INTENDED USE
For the quantitative in vitro determination of albumin in serum and plasma. This product is suitable for Manual use.

Cat. No.
AB 362  R1. BCG concentrate  6 x 13.5 ml
6 x 100 ml  CAL. Standard  1 x 5.5 ml

CLINICAL SIGNIFICANCE (1)
Albumin is the most abundant serum protein representing 55-65% of the total protein. It is synthesised in the liver and has a half-life of 2 to 3 weeks.
The main biological functions of albumin are to maintain the water balance in serum and plasma and to transport and store a wide variety of ligands e.g. fatty acids, calcium, bilirubin and hormones such as thyroxine.
Albumin also provides an endogenous source of amino acids. Hypoalbuminaemia is associated with the following conditions: analbuminaemia; impaired albumin synthesis in the liver; liver disease; malnutrition or malabsorption; generalised shock; burns or dermatitis; kidney disease and intestinal disease.
Hyperalbuminaemia has little diagnostic relevance except, perhaps in dehydration.

PRINCIPLE (2)
The measurement of serum albumin is based on its quantitative binding to the indicator 3,3',5,5'-tetrabromo-m cresol sulphonephthalein (bromocresol green, BCG). The albumin-BCG-complex absorbs maximally at 578 nm, the absorbance being directly proportional to the concentration of albumin in the sample.

SAMPLE PREPARATION AND COLLECTION
Serum, heparinized plasma or EDTA plasma. Normal procedures for collecting and storing serum may be used for samples to be analysed by this method. Serum is stable for 3 days at +2 to +8°C, or 6 months at -20°C.

REAGENT COMPOSITION

<table>
<thead>
<tr>
<th>Contents</th>
<th>Initial Concentration of Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1. BCG concentrate</td>
<td>Succinate buffer 75 mmol/l; pH 4.2</td>
</tr>
<tr>
<td></td>
<td>Bromocresol green 0.15 mmol/l</td>
</tr>
<tr>
<td></td>
<td>Brij 35</td>
</tr>
<tr>
<td></td>
<td>Preservative</td>
</tr>
<tr>
<td>CAL. Standard</td>
<td>See lot specific insert.</td>
</tr>
</tbody>
</table>

SAFETY PRECAUTIONS AND WARNINGS
For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Caution: Standard
Human source material from which this product has been derived has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HBsAg) and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety data sheets are available on request.
The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

STABILITY AND PREPARATION OF REAGENT AND STANDARD
R1. BCG Concentrate
Dilute the contents of one bottle with 87 ml of distilled water. Stable for 3 months at +15 to +25°C.

CAL. Standard
Contents ready for use. Stable up to expiry date when stored at +15 to +25°C.

MATERIALS PROVIDED
BCG Concentrate
Albumin Standard

MATERIALS REQUIRED BUT NOT PROVIDED
Pipetting device suitable for the delivery of 10 μl and 3.0ml.
Timing device and water bath or heating block to maintain temperature between 20 - 25°C.
A spectrophotometer with wavelength capability of 600 to 650nm.
Randox Assayed Multisera Level 2 (Cat. No. HN 1530) and Level 3 (Cat. No. HE 1532)

PROCEDURE (3)

| Wavelength: | Hg578 nm or Hg623 nm |
| Spectrophotometer: | 630 nm (600-650 nm) |
| Cuvette: | 1 cm light path |
| Incubation Temperature: | 20 - 25°C |
| Measurement: | against reagent blank |

Pipette into test tubes:

<table>
<thead>
<tr>
<th>Reagent</th>
<th>Standard</th>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distilled H₂O</td>
<td>0.01 ml</td>
<td>-----</td>
</tr>
<tr>
<td>Standard (CAL)</td>
<td>0.01 ml</td>
<td>----</td>
</tr>
<tr>
<td>Serum or Plasma</td>
<td>0.01 ml</td>
<td>----</td>
</tr>
<tr>
<td>BCG reagent (R1)</td>
<td>3.00 ml</td>
<td>3.00 ml</td>
</tr>
</tbody>
</table>
Mix and incubate for 5 minutes at +20 to +25°C. Measure the absorbance of the sample (A_{sample}) and of the standard (A_{standard}) against the reagent blank.

**CALCULATION**

The albumin concentration in the sample may be calculated from the following formula:

\[
\text{Albumin Concentration (g/l or g/dl)} = \frac{A_{sample}}{A_{standard}} \times \text{Concentration of standard}
\]

**QUALITY CONTROL**

Randox Assayed Multisera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error the following steps should be taken:
1. Check instrument settings and light source.
2. Check cleanliness of all equipment in use.
3. Check water, contaminants ie bacterial growth may contribute to inaccurate results.
4. Check reaction temperature.
5. Check expiry date of kit and contents.
6. Contact Randox Laboratories Customer Technical Support, Northern Ireland (028) 94422413.

**INTERFERENCE**

The following analytes were tested up to the following levels and were found not to interfere:

- Bilirubin: 500 \( \mu \)mol/l
- Intralipid\( ^\text{®} \): 1.2%
- Triglycerides: 22.75 mmol/l
- Haemoglobin: 6 g/l

**NORMAL VALUES IN SERUM**(2)

- Adults: 38 - 44 g/l (3.8 - 4.4 g/dl)
- Neonates: 38 - 42 g/l (3.8 - 4.2 g/dl)

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

**LINEARITY**

This method is linear up to 60 g/l (6 g/dl). If the concentration exceeds this value the sample should be diluted 1+1 with 0.9% NaCl solution and reassayed. Multiply the result by 2.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

The following performance data were obtained using a COBAS MIRA analyser at 37°C. Please contact Randox Laboratories for information regarding other automated analysers.

**SENSITIVITY**

The minimum detectable albumin concentration has been determined by testing replicate dilutions of a suitable control and found to be 4.44 g/l (0.444 g/dl). Sensitivity is expressed as the lowest measurable concentration that may be detected with acceptable precision (% CV \( \leq 10\% \)). Serial dilutions of a suitable control material are prepared to give a range of analyte concentrations. Ten replicates of each dilution are tested in an assay and the percentage coefficient of variation at each dilution is calculated. The lowest analyte concentration with a percentage coefficient of variation \( \leq 10\% \) is considered representative of the assay sensitivity.

**REFERENCES**


**REVISED**

Revised 14 Jan 08 aw