**Sodium FS**

Diagnostic reagent for quantitative in vitro determination of sodium in serum or plasma on photometric systems

**Order Information**

Cat. No.
1 4808 99 10 021 R1 5 x 15 mL + R2 1 x 25 mL

**Summary** [1-4]

Sodium (Na⁺) is the major positive ion in the extracellular fluid compartment (ECF) and is mainly responsible for the osmotic pressure in plasma. Its concentration in blood is regulated by adjusting the water content of the ECF and by maintaining total body sodium at a constant level within a narrow range. Sodium is excreted or resorbed by the kidneys, depending on the hormonal control of water homeostasis by aldosterone and antidiuretic hormone (ADH).

Measurement of Na⁺ levels in serum is used for diagnosis of fluid and electrolyte imbalance, disorders of acid-base balance or excessive sodium intake. Furthermore, abnormal sodium values may indicate edema, renal diseases (e.g. diabetes insipidus), endocrine diseases like hypothyroidism and the syndrome of inappropriate antidiuretic hormone secretion (SIADH).

**Method**

Enzymatic photometric test

**Principle**

β-galactosidase catalyzes the conversion of o-nitrophenyl-β-D-galactopyranoside (ONPG) to o-nitrophenol and galactose. The activity of β-galactosidase depends on the sodium concentration in the sample. The absorbance increase at 405 nm is proportional to the sodium concentration in the sample.

**Reagents**

**Components and Concentrations**

<table>
<thead>
<tr>
<th></th>
<th>THAM buffer</th>
<th>pH 9.0</th>
<th>Chelator</th>
<th>0.5%</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1: β-galactosidase</td>
<td>0.01%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R2: THAM buffer</td>
<td>pH 8.8</td>
<td>ONPG</td>
<td>0.2%</td>
<td></td>
</tr>
</tbody>
</table>

**Storage Instructions and Reagent Stability**

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

**Warnings and Precautions**

1. The sodium test is very susceptible to sodium contamination. The sole use of ultrapure glass ware and disposable material is strongly recommended.
2. In very rare cases, samples of patients with gammopathy might give falsified results [7].
3. 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.
4. For professional use only!

**Waste Management**

Please refer to local legal requirements.

**Reagent Preparation**

The reagents are ready to use.

**Materials required but not provided**

General laboratory equipment

**Specimen**

Serum or plasma (lithium heparin)

Stability [5]:

- 2 weeks at 20 – 25°C
- 2 weeks at 4 – 8°C
- 1 year at –20°C

Discard contaminated specimens! Freeze only once!

**Assay Procedure**

**Application sheets for automated systems are available on request.**

**Wavelength**

405/660 nm (bichromatic)

**Optical path**

1 cm

**Temperature**

37°C

**Measurement**

Against reagent blank

<table>
<thead>
<tr>
<th>Blank</th>
<th>Sample or calibrator</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 µL</td>
<td>-</td>
</tr>
</tbody>
</table>

**Dist. Water**

40 µL 900 µL 900 µL

Mix, incubate for 5 min. at 37°C

**Reagent 1**

300 µL 300 µL

Mix, incubate at 37°C, read absorbance A1 after 1 min. and start stopwatch. Read absorbance A2 after 1 min. and absorbance A3 after 2 min. at 37 °C and calculate ∆A/min.

**Sodium [mmol/L] = ∆A/min. Sample x Conc. Calibrator [mmol/L] / ∆A/min. Calibrator**

**Calculation**

The concentration of sodium in unknown samples is derived from a linear calibration curve. It is obtained with the levels 1/2 and 3/4 of the electrolyte calibrator TruCal E.

Daily calibration is required.

