**Albumin Reagent**

**BCG Method**

**PRODUCT SUMMARY**
- **Stability**: Until Expiry at 2-25°C
- **Linear Range**: Up to 60 g/L (6.0 g/dL)
- **Specimen Type**: Serum
- **Method**: Endpoint
- **Reagent Preparation**: Supplied ready to use.

**SYMBOLS IN PRODUCT LABELLING**
- **Authorized Representative**: For in vitro diagnostic use
- **Batch code/Lot number**: Use by/Expiration Date
- **Catalogue number**: CAUTION. CONSULT INSTRUCTIONS FOR USE
- **Consult instructions for use**: Manufactured by
- **Exclamation Mark**: Thermo Scientific

**INTENDED USE**
This reagent is intended for the in vitro quantitative determination of Albumin in human serum.

**CLINICAL SIGNIFICANCE**
Albumin is quantitatively the major single contributor to the plasma total protein and performs a number of functions including:
(i) Regulation of the distribution of extracellular fluid and performs a number of functions including:
(ii) Acts as a transport agent for a wide variety of substances such as hormones, lipids, vitamins, calcium and trace metals and
(iii) Forms part of the amino acid pool.
Measurement of total protein levels alone may be misleading, and may be normal in the face of quite marked changes in the constituent proteins. For example - a fall in albumin may roughly be balanced by a rise in immunoglobulin levels. This is quite a common combination.

True hyperalbuminaemia probably does not occur and an increase in albumin concentration is usually only encountered in dehydration due to the reduced plasma water content or artefactually, as a result of venous stasis during venipuncture (Most common cause).

Hypoalbuminaemia occurs as a result of -
(i) Overhydration due to water excess,
(ii) Excessive protein loss through the skin after severe burns, from the kidney in the nephrotic syndrome and through the intestine in protein losing enteropathy,
(iii) Decreased synthesis due to dietary deficiency, liver disease or malabsorption or,
(iv) Increased catabolism.

**METHODODOLOGY**
Several procedures are currently available for the determination of albumin and include dye binding methods, electrophoresis, immunological and salt fractionation.

The most commonly used procedures are the dye binding methods of which Bromocresol Green (BCG) is the most popular. However, one of the major drawbacks of this method is its lack of specificity. Despite the many published modifications, existing BCG methods still tend to overestimate low concentrations of albumin due to non specific reactions with other plasma proteins.

This kit is based on the method of Doumas et al. in which albumin binds with BCG causing a shift in the absorption spectra of the dye. The dye-albumin complex formed has an absorbance peak at 625nm which is proportional to the concentration of albumin in the sample.

**REAGENT COMPOSITION**

<table>
<thead>
<tr>
<th>Active Ingredients</th>
<th>Concentration</th>
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<tbody>
<tr>
<td>Succinate buffer</td>
<td>90 mmol/L</td>
</tr>
<tr>
<td>Bromocresol Green</td>
<td>0.26 mmol/L</td>
</tr>
</tbody>
</table>

pH 4.10 ± 0.1 at 20°C

Reagent also contains surfactant and stabilizers necessary for optimum reagent performance.

**Hazard Symbol: Exclamation Mark**
**Signal Word: Warning**

**Hazard Statements**
- **HS19 Causes serious eye irritation**

**Precautionary Statements - Prevention**
- Wash face, hands and any exposed skin thoroughly after handling
- Wear protective gloves/protective clothing/eye protection/face protection
- Wear eye/face protection

**Precautionary Statements - Response**
- Eyes: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

**STABILITY AND STORAGE**
When stored at 2-25°C the reagent is stable until the expiration date stated on the bottle and kit box label.

**Indications of Reagent Deterioration:**
- Turbidity,
- Presence of a precipitate; and/or
- Failure to recover control values within the assigned range.

**SPECIMEN COLLECTION AND HANDLING**
- **Serum**: Use non-haemolysed serum collected without prolonged venous stasis.
- **Storage**: Specimens are stable for at least 20 days when stored at 4°C.

**ADDITIONAL EQUIPMENT REQUIRED BUT NOT PROVIDED**
- If required, pipettes for accurately dispensing measured volumes.
- A clinical chemistry analyzer capable of maintaining constant temperature (37°C) and measuring absorbance at 630nm.
- Analyzer specific consumables, eg: sample cups.
- Normal and Abnormal assayed control material.
- Calibrator or suitable aqueous Albumin standard.

**ASSAY PROCEDURE**
These instructions are for manual instrumentation but can be adapted to most automated instruments. Specific instructions are available upon request.

