**TECO DIAGNOSTICS**
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# ALBUMIN – BCG METHOD
## TC MATRIX-160

**INTENDED USE**
For the quantitative determination of albumin in serum or plasma on TC Matrix analyzers.

**SUMMARY AND EXPLANATION OF THE TEST**
Albumin is the most abundant individual protein in serum. The reference range for serum albumin in an adult (>18-60 years) is 35-50 g/L (3.5-5.0 g/dL).[6] The liver is the site of synthesis of albumin and hence liver disease is one of the most common causes of decreased albumin level. Other conditions such as congestive heart failure, malnutrition, starvation, nephritis, glomerulonephritis, leukemia and severe burns also resulted in the decrease of albumin level.
Albumin levels may be elevated in dehydration, shock, hemoconcentration, or upon administration of large quantities of concentrated albumin intravenously.
Bromocresol green (BCG), an ionic dye, binds tightly to albumin when serum is added. The albumin- BCG complex absorbs light at 630 nm more intensively than BCG alone.
The TC Matrix System automatically proportions the appropriate sample and reagent volumes into the cuvette. The system monitors the change in absorbance at 700 nanometers. This change in absorbance is directly proportional to the concentration of albumin in the sample and is used by the TC Matrix System to calculate and express albumin concentration.

Albumin + BCG ------→ Albumin-BCG complex.

**REAGENT PREPARATION**
No preparation is required.

**REAGENT COMPOSITION**
Bromocresol green: 0.28 mmol/L
Also non-reactive chemicals for optimal system performance.

**REAGENT STORAGE AND STABILITY**
Albumin reagent stored unopened at room temperature is stable until the expiration date shown on the bottle label. Once opened, Albumin reagent is stable for 30 days, or until the expiration date on the label.
DO NOT FREEZE.

**SPECIMEN COLLECTION AND HANDLING**
1. The test can be performed on serum or plasma. For serum, blood is drawn into a tube which does not contain anticoagulant and is allowed to clot. The serum is then separated from the clot. A maximum limit of two hours from the time of collection is recommended.
2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum and plasma should be stored at 2ºC to 8ºC. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15ºC to -20ºC. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.
3. For plasma, add whole blood directly into a tube containing anticoagulant. Acceptable anticoagulants are listed in the "LIMITATIONS" section.

**CALIBRATION**
1. Calibrator required: TECO MULTI Calibrator is needed but is not provided in the kit.
2. The system must have a valid calibration in memory before controls or patient samples can be run.
3. The TC Matrix system will automatically perform checks on the calibration and produce data at the end of calibration.

**MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT**
TECO MULTI Calibrator.
At least two levels of control material.

**LIMITATIONS**
1. The anticoagulants Potassium Oxalate, Sodium Fluoride and Sodium Citrate were found to be incompatible with this method.
2. The anticoagulants EDTA, Lithium Heparin, Sodium Heparin, Ammonium Heparin were found to be compatible with this method.

**INTERFERENCE**
1. Hemoglobin may interfere with this methodology.
2. Lipemic samples >3+ should be ultra-centrifuged and the analysis performed on the infranate.
3. On this method, refer to the work of Young for a review of drug and comprehensive list of substances which affect the Albumin level.[10]

**EXPECTED VALUE**
3.5-5.0 g/dL or 35~50 g/L

**PRECAUTIONS**
1. For in vitro diagnostic use only.
2. Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.
3. Each laboratory should perform quality control testing to assure the results are reliable before testing the specimens.

**PROCEDURES**

| | | | |
|---|---|---|---|
| Test Name: | Albumin | R1: | 200 |
| Full Name: | Albumin | R2: | 0 |
| Pri. Wave: | 630 nm | SAMPLE VOLUME: | 2.0 |
| Sec. Wave: | 700 nm | Calibration Type: | 2 point linear |
| Assay/ Point: | 1 point end | K Value: | / |
| Start - End: | 1 - 15 | Point: | 2 |
| Decimal place: | 2 | Blank Type: | Reagent |
| Unit: | g/dL | Point 0 (Blank) Con.: | 0.0 |
| Linearity Range: | 1.0000 - 8.0000 | Point 1 (STD) Con.: | calibrator/ standard |
| Correlation Factor: | 1.0000 - 0.0000 | | |

**PERFORMANCE CHARACTERISTICS**
**Analytical Range:** 1.0-8.0 g/dL
For albumin analysis using Teco Diagnostics' Albumin Reagent on TC Matrix System, this method has been demonstrated to be linear from 1.0-8.0 g/dL.

**Accuracy:** Comparison study was performed on TC Matrix System from 40 samples. Beckman Coulter Albumin reagent was used to compare with Albumin Reagent. The results of this study yield a correlation coefficient of 0.991 with a regression equation of y=0.991X + 0.200.

**Precision:** Within Run precision for Albumin Reagent was determined following a modification of NCCLS EP5-A. Two commercial human serum samples were assayed on TC Matrix System for 25 times.

| Sample | Sample 1 | Sample 2 |
|---|---|---|
| N | 25 | 25 |
| Mean (g/dl) | 4.0 | 2.8 |
| Standard Deviation (g/dl) | 0.09 | 0.07 |
| Coefficient of Variation (%) | 2.1 | 2.0 |

Run-Day precision for Albumin Reagent was determined following a modification of NCCLS EP5-A. Two commercial human serum samples were assayed on TC Matrix Systems five times per day for five days for the total of 25 values.

| Sample | Sample 1 | Sample 2 |
|---|---|---|
| N | 25 | 25 |
| Mean (g/dl) | 4.0 | 2.8 |
| Standard Deviation (g/dl) | 0.08 | 0.08 |
| Coefficient of Variation (%) | 2.1 | 2.2 |

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