**Conversion factor**

Sodium [mmol/L] = Sodium [mEq/L]

Sodium [mmol/L] x 2.30 = Sodium [mg/dL]

**Calibrators and Controls**

For calibration, Diasys TruCal E calibrator is recommended. The assigned values of TruCal E have been made traceable to the NIST Standard Reference Material® SRM 956. Diasys TruLab N and P controls should be assayed for internal quality control. 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 E</td>
<td>1 9310 99 10 079</td>
</tr>
<tr>
<td>TruLab N</td>
<td>5 9000 99 10 062</td>
</tr>
<tr>
<td>TruLab P</td>
<td>5 9050 99 10 062</td>
</tr>
<tr>
<td>TruLab P</td>
<td>5 9050 99 10 062</td>
</tr>
</tbody>
</table>
Performance characteristics

Measuring range
The test has been developed to determine sodium concentrations within a measuring range from 100 to 180 mmol/L.

Specificity/Interferences

<table>
<thead>
<tr>
<th>Interfering substance</th>
<th>Interferences</th>
<th>Sodium [mmol/L]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascorbic acid</td>
<td>up to 55 mg/dL</td>
<td>127</td>
</tr>
<tr>
<td>Conjugated bilirubin</td>
<td>up to 20 mg/dL</td>
<td>147</td>
</tr>
<tr>
<td>Unconjugated bilirubin</td>
<td>up to 55 mg/dL</td>
<td>133</td>
</tr>
<tr>
<td>Lipemia (triglycerides)</td>
<td>up to 1000 mg/dL</td>
<td>139</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>up to 500 mg/dL</td>
<td>125</td>
</tr>
<tr>
<td>Calcium</td>
<td>from 2 to 7.7 mmol/L</td>
<td>139</td>
</tr>
<tr>
<td>Copper</td>
<td>up to 60 µmol/L</td>
<td>124</td>
</tr>
<tr>
<td>Iron</td>
<td>up to 260 µmol/L</td>
<td>141</td>
</tr>
<tr>
<td>Lithium</td>
<td>up to 3.7 mmol/L</td>
<td>134</td>
</tr>
<tr>
<td>Magnesium</td>
<td>up to 15 mmol/L</td>
<td>135</td>
</tr>
<tr>
<td>Potassium</td>
<td>from 3 to 13 mmol/L</td>
<td>122</td>
</tr>
<tr>
<td>Zinc</td>
<td>up to 80 µmol/L</td>
<td>127</td>
</tr>
</tbody>
</table>

For further information on interfering substances refer to Young DS [6].

Limit of Detection
The lower limit of detection is 22 mmol/L.

Precision

<table>
<thead>
<tr>
<th>Intra-assay n = 20</th>
<th>Mean [mmol/L]</th>
<th>SD [mmol/L]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>130</td>
<td>1.24</td>
<td>0.95</td>
</tr>
<tr>
<td>Sample 2</td>
<td>144</td>
<td>0.989</td>
<td>0.69</td>
</tr>
<tr>
<td>Sample 3</td>
<td>150</td>
<td>0.885</td>
<td>0.59</td>
</tr>
</tbody>
</table>

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<tbody>
<tr>
<td>Sample 1</td>
<td>130</td>
<td>1.82</td>
<td>1.40</td>
</tr>
<tr>
<td>Sample 2</td>
<td>143</td>
<td>2.03</td>
<td>1.42</td>
</tr>
<tr>
<td>Sample 3</td>
<td>149</td>
<td>2.49</td>
<td>1.67</td>
</tr>
</tbody>
</table>

Method comparison
A comparison of DiaSys Sodium FS (y) with Flame Atomic Emission Spectrometry ((x) FAES) using 122 samples in the range of 121 – 162 mmol/L showed deviations between –9.55 and 2.44% to the comparison method.

A comparison of DiaSys Sodium FS (y) with ion-selective electrode ((x) ISE respons®920) using 122 samples in the range of 121 – 162 mmol/L showed deviations of –6.52 and 4.77% to the comparison method.

Reference Range [1]
Adults: 135 – 145 mmol/L
Children:
0 – 7 days 133 – 146 mmol/L
7 – 31 days 134 – 144 mmol/L
1 – 6 month(s) 134 – 142 mmol/L
6 months – 1 year 133 – 142 mmol/L
> 1 year 134 – 143 mmol/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