

SODIUM (Na)

Diagnostic reagent for determination of Sodium concentration.

Liquid. Dual reagents. Store at +2/+8°C. For in Vitro Diagnostic Use (IVD). Do not freeze.

Ref No	Package	Ref No	Package	Ref No	Package	Ref No	Package
BB260	208 mL	L3211	80 mL	PL2268	64 mL	ZA65	100 mL
LM460	80 mL	M3092	200 mL	S2480	100 mL	ZA70	30 mL
L3210	80 mL	M3D143	40 mL			ZA71	120 mL

Changes made in the instructions for use are marked as grey.

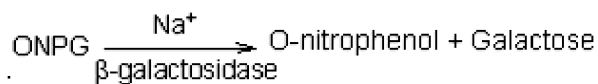
INTENDED USE

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

Reagent stability and storage data have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol.

TEST SUMMARY AND PROCEDURE ^{1, 2, 3, 4, 5}

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.



SAMPLE

Serum and plasma treated with lithium heparinate are collected according to the standard procedures.

Sample is stable for:

- 2 weeks at +20/+25°C,
- 2 weeks at +2/+8°C,
- 1 year at -20°C.

TEST PARAMETERS

Method : Enzymatic Colorimetric
 Wavelength : 405 nm (Sub: 660nm)
 Linearity : 200 mmol/L

Unit Conversion:

mg/dL x 0.4345 = mmol/L

REFERENCE INTERVAL (NORMAL VALUES) ⁷

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

It is recommended that each laboratory establish its own normal range.

REAGENT COMPONENTS

Reagent1: Buffer/Enzymes

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

Reference interval has been verified by using CLSI EP28-A3c protocol.

Reagent 2: Enzyme

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

QUALITY CONTROL AND CALIBRATION

Calibration: The assay requires the use of Arcal Auto Calibrator or Sodium Calibrator.

Arcal Auto Calibrator-Lyophilized

Ref.No: A39052

Ref.No: A39054

Ref.No: A39055 (For Olympus AU series.)

Sodium Calibrator

Ref.No: ZB83

REAGENT PREPARATION

Reagents are ready for use.

Reagents must not be kept on the instrument. After the study, the reagent must be tightly closed and stored at +2/+8°C. Make sure that the cover to be used during storage does not carry the risk of contamination. Calibration stability is 15 days for products stored at +2/+8°C in a closed with a cap after the study. Calibration period is 1 day for reagents that remain on the device during the onboard period. Calibration stability depends on

REAGENT STABILITY AND STORAGE ⁶

Reagents are stable at +2/+8°C till the expiration date stated on the label which is only for closed vials.

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

the application characteristics and cooling capacity of the autoanalyzer used.

Control: Commercially available control material with established values determined by this method can be used. We recommend:

Arcon N Level 1 Control- Lyophilized
Ref.No: A3910
Ref.No: A3912 (For Olympus AU series.)
Ref.No: A3913 (For BS series.)
Ref.No: A3914 (For Erba.)

Arcon P Level 2 Control- Lyophilized
Ref.No: A3920
Ref.No: A3922 (For Olympus AU series.)
Ref.No: A3923 (For BS series.)
Ref.No: A3924 (For Erba.)

At least two level controls must be run once in every 24 hours. Each laboratory should determine its own quality control scheme and procedures. If quality control results are not within acceptable limits, calibration is required.

PERFORMANCE CHARACTERISTICS

Limit of Detection (LoD): The limit of the test detection is 15.08 mmol/L.

Limit of Quantitation (LoQ) [LoQ values are based on Coefficient of Variation Percentage (CV) \leq 20%]:⁸ 70 mmol/L

LoD and LoQ values have been verified by using CLSI EP17-A protocol.

High Linearity: This method is linear up to 200 mmol/L.

For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilution factor.

Linearity may considerably vary depending on the instrument used.

Precision Studies:⁹

Repeatability (Within Run) (Intra-Assay)

Mean Concentration	SD*	CV%	n
143.25	1.146	0.800	40
156.38	0.966	0.617	40

Repeatability (Day to Day) (Inter-Assay)

Mean Concentration	SD	CV%	n
144.48	1.68	1.16	40
158.76	2.79	1.76	40

*SD: Standard Deviation

Precision Studies data have been verified by using CLSI EP05-A3 protocol.

Method Comparison:^{10, 11}

Correlation with a comparative method is: $r = 0.99$
 According to Passing-Bablok Fit:
 Slope: 0.94
 Intercept: 5.75

Interference:^{3, 4, 12}

No significant interference were observed for the following concentrations up to the interferent concentration given.

