**INTENDED USE**
- ELITech Clinical Systems ISE Na, K, Cl, Total CO₂ is intended for use with ELITech Clinical Systems ISE Reference solution, ISE Diluent in the quantitative in vitro determination of sodium (Na⁺), potassium (K⁺), Chloride (Cl⁻), and total CO₂ in human serum and plasma on ELITech Clinical Systems Selectra Pro Series Analyzers equipped with ISE module.
- Sodium measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders. Potassium measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders. Bicarbonate concentration is measured using the sodium and potassium electrodes associate with changes in bicarbonate balance.
- It is not intended for use in Point of Care settings.

**CLINICAL SIGNIFICANCE**
- Sodium is the major cation of extracellular fluid and plays a role in maintaining the distribution of fluid and the osmotic pressure in the extracellular fluid. The increase in serum sodium can be caused by an excessive loss or an insufficient intake of water (polyuria, etc.), or an excessive intake of salt, or by decreases in the renal excretion of sodium. Sodium is required for normal sodium excretion in sweat, diarrhea, diuresis, or the renal excretion of water.
- Potassium is the major intracellular ion. The increase of potassium concentration can be caused either by an increment of the load, or by a transcellular redistribution (polyuria, acute renal failure, dehiscence, sequestration of internal residues, stress hypertension, etc.). On the contrary, the potassium concentration can decrease in case of insufficient intake, renal narcotic agents, cortisol excess or over renal deaths in the glomerular-tubular (pumping) disorders, diseases, toxic, obvious suppression of the intestine.
- Chloride is the major anion of extracellular fluid and is positively correlated with sodium. Its concentration is useful to determine the state of the chloride balance. A decrease in chloride may be observed in the case of metabolic acidosis or in the case of metabolic alkalosis.
- Total CO₂ is used in the diagnosis and treatment of respiratory acid-base balance. It is recommended to recalibrate after setting-up of a new vial of ISE Reference Solution or of ISE Diluent then every 4 hours when quality control results fall outside the established range, after replacing electrode, and after ISE cleaning and maintenance.

**METHOD**
- Indirect potentiometric measurement with ion Selective Electodes.

**SOLUTION COMPOSITION**
- ISE Reference Solution: SOLNA
  - Buffered solution with 9.5 mmol/L of sodium; 0.13 mmol/L of potassium; 7.8 mmol/L of chloride; 1.79 mmol/L of total CO₂ and sufficient analyte to calibrate the meter.
- ISE Diluent: DIL
  - Buffered solution and surfactant.

**MATERIAL REQUIRED BUT NOT PROVIDED**
- ISE CALIBRATIONS
- ISE CONTROL: Control serum, level 1, ref. CONT-0046, 10 x 5 mL.
- ISE CONTROL II, control serum, level 2, ref. CONT-0047, 10 x 5 mL.
- ISE CLEANER/CONDITIONER, ref. ISCC-0280, SOLN B : 6 x 8 mL + SOLN C : 3 x 25 mL
- ISE module
- General Laboratory equipment

**WARNINGs AND PRECAUTIONS**
- These reagents are for professional in vitro diagnostic use only.
- ISE Reference Solution SOLNA and ISE Diluent DIL are clear to hazy (turbid/yellowish) and hygroscopic.

**REFERENCE VALUES**

**INTENDED USE**
Serum or lithium heparinized plasma free of hemolysis, obtained anaerobically for total CO₂. After collection, all samples should be promptly separated from cells to avoid shifts in the ionic equilibrium as a result of cell metabolism and pH changes.

**STABILITY OF SOLUTIONS**
- Store ISE Reference solution SOLNA and ISE Diluent DIL at 5 to 25 °C and protected from light.
- Store at room temperature for 3 months (up to 12 months may be stored at refrigerator temperature).
- Store at refrigerator temperature for 3 months (up to 12 months may be stored at freezer temperature).

**PREPARATION**
- Dependent or serum samples should be in accordance with local, state and Federal regulatory requirements.

**REAGENT DETERIORATION**
- These solutions are ready to use.

**STABILITY OF SOLUTIONS**
- Store ISE Reference solution SOLNA and ISE Diluent at 10-18 °C. Do not freeze.
- The solutions are stable until the expiry date stated on the label.

**SAMPLES**
- Serum
  - Serum or lithium heparinized plasma free of hemolysis, obtained anaerobically for total CO₂.
  - After collection, all samples should be promptly separated from cells to avoid shifts in the ionic equilibrium as a result of cell metabolism and pH changes.
- Storage
  - Samples should be stored tightly capped before analysis.

**REFERENCE VALUES**

**QUALITY CONTROL**
- To ensure adequate quality, two levels of control sera such as ISE CONTROL I and ISE CONTROL II 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. Values fall outside of the defined ranges should be treated with caution. Quality control materials should be used in accordance with local, state, and/or national guidelines.

