

## Sodium FS\*

Diagnostic reagent for quantitative in vitro determination of sodium in serum or plasma on DiaSys respons<sup>®</sup>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

<b>R1:</b>	THAM buffer	pH 9.0	5.5%
	Chelator		0.15%
	β-galactosidase		0.01%
<b>R2:</b>	THAM buffer	pH 8.8	0.2%
	o-nitrophenyl galactosidase		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.
- To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons<sup>®</sup>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.
- 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.

#### 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<sup>®</sup> 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 110 – 180 mmol/L sodium	
Limit of detection**	22 mmol/L sodium
On-board stability	4 weeks
Calibration stability	1 day

Interfering substance	Interferences < 3.0 %	Sodium [mmol/L]
<b>Ascorbate</b>	up to 50 mg/dL	127
	up to 50 mg/dL	147
<b>Conjugated bilirubin</b>	up to 20 mg/dL	133
	up to 60 mg/dL	147
<b>Unconjugated bilirubin</b>	up to 55 mg/dL	133
	up to 60 mg/dL	155
<b>Lipemia (triglycerides)</b>	up to 1000 mg/dL	122
	up to 1000 mg/dL	153
<b>Hemoglobin</b>	up to 500 mg/dL	125
	up to 300 mg/dL	148
<b>Calcium</b>	from 2 to 7.7 mmol/L	139
	from 2 to 8.0 mmol/L	147
<b>Copper</b>	up to 60 µmol/L	124
	up to 60 µmol/L	141
<b>Iron</b>	up to 260 µmol/L	127
	up to 200 µmol/L	155
<b>Lithium</b>	up to 3.7 mmol/L	134
	up to 3.3 mmol/L	150
<b>Magnesium</b>	up to 15 mmol/L	135
	up to 15 mmol/L	154
<b>Potassium</b>	from 3 to 13 mmol/L	122
	from 3 to 13 mmol/L	153
<b>Zinc</b>	up to 80 µmol/L	127
	up to 80 µmol/L	145

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

Precision			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mmol/L]	130	144	150
Coefficient of variation [%]	0.95	0.69	0.59
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mmol/L]	130	143	149
Coefficient of variation [%]	1.40	1.42	1.67

\*\* 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 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<sup>®</sup> 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

1. Thomas L. Clinical Laboratory Diagnostics. 1<sup>st</sup> ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 287-295.
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3. Delaney MP, Price CP, Newman DJ, Lamb E. Kidney disease. In: Burtis CA, Ashwood ER, Bruns DE editors. Tietz Textbook of Clinical Chemistry. 4<sup>th</sup> ed. St. Louis: W.B Saunders Company; 2006. p. 1671-1745.
4. Demers LM, Vance ML. Pituitary Function. In: Burtis CA, Ashwood ER, Bruns DE editors. Tietz Textbook of Clinical Chemistry. 4<sup>th</sup> ed. St. Louis: W.B Saunders Company; 2006. p. 1967-2002.
5. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1<sup>st</sup> ed. Darmstadt: GIT Verlag; 2001; p. 44-5.
6. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, CD: The American Association for Clinical Chemistry Press 2000.
7. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.

## Manufacturer



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## Sodium FS

### Application for serum and plasma

Test Details		Test Volumes		Reference Ranges	
Test	: Naenz			Auto Rerun	<input type="checkbox"/>
Report Name	: Sodium enz			Online Calibration	<input type="checkbox"/>
Unit	: mmol/L	Decimal Places	: 1	Cuvette Wash	<input type="checkbox"/>
Wavelength-Primary	: 405	Secondary	: 660	Total Reagents	: 2
Assay Type	: Rate-A	Curve Type	: Linear	Reagent R1	: Naenz R1
M1 Start	: 0	M1 End	: 0	Reagent R2	: Naenz R2
M2 Start	: 20	M2 End	: 25	<b>Consumables/Calibrators:</b>	
Sample Replicates	: 1	Standard Replicates	: 3	TruCal E L1 or L2	: *
Control Replicates	: 1	Control Interval	: 0	TruCal E L3 or L4	: *
Reaction Direction	: Increasing	React. Abs. Limit	: 1.200		
Prozone Limit %	: 0	Prozone Check	: Lower		
Linearity Limit %	: 0	Delta Abs./Min.	: 0.0000		
Technical Minimum	: 100.0000	Technical Maximum	: 250.0000**		
Y = aX + b	a = 1.0000	b =	0.0000		

\* 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 Volumes		Reference Ranges	
Test	: Naenz				
Sample Type	: Serum				
<b>Sample Volumes</b>				<b>Sample Types</b>	
Normal	: 6.00 $\mu$ L	Dilution Ratio	: 1 X	<input checked="" type="checkbox"/> Serum	
Increase	: 6.00 $\mu$ L	Dilution Ratio	: 1 X	<input type="checkbox"/> Urine	
Decrease	: 6.00 $\mu$ L	Dilution Ratio	: 1 X	<input type="checkbox"/> CSF	
Standard Volume	: 6.00 $\mu$ L			<input checked="" type="checkbox"/> Plasma	
<b>Reagent Volumes and Stirrer Speed</b>				<input type="checkbox"/> Whole Blood	
RGT-1 Volume	: 135 $\mu$ L	R1 Stirrer Speed	: Medium	<input type="checkbox"/> Other	
RGT-2 Volume	: 45 $\mu$ L	R2 Stirrer Speed	: Medium		

Test Details		Test Volumes		Reference Ranges	
Test	: Naenz				
Sample Type	: Serum				
Reference Range	: DEFAULT				
Category	: Male				
<b>Reference Range</b>				<b>Sample Types</b>	
	Lower Limit	Upper Limit		<input checked="" type="checkbox"/> Serum	
	(mmol/L)	(mmol/L)		<input type="checkbox"/> Urine	
Normal	: 135.00	: 145.00		<input type="checkbox"/> CSF	
Panic	: 0.00	: 0.00		<input checked="" type="checkbox"/> Plasma	
				<input type="checkbox"/> Whole Blood	
				<input type="checkbox"/> Other	