Potasium（K^+）Test Kit（Enzymatic）

【NAME】

Name:Potasium（K）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 Potasium（K) in human serum,plasma on both manual and automatd systems.

(1)Serum Potasium increase often occur in the following situations: ① Acute renal failure, potassium excretion dysfunction when urine intoxication; ② the adrenal cortex hypofunction;③ a variety of reasons of respiratory acidosis and metabolic acidosis;④ Severe hemolysis, a large number of input banked blood, crush syndrome, burn, etc.; ⑤ Extensive use of potassium drugs; ⑥ High permeability dehydration.

(2)Serum Potasium reduce often appears in the following situations: ①such as severe infection, chronic wasting disease long-term inappete-nce and fast after the surgery time is too long and did not pay attent-ion to the potassium supplement;②Adrenal cortex hyperfunction. long-term heavy use of adrenal cortex hormone;Many long-term use of diuretics;acute renal failure stage by anuresis into the polyuria;③Alkali poisoning;Diabetic patients using insulin or insulin and glucose as en ergy mixture is used;④ A large number of input without liquid potass ium, plasma dilution, lower the serum potassium.

【METHODOLOGY】

Potasium detection by potasium dependent pyruvate kinase catalytic enol phosphate type pyruvate (PEP) enzyme kinetics reaction ,Its product (pyruvic acid salt) and NADH reaction generated NAD^+ under the action of lactate dehydrogenase (LDH),the product (NAD^+) absorbance value is proportional to the concentration of potassium in the 340 nm.

$$\text{PEP} + \text{ADP} \xrightarrow[\text{Pyruvate kinase（PK）}]{K^+} \text{Pyruvic acid salt} + \text{ATP}$$

$$\text{Pyruvic acid salt} + \text{NADH} + H^+ \xrightarrow{\text{LDH}} \text{Lactic acid} + NAD^+$$

【REAGENT COMPOSITION】

Reagent 1（R1）：

Tris buffer PH8.2	250mmol/L
Cryptand	12mmol/L
PEP	≥3.0mmol/L
ADP	≥3.2mmol/L
α-ketone glutaric acid	≥1.2mmol/L
NADH	≥0.35mmol/L
GLDH	≥11U/mL
PK	≥1.2U/mL

Reagent 2（R2）：

LDH	≥65U/mL

【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 lithium heparin anticoagulant blood plasma.

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

When the bilirubin concentration of sample≤665umol/L,Hb ≤1g/L,TG ≤24.2mmol/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	340nm
Cuvette light path	1.0cm
Temperature	37℃
Assay Type	fix-time

3.Calibration procedure:

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

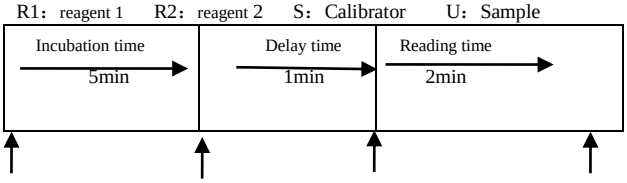
4. Quality control program:

Determination of K 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:50μl;	R2:600ul R1:1800μl	Recording absorbance A1	Recording absorbance A2 value，calculate ΔA/min

【CACULATION】

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

【REFERENCE RANGE】

3.5~5.1mmol/L(13.7~19.9mg/dL)

Unit conversion μmol/L ×3.9g/mol=mg/dL

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】

K 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≥1.7000,(340nm，lcm optical path).

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

3．Accuracy：relative deviation ≤10％.

4．Linearity range：0~10mmol/L(7.8~39.0mg/dL)，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.

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