Electrolyte Analyzer Supporting Reagent
(Ion Selective Electrode Method)

【Name】Electrolyte Analyzer Supporting Reagent (Ion Selective Electrode Method)

【Specification】

Reagent		Model	Specification
Calibration Solution (Two points calibration)	Low level	URIT C	1 mL/bottle×10
	Medium level		1 mL/bottle×10
	High level		1 mL/bottle×10

【Intended Use】

Calibration Solution of Electrolyte Analyzer.

Clinically used for the diagnosis of surgery, burns, diarrhea, shock, acute myocardial infarction, vomiting, adrenal insufficiency, renal failure, central diabetes insipidus, taking diuretics, metabolic acidosis, cancer, vitamin D too much disease, neonatal hypocalcemia, diabetes, familial periodic paralysis, primary aldosteronism, Cushing's syndrome which can cause human electrolyte and acid-base imbalance in the human body.

【Principles of The Examination Method】

This product uses the principle of ion selective electrode method.

Ion selective electrode method: In the relatively constant temperature conditions, the collected potential signal of the ion in the solution should be proportional to the logarithm of the ion activity or to the concentration of the ion in the solution.

【Ingredient】

Reagent composition	Main composition	
Calibration Solution （Two points calibration）	Organic Buffer	<0.1%
	Inorganic salts	<2.0 %
	Preservative	<0.05%

【Storage and Shelf Life】

1. Reagent should be stored at 2℃~ 40℃, keep dry and ventilated, avoid direct light.

2. Reagent is stable for 2 years, After opening, the reagent is stable for 30 days when stored in the prescripted condition.

【Required Equipment】

Electrolyte Analyzer：URIT-910A, URIT-910C, URIT-900

【Examination Method】

1. Calibration procedure

After starting the calibration process, the instrument collects the potential signal of Standard Solution A and Standard Solution B, and performs the data processing according to the formula (1), calculating the slope of the curve and storing the potential value of Standard Solution A and the slope data of the slope.

$$S = (E_B - E_A) / \lg(C_B / C_A) \cdots\cdots\cdots (1)$$

2. Quality control

Use the measurement Calibration Solution C to perform routine operation on the instrument according to its operating method.

3. Calculation of examination results

The instrument collects the potential signal of the sample and performs the data processing according to the formula (2) to calculate the molar concentration in the sample.

$$C_x = C_A \times 10^{(E_x - E_A)/S} \cdots\cdots\cdots\cdots\cdots (2)$$

Above the two types:

Cx, Ex——The molar concentration and potential value of the sample

C_A, E_A ——The molar concentration and potential value of Standard Solution A

C_B, E_B——The molar concentration and potential value of Standard Solution B

S——The actual slope of the electrode measured by two correction fluids

【Reference Range】

adult	Serum samples
K^+	3.5～5.5
Na^+	135.0～145.0
Cl^-	96.0～106.0
Ca^{2+}	1.10～1.35
pH	7.35～7.45

K^+, Na^+, Cl^-, Ca^{2+} unit is mmol/L. This reference range is derived from the test of 120 healthy individuals and is for reference only. Due to differences in geographical, ethnic, gender and age, it is recommended that each laboratory determine their reference interval respectively.

The upper limit and lower limit of the reference are usually determined in the range $\bar{X} \pm 2SD$, 2SD represents 95% of the standard deviation.

【Warnings and Precautions】

1. For in vitro diagnostic use only.

2. This product contains preservatives. DO NOT swallow. Avoid contacting with skin and eyes.

3. If using other outsourcing quality control, please note that it should not contain sodium azide.

4.If the reagent is not used up in one month after opening the bottle, it should be treated as waste liquid.

5.Unused reagent should be stored in the specified method and used within the validity period. Expired reagents, waste liquid and samples should be treated according to the relevant medical waste disposal regulations.

【Symbols on Packing Box and Label】

Temperature limit	Consult instructions for use
In vitro diagnostic medical device	Batch code
Use-by date	Keep away from sunlight
Date of manufacture	

【Reference】

[1] Shang Hong, Wang Yusan, Shen Ziyu, The National Clinical Test Regulation of Operation (the fourth edition), People's Medical Publishing House, 2014：243-259.

[2] Han Zhijun, Automatic analysis of commonly used items in clinical chemistry. Shenyang: Liaoning Science and Technology Press, 1991, 252.

【Basic Information】

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