SBio SODIUM KIT

(Colorimetric Method)

(For invitro diagnostic use only)

REF	90710050
Σ	50 Tests

CE

30°C / 15°C Store at R.T.	Manufacturer / This way up	IVD *In vitro* Diagnostic Medical Device	L1 Precipitating Reagent	Colorimetric Colorimetric Method	
Use by (Last day of stated month)	Consult Instructions for use	LOT Batch Number	L2 Acid Reagent	S Na^+ / K^+ Standard (150/5 mmol/l)	
Date of Manufacture	REF Catalogue Number	Σ Contains sufficient for <n> tests	L3 Colour Reagent	EC REP Authorised Representative in the European Community	

INTENDED USE

Sodium Kit is used for the determination of Sodium in serum.

PRINCIPLE OF THE TEST

Sodium is precipitated as a triple salt with magnesium and Uranyl acetate. The excess of uranyl ions are reacted with ferrocyanide in an acidic medium to develop a brownish colour. The intensity of the colour produced is inversely proportional to the concentration of sodium in the sample.

Uranyl ions + Mg ions + Na^+ ⟶ UranylMgNa precipitate

Free Uranyl ions + $K_xFe(CN)_6$ ⟶ Brown Coloured Complex

CLINICAL SIGNIFICANCE

Sodium is required by all cells in the body to maintain a normal fluid balance. Sodium plays a key role in normal nerve and muscle function. Sodium is taken in through food and drink and lost primarily in sweat and urine. Healthy kidneys maintain a consistent level of sodium in the body by adjusting the amount excreted in the urine. When sodium intake and loss are not in balance, the total amount of sodium in the body is affected. Changes in the total amount of sodium are closely linked to changes in the volume of water in the blood. A loss of sodium from the body does not necessarily cause the level of sodium in the blood to decrease but does cause blood volume to decrease. When blood volume decreases, blood pressure also decreases, heart rate increases, and light-headedness and sometimes shock occur.

PRESENTATION

	50 Tests
L1 : Precipitating Reagent	110 ml
L2 : Acid Reagent	150 ml
L3 : Colour Reagent	20 ml
S : Na^+ / K^+ Standard (150/5 mmol/l)	5 ml

COMPOSITION

Sodium: Magnesium Acetate 140 mmol; Uranyl Acetate 19 mmol; Potassium Ferrocyanide 240 mmol.

STORAGE / STABILITY

Contents are stable at R.T. till the expiry date mentioned on the labels.

SAMPLE REQUIRED

Serum, free from haemolysis is required. Serum should be separated from the clot immediately / as soon as possible.

REAGENT PREPARATION

Reagents are ready to use.

SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.

This product requires the handling of human specimen. It is recommended that all human sourced material are considered potentially hazardous and are handled in accordance with the OSHA standard on blood borne pathogens.

Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

Handle specimen, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

PROCEDURE

Wavelength / filter : 530 nm (Hg 546) / Green

Temperature : R.T.

Light path : 1 cm.

MATERIAL REQUIRED BUT NOT PROVIDED

General laboratory instrumentation like Spectrophotometer/Analyzer, Thermostatic Cuvette holder, Cuvettes, Micropipettes, Test tubes, Waterbath, Stopwatch/Timer.

1. Precipitation:

Pipette into clean dry test tubes labelled as Standard (S) and Test (T):

Addition Sequence	S (ml)	T (ml)
Precipitating Reagent (L1)	1.0	1.0
Na^+/K^+ Standard (S)	0.02	--
Sample	--	0.02

Mix well and let stand at R.T. for 5 mins. with shaking well intermittently. Centrifuge at 2500 to 3000 RPM to obtain a clear supernatant.

2. Colour Development:

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

Addition Sequence	B (ml)	S (ml)	T (ml)
Acid Reagent (L2)	1.0	1.0	1.0
Supernatant from Step 1	--	0.02	0.02
Precipitating Reagent (L1)	0.02	--	--
Colour Reagent (L3)	0.1	0.1	0.1

Mix well and incubate at R.T. for 5 mins. Measure the absorbance of the Blank (Abs.B), Standard (Abs.S), and Test Sample (Abs.T) against distilled water within 15 mins.

CALCULATIONS

$$\text{Sodium in mmol/l} = \frac{\text{Abs. B - Abs.T}}{\text{Abs. B - Abs.S}} \times 150$$

QUALITY CONTROL

The following process is recommended for QC during the assay of SBio Sodium. *Define and establish acceptable range for your laboratory.

1. Two levels of control (Normal and Abnormal) are to be run on a daily basis.
2. If QC results fall outside acceptance criteria, recalibration may be necessary.
3. Review QC results and run acceptance criteria following a change of reagent lot.

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity:

The Sodium assay is linear upto 200 mmol/l. If values exceed this limit, dilute the sample with deionised water (free from Na^+ ions) and repeat the assay. Calculate the value using the proper dilution factor.

Limit of detection:

The limit of detection for Sodium is 1 mmol/l.

Interferences:

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Precision:

Precision studies were performed with two controls using NCCLS protocol EP5-A. The results of the precision studies are shown below:

Sample	Within-run		Between-run		Total	
	Mean	CV%	Mean	CV%	Mean	CV%
Control 1	128.74	1.96	124.76	2.72	253.5	4.68
Control 2	151.15	5.35	143.71	2.04	294.86	7.39

Method comparison:

Comparative studies were done to compare our reagent with another commercial Sodium. No significant differences were observed. Details of the comparative studies are available on request.

REFERENCE RANGE

Sodium : 135 - 155 mmol/l

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

NOTES

The sodium reaction is an inverse reaction and hence the blank has higher absorbance than the standard or test. During precipitation, inadequate shaking or centrifugation will result in lower values. Separate serum from the clot as soon as possible. Turbid or icteric samples may produce falsely elevated results. Do not use deteriorated or leaking reagents.

REFERENCES

(1) Maruna, R.F.L., (1958) Clin. Chem. Acta. 2: 581. (2) Trinder, P., (1 951) Analyst 76: 596. (3) Terri, A.E., et. al. (1958) J. Clin. Path. 29: 86. (4) Sunderman, F.W., et. al. (1959) Am. J. Clin. Path. 29: 95. (5) Schales, O., Schales, S.S., (1941) J. Biol. Chem. 140: 879. (6) Schoenfeld. R.G., Lewellen, C.J., (1964) Clin. Chem. 10: 553.

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EC REP

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