



Instructions For Use

GENESIS

Sodium (Colorimetric Method)

Cat no.	size
1304 101	2*25
1304 102	4*25

INTENDED USE

Sodium Reagent is intended for the in vitro Quantitative diagnostic determination of Total Sodium in human serum and plasma.

DIAGNOSTIC CHARACTERISTICS

Sodium and Potassium are the major cations of extracellular and intracellular fluids respectively. Sodium maintains the normal distribution of water and the osmotic pressure in the various fluid compartments. Potassium influences the acid base balance and osmotic pressure including water retention. Increased sodium levels are found in severe dehydration and excessive polyuria, metabolic acidosis, diarrhea and renal insufficiency. Increased potassium levels are found in renal failure, dehydration, shock and adrenal treatment with sodium salts.

Decreased levels are found in severe insufficiency. Decreased levels are found in malnutrition, gastrointestinal fluid loss, and hyperactivity of the adrenal cortex.

ASSAY PRINCIPLE

The Present method (Mg-Uranylacetate Method) is based on reaction of sodium with a selective chromogen producing a chromophore whose absorbance varies directly as the concentration of sodium in the test specimen

COMPOSITION

Reagent (R)	Chromogen	0.03 gm/L
	EDTA	25 mmol/L
	Dimethyl sulfoxide (DMSO)	75 mmol/L
	preservatives	0.05%
	Antifoam	0.01 %
Standard (S)	Sodium standard	150 mmol/l

PRECAUTIONS AND WARNING

Do not ingest or inhale. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries, seek medical advice immediately.

REAGENT PREPARATION, STORAGE AND STABILITY

Reagents and standard are ready-to-use. When stored at 2-8°C; they are stable up to the expiry date stated on the label. Once opened, the reagent and standard are stable for 3 months at the specified temperature.

SPECIMEN COLLECTION AND PREPARATION

Serum and Heparin plasma freshly drawn non-hemolized

Stability: Serum Sodium is stable for at least 24 hours at room temperature and two weeks at 2-8°C.

Urine: Urine diluted 1+1 with distilled water can be used for Sodium estimation.

PROCEDURE

1. Bring the reagent to room temperature

2. Assay parameters

Wavelength	630 nm
Optical path	1 cm
Assay type	colorimetric end-point
Direction	Increase

3. Adjust the instrument against blank

Symbols in Product Labeling			
	Authorized Representative		Expiry date
	For in-vitro diagnostic use		CAUTION, consult instructions for use
	Catalogue number		Manufactured by
	Lot number		Temperature Limit
	Consult instructions for use		

Pipette into clean test tubes:

	Blank	Standard	Sample
Reagent	1.0 ml	1.0 ml	1.0 ml
Standard (µL)		10 µL	
Sample (µL)			10 µL

Mix well and let stand 5 minutes at room temperature, and then read absorbance of sample and standard against reagent blank. The color is stable for at least 1 hour.

CALCULATION

$$\frac{A_{\text{Sample}}}{A_{\text{Standard}}} \times 150 = \text{Serum Sodium Concentration}$$

REFERENCE VALUES

Serum/Plasma: Serum 135 – 150 mmol/l.

QUALITY CONTROL

It is recommended to use the Control Serum level I and II to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control

METROLOGICAL CHARACTERISTICS

Measuring range: From detection limit of 40 mmol/L to linearity limit of 400mmol/L.

Analytical sensitivity: 1 mmol/L

Linearity limit: 20.0 mg/dL.

For higher values dilute sample 1/2 with physiological saline and repeat measurement.

-Repeatability (within run):

	Level 1	Level 2
n	20	20
Mean (mg/dL)	140	170
SD	0.72	1.44
CV%	0.51	0.84

-Reproducibility (run to run):

	Level 1	Level 2
n	20	20
Mean (mg/dL)	140	170
SD	0.76	1.58
CV%	0.54	0.93

INTERFERENCES

Hemoglobin: Demonstrates positive interference

Lipemic: No significant interference

Anticoagulants: Citrate and oxalate must be avoided

BIBLIOGRAPHY

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4. Trinder, P:Analyst, 76:596, (1951)