DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
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Sodium
Enzymatic

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

REF	Kit Size	Configuration
914605	5 x 100 mL	3 x 120 mL R1 + 2 x 90 mL R2
914607	6 x 25 mL	4 x 25 mL R1 + 2 x 25 mL R2
909610	3 x 20 mL	2 x 20 mL R1 + 2 x 10 mL R2
990911	1 x 60 mL	1 x 40 mL R1 + 1 x 20 mL R2
9A0852	3 x 20 mL	2 x 20 mL R1 + 2 x 10 mL R2
9T1052	3 x 20 mL	2 x 20 mL R1 + 2 x 10 mL R2
9E1852	2 x 60 mL	2 x 40 mL R1 + 2 x 20 mL R2

Additionally available:

909680	2 x 3 mL	Sodium Standard Set (2 levels)	
D98481	12 x 5 mL	Control normal	Diacon N
D14481	5 x 5 mL	Control normal	Diacon N
D98481SV	1 x 5 mL	Control normal	Diacon N
D98482	12 x 5 mL	Control abnormal	Diacon P
D14482	5 x 5 mL	Control abnormal	Diacon P
D98482SV	1 x 5 mL	Control abnormal	Diacon P

For professional in vitro diagnostic use only.

GENERAL INFORMATION

Method	Enzymatic, 2 Point Kinetic (fixed time)
Shelf life	15 months
Storage	2 – 8°C
Wavelength	405 nm
Temperature	37 °C
Sample	Serum

INTENDED USE

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

DIAGNOSTIC SIGNIFICANCE

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

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

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.

ONPG: o-Nitrophenyl-β-D-glycoside

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 %

MATERIAL REQUIRED BUT NOT PROVIDED

- Clinical chemistry analyser.

REAGENT PREPARATION

The reagents are ready to use.

STORAGE AND STABILITY

Conditions:	Protect from light. Close immediately after use. Do not freeze the reagents!
Storage	at 2 – 8 °C
Stability:	up to the indicated expiration date

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.

SPECIMEN COLLECTION AND STORAGE

Serum is the recommended sample type for the Dialab Sodium reagent.

AUTOMATED TEST 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)

Special adaptations for automated analysers can be made on request.

QUALITY CONTROL AND CALIBRATION

We recommend that each laboratory uses Sodium controls to validate the performance of the Sodium assay.
We recommend the Dialab controls **Diacon N** (control serum with values in the normal range) and **Diacon P** (control serum with values in the 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 Dialab **Sodium Standard Set (2 levels)**.

PERFORMANCE CHARACTERISTICS

LINEARITY, MEASURING RANGE

This method is linear between sodium concentrations of 80 and 180 mmol/L (184 and 414 mg/dL).

SENSITIVITY/LIMIT OF DETECTION

The lower limit of detection is 80 mmol/L.

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

SPECIFICITY/INTERFERENCES

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

METHOD COMPARISON

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:

$y = 1.05\ x - 2.23$ mmol/L; $R^2 = 0.98$

TRACEABILITY

The assigned values for Sodium Standard Set set have been made traceable to the ISE method.

EXPECTED VALUES [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.

LIMITATIONS

- When Sodium and Potassium are requested together, Sodium is assayed immediately before Potassium.
- Eventual Sodium, Enzymatic carry-over to reagents Magnesium (Xylidyl blue), Protein Total in Urine/CSF (Pyrogallol red) and Triglycerides (GPO-PAP). The actual carry-over depends on the analyser.

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WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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.