Audit Diagnostics

CE

SODIUM-LQ

SODIUM-LQ

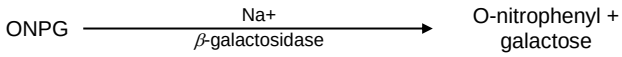
O-Nitrophenyl-β-D-Glucoside

Quantitative determination of Sodium
IVD

Store at 2-8ºC

INTENDED USE
For the quantitative *in vitro* determination of Sodium in serum.

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



ONPG = o-nitrophenyl -ß-D-galactopyranose

CLINICAL SIGNIFICANCE
In healthy individual, an extracellular fluid level of sodium is regulated to maintain at 136 -146 mmol/L (313 -336 mg/dL[1-2]). Small deviations from normal level 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 by American Association of Clinical Chemistry 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.

REAGENTS

R 1	GOOD'S buffer, pH 8,5	
	Cryptand	> 0,4 mmol/L
	β–D-galactosidase	< 8 U/mL
	Proclin 300	0,02%
R2	GOOD'S buffer, pH 6,5	
	O-nitrophenyl β–D-glycoside	> 0,5 mmol/L
	Proclin 300	0,02%
CAL L & H	Sodium aqueous primary standard	

PREPARATION
All the reagents are ready to use.

CALIBRATION
This assay should be calibrated using the enclosed L and H sodium standards. Sodium concentration in sample is determined from the calibration curve using the included L & H sodium standards.

STORAGE AND STABILITY
All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC, protected from light and contaminations prevented during their use.
Do not freeze. Do not use reagents over the expiration date.

ADDITIONAL EQUIPMENT
- Spectrophotometer or colorimeter measuring at 405 nm.
- Thermostatic bath at 37ºC (± 0,1ºC)
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment (Note 1).

SAMPLES (Note 3)
This assay is formulated for use with non hemolysed serum.
No special handling or pretreatment is needed.
Serum is the recommended sample type for this assay.

PROCEDURE
1. Assay conditions:
   Wavelength: ..... 405 nm
   Cuvette: ..... 1 cm light path
   Constant temperature: 37ºC
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette(Note 2):

	Blank	Calibrator L & H	Sample
R1 (µL)	600	600	600
Distilled water	24	--	--
Calibrator (µL)	--	24	--
Sample (µL)	--	--	24

4. Mix and incubate for 5 minutes at 37ºC.
5. Add:

	Blank	Calibrator L & H	Sample
R2 (µL)	300	300	300

6. Mix and read the absorbance after 120 s (A_1) and 240 s (A_2).
7. Calculate: $\Delta A = A_2 - A_1$.

CALCULATIONS

$$\frac{(A2-A1)\text{Sample} - (A2-A1)\text{Blank}}{(A2-A1)\text{Calibrator} - (A2-A1)\text{Blank}}$$

Interpolate the ΔA obtained into the calibration curve.

QUALITY CONTROL
Controls Sera are recommended to monitor the performance of assay procedures: CONTROL H Normal and Pathologic.

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
136 - 146 mmol/L (313 - 336 mg/dL)
These values are for orientation purpose; each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS
Measuring range: From *detection limit* of 80 mmol/L to *linearity limit* of 180 mmol/L.
Precision:

	Intra-assay (n=20)	
Mean (mmol/L)	128,9	155,8
SD (mmol/L)	1,57	1,72
CV (%)	1,20	1,10

Intra-assay (n=20)	
128,9	155,8
2,01	2,56
1,56	1,65

Sensibility: 1 mmol/L = 0,003512355 (A)
Accuracy: Results obtained using Audit Diagnostics reagents (y) did not show systematic differences when compared with other commercial reagent (x).
The results obtained using 53 samples spanning the range 86,2 to 174,7 mmol/L were the following:
Correlation coefficient $(r)^2$: 0,9801
Regression equation: y= 1,0516x – 2,2343
The results of the performance characteristics depend on the analyzer used.

INTERFERENCES
The following substances normally present in serum produced less than 10% deviation at the listed concentrations: NH_4Cl at 1,5 mmol/L, KPi at 2,0 mmol/L, $CaCl_2$ at 7,5 mmol/L, KCl at 10 mmol/L, $CuCl_2$ at 0,5 mmol/L, $ZnCl_2$ at 0,5 mmol/L, $FeCl_3$ at 0,5 mmol/L, Glucose at 5 mmol/L, ascorbate 10 mmol/L, bilirubin at 40mg/dL, bilirubin conjugate 40 mg/dL, hemoglobin 500 mg/dL, and triglyceride 1000 mg/dL.

NOTES
1. In order to avoid contamination it is recommended to use disposable material.
2. Use clean disposable pipette for its dispensation.
3. When Sodium and Potassium are requested together, sodium is assayed immediately before Potassium.
4. **Audit Diagnostics has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.**

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

Manufactured By: AUDIT DIAGNOSTICS
Business & Technology Park, Carrigtwohill, Co. Cork (Ireland)
Tel: 00353 - (0) 21 – 4533 652 *Fax:* 00353 - (0) 21 – 4533 653
E-mail: info@auditdiagnostics.ie *Website:* www.auditdiagnostics.ie