**Albumin FS**

Diagnostic reagent for quantitative in vitro determination of albumin in serum or plasma on Sysmex BX-Series

**Order Information**

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Kit size</th>
<th>Number of tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 0220 99 10 971</td>
<td>R1 x 3 x 16.5 mL</td>
<td>BX-3010 3 x 100 tests</td>
</tr>
<tr>
<td></td>
<td></td>
<td>BX-4000 3 x 73 tests</td>
</tr>
</tbody>
</table>

**Method**

Photometric test using bromocresol green

**Principle**

In the presence of bromocresol green at a slightly acid pH, serum albumin produces a color change of the indicator from yellow-green to green-blue.

**Reagents**

- **Components and Concentrations**
  - Citrate buffer pH 4.2 30 mmol/L
  - Bromocresol green 0.26 mmol/L

**Storage Instructions and Reagent Stability**

The reagent is stable up to the end of the indicated month of expiry, if stored at 2 – 25°C, protected from light and contamination is avoided. Do not freeze the reagent!

**Warnings and Precautions**

1. In very rare cases, samples of patients with gammopathy might give falsified results [6].
2. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
3. For professional use only!

**Waste Management**

Please refer to local legal requirements.

**Reagent Preparation**

The reagent is ready to use. The bottles are placed directly into the reagent trays.

**Specimen**

- Serum, heparin plasma or EDTA plasma
- Stability [1]:
  - 2.5 months at 20 – 25°C
  - 5 months at 4 – 8°C
  - 3 months at -20°C
- Only freeze once. Discard contaminated specimens.

**Calibrators and Controls**

For calibration, DiaSys TruCal U calibrator is recommended. The assigned values of TruCal U have been made traceable to the reference material ERM-DA470. For internal quality control DiaSys TruLab N and P controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Kit size</th>
</tr>
</thead>
<tbody>
<tr>
<td>TruCal U</td>
<td>5 9100 99 10 063 20 x 3 mL</td>
</tr>
<tr>
<td>TruLab N</td>
<td>5 9100 99 10 064 6 x 3 mL</td>
</tr>
<tr>
<td>TruLab P</td>
<td>5 9000 99 10 062 20 x 5 mL</td>
</tr>
<tr>
<td></td>
<td>5 9050 99 10 061 6 x 5 mL</td>
</tr>
</tbody>
</table>

**Performance Characteristics**

- Measuring range up to 6 g/dL (60 g/L) albumin (in case of higher concentrations re-measure samples after manual dilution with NaCl(9 g/L) solution or use rerun function)
- Limit of detection [1]: 0.1 g/dL (1 g/L) albumin
- On-board stability: 6 weeks
- Calibration stability: 6 weeks

**Interfering substance**

- Ascorbate up to 30 mg/dL 4.33 g/dL (43.3 g/L)
- Hemoglobin up to 300 mg/dL 4.29 g/dL (42.9 g/L)
- Bilirubin, conjugated up to 60 mg/dL 4.31 g/dL (43.1 g/L)
- Bilirubin, unconjugated up to 60 mg/dL 4.31 g/dL (43.1 g/L)
- Lipemia (triglycerides) up to 1200 mg/dL 3.97 g/dL (39.7 g/L)

For further information on interfering substances refer to Young DS [5].

**Precision (BX-4000)**

<table>
<thead>
<tr>
<th>Within run (n=20)</th>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [g/dL]</td>
<td>3.51</td>
<td>4.13</td>
<td>4.92</td>
</tr>
<tr>
<td>Mean [g/L]</td>
<td>35.1</td>
<td>41.3</td>
<td>49.2</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>0.894</td>
<td>0.467</td>
<td>0.489</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Between run (n=20)</th>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [g/dL]</td>
<td>3.83</td>
<td>4.45</td>
<td>4.96</td>
</tr>
<tr>
<td>Mean [g/L]</td>
<td>38.3</td>
<td>44.5</td>
<td>49.6</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>0.872</td>
<td>0.419</td>
<td>0.848</td>
</tr>
</tbody>
</table>

