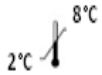
SODIUM REAGENT KIT (COLORIMETRIC METHOD)

IVD For *in vitro* diagnostic and professional use only



Store at (2-8 °C) CE

INTENDED USE

Atlas Sodium kit is for quantitative determination of sodium in human serum and plasma.

INTRODUCTION

Sodium is the major cation of the 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 sodium chloride contained in ingested foods. Only about one-third of 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: 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, and diabetic coma after therapy with insulin, excess treatment with sodium salts. [1,2]

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.

MATERIALS

Materials Provided

- Filtrate Reagent: Uranyl Acetate 2.1 mM and Magnesium Acetate 20 mM in ethyl alcohol.
- Acid Reagent: A diluted acetic acid, 166.7 ml/L.
- Sodium Color Reagent: Potassium Ferro cyanide, 2.1 mM, Sodium azide, 1g/L, and fillers.
- Sodium Standard: Sodium Chloride8.775 g/L and sodium azide, 1 g/L: 150 mEq/L of sodium.

Materials Required But Not Provided

- Spectrophotometer.
- Centrifuge.
- Test tube/rack.
- Timer

Packaging Contents

REF **8.05.34.0.0020: 1x20 ml Acid Reagent, 1x20 ml Filtrate Reagent, 1x1 ml Color Reagent, 1x5 ml Standard).**

REF **8.05.34.0.0024: 1x24 ml Acid Reagent, 1x24 ml Filtrate Reagent, 1x1.2 ml Color Reagent, 1x5 ml Standard).**

REF **8.05.34.0.0050: 1x50 ml Acid Reagent, 1x50 ml Filtrate Reagent, 1x2.5 ml Color Reagent, 1x5 ml Standard).**

REF **8.05.34.0.0060: 1x60 ml Acid Reagent, 1x60 ml Filtrate Reagent, 1x3 ml Color Reagent, 1x5 ml Standard).**

REF **8.05.34.0.0100: 1x100 ml Acid Reagent, 1x100 ml Filtrate Reagent, 1x5 ml Color Reagent, 1x5 ml Standard).**

REAGENT STORAGE AND STABILITY

- All kit components are stable until the expiration date printed on label when stored tightly closed at 2-8°C, protected from light and contaminations prevented during use.
- Do not use reagents beyond the expiration date.
- Presence of turbidity is considered as a sign of reagent deterioration or contamination.

PRECAUTIONS AND WARNINGS

- For *in vitro* diagnostic and professional use only.
- Protective clothing should be worn when handling the reagents.
- The reagent is considered toxic, so do not drink or eat in the laboratory where the assay is conducted.
- Wash hands and the test table top with water and soap once the testing is done.
- If spillage of reagent occurs clean with disinfectants, (Disinfectant used could be irritable so handle with care). The reagents should be used as supplied and according to the procedure mentioned below.
- Do not use these reagents if the label is missing or damaged.
- Do not use the kit if damaged or glass vials are broken or leaking, and discard the contents immediately.
- Test materials and specimens should be discarded properly in a biohazard container.
- The test is for well-trained professional healthy users not for lay users.
- Close the vial tightly after each test.

COLLECTION, HANDLING AND PREPARATION OF SPECIMEN

- Fresh serum is the specimen of choice.
- Plasma from non-sodium containing anticoagulants (e.g., lithium, calcium, magnesium or heparin) is an acceptable alternative.

SPECIMEN STORAGE AND STABILITY

- Specimens can be stored at room temperature (15-30°C) or refrigerated (2-8 °C).
- Sodium is stable for at least 24 hours at room temperature and 2 weeks when refrigerated.

REAGENT PREPARATION AND IN-USE STABILITY

- All Kit components are **Ready to use**.
- All kit components are stable until the expiration date printed on label when stored tightly closed at 2-8°C, protected from light and contaminations prevented during use.

PROCEDURE

Filtrate Preparation:

1. Label test tubes: blank, standard, control, patient, etc.
2. Pipette **1.0 ml** of **Filtrate Reagent** to all tubes.
3. Add **50 µl** of **distilled water** to blank labeled tube, **standard** to the standard labeled tube, **control** to the control labeled tube, **patient sample** to the patient labeled tube, etc.
4. **Shake all tubes vigorously and continuously exactly for 3 minutes (we suggest using a vortex mixer).**
5. 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

1. Label test tubes corresponding to the above Filtrate tubes.
2. Pipette **1.0 ml Acid Reagent** to all tubes.
3. Add **50 µl** of **Supernatant** to respective tubes and mix.
4. Add **50 µl** of **Color Reagent** to all tubes and mix.
5. Zero spectrophotometer with distilled water at 550 nm.
6. Read and record absorbance of all tubes.

Note: The absorbance should be read directly after adding the color.

The chemistry reaction of this procedure involves a reduction in absorbance, as opposed to the usual absorbance increase. The absorbance of blank should be higher than the test samples.

CALCULATIONS

$$\frac{\text{(Abs. of Blank - Abs. of S)}}{\text{(Abs. of Blank - Abs. of STD)}} \times \text{Conc. of STD (mEq/L)} = \text{Conc. of S (mEq/L)}$$

Assume the Standard with a sodium value of 150 mEq/L, gave an absorbance of 0.803 while the Sample and the Blank had absorbances of 0.880 and 1.406 respectively. The sodium concentration of the Sample may then be calculated as follows:

$$\frac{(1.406 - 0.880)}{(1.406 - 0.803)} \times 150 = \frac{0.526}{0.603} \times 150 = 130 \text{ mEq/L}$$

REFERENCE VALUES

135 - 155 mEq/L

QUALITY CONTROL

- It is recommended that controls be included in each set of assays.
- Commercially available control material with established sodium values may be used for quality control.
- The assigned value of the control material must be confirmed by the chosen application.
- Failure to obtain the proper range of values in the assay of control material may indicate reagent deterioration, instrument malfunction, or procedural errors.

LIMITATIONS AND INTERFERING FACTORS

- When preparing filtrates, inadequate shaking or centrifugation will cause falsely lowered test results.
- 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

- Linearity: 200 mEq/L.
- Sensitivity: Based on an instrument resolution of A = 0.001, the present method has a sensitivity of 0.5 mEq/L.
- Comparison: A comparison between this procedure and flame photometric analysis produced a regression equation of Y = 0.69X + 4.5 with a coefficient of correlation of 0.92.

4. Precision Study:

	Within Run		Run to Run	
Mean (mEq/L)	146	127	148	139
Std.	7	4	5	14
CV%	5	3	4	10

REFERENCES

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).

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- Henry, R.F., et al., Clinical Chemistry Principles and Technics, 2nd Ed., Harper and Row, Hagerstein, M.D., (1974).
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ATLAS Medical GmbH
Ludwig-Erhard Ring 3
15827 Blankenfelde-Mahlow
Germany
Tel: +49 - 33708 – 3550 30
Email: Info@atlas-medical.com
Website: www.atlas-medical.com

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry