

Reagent for Electrolyte Analyzer

【Product name】

Chinese name: 电解质分析仪专用配套试剂（离子选择电极法）

English name: Reagent for Electrolyte Analyzer

【Packing specification】

Solution name	Packing specification			
Standard Solution A	1100ml/bag	430ml/bottle (bag)	350ml/bottle (bag)	
Standard Solution B	430ml/bag	70ml/bottle (bag)	350ml/bottle (bag)	110ml/bottle (bag)
CO2 Standard Solution 1	110ml/bottle	5ml/bottle		
CO2 Standard Solution 2	110ml/bottle	5ml/bottle		
QC Solution 1	110ml/bottle	5ml/bottle	3ml/bottle	1.7ml/bottle
QC Solution 2	110ml/bottle	5ml/bottle	3ml/bottle	1.7ml/bottle
QC Solution 3	110ml/bottle	5ml/bottle	3ml/bottle	1.7ml/bottle

【Intended use】

Used for the correction and maintenance of IMS-972, IMS-972Plus, IMS-972Popular, H900, IMS-986, IMS-986Plus, IMS-986Popular, IMS-988, H930, H960, H980, H981, H982, H983, EM-100, EM-120, EM-130, M-900, M-930, M-960 Electrolyte Analyzers (ISE:K⁺, Na⁺, Cl⁻, Ca²⁺, pH, Li⁺, Mg²⁺, CO₂) produced by our company.

【Principle of inspection】

The reagent package has a stable pH and a constant ionic concentration, which can be accurately calibrated by an electrolyte analyzer. At the same time, the stability of the whole system can be maintained and the accuracy of the measurement results can be improved when the sample is measured.

【Major component】

Consist of NaCl, KCl, CaCl₂, NaAc, LiAc, MgAc₂, NaHCO₃, pH buffer agent, surfactant, Prcolin. In addition, the LiAc and MgAc add only in reagents containing the corresponding test items. Otherwise, calibration solutions for different batches of test items can be interchanged. The concentration of each component in the reagent is shown in the following table.

Solution name	Ion project	Concentration index
Standard Solution A	K ⁺	4.00mmol/L
	Na ⁺	140.0mmol/L
	Cl ⁻	100.0mmol/L
	Ca ⁺⁺	2.50mmol/L
	pH	6.840
	Li ⁺	2.50mmol/L
Standard Solution B	Mg ⁺⁺	2.00mmol/L
	K ⁺	8.00mmol/L
	Na ⁺	110.0mmol/L
	Cl ⁻	70.0mmol/L
	Ca ⁺⁺	1.25mmol/L
	pH	7.384
CO2 Standard Solution 1	Li ⁺	1.25mmol/L
	Mg ⁺⁺	1.00mmol/L
	K ⁺	3.15mmol/L
	Na ⁺	125.0mmol/L
	Cl ⁻	90.0mmol/L
	Ca ⁺⁺	0.70mmol/L
QC Solution 1	pH	7.200
	Li ⁺	0.60mmol/L
	Mg ⁺⁺	0.50mmol/L
	K ⁺	4.30mmol/L
	Na ⁺	145.0mmol/L
	Cl ⁻	100.0mmol/L
QC Solution 2	Ca ⁺⁺	1.40mmol/L
	pH	7.380
	Li ⁺	1.20mmol/L
	Mg ⁺⁺	0.70mmol/L
	K ⁺	6.30mmol/L
	Na ⁺	150.0mmol/L
QC Solution 3	Cl ⁻	115.0mmol/L
	Ca ⁺⁺	2.10mmol/L
	pH	7.560
	Li ⁺	1.80mmol/L
	Mg ⁺⁺	0.90mmol/L

【Storage conditions and validity】

Storage environment should be clean, ventilated, avoiding insolation. The temperature is 0 to 40 degrees centigrade. The relative humidity is not more than 90%. Otherwise, it can't be freeze. The solution is

valid for two years. After opening, it is valid for 30 days.

【Applicable instrument】

Applicable for IMS-972 series, H900 series of electrolyte analyzer.

【Sample requirements】

Sampling and processing of samples should be done by professionals to avoid hemolysis and affect measurement results. In addition, attention should be paid to these matters.