**SYSTEM PARAMETERS**
- **Temperature**: 37°C
- **Wavelength**: 630nm
- **Assay Type**: Endpoint
- **Direction**: Increase
- **Sample : Reagent Ratio**: 1:100
- **eg: Sample Vol**: 3µL
- **Reagent Vol**: 300µL
- **Incubation Time**: 90 seconds
- **Reagent Blank Limits**: Low 0.0 AU, High 2.0 AU
- **Linearity**: 0 - 60 g/L (0.0 - 6.0 g/dL)
- **Analytical Sensitivity**: 0.033 Abs per g/L (0.33 Abs per g/dL)

**CALCULATIONS**
Results are calculated, usually automatically by the instrument, as follows:
**NOTES**

1. The reagent and sample volumes may be altered proportionally to accommodate different spectrophotometer requirements.
2. The temperature of the reaction is not critical, however the temperature of the spectrophotometer should be held constant.
3. Final absorbance readings should be taken less than 90 seconds after sample addition.
4. Decreasing the sample volume to reagent volume ratio to 1:200 will increase the observed linearity to 100 g/L or 10 g/dL. Subsequently, sensitivity will be reduced.
5. Unit conversion: g/L x 0.1 = g/dL.

**CALIBRATION**

Calibration is required. A suitable bovine or human Albumin Standard(s) or a serum based calibrator, with an assigned value traceable to a primary standard (eg NIST or IRMM) is recommended. For calibration frequency on automated instruments, refer to the instrument manufacturers specifications. However, calibration stability is contingent upon optimum instrument performance and the use of reagents which have been stored as recommended in the stability and storage section of this package insert. Recalibration is recommended at anytime if one of the following events occurs:-

- The Lot number of reagent changes.
- After preventative maintenance is performed or a critical component is replaced.
- Control values have shifted or are out of range and a new vial of control does not rectify the problem.

**QUALITY CONTROL**

To ensure adequate quality control, normal and abnormal control with assayed values should be run as unknown samples:-

- At least every eight hours.
- When a new bottle of reagent is used.
- After preventative maintenance is performed or a critical component is replaced.

Control results falling above the upper limit or below the lower limit of the established ranges indicate the assay may be out of control.

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 are still out of control, recalibrate with fresh calibrator, then repeat the test.
- If results are still out of control, perform a calibration with fresh reagent, then repeat the test.
- If results are still out of control, contact Technical Services or your local distributor.

**LIMITATIONS**

1. Studies to determine the level of interference from haemoglobin, bilirubin and lipaemia were carried out and the following results were obtained:

   - **Haemoglobin**: No interference from haemoglobin up to 540mg/dL.
   - **Bilirubin**: No interference from bilirubin up to 340µmol/L (20mg/dL).
   - **Lipaemia**: No interference from lipaemia, measured as triglycerides, up to 15.7 mmol/L (1380mg/dL).

2. **Young DS** has published a comprehensive list of drugs and substances which may interfere with this assay.

**EXPECTED VALUES**

- **Ambulant Male**: 35-48g/L (3.5 - 4.8 g/dL)
- **Ambulant Female**: 33-45g/L (3.3 - 4.5 g/dL)

In non ambulatory hospitalised patients the haemodilution of recumbency may reduce the albumin levels by up to 5g/L. The quoted values were derived from non selected male (100) and female (100) blood donors and should serve as a guide only. It is recommended that each laboratory verify this range or derive a reference interval for the population that it serves.

**PERFORMANCE DATA**

The following data was obtained using the Albumin reagent on an automated clinical chemistry analyzer.

**IMPRECISION:**

Imprecision was evaluated using two levels of commercial control and following the NCCLS EP5-T procedure.

- **Within Run**
  - Number of data points: 80
  - Mean (g/L / g/dL): 29 / 2.8
  - SD (g/L / g/dL): 0.47 / 0.05
  - CV (%): 1.7

- **Between Day**
  - Number of data points: 80
  - Mean (g/L / g/dL): 29 / 2.8
  - SD (g/L / g/dL): 0.6 / 0.06
  - CV (%): 2.1

**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.

- **Number of data points**: 80
- **Range of results**: 7 - 48 g/L (0.7 - 4.8 g/dL)
- **Slope**: 0.935
- **Intercept**: 1.7 g/L (0.17 g/dL)
- **Correlation coefficient**: 0.979

**LINEARITY**

When run as recommended the assay is linear to 60 g/L (6.0 g/dL).

**ANALYTICAL SENSITIVITY**

When run as recommended the sensitivity of the assay is 0.033A per g/L (0.33A per g/dL).

**REFERENCES**


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