



Electrolyte Analyzer Supporting Reagent (Ion Selective Electrode Method and Pressure Method)

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

【Specification】

Reagent	Model	Specification
Reagent Kit II:		
Standard Solution A	URIT A	400 mL/bottle×1
Standard Solution B	URIT B	100 mL/bottle×1
Electrode cleaning solution	URIT C	20 mL/pack

【Intended Use】

For the quantitative determination of ion potassium (K⁺), ion sodium (Na⁺), ion chlorine (Cl⁻), ionized calcium (Ca²⁺) and pH in human serum in vitro. 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
Standard Solution A	Buffer <0.1 % Inorganic salts <3.0 %
Standard Solution B	Preservative <0.05 %.
Electrode cleaning solution	Hypochlorite de sodium < 0,1 % Surfactant < 1,0 % Conservative < 0,05 %

【Storage and Shelf Life】

1. Reagent should be stored at 2°C~ 40°C, 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 prescribed condition.

【Required Equipment】

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

【Primary Sample Requirements】

1. The sample should be human serum.
2. The sample can not have hemolysis, lipid blood, can not have coagulation or blood clots.
3. When preparing a serum sample, do not add substances that may cause errors in measurement. For example, surfactants, anticoagulants can interfere with the measurement.
4. Serum samples can be stabilized for 3 days when stored at 2°C~8°C and should be kept to room temperature before using.

【Examination Method】

1. Reagent preparation

The reagent can be used directly.

2. Determination conditions

Supporting electrolyte analyzer with test environment conditions of 10°C~30°C.

3. Test method

The reagent can be used directly after loading into the instrument, and test is performed according to the operation instruction of the instrument.

4. 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.

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

5. Quality control

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

6. 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.

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

Above the two types:

- C_x, E_x—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⁻, Ca²⁺ 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.



【Interpretation of Results】

The accuracy of the results depends on the calibration of the instrument and the control of the sample in vitro time.

【Limitations of the Examination Results】

1. The test results of this product need to be evaluated in combination with the doctor's clinical diagnosis.
2. pH value is mainly used to correct the ion calcium, which is not for clinical reference.
3. The good storage environment of this product and sample can ensure the reliability of test.
4. The sample can not have blood clots or blood clots, hemolysis, dissolved fat.








【Performance characteristics】

Test items		K ⁺	Na ⁺	Cl ⁻	Ca ²⁺	pH
AccuracyB (%) or (mmol/L)		≤2.0%	≤2.0%	≤2.0%	≤5.0% or 0.05mmol/L	≤1.0%
Linearity	Linear interval	1.5~7.5 mmol/L	100.0~180.0 mmol/L	80.0~160.0 mmol/L	0.50~2.50 mmol/L	7.00~8.00
	Linear deviation (D)	≤3.0%	≤2.0%	≤2.0%	≤5.0% or 0.05mmol/L	≤1.0%
	The linear correlation coefficient r	≥0.995	≥0.995	≥0.995	≥0.995	≥0.995
Precision CV(%)		≤1.0%	≤1.0%	≤1.0%	≤1.5%	≤0.5%
Batch difference CV(%)		≤3.0%	≤3.0%	≤3.0%	≤5.0%	≤1.0%
Stability		Accuracy, linearity, repeatability of the reagents that are stored at 2°C ~ 40°C to the end of the period should meet the requirements.				

【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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- 【Service Life】** Refer to the packing box or label.
- 【Release Date】** In May, 2019
- 【Version】** 05/2019-C1

