# SODIUM
# (Uranyl Acetate)

## INTENDED USE

Vitro sodium reagent is intended for the determination of sodium in human serum and plasma on both automated and manual systems.

## METHOD

Colorimetric endpoint method.

## CLINICAL SIGNIFICANCE

Sodium is the major cation of extracellular 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 the sodium chloride contained in ingested foods. Only about one-third of the total body sodium is contained in the skeleton since most of it is contained in the extracellular body fluids.[1,2]

Hyponatremia (low serum sodium level) is found in a variety of conditions including the following: severe polyuria, metabolic acidosis, Addison's disease, diarrhea, and renal tubular disease. Hypernatremia (increased serum sodium level) is found in the following conditions: hyperadrenalism, severe dehydration, diabetic coma after therapy with insulin, excess treatment with sodium salts[1,2].

## ASSAY PRINCIPLE

The present method is based on modifications of those first described by Maruna[3] and Trinder[4] in which sodium is precipitated as the triple salt, sodium magnesium uranyl acetate, with the excess uranium then being reacted with ferrocyanide, producing a chromophore whose absorbance varies inversely as the concentration of sodium in the test specimen.

## EXPECTED VALUES

135 - 155 mEq/L

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference range. For diagnostic purposes, the sodium results should always be assessed in conjunction with the patient's medical history, clinical examination, and other findings.

## REAGENTS

| | | | |
|---|---|---|---|
| $R_1$ | Sodium standard | 150 | mEq/dl |
| $R_2$ | Magnesium Acetate | 20 | mmol/l |
| | Uranyl Acetate | 2.1 | mmol/l |
| | In ethyl alcohol | | |
| $R_3$ | Diluted Acetic Acid | | |
| $R_4$ | Potassium ferrocyanide | | |

- **Reagent Preparation & Stability**

All reagents are ready for use and stable up to the expiry date given on label when stored at 15–25 $^0$C.

## SPECIMEN

Freshly drawn serum is the specimen of choice and a 50 µl (0.05 ml) amount is required. Plasma from non-sodium containing anticoagulants (e.g., lithium, calcium, magnesium or heparin) is an acceptable alternative. Sodium is stable for at least 24 hours at room temperature and 2 weeks when refrigerated.[1,2]

## PROCEDURE

- **Manual Procedure**

**Filtrate Preparation**

| | Blank | Standard | Specimen |
|---|---|---|---|
| $R_2$ | 500 µl | 500 µl | 500 µl |
| Standard | …… | 20 µl | …… |
| Specimen | …… | …… | 20 µl |
| Distilled water | 20 µl | …… | …… |

Shake all tubes vigorously and continuously exactly for 3 minutes. Centrifuge tubes at high speed (1,500 g ) for 10 minutes and test supernatant fluids as described below, taking care not to disturb the protein precipitate.

**COLOR DEVELOPMENT:**

| | |
|---|---|
| Wavelength | 550 nm |
| Cuvette | 1 cm light path |
| Temperature | 20 - 25 $^0$C |
| Zero adjustment | against distilled water |
| Specimen | Serum or plasma |

| | Blank | Standard | Specimen |
|---|---|---|---|
| $R_3$ | 500 µl | 500 µl | 500 µl |
| Standard | …… | 20 µl | …… |
| Specimen | …… | …… | 20 µl |
| $R_2$ | 20 µl | …… | …… |
| $R_4$ | 20 µl | 20 µl | 20 µl |

Mix, and Incubate for 5 minutes at room temperature Measure the absorbance of blank, specimen ($A_{specimen}$) and standard ($A_{standard}$) against distilled water.

The color is stable for 30 minutes.

## CALCULATION

Calculate the sodium concentration in serum by using the following formulae:

Serum sodium Concentration=

$$\frac{(\text{Ab blank} - \text{Ab Specimen})}{(\text{Ab blank} - \text{Ab Standard})} \times \text{Standard value}$$

## QUALITY CONTROL

It is recommended that controls (normal and abnormal) be included in:

- Each set of assays, or
- At least once a shift, or
- When a new bottle of reagent is used, or
- After preventive maintenance is performed or a clinical component is replaced.

