Sodium Assay Kit (Na)

Method: Enzymatic

Cat .No.	Size	Instrument
GB4NA	R1:3×60 ml R2:3×20 ml	For Hitachi 717 & Shimadzu CL7200/8000
GS4NA	R1:3×60 ml R2:3×20 ml	For Hitachi917 & OlympusAU640/400/600
GB4NA/S	R1:1×60 ml R2:1×20 ml	For Hitachi 717 & Shimadzu CL7200/8000
GS4NA/S	R1:1×60 ml R2:1×20 ml	For Hitachi917 & OlympusAU640/400/600
Calibrator 1	1×3ml	
Calibrator 2	1×3ml	

INTENDED USE

For the *in vitro* quantitative determination of sodium in serum or heparin lithium anticoagulative plasma.

ASSAY PRINCIPLE[1]

Sodium is determined enzymatically via sodium dependent β-galactosidase activity with ONPG as substrate. The absorbance at 405 nm of the product O-nitrophenyl is proportional to the sodium concentration.

$$\text{ONPG} \xrightarrow[\beta\text{-galactosidase}]{Na^+} \text{o-nitrophenol} + \text{galactose}$$

ONPG = o-nitrophenyl -β-D-galactopyranose

SAMPLE COLLECTION AND PREPARATION

Serum, plasma treated with lithium heparinate.
Serum samples are stable for 3 days at 2-8℃.

REAGENT COMPOSITION

Contents	Concentration of Solutions
R1. Buffer/Enzymes	
Tris buffer	450 mmol/L, pH 9.0
Cryptand	5.4mmol/L
β-galactosidase	≥0.8 U/ml
R2. Substrate	
Tris buffer	10.0 mmol/L, pH 9.0
O-nitrophenyl galactoside	5.5 mmol/L
Calibrator 1	120mmol/L
Calibrator 2	160mmol/L

STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃. The reagent once opened is stable for 4 weeks on board the instrument at 2-8℃.

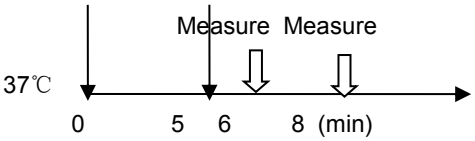
Calibrators

Calibrators are ready for use.
Stable up to expiry date when stored at 2-8℃.

ASSAY PROCEDURE

Test Procedure for Analyzers (HITACHI 7170/917)
Assay Mode: 2 Point Rate, 20-26
Wave Length (main/sub): 405 nm/660 nm

Sample: 8μl
R1: 180 μl R2: 60 μl



1. Mix 8 μl sample with 180 μl R1 and incubate at 37℃ for 5 minutes.
2. Add 60 μl R2 into cuvette, mix and incubate for 1 minute at 37℃.
3. Read initial absorbance and start timer simultaneously, read again after 1 and 2 minutes.
4. Calculate absorbance change per minute (ΔA/min).

CALIBRATION

1. This assay should be calibrated using the enclosed two level calibrators.
2. Construct the calibration curve according to the different absorbance change and concentration of the two level calibrators.
3. The sample concentration is read from the calibration curve with its absorbance.
4. This assay should be calibrated daily.

QUALITY CONTROL

Randox Assayed Multisera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.
4. Check the quality of the water used for reagents reconstitution.

NORMAL VALUE[2]

136 -146 mmol/L (313 -336 mg/dl) .
It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The method is linear up to 195 mmol/L. Sample above this concentration should be diluted with 0.9% NaCl and reassay. Multiply the result by dilution factor.

PRECISION

The CV of the test should be less than 5%

Intra assay precision		
N=20	Level1	Level 2

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CE

Revised 01DEC11 version 0906

Mean (mmol/L)	143.25	156.38
SD	1.146	0.966
CV	0.80%	0.62%
Inter assay precision		
N=5	Level1	Level 2
Mean (mmol/L)	144.48	158.76
SD	1.044	1.260
CV	0.72%	0.79%

SENSITIVITY
The minimum detectable concentration of sodium with an acceptable lever of precision was determined as 15.08 mmol/L.

INTERFERENCE
The following analytes were tested up to the levels indicated and found not to interfere:

Intralipid:	1000 mg/dl
Bilirubin:	50 mg/dl
Hemoglobin:	500 mg/dl
Vc:	50 mg/dl
K^+:	10 mM
Ca^{2+} :	8 mM
Fe^{3+} :	200 μM
Mg^{2+}:	5 mM
Cu^{2+}:	60 μM
Zn^{2+}:	80 μM

CORRELATION
This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:
Y=1.0074X-4.2122, and a correlation coefficient of 0.9723. seventy patient samples were analyzed spanning the range 110.6 mmol/l to 191.5 mmol/L.

PROCEDURE NOTES
When Sodium and Potassium are requested together Sodium is assayed immediately before Potassium.

SAFETY PRECAUTIONS AND WARNINGS
1. For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. All specimens used in this test should be considered potentially infectious. Universal precautions as they apply at your facility should be used for handling and disposing of materials during and after testing.

REFERENCES
1. Berry, M. N. et al., (1988) Clin. Chem. 34,2295.
2. Tietz, N. W. (1983) Clinical guide to Laboratory Tests, p384 W.B. Saunders Co., Philadelphia.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

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