**USES**
- FDA-Approved
- CLIA-88 approved
- CE-marked

**Correlation**
- A comparative study has been performed between an ELITech Clinical Systems Selectra Pro Series Analyzer and FDA-approved system equipment in the conditions described below according to CLSI EP9-A2 protocol. (8). The parameters of linear regressions are as follows:

**REFERENCE VALUES**

**METHOD**
- Indirect potentiometric measurement with ion Selective Electodes.

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- ISE Reference Solution: SOLNA
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In vitro diagnostic reagent, for professional use only

**Designations**
- ISE Reference Solution ISRS-0800
- ISE Diluent ISDI-0250

**Kit composition**
- SOLNA 1 x 500 mL DIL
- 72 x 25 mL

**Notes**
1. Hemolysis may increase the potassium concentration of 0.5 mmol/L, because of high-potassium-concentrated plasma. 
2. Hyponatremia or hypernatremia lead to a negative bias in the measurement of electrolytes because of diffusion effects.

### Table 1: Reproducibility

<table>
<thead>
<tr>
<th>Analyte</th>
<th>mEq/L</th>
<th>CV (%)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>Low</td>
<td>1.0</td>
<td>1.1</td>
</tr>
<tr>
<td></td>
<td>Medium</td>
<td>0.8</td>
<td>0.9</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>0.6</td>
<td>0.7</td>
</tr>
<tr>
<td>Potassium</td>
<td>Low</td>
<td>1.0</td>
<td>1.1</td>
</tr>
<tr>
<td></td>
<td>Medium</td>
<td>0.8</td>
<td>0.9</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>0.6</td>
<td>0.7</td>
</tr>
</tbody>
</table>

### Table 2: Linearity

<table>
<thead>
<tr>
<th>Analyte</th>
<th>mEq/L</th>
<th>Linear regression (mEq/L)</th>
<th>Correlation coefficient (r)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>Low</td>
<td>111.1 - 159.9</td>
<td>0.996</td>
</tr>
<tr>
<td>Potassium</td>
<td>Low</td>
<td>110.7 - 1.7</td>
<td>0.980</td>
</tr>
</tbody>
</table>

### Table 3: Stability on analyzer

<table>
<thead>
<tr>
<th>Analyte</th>
<th>mEq/L</th>
<th>Stability on analyzer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>Low</td>
<td>3 days</td>
</tr>
</tbody>
</table>

### Table 4: Interference

<table>
<thead>
<tr>
<th>Analyte</th>
<th>mEq/L</th>
<th>Interference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>Low</td>
<td>No significant interference</td>
</tr>
<tr>
<td></td>
<td>Medium</td>
<td>No significant interference</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>No significant interference</td>
</tr>
<tr>
<td>Potassium</td>
<td>Low</td>
<td>No significant interference</td>
</tr>
<tr>
<td></td>
<td>Medium</td>
<td>No significant interference</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>No significant interference</td>
</tr>
</tbody>
</table>

**BIBLIOGRAPHY**
6. Studies have been performed to determine the level of interference from different compounds according to CLSI EP7-A2 protocol. The percentage of recovery of initial value for each analyte is indicated in the tables below.
7. The measuring ranges are as follows:

#### Sodium
- Low level: 40 mEq/L
- Medium level: 100 mEq/L
- High level: 200 mEq/L

#### Potassium
- Low level: 2.0 mEq/L
- Medium level: 10.0 mEq/L
- High level: 20.0 mEq/L

#### Chloride
- Low level: 80 mEq/L
- Medium level: 120 mEq/L
- High level: 250 mEq/L

#### Total CO₂
- Low level: 10.8 mEq/L
- Medium level: 25.0 mEq/L
- High level: 50.0 mEq/L

#### Interferents
- Conjugated bilirubin: No significant interference up to 25 mg/dL (427 μmol/L)...
- Unconjugated bilirubin: No significant interference up to 36 mg/dL (616 μmol/L)...
- Other compounds may interfere.


#### Correlation

<table>
<thead>
<tr>
<th>Analyte</th>
<th>mEq/L</th>
<th>Linear regression (mEq/L)</th>
<th>Correlation coefficient (r)</th>
</tr>
</thead>
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<td>Low</td>
<td>110.7 - 1.7</td>
<td>0.980</td>
</tr>
</tbody>
</table>

### Table 5: Summary

<table>
<thead>
<tr>
<th>Analyte</th>
<th>mEq/L</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>Low</td>
<td>Recovery is within ± 6.2 % of initial value at concentrations of 2.00 and 6.00 mEq/L</td>
</tr>
<tr>
<td></td>
<td>Medium</td>
<td>Recovery is within ± 3.0 % of initial value at concentrations of 120.0 and 160.0 mEq/L</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>Recovery is within ± 10 % of initial value at concentrations of 20 and 35 mEq/L</td>
</tr>
<tr>
<td>Potassium</td>
<td>Low</td>
<td>Recovery is within ± 6.2 % of initial value at concentrations of 2.00 and 6.00 mEq/L</td>
</tr>
<tr>
<td></td>
<td>Medium</td>
<td>Recovery is within ± 3.0 % of initial value at concentrations of 120.0 and 160.0 mEq/L</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>Recovery is within ± 10 % of initial value at concentrations of 20 and 35 mEq/L</td>
</tr>
</tbody>
</table>

**Symbols**
- ET: Batch code
- CL: Ceral induction for use
- ID: In vitro diagnostic medical device
- M: Manufacturer
- T: Temperature limit
- U: Use by
- C: Catalogue number
- D: Dissert
- S: Solution X

For Technical questions, Please call or contact
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