BIOBASE

Sodium (Na) Test Kit（Enzymatic）

【NAME】

Name:Sodium (Na) Test Kit（Enzymatic）

【Package】

R1:60mL×2	R2:20mL×2	R1:18mL×4	R2:6mL×4
R1:18mL×1	R2:6mL×1	R1:60mL×1	R2:20mL×1
R1:40mL×3	R2:20mL×2	R1:48mL×2	R2:16mL×2
R1:45mL×2	R2:15mL×2	R1:90mL×1	R2:30mL×1

2×200Tests

【INTENDE USE】

The reagent is intended for the in vitro quantitative determination of Sodium (Na) in human serum,plasma on both manual and automatd systems.

Serum sodium reduce often occur in the following situations: Vomiting, diarrhea and other gastrointestinal loss of sodium; nephritis, nephrotic syndrome, adrenal insufficiency, diabetes insipidus, diabetes, urinary loss of sodium; burn skin, sweat sodium loss.; High serum sodium often appears in the following situations: traumatic brain injury, cerebral vascular accident, pituitary tumor, severe dehydration, adrenal cortex hyperfunction.

【METHODOLOGY】

Sodium detection by sodium dependent β - galactosidase enzyme catalyzed ONPG kinetics reaction,the product (O- Nitrophenol) absorbance value is proportional to the concentration of sodium in the 405nm.

$$\text{ONPG} \xrightarrow[\beta\text{-galactose glucoside enzyme}]{\text{Na+}} \text{O- Nitrophenol + Galactosum}$$

ONGP: O - Nitrophenol - β - D - Pyran galactose

【REAGENT COMPOSITION】

Reagent 1（R1）：

Tris buffer PH9.0	450mmol/L
Cryptand	5.4mmol/L
β-galactose glucoside enzyme	≥0.8U/mL

Reagent 2（R2）：

Tris buffer PH9.0	10.0mmol/L
O -Nitrophenol - β-D- Pyran galactose	5.5mmol/L

【STABILITY AND STORAGE】

Unopened, avoid light preservation in 2 ~ 8 ℃, valid for 12 months;

Opened, avoid contamination preservation in 2 ~ 8 ℃, valid for 1 month.

【SPECIMEN COLLECTION AND HANDLING】

Serum or heparin anticoagulant blood plasma.

Sample stability: 2～8℃ preservation stability in 3 days;

When the bilirubin concentration of sample≤0.5g/L, Hb≤5g/L, TG≤30g/L,VC≤0.5g/L, was not observed clearly disturbance.

【APPLICABLE INSTRUMENT】

BIOBASE 、HITACHI、OLYMPUS、BECKMAN、GLAMOUR、ABBOTT、TOSHIBA, etc. fully automatic biochemical analyzer..

【TESTING SPECIFICATION】

1.Use requirement:Liquid reagent use after opening

2.Test condition:

Wavelength	405nm
Cuvette light path	1.0cm
Temperature	37℃
Assay Type	fix-time

3.Calibration procedure:

Two calibration with deionized water and Na calibration.Calibration another purchase, it is recommended to use RANDOX,or other traceability calibration.

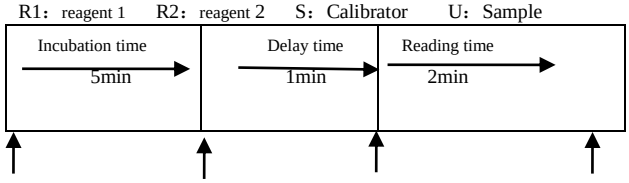
4. Quality control program:

Determination of Na quality control products, test results within the scope of quality control can test the samples.

5. OPERATIONG STEPS

Double reagent operation:

R1：reagent 1 R2：reagent 2 S：Calibrator U：Sample



Distilled water、U or S:40μl;	R2:400ul R1:1200μl	Recording absorbance A1	Recording absorbance A2 value，calculate ΔA/min

【CACULATION】

$$\text{Na sample concentation} = \frac{\text{Sample}\triangle A/\text{min}}{\text{Calibrator}\triangle A/\text{min}} \times \text{Standard concentation}$$

【REFERENCE RANGE】

136~146mmol/L

By clinical trials, choose no less than 100 newborn or adults blood specimens, tested by automatic biochemical analyzer, and then processing the testing value with statistical method, calculating out the reference range.

【THE LIMITATIONS OF TESTING RESULTS】

Na testing is just one of the standard that clinicist diagnose the patient. Clinical physicians should according to patients' bodies, history and other diagnostic program, to get comprehensive judgment.

【THE INTERPRETATION OF TEST RESULTS】

Human error, the processing of specimen, analysis instrument deviation, etc. all can affect the measurement result；When one sample deviates from the expected value too far, need to be tested again.

【PERFORMANCE INDEX】

1．Reagent blank absorbance≤0.5000，(405nm，lcm optical path).

2．Precision：repeatability CV≤10%；batch variations R≤10%.

3．Accuracy：relative deviation ≤10%.

4．Linearity range：80~180mmol/L，r≥0.990.

5. Stability：All package reagent, non corrosive gas and avoid light, preservation in 2~8 ℃, stable 12 months.

【ATTENTION】

1.When the simultaneous determination of sodium and potassium project, please first test Na.

2. Different batches reagents cannot mix, when replacing reagents batch number, please calibration again.

3.The opened reagent should be airtight store according to the specified method , never use expired.

4.Liquid waste disposal: Suggest follow local regulations.

【Production enterprise licence number】:鲁食药监械生产许 20080002 号

【Registration certificate number】:鲁食药监械（准）字 2010 第 2400280 号

【Product standard number】:YZB/鲁 0206-2010

Biobase Biodustry(Shandong)Co.,Ltd

Add: BIOBASE Biological industrial park, Mingshui Economic development zone, Jinan, China, 250200

Tel: 0086-0531-91219801 Fax: 0086-0531-81219804