SODIUM-d

Enzymatic. Colorimetric

Quantitative determination of Sodium

CE IVD

PACKAGING

Ref.: 101-0688	Cont.: 3 x 20 / 3 x 9 mL

Store at 2 - 8º C

CLINICAL SIGNIFICANCE

Sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hyper-tension, Addison's disease, dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

PRINCIPLE OF THE METHOD [1]

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

$$\text{ONPG} \xrightarrow[\text{ϑ-galactosidase}]{\text{Na+}} \text{o-nitrophenol} + \text{galactose}$$

ONPG = o-nitrophenyl - ϑ -D-galactopyranose

REAGENTS

R 1 Buffer / Enzymes	Tris buffer, pH 9.0 Cryptand ϑ-galactosidase	450 mmol/L 5.4 mmol/L ≥ 0.8 U/mL
R2 Diluent / Substrate	Tris buffer O-nitrophenyl galactoside	10.0 mmol/L 5.5 mmol/L

Optional (not included in the kit)

Contro-N	Ref.: 101-0252	4 x 5 mL	Lyophilized human control serum
	Ref.: 101-0083	20 x 5 mL	
Contro-P	Ref.: 101-0253	4 x 5 mL	Lyophilized human control serum
	Ref.: 101-0084	20 x 5 mL	

PREPARATION

R1. Buffer/Enzymes

Transfer the contents of one bottle Buffer R1a to one bottle Enzyme R1b and dissolve by swirling gently, ensuring that the entire contents are completely dissolved. Transfer the entire contents to Buffer R1a rinsing vial R1b several times. Avoid the formation of foam.

R2. Diluent/Substrate

Transfer the contents of one bottle Diluent R2a to one bottle Substrate R2b and dissolve by swirling gently, ensuring that the entire contents are completely dissolved . Transfer the entire contents to Diluent R2a rinsing vial R2b several times. Avoid the formation of foam.

STORAGE AND STABILITY

R1 is stable for 2 weeks at 2 - 8° C or 5 days at 15 - 25° C.
R2 is stable for 4 weeks at 2 - 8° C or 2 weeks at 15 - 25° C.
Do not use reagents over the expiration date.

ADDITIONAL EQUIPMENT

- Spectrophotometer or colorimeter measuring at 405 nm.
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment (Note 1).

SAMPLES

Serum, plasma treated with lithium heparinate.

PROCEDURE

Notes: CHRONOLAB SYSTEMS has instruction sheets for several automatic analyzers. Instructions for many of them are available on request. In order to avoid contamination it is recommended to use disposable material.

1. Assay conditions:
   Wavelength: 405nm
   Cuvette: . . . . . 1 cm light path
   Constant temperature . . . . . 37º C / 15 - 25º C
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

	Standard	Sample
R1	720 µL	720 µL
R2	290 µL	290 µL
Standard	30 µL	----
Sample	----	30 µL

4. Mix and read the absorbance after 60 s (A_1) and 120 s (A_2).
5. Calculate: $\Delta A = A_2 - A_1$.

CALCULATIONS

$$\frac{(\Delta A)\,\text{Sample}}{(\Delta A)\,\text{Calibrator}} \times \text{Calibrator conc} = \text{mmol/L sodium in the sample}$$

QUALITY CONTROL

Control Sera are recommended to monitor the performance of assay procedures.
If control values are found outside the defined range, check the instrument, reagent and calibration for problems.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES [2]

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

These values are for orientation purpose; each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Linearity: The method is linear between sodium concentrations of 37.3 and 187.8 mmol/L

Sensitivity: The minimum detectable concentration of sodium with an acceptable level of precision was determined as 37.3 mmol/L.

Precision:

	Intra-assay (n=20)			Inter-assay (n=20)		
Mean (mmol/L)	47.4	125	180	62.9	125	160
SD	0.76	1.54	1.08	4.99	2.51	1.94
CV (%)	1.60	1.23	0.60	7.94	2.01	1.21

Accuracy: Results obtained using CHRONOLAB reagents (y) did not show systematic differences when compared with other commercial reagent (x). The results obtained using 40 samples spanning the range 119 to 226 mmol/L were the following:
Correlation coefficient (r): 0.98.
Regression equation: y= 1.12x - 13
The results of the performance characteristics depend on the analyzer used.

BIBLIOGRAPHY

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.

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