Components and Concentrations

The sodium concentration in the sample. The absorbance increase at 405 nm is proportional to the activity of β-galactosidase (ONPG) to o-nitrophenol and galactose. The reagent rotor. Warm up reagents to room temperature before use.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor. Warm up reagents to room temperature before use.

Reagents

Components and Concentrations

| R1: | THAM buffer pH 9.0 | 5.5% | Chelator | 0.15% | 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.

Warnings and Precautions

1. The sodium test is very susceptible to sodium contamination. The sole use of ultrapur 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.

Specimen

Serum or plasma (lithium heparin)

Stability [1]: 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

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. 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 E</td>
<td>1 9310 99 10 079 4 x 3 mL</td>
</tr>
<tr>
<td>TruLab N</td>
<td>5 9000 99 10 062 20 x 5 mL</td>
</tr>
<tr>
<td>TruLab P</td>
<td>5 9050 99 10 062 20 x 5 mL</td>
</tr>
<tr>
<td>5 9050 99 10 061 6 x 5 mL</td>
<td></td>
</tr>
</tbody>
</table>

Performance Characteristics

Measuring range 100 - 180 mmol/L sodium

Limit of detection* 42 mmol/L sodium

On-board stability 4 weeks

Calibration stability 1 day

Interfering substance Interferences < 3.0% Sodium [mmol/L]

Ascorbic acid up to 50 mg/dL 133
Conjugated bilirubin up to 30 mg/dL 134
Unconjugated bilirubin up to 60 mg/dL 135
Lipemia (triglycerides) up to 1000 mg/dL 132
Hemoglobin up to 900 mg/dL 127
Calcium from 2 to 10 mmol/L 132
Iron up to 200 µmol/L 134
Lithium up to 3.7 mmol/L 136
Magnesium up to 15 mmol/L 135
Potassium from 3 to 12 mmol/L 126
Zinc up to 80 µmol/L 131

For further information on interfering substances refer to Young DS [2].

Precision

Within run (n=20) Sample 1 Sample 2 Sample 3
Mean [mmol/L] 132 138 149
Coefficient of variation [%] 1.46 1.04 1.10

Between run (n=20) Sample 1 Sample 2 Sample 3
Mean [mmol/L] 131 144 151
Coefficient of variation [%] 2.30 2.11 1.56

Method Comparison

A comparison of DiaSys Sodium FS (y) with Flame Atomic Emission Spectrometry ((x) FAES) using 128 samples in the range of 118 – 166 mmol/L showed deviations between –6.25 and 3.56% to the comparison method.

A comparison of DiaSys Sodium FS (y) with Ion-Selective Electrode ((x) ISE respons® 920) using 128 samples in the range of 118 – 166 mmol/L showed deviations between –3.72 and 6.64% to the comparison method.

Conversion factor

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

Reference Range [3]

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 samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Identification
This method is usable for analysis: Yes
Twin reaction: No
Name: NA
Shortcut: Reagent barcode reference: 057
Host reference:

Technic
Type: Linear kinetic
First reagent [µL]: 135
Blank reagent: Yes
Sensible to light: Yes
Second reagent [µL]: 45
Blank reagent: Yes
Sensible to light: Yes
Main wavelength: [nm]: 405
Secondary wavelength: [nm]: 660
Polychromatic factor: 1.000
1 st reading time: [min:sec]: 5:36
Last reading time: [min:sec]: 7:36
Reaction way: Increasing

Sodium FS
Substrate depletion: Absorbance limit
Linéarity: Maximum deviation [%]: 100
Fixed Time Kinetics
Substrate depletion: Absorbance limit
Endpoint
Stability: Largest remaining slope
Prozone Limit [%]

Reagents
Decimals
Units

Sample
Diluent: System water
Hemolysis:
Agent [µL]: 0 (no hemolysis)
Cleaner
Sample [µL]: 0

Technical limits
Concentration technical limits-Lower: 100
Concentration technical limits-Upper: 190

Sodium FS
Normal volume [µL]: 6
Normal dilution (factor): 1
Below normal volume [µL]: 6
Below normal dilution (factor): 1
Above normal volume [µL]: 6
Above normal dilution (factor): 1

URINE
Normal volume [µL]: 6
Normal dilution (factor): 1
Below normal volume [µL]: 6
Below normal dilution (factor): 1
Above normal volume [µL]: 6
Above normal dilution (factor): 1

PLASMA
Normal volume [µL]: 6
Normal dilution (factor): 1
Below normal volume [µL]: 6
Below normal dilution (factor): 1
Above normal volume [µL]: 6
Above normal dilution (factor): 1

CSF
Normal volume [µL]: 6
Normal dilution (factor): 1
Below normal volume [µL]: 6
Below normal dilution (factor): 1
Above normal volume [µL]: 6
Above normal dilution (factor): 1

Whole blood
Normal volume [µL]: 6
Normal dilution (factor): 1
Below normal volume [µL]: 6
Below normal dilution (factor): 1
Above normal volume [µL]: 6
Above normal dilution (factor): 1

Calibrators details
Calibrator list
Concentration
Cal. 1/Blank
Cal. 2
Cal. 3
Cal. 4
Cal. 5
Cal. 6
Max delta abs.
Cal. 1: 0.1
Cal. 2: 0.1
Cal. 3
Cal. 4
Cal. 5
Cal. 6
Drift limit [%]: 0.8

Calculations
Model: X
Degree: 1

* Enter calibrator value

Range
Gender: All
Age
SERUM
URINE
PLASMA
CSF
Whole blood

Contaminants
Please refer to r910 Carryover Pair Table

Results
Decimals: 1
Units: mmol/L
Correlation factor-Offset: 0.000
Correlation factor-Slope: 1.000

Application responses®910
May 2019/6