

ABAXIS TB 07-02

SODIUM PRECISION OF ISE VS. ENZYMATIC MEASUREMENT

INTRODUCTION: The Piccolo® uses an enzymatic method for measuring electrolytes (Na, K, Cl) in the blood. Virtually all other analyzers measure electrolytes using an ISE (Ion Selective Electrode). Included below is a summary that specifically addresses the differences when measuring Na (SODIUM) by ISE and the enzymatic method of the Piccolo®.

SODIUM (Na) is the major cation in the blood and accounts for over half of its osmotic strength. Osmotic strength is critical for maintaining normal distribution of water in circulatory system. It also plays an important role in maintaining blood pressure. The normal range for sodium is typically considered to be 135-145 mmol/L, when measured using an ISE. The normal range for sodium measured with the Piccolo is 128 – 145 mmol/L.

HYPERNATREMIA- (high sodium concentrations) is often associated with the disease states of

- Dehydration
- Diabetes insipidus (renal loss of water with retention of sodium)
- Hyperaldosteronism, seen in Cushing's disease and adrenal hyperplasia. (retention of sodium and loss of potassium)

HYPONATREMIA- (low sodium concentrations) are seen in

- Overhydration (water intoxication)
- Diuretics (especially with use in patients with CHF)
- SIADH -Syndrome of Inappropriate Antidiuretic Hormone Secretion
- Adrenal failure (aldosterone deficit)
- Diabetic hyperosmolarity

The clinical usefulness (utility) of any diagnostic test is determined by two important criteria:

- 1. analytical precision- how accurately the analyte can be measured**
- 2. biological variability- how tightly the body regulates the analyte.**

ION SELECTIVE ELECTRODES (ISE) is the most common technique used to measure electrolytes. This method is fast (1 minute), with a high specificity and good precision .

Analyte measurement on the Piccolo® is spectrophotometric, based on an enzymatic reaction of B-galactosidase.

SODIUM- WHY PRECISION MATTERS

- Analytes with narrow normal ranges require good precision.
- The precision that an analyte can be measured directly relates to its clinical utility.
- Precision is usually expressed as the percent coefficient of variation (%CV) and is calculated by dividing the standard deviation (SD) by the mean or average of repeated measurements.
[%CV = (SD/Mean) x 100].

For example:

Sodium (NR: 128 – 145 mmol/L)

– Effect of a CV of 2.5% with a sample with a Na concentration of 140 mmol/L

- $CV = SD/x$
 - Plugging in the numbers: $0.025 = SD/140$
 - Solving for SD, one standard deviation = 3.5 mmol/L
- In this case, if actual Na is 140 mmol/L, Piccolo® method would measure this as being anywhere between 133 – 147 mmol/L. [$140 - (2 \times 3.5) = 133$; and $[140 + (2 \times 3.5)] = 147$]

Piccolo precision is approximately 1.6-1.8%

- Thus, a specimen with a true Na concentration of 140 mmol/L would have its concentration measured as some value between 136 and 144 mmol/L.

Methods to verify inappropriate Na results:

ANION GAP

- The anion gap is calculated as $Na - (Cl + HCO_3)$
- Normally 8-12 [$140 - (103 + 25)$] (mean of normal examples)
 - Increases of the AG are associated with acidosis.
 - Decreases not associated with any normal or abnormal conditions.
 - Decreased AG usually suggests that one or more of the measured electrolytes are incorrect.

The Anion Gap as a quality control measure:

FOR EXAMPLE

Na = 128; Cl = 102; TCO₂ = 23

AG = $128 - [102 + 23] = 3$

- For ISE-based methods; AG < 1 are always repeated as a QC check.
- For Piccolo, normal AGs are approximately -4 to 12. AGs < -4 suggest that electrolytes should be repeated.

Summary:

The Piccolo method for Na measurement is accurate. Due to fundamental differences between ISE and enzymatic measurement techniques, these differences will generate electrolyte results that could possibly appear to be outside normal expectations, and differ from results obtained by other labs. The Piccolo® reference range for sodium stated in the package insert is 128 – 145 mmol/L.

For any questions, please contact Abaxis Technical Support, 1-800-822-2947.