



Instructions for Calibration Standard Solution



GIÁM ĐỐC
Thị Bé Ca

【Product Name】

Calibration Standard Solution

【Package】

Model	Component	Net content
AFT-A8III	R1: A standard solution	1000ml/Bag
	R2: B standard solution	250ml/Bag
	R3: Clean solution	60ml/Bag

【Intended use】

This reagent is used for calibrating and flushing Cornley's electrolyte analyzer.

【Principle of the method】

ISE method: Under constant temperature, the potential measured by the analyzer is directly proportional to the logarithm of ion activity in the solution. Activity is related to concentration through activity coefficient factor in the relation $a = f \cdot C$.

Pressure measurement: The sample is reacted with a relatively strong acid in an airtight reaction cell to generate CO₂ gas. The pressure inside the cell increases and this pressure change is sensed by a tonometer and converted into electrical signal. Then the processor will calculate the concentration and display/ print the report accordingly.



【Major ingredients】

KCl, NaCl, NaAc, CaCl₂, LiCl, NaClO, Na₂CO₃, pH buffer, surface active agent, preservative agent.

Concentration	Standard solution A	Standard solution B	TCO ₂ standard solution
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	~
Li ⁺ (mmol/L)	0.3	1.2	~
pH	7.40	7.00	~
TCO ₂ (mmol/L)	~	~	25

【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 18 months 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 employing 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 (ISE method):

A two point calibration is carried out to determine a line model. The slope of this line can be calculated from equation 1. E_A and E_B is the potential respectively measured from Standard solution A and Standard solution B.

Sampling:

The potential of E_x from a sample is measured, its ion concentration can be calculated from equation 2.

$$S = (E_B - E_A) / \lg(M_B / M_A) \dots \dots \dots (1)$$

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

M_x, M_A, M_B is respectively ion concentration of sample, standard solution A, standard solution B.
 E_x, E_A, E_B is the potential respectively measured from sample, standard solution A, standard solution B.
 S is the slope calculated from standard solution A and B.

Pressure measurement:

The calibration solution or the sample is mixed with the TCO_2 reaction solution, and the CO_2 released passes through the pressure sensor to generate a pressure signal, and it will be compared to the pressure signal generated by the calibration solution. Then it can calculate the concentration of TCO_2 in the sample.

$$C_x = C_A \times \frac{V_x}{V_A} \dots\dots\dots (3)$$

C_x, C_A is respectively ion concentration of sample, TCO_2 standard solution.
 V_x, V_A is the potential respectively measured from sample, TCO_2 standard solution.

【Reference Range】

Adult	Serum	Urine/(24h)	Cerebrospinal fluid
K^+ (mmol/L)	3.50~5.20	25.00~100.00	~
Na^+ (mmol/L)	136.0~145.0	130.0~260.0	~
Cl^- (mmol/L)	96.0~108.0	170.0~250.0	120.0~132.0
Ca^{2+} (mmol/L)	1.10~1.34	~	~
Lithium(mmol/L)	~	~	~

TCO_2	Serum(or Plasma) (mmol/L)
Adult	22~29
Child	18~27

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

【Limitations】

pH is used to correct Calcium ion and its value is inapplicable to clinical applications.







【Performance Characteristics】



Item	K^+	Na^+	Cl^-	Ca^{2+}	Li^+	pH	TCO_2 Standardsolution	TCO_2 Reaction solution
Linearity	coefficient	≥ 0.9900	≥ 0.9900	≥ 0.9900	≥ 0.9900	≥ 0.9900	~	≥ 0.9900
	deviation	$\leq 3.0\%$	$\leq 1.0\%$	$\leq 2.0\%$	$\leq 5.0\%$	$\leq 2.0\%$	~	≥ 0.9900
Precision mmol/L	≤ 0.20	≤ 6.7	≤ 6.2	≤ 0.10	≤ 0.10	~	$\leq 3.0\%$	$\leq 3.0\%$
Intra-assay CV (%)	$\leq 1.5\%$	$\leq 1.5\%$	$\leq 1.5\%$	$\leq 1.5\%$	$\leq 1.5\%$	$\leq 1.0\%$	≤ 1.5	≤ 1.5
Inter-assay CV (%)	$\leq 3.0\%$	$\leq 3.0\%$	$\leq 3.0\%$	$\leq 5.0\%$	$\leq 5.0\%$	$\leq 1.0\%$	$\leq 1.0\%$	$\leq 1.5\%$
Accuracy Bias(%)	$\leq 2.0\%$	$\leq 1.5\%$	$\leq 3.0\%$	$\leq 5.0\%$	$\leq 5.0\%$	$\leq 1.0\%$	$\leq 1.5\%$	$\leq 5.0\%$
							$\leq 1.5\%$	$\leq 10.0\%$

【Warning and Precautions】

1. The solution contains preservative agent. Avoid contact with 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 (NaN_3CAS)-free are applicable if they are from other manufacturer.

【Symbols】

	For in vitro diagnostic device use		Date of manufacture		Complies with IVD directive 98/79/EC
	Consult instructions for use		Biological risk		

LOT	Batch No.		Expiry date		Temperature limitations
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