Commercially available control material with established sodium values may be routinely used for quality control.

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Failure to obtain the proper range of values in the assay of control material may indicate:

- Reagent deterioration,
- Instrument malfunction, or
- Procedure errors.

The following corrective actions are recommended in such situations:

- Repeat the same controls.
- If repeated control results are outside the limits, prepare fresh control serum and repeat the test.
- If results on fresh control material still remain outside the limits, then repeat the test with fresh reagent.
- If results are still out of control, contact Vitro Technical Services.

## WARNING & PRECAUTION

1. When preparing filtrates, inadequate shaking or centrifugation will cause falsely lowered test results.
2. Blood calcium, chloride and potassium levels of up to 3 times normal reportedly exert no adverse influence on the procedure; phosphorus levels exceeding 5 times normal likewise present no problems.

## PERFORMANCE CHARACTERISTICS

### Imprecision

Reproducibility was determined using in an internal protocol. The following results were obtained.

| | Within Run | |
|---|---|---|
| Control | Level I | Level II |
| Number of samples | 40 | 40 |
| Mean (mEq/dl) | 127 | 147 |
| SD (mEq/dl) | 4 | 7 |
| CV (%) | 3 | 5 |

| | Between Day | |
|---|---|---|
| Control | Level I | Level II |
| Number of samples | 40 | 40 |
| Mean (mEq/dl) | 139 | 148 |
| SD (mEq/dl) | 14 | 5 |
| CV (%) | 10 | 4 |

### Method Comparison

Comparison studies were carried out using another commercially available sodium reagent as a reference. Normal and abnormal human serum samples were assayed in parallel and the results compared by least squares regression. The following statistics were obtained.

Correlation coefficient 0.92

### Sensitivity

The sensitivity is defined as the change of analytical response per unit change in analyte concentration at a pathlength of 1 cm.

When run as recommended the sensitivity of this assay is 0.5 mEq/l.

### Linearity

When run as recommended, the assay is linear up to 200 mEq/l.

## INTERFERING SUBSTANCES

**Anticoagulants:**

Heparin and EDTA are the only accepted anticoagulants.

- **Bilirubin:**
  No significant interference from free or conjugated bilirubin up to a level of 60 mg/dl.
- **Drugs:**
  Young[9] in 1990 has published a comprehensive list of drugs and substances, which may interfere with this assay.
- **Haemoglobin:**
  Haemoglobin levels higher than 3.0 g/l increase the apparent sodium concentration significantly.
- **Lipemia:**
  Intralipid levels higher than 1.0 g/dl increase the apparent sodium concentration significantly.

Vitro sodium reagent is for in vitro diagnostic use only. Normal precautions exercised in handling laboratory reagents should be followed.

- The reagents should be brought to room temperature before use.
- The reagent and sample volumes may be altered proportionally to accommodate different spectrophotometer requirements.
- Valid results depend on an accurately calibrated instrument, timing, and temperature control.
- Don't use the reagent if it is turbid.

## BIBLIOGRAPHY


1. Tietz, N.W., *Fundamentals of Clinical Chemistry*, W.B. Saunder Co., Phila, PA, p. 874.

2. Henry R.F., et. al., *Clinical Chemistry Principles and Technics*, 2nd Ed., Harper and Row, Hagerstein, M.D., (1974).


## SYMBOL DECLARATION

| | |
|---|---|
|  | Manufacturer |
|  | Consult instructions for use |
|  | Batch code (Lot #) |
|  | Catalog number |
|  | Temperature limitation |
|  | In vitro diagnostic medical device |
|  | Use by |
|  | Caution. Consult instructions |
|  | Keep away from light |

## ORDERING INFORMATION

| REF | SIZE |
|---|---|
| 14401 | 2 X 25 ml |
| 14402 | 2 X 50 ml |
| 14403 | 2 X 100 ml |


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