**Method comparison (n=109)**

<table>
<thead>
<tr>
<th>Test x</th>
<th>Albumin FS (BioMajesty 6010C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test y</td>
<td>Albumin FS (BX-4000)</td>
</tr>
<tr>
<td>Slope</td>
<td>1.00</td>
</tr>
<tr>
<td>Intercept</td>
<td>0.000 g/dL (0.00 g/L)</td>
</tr>
<tr>
<td>Coefficient of correlation</td>
<td>0.999</td>
</tr>
</tbody>
</table>

**Conversion factor**

Albumin [g/dL] x 14.49 = Albumin [µmol/L]

Albumin [g/L] x 14.49 = Albumin [µmol/L]

**Reference Range**

- Adults: 3.5 – 5.2 g/dL (35 – 52 g/L)

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

**Literature**


**Manufacturer**

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany
### Chemistry Parameters 1

<table>
<thead>
<tr>
<th>Method No.</th>
<th>Method Name</th>
<th>ALB</th>
<th>Reagent Name</th>
<th>Reagent (µL)</th>
<th>Water (µL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1</td>
<td>ALB</td>
<td>135</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Analytical Parameters

**Print Name**: Albumin  
**Sample Type**: Serum  
**Unit**: g/dL  
**Assay Type**: End  
**Sample Ppt. Wash**: Disable  
**Stirring Speed R1**: Middle  
**Normal Range**

<table>
<thead>
<tr>
<th>Normal Range Name</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male-G1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Male-G2</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Male-G3</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Female-G1</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**Diluent (µL)**: Water (µL)

<table>
<thead>
<tr>
<th>Diluent (High/Prozone)</th>
<th>Normal Volume (µL)</th>
<th>Diluted Sample (µL)</th>
<th>Diluent (µL)</th>
<th>Technical Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0</td>
<td>1.5</td>
<td>0.0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Wave Length**

Prim. 600  
Sec. 700  

**Decimal Point**

- 1

### Chemistry Parameters 2

<table>
<thead>
<tr>
<th>Method No.</th>
<th>Method Name</th>
<th>ALB</th>
<th>Sample Type</th>
<th>Serum</th>
</tr>
</thead>
</table>

**Limit Checks**

- **Duplicate Limit**: 100 mAbs/10  
- **Sensitivity Limit**: 600 mAbs/10  
- **Linearity Limit**: %  
- **Prozone Limit**: Higher %  
- **Absorbance Limit**: Increase  
- **Abs. in reaction**: 25000 mAbs/10  

**Blank measurement**

- **Measurement of Reagent Blank during Run**: 
  - None
- **Reagent blank measurement at calibration**: 
  - Reagent blank (No sample)

**The number of measurement**: 

- **Duplicate Limit**: 30 mAbs/10

**Instrument Factor**

<table>
<thead>
<tr>
<th>a</th>
<th>b</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>
**Calibration Registration**

- **Method No.**
- **Method Name:** ALB
- **Sample Type:** Serum
- **Replication:** Duplicate
- **Check Interval:** 42
- **Test without calibration:** Disable
- **Calibration Type:** Linear
- **Reagent Lot:** New

**Analytical Parameters**

- **Reagent Lot No.**
  - (R1)
  - (R2)
- **Last**
- **Calibrator Name:** TruCal U
- **Conc.**
  - C1
  - C2
  - C3
  - C4
  - C5
  - C6
  - C7
- **WORK**
  - C1 Blank
  - Reagent Blank for C1
- **MASTER**
- **Calibr. Lot No.**
- **All**

The calibration curve is lot dependent.

