

Sodium FS*

Diagnostic reagent for quantitative in vitro determination of sodium in serum or plasma on DiaSys respons[®]910

Order Information

Cat. No. 1 4808 99 10 921

4 twin containers for 100 tests 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		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 is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagents.

Warnings and Precautions

- The sodium test is very susceptible to sodium contamination. The sole use of ultrapure glass ware and disposable material is strongly recommended.
- In very rare cases, samples of patients with gammopathy might give falsified results [7].
- 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.
- 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. Warm up reagents to room temperature before use.

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.

	Cat. No.	Kit size
TruCal E	1 9310 99 10 079	4 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL

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
	up to 50 mg/dL	148
Conjugated bilirubin	up to 30 mg/dL	134
	up to 20 mg/dL	149
Unconjugated bilirubin	up to 60 mg/dL	135
	up to 60 mg/dL	148
Lipemia (triglycerides)	up to 1000 mg/dL	132
	up to 1000 mg/dL	153
Hemoglobin	up to 500 mg/dL	127
	up to 250 mg/dL	148
Calcium	from 2 to 10 mmol/L	132
	from 2 to 10 mmol/L	149
Copper	up to 60 μ mol/L	121
	up to 60 μ mol/L	143
Iron	up to 200 μ mol/L	134
	up to 270 μ mol/L	157
Lithium	up to 3.7 mmol/L	136
	up to 3.3 mmol/L	150
Magnesium	up to 15 mmol/L	135
	up to 15 mmol/L	153
Potassium	from 3 to 12 mmol/L	126
	from 3 to 13 mmol/L	154
Zinc	up to 80 μ mol/L	131
	up to 80 μ mol/L	150

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]	123	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

** according to NCCLS document EP17-A, vol. 24, no. 34

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

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Manufacturer

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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:	057

Technic	
Type:	Linear kinetic
First reagent:[μ L]	135
Blank reagent	Yes
Sensitive to light	
Second reagent:[μ L]	45
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	405
Secondary wavelength:[nm]	660
Polychromatic factor:	1.0000
1 st reading time [min:sec]	5:36
Last reading time [min:sec]	7:36
Reaction way:	Increasing
Linear Kinetics	
Substrate depletion: Absorbance limit	0.3400
Linearity: Maximum deviation [%]	100.0000
Fixed Time Kinetics	
Substrate depletion: Absorbance limit	
Endpoint	
Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	System water
Hemolysis:	
Agent [μ L]	0 (no hemolysis)
Cleaner	
Sample [μ L]	0
Technical limits	
Concentration technical limits-Lower	100.0000
Concentration technical limits-Upper	180.0000
SERUM	
Normal volume [μ L]	6.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	
Above normal dilution (factor)	
URINE	
Normal volume [μ L]	6.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	
Above normal dilution (factor)	
PLASMA	
Normal volume [μ L]	6.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	
Above normal dilution (factor)	
CSF	
Normal volume [μ L]	6.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	
Above normal dilution (factor)	
Whole blood	
Normal volume [μ L]	6.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	
Above normal dilution (factor)	

Results	
Decimals	1
Units	mmol/L
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	>=135.0 <=145.0
URINE	
PLASMA	>=135.0 <=145.0
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants	
Please refer to r910 Carryover Pair Table	

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 [%]	0.80

Calculations	
Model	X
Degree	1

* Enter calibrator value