# Sodium Enzymatic Assay Kit (Liquid Stable)

Catalog Number: BQ 011-EAEL

**Intended Use**

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.

**Reagent Composition**

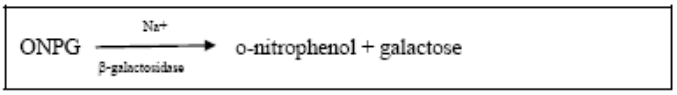
| Reagent | Composition | Quantity |
|---|---|---|
| R1 | Good's Buffer (pH 8.5)<br>Cryptand (>0.4mM), β –galactosidase (<8 U/mL)<br>Proclin 300 (0.02%) | 4 x 40 ml |
| R2 | Good's Buffer (pH 6.5)<br>O-Nitrophenyl β-D-glycoside (>0.5 mM)<br>Proclin 300 (0.02%) | 4 x 20 ml |
| Low Calibrator | Buffered sodium<br>(Lot-specific value stated on vial) | 1 x 3 ml |
| High Calibrator | Buffered sodium<br>(Lot-specific value stated on vial | 1 x 3 ml |

**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** [1]

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 = o-nitrophenyl -β-D-galactopyranose*

**Materials Required but not Provided**

An analyzer capable of dispensing 2 reagents and of measuring absorbance at 405 nm with temperature control (37ºC).

Normal and Abnormal sodium controls are recommended.

**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 ºC.

**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 Sodium Assay.

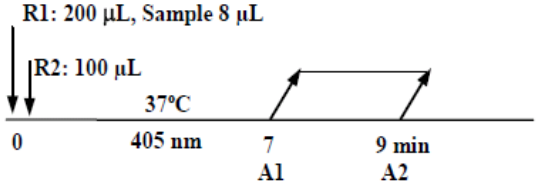
**Precautions**

Do not pipette by mouth. Exercise the normal precautions 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.

The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

**Automated Chemistry Analyzer Assay Scheme**




**Calibration**

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

This assay uses a linear calculation and a reagent blank. Ensure that: on the Calibration Checks screen, the following are selected for this test:

Sampling Method for Calibrators

- Duplicate

Reagent Blank measurement

- Enable Reagent Blank
- Daily
- Reagent Blank System Water

**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.

Normal Level and High Level of serum controls 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 in bacterial growth may contribute to inaccurate results.
4. Check reaction temperature.
5. Check expiry date of kit and contents

**Results**

Sodium results are printed out in mmol/L.

**Reference Range** [2]
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 Enzymatic Sodium 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:

**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% |

**Total**

| | **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**
Interference for the sodium enzymatic assay was evaluated on a Hitachi 717 analyzer. The following substances normally present in serum produced less than 10% deviation at the listed concentrations: $NH_4Cl$ at 1.5 mM, KPi at 2.0 mM, $CaCl_2$ at 7.5 mM, KCl at 10 mM, , $CuCl_2$ at 0.5 mM, $ZnCl_2$ at 0.5 mM, $FeCl_3$ at 0.5 mM, Glucose at 5 mM, ascorbate at 10 mM, Bilirubin at 40 mg/dL, Bilirubin conjugate 40 mg/dL, hemoglobin 500 mg/dL, and triglyceride 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

**HITACHI 717 Parameters**
Temperature: 37 °C

Use the following parameter with included calibrator for calibration.

PROGRAM 2 CHEMISTRY PARAMETERS

| | |
|---|---|
| TEST | * (NA) |
| ASSAY CODE | 2 - 30 - 40 |
| SAMPLE VOLUME (Tl) | 8 - 8 |
| R 1 VOLUME (Tl) | 200 - 50 - 0 |
| R 2 VOLUME (Tl) | 100 - 50 - 0 |
| WAVELENGTH (nm) | 660 - 405 |
| CALIB METHOD LINEAR | 0 - 0 |
| STD 1 CONC-POS | * - * |
| STD 2 CONC-POS | * - * |
| STD 3 CONC-POS | 0 - 0 |
| STD 4 CONC-POS | 0 - 0 |
| STD 5 CONC-POS | 0 - 0 |
| STD 6 CONC-POS | 0 - 0 |
| SD LIMIT | 0.1 |
| DUPLICATE LIMIT | 999 |
| SENSITIVITY LIMIT | 0 |
| ABS. LIMIT (INC/DEC) | 0 - |
| INCREASE | |
| PROZONE LIMIT | 32000 - UPPER |
| EXPECTED VALUE | * - * |
| PANIC VALUE | * - * |
| INSTRUMENT FACTOR | 1.0 |

*Data Entered by operator

**HITACHI 917 Parameters**
Temperature: 37°C

Use the following parameter with included calibrator for calibration.

| |
|---|
| ** ANALYZE** |
| TEST NAME: [SODIUM]<br>ASSAY/POINT: [2 point rate] [10] [23][30][0][0]<br>WAVE (SUB/MAIN): [660] [415]<br>S. VOL. (NORMAL): [8.0][0.0][0]<br>S. VOL. (DECREASE): [4.0][0.0][0]<br>S. VOL. (INCREASE): [16.0][0.0][0]<br>DILUENT: [WATER][0]<br>REAGENT VOL (R1): [200][0][xxxxx][0]<br>REAGENT VOL (R2): [0][0][xxxxx][0]<br>REAGENT VOL (R3): [100][0][xxxxx][0]<br>REAGENT VOL (R4): [0][0][xxxxx][0]<br>ABS LIMIT: [32000][INCREASE] TWIN TESTS: [ ]<br>PROZONE LMIT: [32000][0][UPPER]<br>CELL DETERGENT: [Detergent 1] |
| ** CALIBRATION **<br><br>CALIB TYPE: [Linear] [ ]<br>POINT: [2] SPAN POINT [2]<br>WEIGHT: [0]<br>AUTO CALIBRATION<br>TIME OUT Chg. Over<br>BLANK: [0] CHANGE LOT: [ ]<br>SPAN: [0] CHANGE BOTTLE: [ ]<br>2POINT: [0]<br>FULL: [0]<br>SD LIMIT: [0.1]<br>DUPLICATE LIMIT: [999]<br>SENSITIVITY LIMIT: [0]<br>S1ABS RANGE: [-32000] [32000] |
| ** RANGE**<br><br>TEST CODE: [ xxx ]<br>UNIT: [mmol/L] DATA MODE [on board]<br>CONTROL INTERVAL: [0]<br>INST. FACTOR (Y=aX + b) : a= [1.0] b=[0.0]<br>TECHNICAL LIMIT [*] [*]<br>PANIC VALUE [*] [*] |
| ** STANDARD CONCENTRATION **<br><br>STANDARD SOLUTION<br>CONC: [ * ] [ * ] [0] [0] [0] [0]<br>POSITION: [ * ] [ * ] [0] [0] [0] [0]<br>SAMPLE: [8.0][8.0][0.0] [0.0] [0.0] [0.0]<br>PRE-DILUENT<br>VOLUME: [0.0] [0.0] [0.0] [0.0] [0.0] [0.0]<br>DILUENT: [0] [0] [0] [0] [0] [0]<br>CALIB CODE: [0] [0] [0] [0] [0] [0] |

* Data entered by operator

** These reagent parameters have **not been fully validated** for this analyzer. The parameters are based on BQ Kits knowledge of the analyzer and BQ Kits reagents should perform adequately. **However, you should use these parameters as guidelines in conjunction with your Quality control program for validation. ****