

## Expected Ranges

<div> <div>LOT</div> <div>20250616</div> </div> <div> <div></div> <div>20270615</div> </div>		CONTROL 1	CONTROL 2	CONTROL 3
Na <sup>+</sup>	mmol/L	110.0 – 120.4	133.5 – 143.8	149.5 – 159.7
K <sup>+</sup>	mmol/L	2.65 – 2.91	3.31 – 3.91	5.50 – 5.90
Cl <sup>-</sup>	mmol/L	72.5 – 82.2	93.2 – 103.0	118.1 – 128.0
Ca <sup>++</sup>	mmol/L	2.12 – 2.44	1.23 – 1.51	0.65 – 0.85

**Product Application** Used for quality control in electrolyte analyzer detection systems to monitor and evaluate the accuracy and precision of test results.

**Test Principle** The instrument operates on the principle of ion-selective electrodes: using calibration solutions A and B to calibrate the ion-selective electrodes, obtaining corresponding potential values E1 and E2 for the two solutions. This establishes a calibration equation relating the logarithm of ion concentration to electrode potential (LogC-E). By measuring the potential Ex of an unknown sample with the ion-selective electrode, the concentration Cx of the sample can be calculated. The quality control process is the same as for samples, testing the control material to verify the accuracy and precision of the instrument's calibration procedure.

**Main Components** Composed of sodium chloride (NaCl), potassium chloride (KCl), sodium acetate (NaAc), preservatives, etc.

**Storage Conditions and Shelf Life** 2-30°C with a shelf life of 24 months; after opening, 2-8°C with a shelf life of 1 week. Do not use if the solution appears cloudy, moldy, or shows other signs of contamination.

**Applicable Instruments** Calibration/quality control materials for electrolyte analyzers are suitable for all models of Statlyte C , Statlyte C Plus , and Statlyte Ultra electrolyte analyzers.

**Usage Instructions** Follow the requirements in the instrument's user manual.

**Performance Indicators** Follow the requirements in the instrument's user manual.

**Limitations** Only applicable to electrolyte analyzers with ion-selective electrode sensors.

**Precautions** This product is for use only with the company's electrolyte analyzers and is not intended for other instruments or human testing.



Temperature limits



Refer to instruction manual



In vitro diagnostic medical device



Manufacturer



Batch code



Expiry date



Production date

## References

1. "National Clinical Laboratory Procedures," 4th Edition, edited by Shang Hong, Wang Yusan, and Shen Ziyu, People's Medical Publishing House, 2015.
2. "Clinical Laboratory Management and Technical Procedures," 2nd Edition, edited by Lu Yongshui and Zhang Weimin, Zhejiang University Press, 2014.

## Basic Information

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## Approval and Revision Dates of the Manual

- Approval Date: May 14, 2024