

Sodium

IVD

| Cat. No. | Pack size |
|------------|------------------------|
| 221 01 050 | (1 x 50 ml) 50 tests |
| 221 02 030 | (2 x 30 ml) 60 tests |
| 221 05 030 | (5 x 30 ml) 150 tests |

Intended Use

Sodium reagent is intended for the in-vitro quantitative diagnostic estimation of sodium in human serum on manual systems.

Background

Sodium and Potassium are the major cations of extracellular and intracellular fluids respectively. Sodium maintains the normal distribution of water and the osmotic pressure in the various fluid compartments. Potassium influences the acid base balance and osmotic pressure including water retention. Increased sodium levels are found in severe dehydration and excessive treatment with sodium salts. Decreased levels are found in severe polyurea, metabolic acidosis, diarrhoea and renal insufficiency. Increased potassium levels are found in renal failure, dehydration, shock and adrenal insufficiency. Decreased levels are found in malnutrition, gastrointestinal fluid loss and hyperactivity of the adrenal cortex.

Method

Colorimetric method.

Assay Principle

The Present method is based on reaction of sodium with a selective chromogen producing a chromophore whose absorbance varies directly as the concentration of sodium in the test specimen.

Reagents

Reagent (R) Color Reagent

| | |
|---------------------------|-----------|
| Chromogen | 0.03 gm/L |
| EDTA | 25 mmol/L |
| Dimethyl sulfoxide (DMSO) | 75 mmol/L |
| Preservatives | 0.05 % |
| Antifoam | 0.01 % |

Standard (S) Sodium 150 mEq/l

Precautions and Warnings

Do not ingest or inhale. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Reagent Storage and Stability

Reagents and standard are ready-to-use. When stored at 15 - 25°C; they are stable up to the expiry date stated on the label. Once opened, the reagent and standard are stable for 3 months at the specified temperature.

Deterioration

Failure to recover control values within the assigned range may be an indication of reagent deterioration.

Sample Preparation and Preservation

Serum and plasma

Freshly drawn non-hemolysed serum is the specimen of choice. Heparinised plasma can also be used.

Stability: Serum Sodium is stable for at least 24 hours at room temperature and two weeks at 2-8°C.

Urine

Urine diluted 1+1 with distilled water can be used for Sodium estimation.

Procedure

| | |
|------------------------|------------------------|
| Wavelength | 630 nm |
| Optical path | 1 cm |
| Assay type | colorimetric end-point |
| Direction | Increase |
| Sample: Reagent Ratio | 1:100 |
| Temperature | Room temperature |
| Zero adjustment | Against reagent blank |
| Sensitivity | 55 mEq/l |
| Linearity | 180 mEq/l |
| Incubation | 5 min. |
| Blank absorbance limit | 1.2 |

Pipette into clean test tubes:

| | Blank | Standard | Sample |
|-------------|-------|----------|--------|
| Reagent (R) | 1 ml | 1 ml | 1 ml |
| Standard | | 10 µl | |
| Sample | | | 10 µl |

Mix well and let stand for 5 minutes at Room Temperature. Read absorbances ,A standard and A sample against Reagent Blank at 630 nm.

Calculation

$$\text{Serum Sodium Conc. (mEq/l)} = \frac{A_{\text{Sample}}}{A_{\text{Standard}}} \times 150$$

Quality Control

Normal and abnormal control serum of known concentrations should be analyzed with each run.

Performance Characteristics

Precision

Within run (Repeatability)

| | Level 1 | Level 2 |
|--------------|---------|---------|
| n | 20 | 20 |
| Mean (mEq/l) | 140 | 170 |
| SD | 0.72 | 1.44 |
| CV% | 0.51 | 0.84 |

Run to run (Reproducibility)

| | Level 1 | Level 2 |
|--------------|---------|---------|
| n | 20 | 20 |
| Mean (mEq/l) | 140 | 170 |
| SD | 0.76 | 1.58 |
| CV% | 0.54 | 0.93 |

Methods Comparison

A comparison between Sodium reagent and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.979 was obtained.

Sensitivity

When run as recommended, the minimum detection limit of the assay is 55 mEq/l.

Linearity

The assay is linear up to 180 mEq/l.

Interfering Substances

Hemoglobin and Lithium

Demonstrates positive interference

Lipemia

No significant interference

Other Ions

No adverse influence is exerted on the procedure by blood calcium, chloride and potassium levels of up to 3 times normal values. Hypermagnesemia may interfere with sodium assay.

Anticoagulants

Complexing Anticoagulants such as citrate and oxalate must be avoided.

Expected Values

Serum : 135 – 150 mEq/l.

Urine(24 hr): 40-220 mEq/ 24 hr

Note:

It is recommended for each laboratory to establish and maintain its own reference values. The given data are only an indication.

Analytical Range

55 – 180 mEq/l.

Waste Disposal

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.

S56: dispose of this material and its container at hazardous or special waste collection point.









S57: use appropriate container to avoid environmental contamination.

S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. Tietz, N.W., Fundamentals of clinical Chemistry, W.b. Saunders Co. Phila, P.A. p. 874.
2. Henry R.F., et, al. Clinical Chemistry Principles and Technics. 2nd Ed, Harper and Row, Harper and Row, Hargersein, M.D. (1974)
3. Maruna RFL., Clin Chem. Acta. 2:581, (1958)
4. Trinder, P:Analyst, 76:596, (1951)

SYMBOLS IN PRODUCT LABELLING

| | |
|---|---------------------------------------|
|  | For in-vitro diagnostic use |
|  | Batch Code/Lot number |
|  | Catalogue Number |
|  | Consult instructions for use |
|  | Temperature Limitation |
|  | Use by/Expiration Date |
|  | CAUTION. Consult instructions for use |
|  | Manufactured by |