

SODIUM (Na)

Enzymatic

Diagnostic reagent for determination of Sodium concentration.

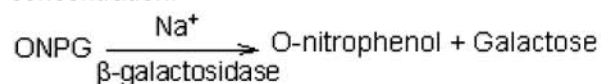
Liquid. Dual Reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

INTENDED USE

The test is applied for the quantitative determination of sodium in serum and plasma.

TEST PRINCIPLE

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



TEST PARAMETERS

Method	: Enzymatic Colorimetric
Wavelength	: 405 nm (Sub: 660nm)
Temperature	: 37°C
Sample	: Serum, plasma
Linearity	: 70 mmol/L - 200 mmol/L

REAGENT COMPOSITION

Reagent1: Buffer/Enzymes

Tris buffer	≤ 480 mmol/L, pH 9.0
Cryptand	≤ 5.6mmol/L
β -galactosidase	≥ 0.8 U/mL

Reagent 2: Enzyme

Tris buffer	≤12.0 mmol/L
pH 9.0	
O-nitrophenyl galactoside	≤ 5.8 mmol/L

REAGENT PREPARATION

All reagents are ready to use.

Reagents are stable up to the expiry date when stored at 2-8°C. Once opened the reagent is stable for 4 weeks on board the instrument at approximately 10°C.

For manual working procedures; if working reagent will be used; shake the Reagent 2 vial gently before pouring its contents into the Reagent 1 bottle. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

REAGENT STABILITY AND STORAGE

Once opened vials are stable minimum 30 days at 2-8°C at optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

SAMPLE

Serum and plasma treated with lithium heparinate are collected by standard procedures.

Sample is stable for 2 weeks at 20 - 25°C, 2 weeks at 2-8°C and 1 year at -20°C.

TEST PROCEDURE

Sample Start

There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

Substrate Start

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

$$\frac{A \text{ Sample}}{A \text{ Standard}} \times \text{conc. of standard}$$

= Sodium in sample (mg/dL)

Unit Conversion

$$\text{mg/dL} * 0.4345 = \text{mmol/L}$$

REFERENCE INTERVAL (NORMAL VALUES) *

136 -146 mmol/L (313 -336 mg/dL)

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

Archem Assayed Multisera, Level 2 and Level 3 are recommended for daily quality control.

This assay should be calibrated using the enclosed two level calibrators.

Construct the calibration curve according to the different absorbance change and concentration of the two level calibrators.

The sample concentration is read from the calibration curve with its absorbance.

Standards supplied are ready for use.

Standards are stable up to expiration date when stored at 2-8°C.

When sodium and potassium are requested together, sodium is assayed immediately before Potassium.

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 15 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity: 70 mmol/L

High Linearity: This method is linear up to 200 mmol/L. The minimum detectable concentration of sodium with an acceptable lever of precision was determined as 15.08 mmol/L.

Linearity may considerably vary depending on the instrument used.

Precision Studies:

Repeatability (within run) (Intra-assay)

Mean conc.	SD	CV	n
143.25	1.146	0.8%	20
156.38	0.966	0.617%	20

Reproducibility (run to run) (Inter-assay)

Mean conc.	SD	CV	n
144.48	1.68	1.16%	20
158.76	2.79	1.76%	20

Sensitivity (LOD): Detection limit of this test is 15.08 mmol/L.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

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

Introlipid	≤ 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.

Methods comparison and a correlation: This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

$Y = 0.94x + 5.75$, and a correlation coefficient of 0.99

70 patient samples were analyzed spanning the range

77.31mmol/L to 156.92mmol/L.

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1&R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

R36/38 : Irritating to eyes and skin.

S20/21 : When using, do not eat, drink or smoke.

S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S28 : After contact with skin wash immediately with plenty of water.

S36/37/39: Wear suitable protective clothing, gloves

and eye/face protection.

S45 : In case of accident or if you feel unwell, seek medical advice immediately.

S56 : Dispose of this material and its container at hazardous or special waste collection point.

S57 : Use appropriate container to avoid environmental contamination.

S61 : Avoid release in environment. Refer to special instructions/safety data sheets.

Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CV% : Coefficient of Variation Percentage

GLP : Good Laboratory Practice

IU : International Unit

mA : miliabsorbance

mL : mililiter





ONPG : o-nitrophenyl - β -D-galactopyranose

NCCLS: National Committee for Clinical Laboratory Standards

QC : Quality Control

REFERENCES

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3. Wu, Alan H.B. Tietz Clinical Guide to Laboratory Tests. 4th ed. Saunders Elsevier, St. Louis, MO: 2006, 992-996.
4. Berry, M. N. et al., (1988) Clin. Chem. 34,2295.
5. Clinical and Laboratory Standards Institute (formerly NCCLS). Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Second Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2004. NCCLS Document EP05-A2.
6. Eisenman G. Glass Electrodes for Hydrogen and Other Cations, Principles and Practice. New York: Marcel Dekker Inc.; 1967:2.

R1	Reagent 1
R2	Reagent 2
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing