respons®920

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-galacatopyranoside (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

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 gammopathy 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.

	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]
Ascorbic acid	up to 50 mg/dL	127
	up to 50 mg/dL	147
Conjugated bilirubin	up to 20 mg/dL	133
	up to 60 mg/dL	147
Unconjugated bilirubin	up to 55 mg/dL	133
	up to 60 mg/dL	155
Lipemia (triglycerides)	up to 1000 mg/dL	122
	up to 1000 mg/dL	153
Hemoglobin	up to 500 mg/dL	125
	up to 300 mg/dL	148
Calcium	from 2 to 7.7 mmol/L	139
	from 2 to 8.0 mmol/L	147
Copper	up to 60 µmol/L	124
	up to 60 µmol/L	141
Iron	up to 260 µmol/L	127
	up to 200 µmol/L	155
Lithium	up to 3.7 mmol/L	134
	up to 3.3 mmol/L	150
Magnesium	up to 15 mmol/L	135
	up to 15 mmol/L	154
Potassium	from 3 to 13 mmol/L	122
	from 3 to 13 mmol/L	153
Zinc	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® 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]

* fluid stable

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

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7. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.

Manufacturer

IVD CE

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respons®920

Sodium FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	Naenz				Auto Rerun		☐
Report Name	:	Sodium enz				Online Calibration		☐
Unit	:	mmol/L	Decimal Places	:	1	Cuvette Wash		☐
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	**Consumables/Calibrators:**		
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	*to be set as “Blank” in consumables		
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		

Sample Volumes

Normal	:	6.00	µL	Dilution Ratio	:	1	X
Increase	:	6.00	µL	Dilution Ratio	:	1	X
Decrease	:	6.00	µL	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	

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	Naenz		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (mmol/L)	Upper Limit (mmol/L)
Normal	:	135.00	145.00
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other