

## 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  $\beta$ -galactosidase enzyme by the sodium present in the sample and the consequent enzymatic transformation of o-nitrophenyl- $\beta$ -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) | $\beta$ -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 with exactly 15 ml Reagent R1/A. Shake gently until complete dissolution, avoiding any foam.  
Wait 5 minutes before use.

## REAGENT 2 (R2/A+R2/B)

Reconstitute the content of a vial of Reagent R2/B with exactly 10 ml of reagent R2/A. Shake gently until complete dissolution, avoiding any 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.
- REAGENT 2 (R2/A+R2/B), stability 4 weeks at 2-8°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          | $\lambda$ : 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      | 750 $\mu$ l | 750 $\mu$ l | 750 $\mu$ l |
| Reagent R2      | 250 $\mu$ l | 250 $\mu$ l | 250 $\mu$ l |
| Distilled Water | 25 $\mu$ l  | --          | --          |
| Sample          | --          | --          | 25 $\mu$ l  |
| Standard        | --          | 25 $\mu$ l  | --          |

Mix, then incubate for 2' at 37°C. Measure the absorbance of sample (EC), against water. Make at least two readings at a distance of 60". Calculate the average of  $\Delta E/\text{min}$  found for the blank reagent (B), the sample (S) and the standard(STD).

## Calculation

$$\text{Sodium mg/dl} = \frac{\Delta E/\text{min}(S) - \Delta E/\text{min}(B)}{\Delta E/\text{min}(STD) - \Delta E/\text{min}(B)} \times [STD]$$

The factor and the reagent performances are related to 37°C, 1 cm and 405 nm.

## Conversion Values

$$\text{Sodium mg/dl} = \text{Sodium mmol/L} \times 2.3$$

## 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     | $\leq 27$ mg/dl   |
| Triglycerides | $\leq 2500$ 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           |