

PACKAGING

Ref.: 101-0553	Cont.: 1 x 60 mL
Ref.: 101-0764	Cont.: 2 x 60 mL

Store at 2 - 8° C

CLINICAL SIGNIFICANCE

This test is performed when symptoms of a sodium imbalance are present, or when disorders associated with abnormal sodium levels develop. Sodium (Na⁺) is the major positive ion in the fluids outside of cells. The concentration of sodium inside cells is only about 5 mmol/L compared with 140 mmol/L outside. The sodium content of the blood is a result of a balance between the amount in the food and beverages you consume, and the amount your kidneys excrete. (In addition, a small percent is lost through the stool and sweat.) Many factors affect sodium levels, including the steroid hormone aldosterone, which decreases loss of sodium in the urine. ANP (atrial natriuretic protein) is a hormone secreted from the heart that increases sodium loss from the body. Despite the integral relationship between sodium and water, the body regulates them independent of each other if necessary.

PRINCIPLE OF THE METHOD

Sodium is precipitated with Mg-uranyl acetate; the uranyl ions remaining in suspension form a yellow-brown complex with thioglycolic acid. The difference between reagent blank (without precipitation of sodium) and analysis is proportional to the sodium concentration.

REAGENTS

R1	Ammonium thioglycolate	550 mmol/L
	Ammonia	550 mmol/L
R2	Uranyl acetate	19 mmol/L
	Magnesium acetate	140 mmol/L
NA-p CAL	Sodium aqueous primary standard 150 mmol/L	

Optional (not included in the kit)

Contro-N	Ref.: 101-0252	4 x 5 mL	Lyophilized human control serum
	Ref.: 101-0083	20 x 5 mL	
Contro-P	Ref.: 101-0253	4 x 5 mL	Lyophilized human control serum
	Ref.: 101-0084	20 x 5 mL	

PRECAUTIONS

R1: T; R23/24/25: Toxic by inhalation, in contact with skin and if swallowed.
R2: Xn; F; R11: Highly flammable; R20/22: Harmful by inhalation and if swallowed; R33: Danger of cumulative effects.
S7: Keep container tightly closed; S16: Keep away from sources of ignition.No smoking; S20/21: When using do not eat, drink or smoke; S25: Avoid contact with eyes; S27: Take off immediately all contaminated clothing; S28: After contact with skin, wash immediately with plenty of water; S45: In case of accident or if you feel unwell, seek medical advice immediately; S61: Avoid release to the environment. Refer to special instructions/safety data sheets.

PREPARATION

All the reagents are ready to use.

STORAGE AND STABILITY

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

Do not use reagents over the expiration date.

Signs of reagent deterioration:

- Precipitating solution becomes discoloured when exposed to the light. Store protected from light. A slight turbidity does not affect the determination.

ADDITIONAL EQUIPMENT

- Spectrophotometer or colorimeter measuring at 365 nm.
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment ^(Note 1, 2, 3).

SAMPLES

Serum.

PROCEDURE

Notes: CHRONOLAB SYSTEMS has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

NA-p CAL: Proceed carefully with this product because due its nature it can get contaminated easily.

Detergents usually contain high sodium concentrations. The equipment (test tubes, pipettes, stoppers, cuvettes) must therefore be rinsed carefully with distilled water. Avoid contamination by traces of sodium.

Disposable plastic tubes are recommended for the determination to avoid contaminations.

Avoid the contact with metal materials.

Calibration with the aqueous standard may cause a systematic error in automatic procedures. In these cases, it is recommended to use a serum Calibrator.

1. Assay conditions:
Wavelength: 410 nm
Cuvette: 1 cm. light path
Temperature 37° C / 15 - 25° C
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

	Standard	Sample
Standard (µL)	20	--
Sample (µL)	--	20
Precipitating sol. (mL)	1.0	1.0

4. Close tubes and mix well. Allow stand for 5 minutes
5. Shake intensively for at least 30 sec. Allow standing for 30 min.
6. Centrifuge at high speed for 5-10 min.
7. Separate the clear supernatant and pipette on another cuvette:

	Blank	Standard	Sample
Precipitating sol. (µL)	20	--	--
Supernatant (µL)	--	20	20
Reagent (mL)	1.0	1.0	1.0

8. Mix and incubate for 5-30 at room temperature.
9. Read the absorbance (A) of the blank, standard and samples. The color is stable for at least 30 minutes.

CALCULATIONS

$$\frac{A_{Blank} - A_{Sample}}{A_{Blank} - A_{STD}} \times 150 \text{ (Standard conc.)} = \text{mmol/L sodium in the sample}$$

Conversion factor: mmol/L = mEq/L.

QUALITY CONTROL

Control sera are recommended to monitor the performance of assay procedures.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems.

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

REFERENCE VALUES¹

Serum :	135 - 155 mmol/L
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These values are for orientation purpose; each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Measuring range: From detection limit of 40 mmol/L to linearity limit of 400 mmol/L.

If the results obtained were greater than linearity limit, dilute the sample 1/2 with distilled water and multiply the result by 2.

Precision:

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (mmol/L)	144	162	134	158
SD	1.89	2.87	3.20	6.70
CV (%)	1.31	1.78	2.39	4.25

Analytical sensitivity: 1 mmol/L = 0.0006 A.

Accuracy: Results obtained using CHRONOLAB reagents did not show systematic differences when compared with other commercial reagents.

The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

A list of drugs and other interfering substances with sodium determination has been reported by Young et. al^{5,6}.

BIBLIOGRAPHY

1. Trinder P., Analyst 76, 596 (1951)
2. Henry R.J. et al., Clin. Chem., Harper & Row New York, Sec. Edit. 643 (1974)
3. ISO 15223 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied.
4. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
5. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.