Liquid Sodium

REF C4950260A 2x60ml

CE IVD For in vitro medical device

Intended Use

Gesan Liquid Stable Enzymatic Sodium Assay is intended for the quantitative in vitro determination of sodium in serum. Measurements obtained by this device are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

Clinical Significance

In healthy individual, an extracellular fluid level of sodium is regulated to maintain at 136 -146 mmole/L (313 -336 mg/dL[1-2]). Small deviations from normal level can have severe health consequences. Sodium has been commonly used in the diagnosis and management of patients with metabolic and cardiovascular disorder and is considered by American Association of Clinical Chemistry to have the potential of severe health consequences if left uncontrolled. Therefore monitoring serum sodium concentration is important in both routine check and emergency rooms.

Assay Principle

Sodium is determined enzymatically via sodium-dependent β-galactosidase activity with ONPG as substrate. The absorbance at 405 nm of the product O-nitrophenyl is proportional to the sodium concentration.

ONPG —(Na+, β-galactosidase)→ O-nitrophenyl + galactose

ONPG = o-nitrophenyl -ß-D-galactopyranose

Reagent Composition

Reagent	Composition
R1	Good's buffer (pH 8.5) Cryptand (>0.4 mM), β-D-galactosidase (<8 U/mL), Proclin 300 (0.02%)
R2	Good's buffer (pH 6.5) O-Nitrophenyl β-D- glycoside (>0.5 mM) Proclin 300 (0.02%)
Low Calibrator	Buffered sodium (Lot-specific value stated on vial)
High Calibrator	Buffered sodium (Lot-specific value stated on vial)

Reagent Stability and Storage

R1 and R2 are provided in ready-to-use liquid form and are stable until their expiry date when stored at 2 to 8°C.

Low and High Calibrators

Calibrators are supplied ready for use. The calibrators are stable up to expiration date marked on the label when stored at 2 to 8°C.

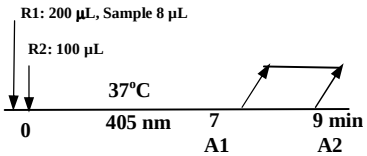
Specimen Collection and Handling

Serum is the recommended sample type for the Gesan Sodium Assay

Precautions

Do not pipette by mouth. Exercise the normal recautions required for handling laboratory reagents. Reagent R1 and R2 contain Proclin 300. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes, or if ingested, seek immediate medical attention. Health and Safety Data Sheets are available on request. The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions. Additional safety information concerning storage and handling of this product is provided within the Material Safety Data Sheet for this product.

Automated Chemistry Analyzer Assay Scheme



Calibration

The use of Low and High Calibrators is recommended for calibration. A 2-point calibration is recommended every week, with change of reagent lot/bottle or as indicated by quality control procedures.

Quality Control

Good laboratory practice recommends the use of control materials. Users should follow the appropriate federal, state and local guideline concerning the running of external quality control.
Gesan Normal and Abnormal Sodium Controls (495CTL) are recommended for daily quality control. The two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check cleanliness of all equipment in use.
3. Check water; contaminants or bacterial growth may contribute to inaccurate results.
4. Check reaction temperature.
5. Check expiry date of kit and contents

Reference Range

136 -146 mmole/L (313 -336 mg/dL)

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population

Limitations

When Sodium and Potassium are requested together, Sodium is assayed immediately before Potassium.

Performance Characteristics Accuracy

The performance of this assay was compared with the performance of a similar sodium assay on a Hitachi 717 analyzer using individual serum samples. Fifty-three serum samples ranging from 86.2 – 174.7 mmol/L gave a correlation coefficient of 0.98. Linear regression analysis gave the following equation:

This method = 1.05 (reference method) - 2.23 mmol/L

Precision

The precision of the Gesan Sodium Enzymatic Assay was evaluated according to NCCLS EP5-A guideline. In the study, two specimens containing 137 ± 13 mM and 160 ± 15 mM sodium were tested with 2 runs per day with duplicates over 10 working days.. The mean value (Mean), standard deviation, and between-day imprecision CV% are calculated and summarized in the following tables:

"Intra-Assay" precision (within-Run)

	Level 1 (137±13mM sodium)	Level 2 (160± 15mM sodium)
Number of Data Points	40	40
Mean (mM)	128.94	155.84
SD (mM)	1.57	1.72
CV%	1.2%	1.1%

"Inter-Assay" precision (between-Run)

	Level 1 (137±13mM sodium)	Level 2 (160± 15mM sodium)
Number of Data Points	40	40
Mean (mM)	128.94	155.84
SD (mM)	2.01	2.56
CV%	1.56%	1.65%

Linearity

This method is linear between sodium concentrations of 80 and 180 mmole/L (184 and 414 mg/dL).

Limit of Detection

The lower detection limit is 80 mM sodium. The higher detection limit is 180 mM sodium

Interference

No interference was observed by precence of:

Bilirubin	≤ 40mg/dl
Hemoglobin	≤ 500 mg/dl
Triglycerides	≤ 1000 mg/dl.

References

1. Berry, M. N. et al., (1988) Clin. Chem. 34,2295
2. Tietz, N. W. (1983) Clinical guide to Laboratory Tests, p. 384 W.B. Saunders Co., Philadelphia

Symbols

CE	CE Mark (98/79 CE regulation)
IVD	in vitro medical device
LOT	Batch Code
	Use by
	Storage temperature limits
	Read instruction for use
	Gesan Production srl

Gesan Production s.r.l.
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