Sodium FS*

Diagnostic reagent for quantitative in vitro determination of sodium in serum or plasma on DiaSys respons®920

Order Information
Cat. No. 1 4808 99 10 921
4 twin containers for 100 determinations each

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
R1: THAM buffer pH 9.0 5.5%
    Chelator
    β-galactosidase 0.01%
R2: THAM buffer pH 8.8 0.2%
ONPG 0.4%

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. DiaSys respons containers provide protection from light. 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. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
3. In very rare cases, samples of patients with gammapathy might give falsified results [7].
4. 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.
5. For professional use only!

Waste Management
Please refer to local legal requirements.

Reagent Preparation
The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Specimen
Serum or heparin 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.

Calibrators and Controls
DiaSys TruCal E calibrator is recommended for calibration. The assigned values of TruCal E have been made traceable to the NIST Standard Reference Material® SRM 956. 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.

Performance Characteristics

<table>
<thead>
<tr>
<th>Measuring range 110 – 180 mmol/L sodium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limit of detection** 22 mmol/L sodium</td>
</tr>
<tr>
<td>On-board stability 4 weeks</td>
</tr>
<tr>
<td>Calibration stability 1 day</td>
</tr>
</tbody>
</table>

Interfering substance Interferences Sodium
<table>
<thead>
<tr>
<th></th>
<th>&lt; 3.0%</th>
<th>[mmol/L]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascorbic acid</td>
<td>up to 50 mg/dL</td>
<td>127</td>
</tr>
<tr>
<td>Conjugated bilirubin</td>
<td>up to 20 mg/dL</td>
<td>133</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>122</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>up to 1000 mg/dL</td>
<td>153</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 280 µmol/L</td>
<td>127</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>150</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].

Precision

<table>
<thead>
<tr>
<th></th>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [mmol/L]</td>
<td>130</td>
<td>144</td>
<td>150</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>0.95</td>
<td>0.69</td>
<td>0.59</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 between –6.52 and 4.77% to the comparison method.

Conversion factor
Sodium [mmol/L] = Sodium [mEq/L]
Sodium [mmol/L] x 2.30 = Sodium [mg/dL]
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
# Sodium FS

**Application for serum and plasma**

<table>
<thead>
<tr>
<th>Test Details</th>
<th>Test Volumes</th>
<th>Reference Ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test</td>
<td>Naenz</td>
<td>Auto Rerun □</td>
</tr>
<tr>
<td>Report Name</td>
<td>Sodium enz</td>
<td>Online Calibration □</td>
</tr>
<tr>
<td>Unit</td>
<td>mmol/L</td>
<td></td>
</tr>
<tr>
<td>Wavelength-Primary</td>
<td>405</td>
<td>660</td>
</tr>
<tr>
<td>Assay Type</td>
<td>Rate-A</td>
<td></td>
</tr>
<tr>
<td>M1 Start</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>M2 Start</td>
<td>20</td>
<td>25</td>
</tr>
<tr>
<td>Sample Replicates</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Control Replicates</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Reaction Direction</td>
<td>Increasing</td>
<td></td>
</tr>
<tr>
<td>Prozone Limit %</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Linearity Limit %</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Technical Minimum</td>
<td>100.0000</td>
<td>250.0000**</td>
</tr>
<tr>
<td>Y = aX + b</td>
<td>a = 1.0000</td>
<td>b = 0.0000</td>
</tr>
</tbody>
</table>

* Please enter calibrator value
** For technical reasons 250 mmol/L has to be programmed. The valid upper measuring limit is 180 mmol/L

### Test Details
- **Test**: Naenz
- **Sample Type**: Serum

### Test Volumes
- **Normal**: 
  - Dilution Ratio: 1 X
  - Standard Volume: 6.00 µL

### Reagent Volumes and Stirrer Speed
- **RGT-1 Volume**: 135 µL
- **R1 Stirrer Speed**: Medium
- **RGT-2 Volume**: 45 µL
- **R2 Stirrer Speed**: Medium

### Reference Range
- **Lower Limit (mmol/L)**: 135.00
- **Upper Limit (mmol/L)**: 145.00
- **Normal**: 
  - Dilution Ratio: 1 X
  - Standard Volume: 6.00 µL

### Sample Types
- Serum
- Urine
- CSF
- Plasma
- Whole Blood
- Other