

Intended Use:

Sodium Test reagent/kit is a medical device intended for estimation of sodium in serum or plasma.

Clinical Significance

Sodium is the major cation of extra-cellular fluid. It plays a central role in the maintenance of the normal distribution of water and the osmotic pressure in the various fluid compartments. The main source of body sodium is sodium chloride contained in ingested foods. Only about one third of the total body's sodium is contained in the skeleton since most of it is contained in the extra-cellular body fluids.

Principle

The Method is based on reaction of Sodium with a selective chromogen producing a chromophore whose absorbance is directly proportional to Sodium concentration in the sample.

Working Reagent Preparation

Reagent is ready to use.

Stability and Storage

Store at RT (<30°C).

All the kit contents are stable until the expiry date stated on the label. Do not use reagents over the expiration date. Store the vials tightly closed protected from light and prevent contaminations during the use.

Materials required

- Photometer or spectrophotometer with a thermostat cell compartment set at 25/30/37°C, capable of reading at 630nm.
- Stopwatch, strip-chart recorder or printer.
- Cuvettes with 1-cm path length
- Pipettes to measure reagent and samples.

Sample and Stability

Serum or plasma

Serum or heparinized plasma free of hemolysis.

Sodium reported to be stable in serum or plasma for at least 2 weeks at 2-8°C.

Assay Procedure

Pipette into clean dry test tubes labeled as, Blank(B), Standard (S) and Test (T)

Addition Sequence	Blank	Std	Test
R1 Sodium Reagent	1000µl	1000µl	1000µl
Standard (S)	-	10µl	-
Sample	-	-	10µl

Mix well and incubate for 5 minutes at RT and read the absorbance at 630nm against Reagent Blank.

Calculation

$$\text{Sodium (mmol/L)} = \frac{\text{Abs. of Test}}{\text{Abs. of Std}} \times 150$$

Quality Control

To ensure adequate quality control (QC), each run should include a set of controls (normal and abnormal) with assayed values handled as unknowns.

If the values are found outside of the defined range, check the instrument, reagents and procedure.

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable results.

Linearity

The procedure is linear up to 180mmol/L. If values exceed this limit, dilute the sample with distilled water and repeat the assay.

Calculate the value using the proper dilution factor.

Test should be first rinse with 1% or 0.1N HNO₃ and then with good quality deionised water before use.

Reference Values

Serum, Plasma : 135 - 155mmol/L

Urine : 40 - 220mmol/L

It is recommended that each laboratory establish its own normal range representing its patient population.

General System Parameters

Mode	End Point
Reaction	Increasing
Wavelength	630 nm
Blank with	Reagent
Sample Volume	10µl
Reagent Volume	1000µl
Std Conc.	150mmol/L
Incub. Temp.	R.T.
Incub. Time	5 min.
Normal Range	135 - 155mmol/L
Linearity	Up to 180mmol/L
Unit	mmol/L

Notes

1. As Sodium is widely distributed ion, care should be taken to avoid contamination. All glassware being used for the test should be first rinse with 1% or 0.1N HNO₃ and then with good quality deionised water before use.
2. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

Reference

1. Maruna RFL (1958) clin. Chem, Acta,
2. 1.581, Sunderman, FW Jr & Sunderman FW (1959) Amej. clin Path, 290953
3. Tietz NW. Fundamentals of Clinical Chemistry, W.B Saunders Co. Phila. PA. P.874

For in vitro Diagnostic use only.