Introlipid	\leq 1000 mg/dL,
Bilirubin	\leq 50 mg/dL,
Hemoglobin	\leq 500 mg/dL,
Vc	\leq 50 mg/dL,
K+	\leq 10 mM,
Ca ²⁺	\leq 8 mM,
Fe ³⁺	\leq 200 μ M,
Mg ²⁺	\leq 5 mM,
Cu ²⁺	\leq 60 μ M,
Zn ²⁺	\leq 80 μ M.

The acceptable interference limit is set 10% below the highest interference concentration within \pm 10% recovery of the target.

Interferences may affect the results due to medication or endogenous substances.

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

WARNINGS AND PRECAUTIONS

IVD: For in Vitro Diagnostic use only.

Do not use expired reagents.

Reagents with two different lot numbers should not be interchanged.

For professional use

Follow Good Laboratory Practice (GLP) guidelines.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

Danger

EUH032	:Releases a very toxic gas if contacts with acid.
H317	:May cause allergic skin reaction.

Precaution

P280	:Use protective gloves / clothes / glasses / mask.
P264	:Wash your hands properly after using.
P272	:Contaminated work clothes should not be allowed to be used outside of the workplace.

Intervention

P302+P352	:Wash with plenty of water and soap if it contacts with skin.
-----------	---

- P333+P313 :Seek medical help if it irritates your skin or develops rash.
- P362+P364 :Remove contaminated clothes and wash properly before using.

Disposal

- P501 :Dispose the vials and contents according to the local regulations.

REFERENCES


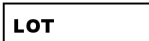
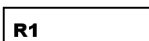
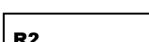
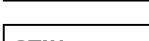
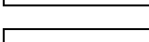
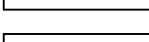
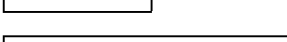
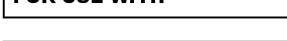






- Tietz, N.W., Fundamentals of Clinical Chemistry, p. 940, W.B. Saunders Co., Philadelphia, 1987.
- Tietz NW. Clinical Guide to Laboratory Test. 2nd ed. Philadelphia, PA: WB Saunders Company; 1995,52.
- Tietz NW. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia, PA: WB Saunders Company; 1995:88-91.
- Tietz NW, ed. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia: WB Saunders 1995:919.
- Tietz Fundamentals of Clinical Chemistry. 5th ed. Burtis CA, Ashwood ER, eds. Philadelphia, PA: WB Saunders Company; 2001:605.
- Clinical and Laboratory Standards Institute (CLSI). Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline. CLSI Document EP25-A. Wayne, PA: CLSI; 2009.
- Clinical and Laboratory Standards Institute (CLSI). Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition. CLSI Document EP28-A3c. Wayne, PA: CLSI; 2010.
- Clinical and Laboratory Standards Institute (CLSI). Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline. CLSI Document EP17-A. Wayne, PA: CLSI; Vol. 24 No. 34.
- Clinical and Laboratory Standards Institute (CLSI). Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014
- Passing-Bablok W et al. A General Regression Procedure for Method Transformation. J Clin Chem Clin Biochem 1988;26:783-79.
- Clinical and Laboratory Standards Institute (CLSI). Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition; Approved Guideline. CLSI Document EP09-A2. Wayne, PA: CLSI; Vol. 22 No. 19.
- Clinical and Laboratory Standards Institute (CLSI). Interference Testing in Clinical Chemistry; Approved Guideline. CLSI Document EP07. Wayne, PA: CLSI; 3rd Edition. CHERIAN G., SOLDIN ST. Clin. Chem. 27/5:748-752 (1981)
- Young DS. Effects of Drugs on Clinical Laboratory Tests. 3rd ed. Washington: AACC Press; 1990.
- Tietz, N. W. (1983) Clinical guide to Laboratory Tests, p384 W.B. Saunders Co., Philadelphia.
- Wu, Alan H.B. Tietz Clinical Guide to Laboratory Tests. 4th ed. Saunders Elsevier, St. Louis, MO: 2006, 992-996.
- Berry, M. N. et al., (1988) Clin. Chem. 34,2295.
- 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.
- Eisenman G. Glass Electrodes for Hydrogen and Other Cations, Principles and Practice. New York: Marcel Dekker Inc.; 1967:2.



Archem Sağlık Sanayi ve Tic. A.Ş.
 Mahmutbey Mah. Halkalı Cad. No:124 Kat:4
 Bağcılar/İstanbul/Turkey
 Tel: + 90 212 444 08 92
 Fax: +90 212 629 98 89
 info@archem.com.tr www.archem.com.tr



SYMBOLS

	In Vitro Diagnostic Medical Device
	Lot Number
	Reagent 1
	Reagent 2
	Global Trade Item Number
	Reference Number
	Good Laboratory Practices
	Identifies Products to Be Used Together
	Product of Turkey
	Manufacturer
	Expiration Date
	Temperature Limits
	Consult Instructions for Use
	Caution
	Number of Tests