



SODIUM

REF 495H R1 2x45 ml/R2 1x40 ml



IVD For in vitro medical device

Use

Kit for measurement of sodium in serum or plasma.
Kinetic enzymatic method.

Summary

Sodium measurements are used in the diagnosis and treatment of cirrhosis of the liver, syndrome of Bartler.

Principle

Kinetic analysis. The assay is based on the activation of β -galactosidase enzyme by the sodium present in the sample and the consequent enzymatic transformation of o-nitrophenyl- β -D-galactopyranoside (o-NPG) into o-nitrophenol and galactose. The o-nitrophenol formed is kinetically measured at 405 nm.

Reagents

R1/A	Buffer	pH 8.90
R1/B (Iyo)	β -galactosidase	
R2/A	Buffer	pH 6.20
R2/B (Iyo)	o-NPG	

Reagents Preparation

Let reagents reach room temperature before the ricostitution.

REAGENT 1 (R1/A+R1/B)

Reconstitute the contents of a vial of Reagent R1/B (lyophilized powder) with Reagent R1/A (buffer). Shake gently until complete dissolution, avoid the formation of foam. Wait 5 minutes before use.

REAGENT 2 (R2/A+R2/B)

Reconstitute the content of a vial of Reagent R2/B (lyophilized powder) with R2/A (diluent). Shake gently until complete dissolution, avoid the formation of foam. Wait 5 minutes before use.

Storage And Stability

- Store the kit at 2-8°C.
- REAGENT 1 (R1/A+R1/B), stability 2 weeks at 2-8°C or 5 days at 15°-25°C.
- REAGENT 2 (R2/A+R2/B), stability 4 weeks at 2-8°C or 5 days at 15°-25°C

Precaution in Use

The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998). However the reagent should be handled with care, according to good laboratory practice.

Waste Management

Please refer to the local legal requirements.

Specimen Collection and Preparation

- Serum, plasma with lithium-heparin.
- Do not use sodium - EDTA, as anticoagulant.

Note

- use only sodium, potassium and calcium ions free distilled water.
- In case sodium is defined together with potassium, sodium must be determined directly before potassium (bichannel method).
- The kit, according to this method, must be used in manual procedures. About automatic use follow specific applications.
- Avoid direct light, contamination and evaporation.
- The volumes in the procedure can be changed proportionally.
- In case of complaint or quality control request, refer to the lot number on the package or the lot number on the singles vials.

Procedures

Wavelength λ : 405 nm
 Working temperature 37°C
 Optical path 1 cm
 Reaction kinetic
 Bring the reagents at 15-25°C before using them.

Bireagent procedure

	BLANK	STD	SAMPLE
Reagent R1	500 μ l	500 μ l	500 μ l
Reagent R2	200 μ l	200 μ l	200 μ l
Distilled Water	20 μ l	--	--
Sample	--	--	20 μ l
Standard	--	20 μ l	--

In a cuvette, mix Reagent R1 and serum sample and incubate at 37° for 5 minutes and then add Reagent R2.
 Read absorbance (405nm) at 3 minutes after addition of Reagent R2 as A_1 .
 Incubate for 2 minutes and read the absorbance as A_2 .
 Calculate $\Delta A = A_2 - A_1$

Conversion Values

Sodium mg/dl = Sodium mmol/L x 2.3

Reference Values

Serum/Plasma: 135 -150 mmol/L
 311-345 mg/dl

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

ANALYTICAL PERFORMANCES

Linearity

Reaction is linear up to a concentration of 180 mmol/L. Samples with values exceeding this range must be diluted with saline solution. Then multiply the result for diluting factor.

Analytical Sensitivity

The test sensitivity in terms of detection limit is 80 mmol/L.

"Intra-Assay" precision (within-Run)

Determined on 20 samples for each control (N-H) (Normal-High). Results:

MEAN (U/l)	N = 120	H = 160
S.D.	N = 2.48	H = 4.59
C.V.%	N = 2.06	H = 2.86

"Inter-Assay" precision (between-run)

Determined on 20 samples for each control (N-H). Results:

MEAN (U/l)	N = 123	H = 155
S.D.	N = 4.8	H = 7.31
C.V.%	N = 3.90	H = 4.72

Correlation

A study based comparing this method with a similar method on 20 samples has given a correlating factor $r = 0.985$

Interferences

No interferences was observed by the presence of:

Bilirubin	≤ 27 mg/dl
Triglycerides	≤ 2500 mg/dl

For a comprehensive review of interfering substances, refer to the publication by Young.

Quality Controls

It's necessary, each time the kit is used, to perform quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Bibliography

Available on request.

Symbols

	CE Mark (98/79 CE regulation)
	in vitro medical device
	Batch Code
	Use by
	Storage temperature limits
	Read instruction for use
	Manufacturer in USA

Gesan Production s.r.l.

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