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	Pack
MH-442	40 mL

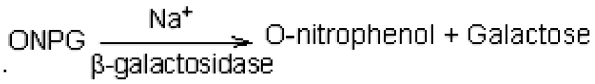
Changes made in the instructions for use are marked as grey.

INTENDED USE

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

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.



TEST PARAMETERS

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

REAGENT COMPONENTS

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

REAGENT PREPARATION

Reagents are ready for use.

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.

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

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/+8ºC,
1 year at -20°C.

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.

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

QUALITY CONTROL AND CALIBRATION

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

Arcal Auto Calibrator-Lyophilized
Ref.No: VT-003

Reagents must not be kept on the instument. 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 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: VT-001

Arcon P Level 2 Control- Lyophilized
Ref.No: VT-002

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) ≤ 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	≤ 1000 mg/dL,
Bilirubin	≤ 50 mg/dL,
Hemoglobin	≤ 500 mg/dL,
Vc	≤ 50 mg/dL,
K+	≤10 mM,
Ca2+	≤ 8 mM,
Fe3+	≤ 200 µM,
Mg2+	≤ 5 mM,
Cu2+	≤ 60 µM,
Zn2+	≤ 80 µM.

The acceptable interference limit is set 10% below the highest interference concentration within ± 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.

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Archem Sağlık Sanayi ve Tic. A.Ş. (With official contract based manufacturing agreement with Validity Sağlık Hiz. Sanayi A.Ş. Company)
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**
info@validity.com.tr **www.validity.com.tr**

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SYMBOLS

IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
R1	Reagent 1
R2	Reagent 2
GTIN	Global Trade Item Number
REF	Reference Number
GLP	Good Laboratory Practices
FOR USE WITH	Identifies Products to Be Used Together
PRODUCT OF TURKEY	Product of Turkey
	Manufacturer
	Expiration Date
	Temperature Limits
	Consult Instructions for Use
	Caution
	Number of Tests