**METHOD**

Blunt. End point.

**PRINCIPLE**

Serum proteins form a coloured complex in the presence of copper salt in alkaline solution.

**REAGENTS COMPOSITION**

Reagent: R

- Potassium iodide: 6 mmol/L
- Potassium sodium tartrate: 21 mmol/L
- Copper sulfate: 6 mmol/L
- Sodium hydroxide: 490 mmol/L

**MATERIAL REQUIRED BUT NOT PROVIDED**

- ELICT 2, calibrator. ref.CAL-0950, 4 x 3 mL.
- ELITROL I, control serum, ref.CONT-0990, 10 x 5 mL.
- ELITROL II, control serum, ref.CONT-0180, 10 x 5 mL.
- General Laboratory equipment.

**WARNINGS AND PRECAUTIONS**

- The reagent R is classified as hazardous.
  - **WARNING:** May be corrosive to metals. Causes skin irritation. Causes serious eye irritation. Harmful to aquatic life with long lasting effects. Wear protective gloves/protective clothing/eye protection/face protection. Avoid release to the environment. If IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Absorb spillage to prevent material damage.
  - For more information, refer to the Safety Data Sheet (SDS).
  - Take normal precautions and adhere to good laboratory practice.
  - Use clean or single use laboratory equipment only to avoid contamination.

**WASTE MANAGEMENT**

Disposal of all waste material should be in accordance with local, state and Federal regulatory requirements.

**STABILITY OF REAGENTS**

Store at 2-8°C and protect from light. The reagent is stable until the expiry date stated on the label. On board stability: Refer to § PERFORMANCE DATA

**PREPARATION**

The reagent is ready to use.

**REAGENT DETERIORATION**

The reagent solution should be clear. Cloudiness would indicate deterioration.

**SAMPLES**

- **Specimen:** Serum
- Plasma in lithium heparin.
- Samples must be free from haemolysis and lipaemia.
- **Storage:** Samples are stable for 7 days at 2-8°C and at least 2 months at -20°C. For longer storage, freeze samples at -70°C.

**REFERENCE VALUES**

<table>
<thead>
<tr>
<th>Serum</th>
<th>Patients at rest</th>
<th>Patients at night</th>
</tr>
</thead>
<tbody>
<tr>
<td>64 - 83 g/dL</td>
<td>60 - 78 g/dL</td>
<td>60 - 78 g/dL</td>
</tr>
</tbody>
</table>

Plasma:

Due to fibrinogen, plasma concentrations are increased from 0.2 to 0.4 g/dL (2 to 4 g/L) compared to serum concentrations.

**Note:** It is recommended that each laboratory establishes and maintains its own reference values. The data given are only for information.

**Conversion factor:**

1 g/dL = 10 g/L

**REFERENCES**

PROB-2550, 12 x 20 mL

**Kit composition:**

R: 12 x 20 mL

**PROCEDURE**

See application included in the barcode indicated at the end of the insert.

Important set-up information:

**MAGNESIUM XLIDYL reagent can be weakly contaminated by TOTAL PROTEIN PLUS on Spectra ProM.**

In order to avoid contamination on Spectra ProM, program the following incompatibilities:

- Software: TouchPro
- Incompatibilities: Probe incompatibilities
- Parameter: Protein - Magnesium

**CALIBRATION**

For calibration, multi-parametric calibrator Elucid 2 must be used. It's traceable to the reference material SRM 906c (of the National Institute of Standards and Technology).

**QUALITY CONTROL**

To ensure adequate quality, control sera such as ELILITROL I (normal control) and ELILITROL II (abnormal control) should be used. These controls should be assayed together with patient samples, at least once a day and after each calibration. The control frequency should be adapted to Quality Control procedures of each laboratory and the regulatory requirements. Results should be within the defined ranges. If values fall outside of the defined ranges, each laboratory should take corrective measures. Quality control materials should be used in accordance with local, state, and/or federal guidelines.

**PERFORMANCE DATA AT 37°C**

**A) On ELITech Clinical Systems Spectra ProM Analyzers**

- **Measuring range:** Determined according to CLSI(5) EP4-A protocol, the measuring range is from 0.20 to 12.00 g/dL (2.0 to 120.0 g/L).

- **Limit of Detection (LoD) and Limit of Quantification (LoQ):** Determined according CLSI(6) EP17-A protocol. 

LoD = 0.03 g/dL (0.3 g/L)

LoQ = 0.10 g/dL (1.0 g/L)

**Precision:**

Determined according to CLSI(6) EP5-A2 protocol.

- **Correlation:**

A comparative study has been performed between an ELITech Clinical Systems Spectra ProM analyzer and another FDA-Approved system equipment (Blurt method) on 100 human serum samples according to CLSI(8) EP2-A protocol.

The sample concentrations were between 0.27 and 11.25 g/dL (2.7 and 112.5 g/L). The parameters of the linear regressions are as follows:

- Linear regression: y = 0.993 x + 0.05 g/dL (0.5 g/L)
- Correlation coefficient: r = 0.997

**Interferences:**

Studies have been performed to determine the level of interference from different compounds according to CLSI(9) EP4-A2 protocol and SBRC recommendations(10). Recovery is within ±10% of initial value at total protein concentration of 4.00 mg/dL, 6.50 mg/dL, and 9.00 mg/dL.

