The compound was proposed by Rodkey and the procedure was further refined today routinely employed in the laboratory because of their simplicity and bromcresol purple and bromcresol green (BCG). The use of the latter.

On the other hand, procedures based on the binding of a dye to albumin, are laboratory use.

Using a biuret reaction of Kjeldahl technique is laborious and time consuming. Determination of albumin after salt fractionation followed by quantitation test summary.

Dermatitis and burns.

2. REAGENTS COMPOSITION

Albumin Reagent

Reactive ingredients:

Brom cresol Green 0.36 mmol/L
Non-reactive ingredients:

Buffers, stabilizers and fillers

Albumin Standard (4 g/dL)

Non-reactive ingredients:

Buffers, stabilizers and fillers

REAGENTS PREPARATION

1. Albumin Reagent. The solution, as provided, is ready to use. Store in refrigerator or at room temperature below 25 °C.

2. Albumin Standard. The solution, as provided, does not require any treatment. Store in refrigerator or at room temperature below 25 °C.

REAGENTS STORAGE AND STABILITY

The Albumin Reagent is stable at room temperature until the expiration date on the label. Avoid exposing the Albumin Reagent to strong sunlight. Avoid contaminating the reagent and the standard: instead of direct pipetting in the original container, transfer required amount to suitable glassware. Do not return remnants to original bottle.

The solution of the Albumin Reagent should be clear, yellow-green in color. If the reagent or the standard becomes turbid, this is evidence of contamination. If the absorbance of the reagent at 628 nm is higher than 0.400 when read against a water blank, do not use. The Albumin reagent is mildly acid; avoid contact with the skin, eyes and mucous membrane. If contact occurs, flush with water.

PRECAUTIONS

Good laboratory safety practices should be followed when handling any laboratory reagent. Refer to a recognized laboratory safety program for additional information. (See GP17-T, Clinical Laboratory Safety; Tentative Guideline (1994), National Committee on Clinical Laboratory Standards, Wayne, PA.)

Intended for in vitro diagnostic use only.

SPECIMEN COLLECTION, PREPARATION AND STORAGE

Use only clear, unhemolyzed serum (preferable) or EDTA plasma. Albumin in serum or plasma is stable for at least 1 month in the refrigerator (2–8 °C).

INTERFERING SUBSTANCES

Less than 10% Interference has been demonstrated from 20.0 mg/dL bilirubin, 500 mg/dL hemoglobin, and 487 mg/dL Intralipid (representative of triglycerides) spiked into serum. Less than 10% positive interference has been demonstrated from 3.0 g/dL γ-globulin. Some samples may show a greater positive bias due to globulin interference. Heparin has been reported to interfere with albumin determination by dye binding methods.

Young et al. have published a comprehensive list of drugs and substances which may interfere with in vitro diagnostic assays, including the determination of albumin.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Spectrophotometer or colorimeter capable of accurate measurements of absorbance at 628 nm.


3. Distilled or deionized water.

4. Pipettes to measure water, reagent, standard and samples.

5. Timer. This is not necessary if the assay is performed in an automated instrument, capable of accurate timing.

MATERIALS PROVIDED

1. Albumin Reagent, ready to use.

2.Albumin Standard, 4 g/dL.

TEST PROCEDURE

Wavelength: 628 nm

Temperature: Room temperature (22–28 °C).

Temperature should remain constant during assays.

<table>
<thead>
<tr>
<th>Blank</th>
<th>Standard</th>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>0.02 mL</td>
<td>–</td>
</tr>
<tr>
<td>Standard</td>
<td>–</td>
<td>0.02 mL</td>
</tr>
<tr>
<td>Sample</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Reagent</td>
<td>3 mL</td>
<td>3 mL</td>
</tr>
</tbody>
</table>

Mix. Read absorbance within 60 seconds against the blank set at 0.

Notes:

The requirement that the absorbance be read within 60 seconds is necessary to obtain accurate results. However, the gradual increase in color noted with time in some serum samples will result in slightly higher results, so that for practical purposes it could be ignored.

CALIBRATION

The assay requires the use of an albumin standard. Use the standard provided with the reagent as directed or other commercially available standards or calibrators.

The use of two Albumin standards, is recommended for multiple point calibration. Albumin Standard (R85261V1) 8 g/dL is also available for testing purposes.

A calibration curve can be made as follows, employing the Albumin Standard, 4 g/dL provided.

<table>
<thead>
<tr>
<th>Blank</th>
<th>2 g/dL</th>
<th>4 g/dL</th>
<th>6 g/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>0.03 mL</td>
<td>0.02 mL</td>
<td>0.01 mL</td>
</tr>
<tr>
<td>Standard</td>
<td>–</td>
<td>0.01 mL</td>
<td>0.02 mL</td>
</tr>
<tr>
<td>Reagent</td>
<td>3 mL</td>
<td>3 mL</td>
<td>3 mL</td>
</tr>
</tbody>
</table>

Mix and read absorbance within 60 seconds against the blank set at 0. Plot the absorbance (y) on the vertical axis against the concentration in the horizontal (x) axis on graph paper.

QUALITY CONTROL

Serum controls recommended to monitor the performance of manual and automated assay procedures, providing a continued screening of the instrument, reagents and techniques. Commercially available control material with established values for albumin concentrations may be used. Assayed
Control Serum Level 1 (R83082) and Level 2 (R83083) are recommended for this purpose.

**CALCULATIONS**

Value of Standard = 4 g/dL

\[
\text{A sample} \times 4 = \text{albumin in sample in g/dL.}
\]

**LIMITATIONS OF THE PROCEDURE**

Samples with albumin concentrations higher than 8 g/dL should be diluted with an equal volume of physiological saline (150 mmol/L sodium chloride in water) and assayed again; multiply results by 2.

**REAGENT PERFORMANCE**

1. **Linearity:** The assay is linear to 8 g/dL.
2. **Correlation:** Employing as a reference a commercial Albumin reagent, based on the same formulation (Gilford) results obtained in 40 serum samples, varying in albumin concentration between 2.02 and 6.35 g/dL, were compared with those obtained using the present reagent. The correlation coefficient was: 0.994 and the regression equation was \( y = 1.033x + 1.033 \).
3. **Precision:**

<table>
<thead>
<tr>
<th></th>
<th>Within Run</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (g/dL)</td>
<td>5.17</td>
</tr>
<tr>
<td>SD</td>
<td>0.033</td>
</tr>
<tr>
<td>CV</td>
<td>0.64</td>
</tr>
<tr>
<td>N</td>
<td>12</td>
</tr>
</tbody>
</table>

**REFERENCE RANGE**

3.5-5.5 g/dL

It is recommended that each laboratory establish its own reference range.

**REFERENCES**