

## COA for Reagent of Electrolyte analyzer

No.: QR-75-38-01-250401

Name: ISE Reagent Pack

Batch: 20250415 Expiry date: 2027.04.14

Tem: 26.0 °C

Relative humidity: 70.0%

The main standard device is shown below

Name	specification	manufacture	Batch	Validity
Electrolyte analyzer	XI-1021F	Shenzhenkaite	JY147	2025.07
CAL serum Level II	20×5ml	RANDOX	1657UN	2025.11
Electrolyte analyzer reagent	ISE Reagent Pack	Shenzhenkaite	20250317	2027.03.16

Items to test:

## 一、Reagent appearance

(Qualified "√" Unqualified "×")

Item	Conclusion	Item	Conclusion	Item	Conclusion
Colorless transparent	√	The solution not having precipitate	√	The solution not having floccule	√

## 二、Reagent volume (Qualified "√" Unqualified "×")

Ideal	Actual	Conclusion
Buffer A:460ml	>460ml	√
Buffer B:360ml	>360ml	√

## 三、performance tests

## 1、Precision in batch

Item	K <sup>+</sup> (≤1.5%)	Na <sup>+</sup> (≤1.5%)	Cl <sup>-</sup> (≤1.5%)	Ca <sup>2+</sup> (≤3.0%)	pH (≤1.0%)	HCO <sub>3</sub> <sup>-</sup> (≤3.0%)
CV	0.23%	0.21%	0.20%	/	/	/

## 2、Precision out batch

Item	K <sup>+</sup> (mmol/L)	Na <sup>+</sup> (mmol/L)	Cl <sup>-</sup> (mmol/L)	Ca <sup>2+</sup> (mmol/L)	pH	HCO <sub>3</sub> <sup>-</sup> (mmol/L)
Allowable deviation	≤0.20	≤3.0	≤2.0	≤0.06	≤0.10	≤0.5
ΔX	0.01	0.04	0.07	/	/	/

## 3、Accuracy (Qualified "√" Unqualified "×")

Item	Standard (mmol/L)	Results			Relative deviation	Conclusion
K <sup>+</sup> (≤3.0%)	3.88	3.89	3.92	3.91	0.69%	√
Na <sup>+</sup> (≤3.0%)	138.0	138.0	138.6	138.3	0.22%	√
Cl <sup>-</sup> (≤3.0%)	96.6	96.8	96.6	96.4	0.00%	√

## 四、package (Qualified "√" Unqualified "×")

Item	Conclusion	Item	Conclusion
Clean packing	√	Label straight no stains	√
The design and the text clear and correct	√	Tight capping and no leakage	√

Test result: Qualified

Inspector signature:

Chen Zhi Song

Approved:

Tang Zi

Date:

2025.4.18