- **Unconjugated Bilirubin:**

No significant interference up to 30.0 mg/dL (513 μmol/L).

- **Conjugated Bilirubin:**

No significant interference up to 29.5 mg/dL (504 μmol/L).

- **Glucose:**

No significant interference up to 307 mg/dL (28.14 mmol/L).

- **Triglycerides:**

No significant interference up to 263 mg/dL (2.97 mmol/L) triglycerides equivalent.

- **Hemoglobin:**

No significant interference up to 300 mg/dL.

- **Iron:**

Induces falsely high results at therapeutic concentrations.

In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom’s macroglobulinemia) can cause unreliable results.(11)

Other compounds may interfere.(12,13)

**Limitations:**

Interferences can be observed in patients treated with a substitute for blood plasma containing dextran.

On board stability/Calibration frequency (refrigerated position): 14 days

Recalibrate when reagent lots change, when quality control results fall outside the established range, and after a maintenance operation.

**B) On ELITech Clinical Systems Spectra ProS Analyzers**

- **Measuring range:**

Determined according to CLSI(5) EP4-A protocol, the measuring range is from 0.20 to 12.00 g/dL (2.0 to 120.0 g/L).

- **Limit of Detection (LOD) and Limit of Quantification (LoQ):**

Determined according CLSI(6) EP17-A protocol.

LoD = 0.03 g/dL (0.3 g/L)

LoQ = 0.10 g/dL (1.0 g/L)

**Limitations:**

Interferences can be weakly contaminated by TOTAL PROTEIN PLUS on Spectra ProS. In order to avoid contamination on Spectra ProS, program the following incompatibilities:

- Software: TouchPro
- Incompatibilities: Probe incompatibilities
- Parameter: Protein - Magnesium

**Software:**

TouchPro

**Other Software:**

Probe incompatibilities

**Parameter:**

Protein - Magnesium

**For Technical questions, please call or contact:**

(855) 354-8324 - www.elitechgroup.com

27 Wellington Road
Lincoln, Rhode Island 02865 - U.S.A.
In vitro diagnostic reagent, for professional use only

- **Precision**
  Determined according to CLSI(7) EP5-A2 protocol.

<table>
<thead>
<tr>
<th>Level</th>
<th>Mean (g/dL)</th>
<th>g/L</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>6.09</td>
<td>40.9</td>
<td>0.8</td>
</tr>
<tr>
<td>Medium</td>
<td>6.67</td>
<td>66.7</td>
<td>0.7</td>
</tr>
<tr>
<td>High</td>
<td>9.19</td>
<td>91.9</td>
<td>0.7</td>
</tr>
</tbody>
</table>

- **Correlation**
  A comparative study has been performed between an ELITech Clinical Systems Selectra ProS Analyzer and another FDA-Approved system equipment (Biuret method) on 100 human serum samples according to CLSI (8) EP9-A2 protocol. The sample concentrations were between 0.27 and 11.25 g/dL (2.7 and 112.5 g/L). The parameters of the linear regressions are as follows:

  Correlation coefficient: \( r = 0.998 \)
  Linear regression: \( y = 1.020 x - 0.03 \) g/dL (0.3 g/L)

- **Interferences**
  Studies have been performed to determine the level of interference from different compounds according to CLSI(9) EP7-A2 protocol and SFBC recommendations (10). Recovery is within ± 10% of initial value at total protein concentration of 4.00 mg/dL, 6.50 mg/dL, and 9.00 mg/dL.

   - Unconjugated Bilirubin:
     No significant interference up to 30.0 mg/dL (513 \( \mu \text{mol/L} \)).
   - Conjugated Bilirubin:
     No significant interference up to 29.5 mg/dL (504 \( \mu \text{mol/L} \)).
   - Glucose:
     No significant interference up to 507 mg/dL (28.14 mmol/L).
   - Tumour:
     No significant interference up to 263 mg/dL (2.97 mmol/L) triglycerides equivalent.
   - Hemoglobin:
     No significant interference up to 250 mg/dL.
   - Dextran:
     Induces falsely high results at therapeutic concentrations.

   In very rare cases, monoclonal gammapathies (multiple myeloma), in particular light type (Waldenstrom’s macroglobulinemia) can cause unreliable results. (11)

   Other compounds may interfere. (12,13)

- **Limitations**
  Interferences can be observed in patients treated with a substitute for blood plasma containing dextran.

- **On board stability/Calibration frequency (refrigerated position)**
  On Board Stability: 14 days
  Calibration frequency: 14 days
  Recalibrate when reagent lots change, when quality control results fall outside the established range, and after a maintenance operation.

**BIBLIOGRAPHY**


**SYMBOLS**

- **TVS**: In vitro diagnostic medical device
- **Temperature limitation**
- **Consult instruction for use**
- **Lot**: Batch code
- **Manufacturer**
- **Use by**
- **Catalogue number**: European Conformity

**REFERENCES**

- Kit composition:
  - PROB-0250, 12 x 20 mL
  - R: 12 x 20 mL

**IMPORTANT NOTE/see § PROCEDURE:**

- **Contamination risk**