<tr>
<td>CV (%)</td>
<td>1.7</td>
</tr>
</tbody>
</table>

**Method Comparison**

Comparison studies were carried out using another commercially available BCG method for Albumin as a reference. Normal and abnormal human serum samples were assayed in parallel and the results compared by least squares regression. The following statistics were obtained:

<table>
<thead>
<tr>
<th>Range of results</th>
<th>Correlation coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.7 - 4.8 g/dl</td>
<td>0.979</td>
</tr>
</tbody>
</table>

**Sensitivity**

The sensitivity is defined as the change of analytical response per unit change in analyte concentration at a pathlength of 1 cm.

When run as recommended the sensitivity of this assay is 0.2 g/dl.

**LINEARITY**

When run as recommended, the assay is linear up to 7.0 g/dl.

If result exceeds 7.0 mg/dl, specimen should be diluted with 0.9% NaCl solution and reassayed. Multiply the result by the dilution factor.

**BIBLIOGRAPHY**


**SYMBOL DECLARATION**

Manufacturer
Consult instructions for use
LOT
Batch code (Lot #)
REF
Catalog number
TEMP
Temperature limitation
IVD
In vitro diagnostic medical device
Use by
Caution. Consult instructions
Keep away from light

**ORDERING INFORMATION**

<table>
<thead>
<tr>
<th>REF</th>
<th>SIZE</th>
<th>REF</th>
<th>SIZE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1011</td>
<td>2 X 100 ml</td>
<td>1014</td>
<td>1 x 1000 ml</td>
</tr>
<tr>
<td>1012</td>
<td>4 X 125 ml</td>
<td>1015</td>
<td>4 x 250 ml</td>
</tr>
<tr>
<td>1013</td>
<td>1 X 500 ml</td>
<td>1016</td>
<td>2 x 500 ml</td>
</tr>
</tbody>
</table>

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