

# ISE Blood Quality Control Instruction

**【Name】**  
ISE blood quality control  
**【Packaging Specification】**

Product Models	Packaging Specification	Product Models	Packaging Specification
ISE blood quality control HIGH	Freeze-dried powder 0.18g/bottle×1, dissolved liquid 4 mL / bottle×1	ISE blood quality control LOW	Freeze-dried powder 0.18g/bottle×1, dissolved liquid 4 mL / bottle×1
	Freeze-dried powder 0.18g/bottle×2, dissolved liquid 4 mL / bottle×2		Freeze-dried powder 0.18g/bottle×2, dissolved liquid 4 mL / bottle×2
	Freeze-dried powder 0.18g/bottle×3, dissolved liquid 4 mL / bottle×3		Freeze-dried powder 0.18g/bottle×3, dissolved liquid 4 mL / bottle×3
	Freeze-dried powder 0.18g/bottle×5, dissolved liquid 4 mL / bottle×5		Freeze-dried powder 0.18g/bottle×5, dissolved liquid 4 mL / bottle×5

**【Intended Use】**

This product is applicable to the ion-selective electrode module of CS series Auto-Chemistry analyzers for measuring electrolyte. The accuracy of serum measurement result can be confirmed in the linear range of instrument measurement by measuring this product.

**【Main Components】**

Sodium chloride, potassium dihydrogen phosphate, sodium bicarbonate, albumin

**【Storage Condition and Period of Validity】**

Stored at 2°C~8°C, ISE blood quality control is within the expiry date of 1 year.

**【Suitable Device】**

Applicable to CS series Auto-Chemistry analyzers

**【Testing Method】**

Take out each bottle of freeze-dried powder and dissolved liquid and accurately aspirate 3ml dissolved liquid with a micropipette and discharge it into the bottle of freeze-dried powder dissolved liquid, place it at room temperature for about 20 minutes, and then slowly reverse to mix it until it is fully dissolved, sequently, pour it into sample cup for use.

**【Performance Index】**

1. Freeze-dried powder water content: water content shall be no more than 5.0%.
2. Quality control range:

2.1. The quality range shall meet the requirement of Table 1.

Table 1. Quality Control Range Unit: mmol/L

Quality Control Item	HIGH	LOW
Na <sup>+</sup>	158±7.9	123±6.15
K <sup>+</sup>	6.4±0.512	2.9±0.232
Cl <sup>-</sup>	128±6.4	86±4.3

2.2. The accuracy of index weight: Use Roche 9180 Electrolyte Analyzer to test the samples, and the test result shall be within the quality control range.

3. Between-bottles homogeneity: the between-bottles homogeneity in high level product and low level product CV shall be no more than 5.0%.

**【Explanation of Test Results】**

Please conduct retesting after check the instrument-reagent according to the User's Manual the time the result exceeds the range of quality control.

**【Limit】**

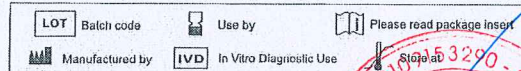
ISE blood sample quality control can only be used for determination of electrolyte tested by ISE indirect method.

**【Reference Value】** See Table 1.

**【Note】**

1. This product is applicable to Invitro diagnostic only;
2. Rinse the skin or clothes with water when contaminated by reagent;
3. To avoid heat and direct sunlight;
4. Reagent should be run out within 7 days after unsealing.

**【Symbol】**



**【Instructions Approval and Modification Date】** 06/2014

**【LOT No.】**



**GIÁM ĐỐC**  
*Lãng Đỗ Dũng*