TRUEchemie Sodium Test Kit (Colourimetry)

for the quantitative determination of Sodium concentration in serum or plasma

INTENDED USE

The TRUEchemie Sodium Test Kit (Colourimetry) is used for the quantitative determination of Sodium concentration in human serum or plasma.

INTRODUCTION

Sodium is the major cation of extra-cellular 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 the total body's sodium is contained in the skeleton since most of it is present in the extra-cellular body fluids.

PRINCIPLE

The Method is based on reaction of Sodium with a selective chromogen producing a chromophore whose absorbance is directly proportional to Sodium concentration in the test specimens which can be photometrically measured.

PACK SIZE

Kit Size	50 T
Cat. No.	ADX373
Kit Contents	
1) Sodium Reagent	50 x 1 ml
2) Sodium Standard (150 mmol/L)	1 x 2 ml

REAGENT COMPOSITION

Sodium reagent contains Buffer, Chemicals, Stabilizers & Detergents.

REAGENT PREPARATION

Ready to use reagents.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use.
2. Specimens should be considered infectious and handled appropriately.
3. Avoid ingestion. DO NOT PIPETTE BY MOUTH.
4. The reagent contains sodium hydroxide that is corrosive. In case of contact with skin, flush with water. For eyes, seek medical attention.
5. The disposal of the residues has to be done as per local legal regulations.

CALIBRATION

The procedures are calibrated with the standard solution which is included with each series of tests. The absorbance is used to calculate the results.

REAGENT STORAGE & STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 15-30ºC and contaminations are prevented during their use. Do not use reagents over the expiration date.

SPECIMEN COLLECTION AND STORAGE

Serum or Heparin Plasma.
Sodium is stable for 2 weeks at 2-8°C, contaminated sample should not be used.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipettes to accurately measure required volumes.
2. Test tubes/rack
3. Timer
4. 37 °C heating block or water bath
5. Photometer capable of accurately measuring absorbance at 630 nm

TEST PROCEDURE

Primary wavelength 630 nm

	Blank (µl)	Standard (µl)	Sample (µl)
Sodium Reagent	1000	1000	1000
Sodium Standard	--	10	--
Sample	--	--	10

Mix well and incubate for 5 min. at room temperature (20 - 25 ºC). After incubation, zero the Photometer with the reagent blank. Read and record the incubated Standard and samples.

Calculation: $\frac{\text{Sample OD}}{\text{Standard OD}}$ x 150 = mmol Sodium / L

Note : As Sodium is widely distributed ion, care should be taken to avoid contamination. All glassware being used for the test should be first rinse with 1% or 0.1N HNO_3 and then with good quality deionised water before use.

QUALITY CONTROL

Quality Controls are recommended to monitor the performance of automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

EXPECTED VALUE

Serum, plasma: 135 – 155 mmol/L
It is strongly recommended that each laboratory establish its own normal range

PERFORMANCE CHARACTERISTICS

Sensitivity: 2.3 mmol/L
Linearity: 180 mmol/L under the described assay conditions. If the concentration is greater than linearity (180 mmol/L), dilute the sample with distilled water and repeat the assay. Multiply the result with dilution factor. The linearity limit depends on the sample / reagent ratio, as well as the analyzers used.

PRECISION:

Intra-assay precision within run (n=10)	Mean (mmol/L)	SD (mmol/L)	CV (%)
Control Level - 1	145.7	0.2	0.2
Control Level - 2	122.5	0.3	0.2

Inter-assay precision run to run (n=12)	Mean (mmol/L)	SD (mmol/L)	CV (%)
Control Level - 1	140.5	1.0	0.7
Control Level - 2	124.9	0.5	0.4

The reagent was tested for 12 days, using two different sodium concentrations. The coefficient of variation was <5%.

AUTOMATED PROCEDURE

Appropriate program sheet is available for different analyzers upon request.

METHOD COMPARISON

Results obtained using TRUEchemie Sodium reagent (y) did not show systematic differences when compared with another commercial reagent (x) with similar characteristics. The results obtained is below: The correlation coefficient (r^2) was 0.98 and the regression equation is y=0.939x+7.026. The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

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.

WASTE MANAGEMENT

Please refer to local regulation requirements.

SYSTEM PARAMETERS

Mode	:	End point
Std. Conc.	:	150
Wave length	:	630 nm
Units	:	mmol/L
Flow cell Temp.	:	37 °C
Blank	:	Reagent
Reagent volume	:	1000 µL
Sample volume	:	10 µL
Incubation	:	5 min. at R.T
Low Normal	:	135
High Normal	:	155
Sensitivity	:	2.3
Linearity	:	180
Reaction Slope	:	Increasing

REFERENCES

1. Maruna RFL (1958) clin. Chem, Acta,
2. 1.581, Sunderman, FW Jr & Sunderman FW (1959) Ame j.clin Path, 29.953
3. Tietz NW. Fundamentals of Clinical Chemistry, W.B. Saunders Co., Phila, PA, P.874.
4. ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

Index of Symbols

Consult instructions for use	REF Catalogue number	Caution
IVD *In vitro* diagnostic medical device	LOT Batch code	Non-sterile
15°C 30°C Temperature limit 15-30°C	Do not re-use	Use-by date
Manufacturer	Date of manufacture	Keep dry
		Keep away from sunlight

Do not use if package is damaged — Contains sufficient for <n> tests

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