



CORNLEY

Instructions for Calibration Standard Solution

(ISE method)

【Product Name】

Calibration standard Solution

【Package】

Each package has two kinds of solution inside: R1: Cal A and R2: Cal B.

Model	Component	Net content
AFT-A8	R1: Cal A	650ml
	R2: Cal B	200ml



GIÁM ĐỐC
Trần Thị Bé Ca

【Intended use】

It's used for multi-parameter measuring reagents for electrolyte analyzer(testing items:K,Na,Cl,Ca,pH), K,Na,Cl,Ca pH are calibrated,corrected and cleaned based on the Ion - Selective Electrodes principle.

【Principle of the method】

Under the condition of temperature being relatively constant, the potential signal of ions in the solution collected by equipment should be proportional to logarithm of ion activity.

【Major ingredients】

KCl, NaCl, NaAc, CaCl₂, pH Buffer, Surface active agents, Preservatives.

Name/nominal concentration	calibration A	calibration B
K ⁻ (mmol/L)	4.00	8.00
Na ⁻ (mmol/L)	140.0	110.0
Cl ⁻ (mmol/L)	100.0	70.0
Ca ²⁺ (mmol/L)	1.25	2.50
pH	7.40	7.00

【Storage】

1. The reagent must be stored at 5°C - 25°C in a cool and dry place without direct sunshine. Do not freeze the reagent.
2. Shelf life of unopened package is 1 year under required storage conditions. The package should use up within 3 months once opened.

【Applicable instrument】

This reagent is applicable to use with electrolyte analyzer employed ISE method.

【Specimen requirements】

1. Avoid hemolytic specimen.
2. The specimen must be analyzed within 1 hour.
3. Whole blood should place under room temperature and do not freeze

【Procedure】

Calibration:

Equipment collect potential signals of calibration A and calibration B, and then process data according to the formula(1),calculate it then get the slope of the curve, at last save the potential value of calibration A and data of slope.

Testing: Equipment collect the potential signal of sample, and then process data according to the formula (2), calculate it and then get the the molar concentration of sample.

$$S = (E_R - E_s) / \lg(M_R / M_s) \dots \dots \dots (1)$$

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

M_x , E_x represents the molar concentration value and potential value of the sample
 M_A , E_A represents the molar concentration value and potential value of calibration A
 M_B , E_B represents the molar concentration value and potential value of calibration B
 S represents the actual electrode slope measured by two kinds of calibration.

【Reference Range】

Healthy Adult	Serum
K (mmol/L)	3.50~5.20
Na (mmol/L)	136.0~145.0
Cl ⁻ (mmol/L)	96.0~108.0
Ca ²⁺ (mmol/L)	1.10~1.34

The range in this table is for reference only. Each clinical laboratory is recommended to determine its own reference range.

【Limitations】

The result is affected by equipment and models, the result would be different if we use different equipment.

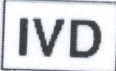


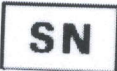




【Performance Characteristics】

Item	K	Na	Cl ⁻	Ca ²⁺	pH	
Linearity Range	linear correlation coefficient r	≥0.9900	≥0.9900	≥0.9900	≥0.9900	—
	Linearity deviation D	≤3.0%	≤1.0%	≤2.0%	≤5.0%	—
Sensitivity of Analysis mmol/L	≤0.20	≤6.7	≤6.2	≤0.10	—	
Within-run CV(%)	≤1.5%	≤1.5%	≤1.5%	≤1.5%	≤1.0%	
Between-run CV(%)	≤3.0%	≤3.0%	≤3.0%	≤5.0%	≤1.0%	
Accuracy Bias(%)	≤2.0%	≤1.5%	≤2.0%	≤5.0%	≤1.0%	

【Warning and Precautions】

1. The solution contains preservative agent in the solution. Avoid contact skin and eyes. Do not swallow.
2. The used reagent package contains waste solution and should be disposed in compliance with local regulation to avoid biological contamination.
3. Always wear gloves to avoid contamination when handling or replacing reagent package.
4. Only QC materials of Sodium aside (NaN₃CAS)-free are applicable if they are from other manufacturer.

【Symbols】

	For in vitro diagnostic device use		Date of manufacture
	Consult instructions for use		Serial No
	Batch No		Use by
	Temperature limitations		Caution

EC	REP	Authorized Representative		
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