Whole blood sample:

- 1) Heparin or heparin lithium should be used as anticoagulant for whole blood sample. Avoid to use heparin, sodium citrate, EDTA, potassium two, and potassium oxalate as anticoagulants. Other anticoagulants may cause errors in the results of measurements.
- 2) The whole blood sample should be analyzed in time and completed within one hour of sample collection, so as to avoid the error caused by the change of sample. Don't forget to wash tubes in time after testing.

Serum and plasma samples:

- 1) Storage of serum and plasma in the refrigerator can be used for analysis. But it should be reverted to room temperature before analysis.

When preparing serum samples, substances that may cause errors in measurement cannot be added, such as surfactant and anticoagulant. It can interfere with measurements and even cause damage to the sensors.

Urine sample:

- 1) Samples should be diluted ten times by using sample dilutions (1:9).
- 2) Boric acid is recommended as a preservative of urine so that other preservatives do not interfere with measurements

【Inspection method】

- 1) Calibration of the instrument is carried out according to the instruction of the instrument.
- 2) The two points are corrected according to the instructions of the instrument under the state of preparation of the instrument.

【Positive judgment value or reference interval】

Electrolyte	Serum	Urine (24 hours)
K	3.5-5.5mmol/L	50-100mmol/L
Na	135-145mmol/L	130-217mmol/L
Cl	98-106mmol/L	170-250mmol/L
Ca	1.09-1.35mmol/L	
Mg	0.60-1.10mmol/L	
CO ₂	20-33mmol/L (Adult)	

Note: it is recommended that each laboratory establish its own reference range.

【Interpretation of test results】

Through the selective response of ion selective electrode to the concentration of various ions in reagent, the detection of various electrolytes was completed, and the basis for the diagnosis of electrolyte in serum and other body fluids was analyzed. It may have an impact on the results. When some anticoagulants are added to the sample. Therefore, we should compare and confirm the experiment with the previous samples.

【Limitations of the inspection method】

- 1) Base on the two-point calibration, the linearity error will be slightly larger when measuring the solution with a relatively wide correction. It is therefore not appropriate to detect specimens beyond clinical limits.
- 2) Only suitable for testing samples in the requirements of samples, other samples can not guarantee the accuracy of the results.

【Product performance index】

Uniformity requirement in batch	Analysis element							
Coefficient of	K ⁺	Na ⁺	Cl ⁻	Ca ⁺⁺	pH	Li ⁺	Mg ⁺⁺	TCO ₂

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variation								
CV/%	≤ 2.0	≤2.0	≤2.0	≤2.0	≤3.0	≤3.0	≤3.0	≤3.5

Batch to batch variation	Analysis element							
Coefficient of variation	K ⁺	Na ⁺	Cl ⁻	Ca ⁺⁺	pH	Li ⁺	Mg ⁺⁺	TCO ₂
CV/%	≤ 2.0	≤2.0	≤2.0	≤2.0	≤3.0	≤3.0	≤3.0	≤3.5

Accuracy requirement	Analysis element							
Relative deviation	K ⁺	Na ⁺	Cl ⁻	Ca ⁺⁺	pH	Li ⁺	Mg ⁺⁺	TCO ₂
V/%	≤3.0	≤3.0	≤3.0	≤5.0	≤3.0	≤5.0	≤5.0	≤5.0

【Attention】

- 1) The reagent for electrolyte analyzer is just used in vitro diagnosis.
- 2) Do not contact with skin or mucous membranes. Once it is splashed on the skin, rinse with plenty of water. If accidentally splashed into eyes, please rinse with plenty of water. If you feel unwell, please be treated by a doctor.
- 3) The reagent kits are transparent liquid with no precipitation or floc. Please confirm the contamination or color change before use. Replace it immediately once you find out.
- 4) If you take this product out of the refrigerator, it should be stored for more than 30 minutes, so that the temperature can be reached at room temperature before measuring.
- 5) All reagents should be used within the validity period of the label.

【Interpretation of identity】No.

【Reference】 《National operation manual for clinical examination 》
The Fourth Edition

Guidelines for preparation of in vitro diagnostic reagent instructions
(CFDA (2014) No. 17)

【Essential information】

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