# ALBUMIN SYSTEM PACK

(BCG METHOD)

B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic chem 400 (Fully Auto Biochemistry Analyzer)

| Code | Product Name | Pack Size |
|---|---|---|
| UNI02 | Albumin System Pack | 4x50 ml |

**INTENDED USE**

Diagnostic reagent for quantitative in vitro determination of Albumin in human serum and plasma.

**CLINICAL SIGNIFICANCE**

Albumin, a major plasma protein, is synthesised in the liver from amino acids which are absorbed from the ileum. It's functions include regulation of distribution of extracellular fluid, transportation of various hormones, vitamins and trace metals.

**Increased levels are observed in**

Dehydration due to reduced plasma water content.
- Stasis during venipuncture which causes fluid to escape into the extravasculer compartment.

**Decreased levels are observed in**

- Excessive protein loss (mainly albumin) - from kidney, skin or intestine.
- Decreased synthesis due to dietary, hepatic disease or malabsorption.
- Increased catabolism in fever, untreated diabetes mellitus and hypertension.

**PRINCIPLE**

Albumin binds with Bromo Cresol Green (BCG) at pH 4.2 causing a shift in absorbance of the yellow BCG dye. The blue-green colour formed is proportional to the concentration of albumin, when measured photometrically between 540-630 nm with maximum absorbance at 630 nm.

**REACTION**

Albumin + Bromocresol green $\xrightarrow[\text{Acidic medium}]{}$ Green-Albumin BCG Complex

**REAGENT COMPOSITION**

**Reagent 1 : BCG Reagent**

| | |
|---|---|
| Bromocresol green | <0.21 mmol/L |
| Succinate Buffer | >50 mmolL |

**REAGENT PREPARATION**

Reagents are liquid, ready to use.

**STABILITY AND STORAGE**

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at +2 - +8°C.

On board stability: Min 30 days if refrigerated (+8 - +14°C) and not contaminated.

**SPECIMEN COLLECTION AND HANDLING**

Use unheamolysed serum or plasma (EDTA, heparin)
It is recommended to follow NCCLS procedures (or similar standardized procedure).

**Stability in serum:** 1 month at +2 - +8°C
1 week at +15 - +25°C

Discard contaminated specimens.

**CALIBRATION**

Calibration with the Beacon Multicalibrator is recommended.

**QUALITY CONTROL**

It's recommended to run normal and abnormal control sera to validate reagent performance

**UNIT CONVERSION**

g/dLx 10 = gm/L

**EXPECTED VALUES**

Serum: 3.4-5.5 gm/dL

**It is recommended that each laboratory verify this range or derives reference interval for the population it serves.**

**PERFORMANCE DATA**

Data contained within this section is representative of performance on Beacon system.
Data obtained in your laboratory may differ from these values.

**Limit of quantification :** 0.1 gm/dL
**Linearity :** 10 gm/dL
**Measuring range :** 0.1 - 10 gm/dL

**PRECISION**

| Intra-assay precision Within run (n=20) | Mean (gm/dL) | SD (gm/dL) | CV (%) |
|---|---|---|---|
| Sample 1 | 4.64 | 0.04 | 0.86 |
| Sample 2 | 3.46 | 0.06 | 1.77 |

| Inter-assay precision Run to run (n=20) | Mean (gm/dL) | SD (gm/dL) | CV (%) |
|---|---|---|---|
| Sample 1 | 6.72 | 0.20 | 2.98 |

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**COMPARISON**

A comparison between Albumin System Pack (y) and commercially available test (x) using 20 samples gave following results:
y = 0.9989x - 0.0292 gm/dl
r = 0.9979

**INTERFERENCES**

Following substances do not interfere:
haemoglobin up to 10 g/l, bilirubin up to 40mg/dl, triglycerides up to 2000 mg/dl.

**WARNING AND PRECAUTIONS**

For in vitro diagnostic use. To be handled by entitled and professionally educated person.
Reagents of the kit are not classified like dangerous but contain less than 0.1% sodium azide - classified as very toxic and dangerous substance for the environment. MSDS will be provided on request.

**WASTE MANAGEMENT**

Please refer to local legal requirements.

Parameter for B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic chem 400
(Fully Auto Biochemistry Analyzer)

| Test Name | ALBUMIN |
|---|---|
| Full Name | ALBUMIN |
| PRI Wave | 630 nm |
| Sec Wave | - |
| Assay/point | 1 Point End |
| Start | - |
| End | 7 |
| Decimal | 2 |
| Unit | gm/dL |
| Linearity Range Low | 0.1 |
| Linearity Range High | 10 |
| Sample Volume | 2 µl |
| Reagent 1 (R1) Volume | 200 µl |
| Reagent 1 (R2) Volume | - |
| Substrate Depleted/Abs.limit | - |
| Linearity | 10 gm/dL |
| Out Of Linearity Range | - |
| Calibration Type | 2 Point linear |
| Points | 2 |
| Blank Type | Reagent |
| Concentration Blank | 0.00 |
| Concentration STD | Refer calibrator value sheet |

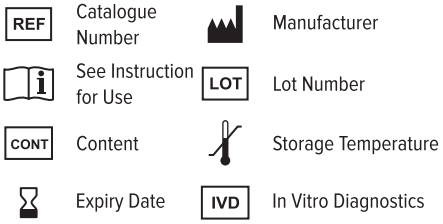
**NOTE**

The program is made as per the in house testing, it can be modified as per requirements.
Clinical diagnosis should not be made on findings of a single test results, but both clinical and laboratory data.

**REFERENCES**

1. Leonard, P. L., Persaud, J., Motwani, R.: Clin. Chim. Acta 35, 409, 1971.
2. Tietz Textbook of Clinical Chemistry and Molecular diagnostics. Burtis, C.A., Ashwood, ER. Bruns, D.E; 5th edition, WB Saunders Company 2012.

**Symbols Used On Labels**




BEA/24/ALB/UN/IFU Ver: 02
28/01/2026