ISE S.r.l.

CUSTOMISED SOLUTIONS
FOR YOUR LABORATORY

Sodium – Instructions for use

CE

IVD

R1: 2x 10 mL R2: 2x5 mL **R3330000098**

REF

Diagnostic reagent for quantitative in vitro determination of Sodium in human serum on photometric systems

TEST PARAMETERS

Method:	enzymatic, 2 Point Kinetic (fixed time)
Wavelength	405 nm
Temperature:	37°C
Sample:	Serum
Linearity:	80 – 180 mmol/L

REAGENT COMPOSITION

COMPONENTS	CONCENTRATION
Reagent 1:	
Good's buffer (pH 8.5)	
Cryptand	> 0.4 mM
β-D-galactosidase	< 8 U/mL
Proclin 300	0.02 %
Reagent 2:	
Good's buffer (pH 6.5)	
o-Nitrophenyl-β-D-glycoside	> 0.5 mM
Proclin 300	0.02 %

REAGENT PREPARATION

The reagents are ready to use.

REAGENT STABILITY AND STORAGE

Conditions:	protect from light
	close immediately after use
	do not freeze!
Storage:	at 2 – 8°C
Stability:	up to the expiration date

MATERIALS REQUIRED BUT NOT PROVIDED

General laboratory equipment

INTERFERING SUBSTANCES

The following substances normally present in the serum produced less than 10% deviation when tested at levels equal to the concentrations listed below.

NH_4Cl	1.5 mM
KPi	2.0 mM
$CaCl_2$	7.5 mM
KCl	10 mM
$CuCl_2$	0.5 mM
$ZnCl_2$	0.5 mM
$FeCl_3$	0.5 mM
Glucose	5 mM
Ascorbic Acid	10 mM
Bilirubin	40 mg/dL
Bilirubin conj.	40 mg/dL
Hemoglobin	500 mg/dL
Triglycerides	1000 mg/dL

AUTOMATED ASSAY PROCEDURE

Wavelength: 405 nm
Reagent 1: 200 µl
Sample: 8 µl
Incubation time: 5 minutes
Reagent 2: 100 µl
1st Reading: after 2 minutes
2nd Reading: after 4 minutes
(time between the 2 readings: 2 minutes)
Reagent blank necessary (daily)
Linear calculation with 2-point calibration (in duplicates)

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

REFERENCE RANGE [2]

136 – 146 mmol/L (313 – 336 mg/dL)

It is recommended that each laboratory establishes its own reference range to reflect the age, sex, diet and geographical location of the population.

DIAGNOSTIC IMPLICATION

Measurements of sodium in serum are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease(caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.
Small deviations from normal levels can have severe health consequences. Sodium has been commonly used in the diagnosis and management of patients with metabolic and cardiovascular disorder and is considered to have the potential of severe health consequences if left uncontrolled. Therefore monitoring serum sodium concentration is important in both routine check and emergency rooms.

TEST PRINCIPLE

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

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

ABBREVATIONS

ONPG = o-Nitrophenyl-β-D-glycoside

PERFORMANCE CHARACTERISTICS

LINEARITY, SENSITIVITY

This method is linear between sodium concentrations of 80 and 180 mmol/L.

ACCURACY

The performance of this assay (y) was compared with the performance of a similar sodium assay (x) using 53 individual serum samples ranging from 86.2 to 174.7 mmol/L. The linear regression gave the following equation:

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Revision A R3330000098 11-2018

y = 1.05 x – 2.23 mmol/L; R^2 = 0.98

PRECISION

Within run precision, n = 40	Mean [mmol/L]	SD [mmol/L]	CV [%]
Sample 1	128.94	1.57	1.2
Sample 2	155.84	1.72	1.1

Inter run precision, n = 40	Mean [mmol/L]	SD [mmol/L]	CV [%]
Sample 1	128.94	2.01	1.56
Sample 2	155.84	2.56	1.65

QUALITY CONTROL

We recommend that each laboratory uses Sodium controls to validate the performance of the Sodium assay.
We recommend the our controls (control serum with values in the normal and abnormal range).

CALIBRATION

A 2-point calibration with a sodium calibrator or standard low and a sodium calibrator or standard high is recommended every week, with change of reagent lot / bottle or as indicated by quality control procedures.
We recommend the our **Sodium Standard Set (2 levels)**.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use by suitably qualified laboratory personnel under appropriate laboratory conditions only.
2. Reagent 1 and 2 contain Proclin 300. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes, or if ingested, seek immediate medical attention.
3. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

1. Berry, M.N. et al., (1988) Clin.Chem. 34,2295
2. Tietz, N.W. (1983) Clinical guide to Laboratory Tests p. 384. W.B. Saunders Co., Philadelphia

Symbols on labels and packaging

IVD = In vitro diagnostic medical device

REF = Catalog Number

LOT = Lot Number

= Manufacturer

= Expiration date

= Temperature limitation

= Instruction for use

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