- **Reagent blank**
  - mAbs/10
  - Last
- **Blank**
  - mAbs/10
  - Last
- **Calibration Curve**
  - Conc.
- **Absorbance**
  - mAbs/10
  - Recalculation

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**Chemistry Parameters**

**Method**
- Name: ALB
- Reagent Name: ALB
- Reagent (µL): 189
- Water (µL): 

**Print Name**
- Albumin
- Sample: Serum
- Unit: g/dL

**Sample**
- R1: ALB
- R2: Enable

**Assay Type**
- End

**Measuring points**
- Start: 11
- End: 13

**Normal Range**

<table>
<thead>
<tr>
<th>No.</th>
<th>Normal Range Name</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Male-G1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Male-G2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Male-G3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Female-G1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Wave Length**
- Prim: 600
- Sec: 700
- Enable: 

**Normal Sampling**
- Sample (µL): 
- Diluent (µL): 

**Technical Range**

<table>
<thead>
<tr>
<th>No.</th>
<th>Normal Range Name</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Rerun (High/Prozone)**

**Rerun (Low)**

**Reagent Name**
- SPT Wash: Enable

**Stirring Speed**
- R1: Middle
- R2: 

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**Chemistry Parameters**

**Method No.**
- Name: ALB
- Sample: Serum

**Limit Checks**
- Duplicate Limit: 100 mAbs/10
- Sensitivity Limit: 600 mAbs/10
- Linearity Limit: % (mAbs/10)/min
- Prozone Limit: % Upper

**Sensitivity**
- mAbs/10

**Absorbance Limit**
- Increase

**Reagent Name**
- Blank measurement: Disable reagent blank and S1 blank
- Measurement of Reagent Blank during Run: None

**Reagent blank limit checks:**
- Duplicate Limit: 30 mAbs/10

**Instrument Factor**
- a: 1.00
- b: 0.00
### Registration Calibration

<table>
<thead>
<tr>
<th></th>
<th>Method</th>
<th>Name</th>
<th>ALB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample</td>
<td>Serum</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sampling</td>
<td>Duplicate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Check Interval</td>
<td>42 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Auto Change Lot</td>
<td>Full Calibration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Auto Interval</td>
<td>hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type</td>
<td>Linear</td>
<td>Lot</td>
<td>New</td>
</tr>
<tr>
<td>Material Name</td>
<td>TruCal U</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Analytical Parameters

<table>
<thead>
<tr>
<th></th>
<th>R Lot No.</th>
<th>R2</th>
<th>Last</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample</td>
<td>Serum</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duplicate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Check Interval</td>
<td>42 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Auto Change Lot</td>
<td>Full Calibration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Auto Interval</td>
<td>hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type</td>
<td>Linear</td>
<td>Lot</td>
<td>New</td>
</tr>
<tr>
<td>Material Name</td>
<td>TruCal U</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Reagent Blank

- **Conc.**
- **WORK**
- **MASTER**
- **Lot No. (S)**
- **All**

<table>
<thead>
<tr>
<th>S1</th>
<th>0</th>
<th>Automatic entry</th>
<th>Automatic entry</th>
<th>S1 Blank</th>
</tr>
</thead>
<tbody>
<tr>
<td>S2</td>
<td></td>
<td>Automatic entry</td>
<td>Automatic entry</td>
<td></td>
</tr>
<tr>
<td>S3</td>
<td></td>
<td>Automatic entry</td>
<td>Automatic entry</td>
<td></td>
</tr>
<tr>
<td>S4</td>
<td>*</td>
<td>Automatic entry</td>
<td>Automatic entry</td>
<td></td>
</tr>
<tr>
<td>S5</td>
<td>*</td>
<td>Automatic entry</td>
<td>Automatic entry</td>
<td></td>
</tr>
<tr>
<td>S6</td>
<td>*</td>
<td>Automatic entry</td>
<td>Automatic entry</td>
<td></td>
</tr>
<tr>
<td>S7</td>
<td>*</td>
<td>Automatic entry</td>
<td>Automatic entry</td>
<td></td>
</tr>
</tbody>
</table>

- **K**
  - **Automatic entry**
  - **S1 Blank**
  - **Reagent Blank for S1**

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