Instructions for Electrolytes Quality Control

(ISE method)

CÔNG TY TNHH THIẾT BỊ KỸ THUẬT BKT

GIÁM ĐỐC

Trần Thị Bé Ca

【Product Name】

Electrolytes Quality Control

【Model】

There levels of Quality control are available in the package: R1: (High Level), R2:(Middle Level)) and R3: (Low Level)

Model	Component	Package
AFT-ISEQC	R1: Electrolyte Quality Control (High Level) 1.0ml	3×1.0ml
	R2: Electrolyte Quality Control (Middle Level) 1.0ml	4×1.0ml
	R3: Electrolyte Quality Control (Low Level) 1.0ml	3×1.0ml

【Intended use】

This reagent is applicable for assayed quality control of ion selective instrumentation.

This reagent is a solution with predetermined levels of K^+、Na^+、Cl^-、Ca^{2+}、pH.

Three levels of control are available to allow performance monitoring within the range:

Level 1, Level 2, Level 3

【Principle of the 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*C.

【Major ingredients】

KCl, NaCl, NaAc, $CaCl_2$, pH buffer, surface active agent, preservative agent.

Expected value	High	Medium	Low
K^+ (mmol/L)	5.82±0.19	3.87±0.19	1.96±0.32
Na^+(mmol/L)	150.9±4.0	130.0±4.0	110.5±7.2
Cl^-(mmol/L)	119.9±2.7	99.6±4.0	84.0±4.8
Ca^{2+}(mmol/L)	1.82±0.23	1.40±0.20	1.00±0.20
pH	7.75±0.12	7.45±0.12	7.10±0.12

【Storage and Stability】

1. The reagent should be stored in a shady,dry environment, avoid direct sunshine, the temperature should be between 2℃ to 25℃. The reagent could not be refrigerated for storage.
2. According to the prescriptive conditions for storage, shelf life of unopened package is18 months from the manufactured date.
3. The opened package should use only once. The reagent should be sampled immediately after opening. Delayed test may affect the final result.

【Applicable instrument】

This reagent is applicable forCornley® electrolyte analyzer employing ISE method.

【Procedure】

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.

The quality control materials are used to verify the accuracy of electrolyte analyzer. Its ion concentrations can be calculated from equation 2, 3 and should be corrected to expected values from equation 6.

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

M_A, M_B is respectively the ion concentration of standard solution A, standard solution B

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.

$$M_{CH} = M_A \times 10^{(E_H - E_A)/S} \cdots\cdots (2) \quad M_{CL} = M_A \times 10^{(E_L - E_A)/S} \cdots\cdots (3)$$

M_{CH}, M_{CL} is respectively the ion concentration of High, Low level of quality control materials.

E_H, E_L is the potential (mV) respectively measured from High, Low level of quality control materials.

$$\text{SLOPE } XV = (M_H - M_L) / (M_{CH} - M_{CL}) \cdots\cdots (4) \quad \text{INTERCEPT } XC = M_H - XV \times M_{CH} = M_L - XV \times M_{CL} \cdots (5)$$

$$M_{Corrected} = M_{measured} \times XV + XC \cdots\cdots (6)$$

【Performance Characteristics】

Item	K^+	Na^+	Cl^-	Ca^{2+}	pH
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%
AccuracyBias(%)	≤2.0%	≤1.5%	≤2.0%	≤5.0%	≤1.0%

【Warning and Precautions】

1. This reagent contains preservative agent. Avoid contact with skin and eyes. Do not swallow.
2. Waste ampoule and residual reagent should be disposed in compliance with local regulation to avoid biological contamination.
3. Discard the reagent if it is cloudy.

【References】

"National clinical examination procedures" (third edition),, *edior in chief- Mr.Ye Y.W,Mr.Wang Y.S 2006*

【Symbols】

IVD	For in vitro diagnostic device use		Date of manufacture
	Consult instructions for use	SN	Serial No
LOT	Batch No		Used by
	Temperature limitation		

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