Memorandum – POC #7

To: UNC Medical Center Attending Physicians, Ambulatory Care Center, and Critical Care Transport

From: Nichole Korpi-Steiner, PhD
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Date: March 25, 2025

Subject: Falsely Elevated pH and Calculated Parameters Using Point-of-Care epoc®

Siemens Healthineers confirmed the occurrence of **falsely elevated pH results using epoc** test cards when whole blood samples are dosed with higher injection volumes (beyond the epoc Reader beep or after the "Analyzing Sample" message has displayed). This impacts select epoc test card lots (All lot numbers with prefix 02 or 12); however, it is unclear at this time if some, or all, test card lots are affected.

Per Siemens, the observed maximum bias, average bias and probability of occurrence (PO) at higher injection volumes are detailed in the table below [1].

pH level	Maximum Bias	Average Bias	PO of Bias>0.04
7.00	+0.043	-0.0125	0.55%
7.35	+0.126	+0.0290	5.84%
7.45	+0.103	+0.0378	10.82%

Falsely elevated epoc pH results may potentially affect the following calculated values:

Calculated Parameter	Potential Impact of Discrepant High pH Values
Calculated Biocarbonate ($HCO3^-$)	False increase in calculated value
Calculated Base Excess	False increase in calculated value
Calculated Oxygen Saturation (cSO_2)	False increase or decrease in calculated value, depends on other parameters (pO2; cHCO3- via PCO2)

Recommendation for epoc testing personnel:

- Stop injecting the whole blood sample as soon as the audio epoc Reader beep and/or “Analyzing Sample” message is displayed to minimize potential for erroneous pH results.

Recommendation for Healthcare Providers:

- Interpret patient pH result and associated calculated parameters (HCO3-, Base Excess, SO2) using point-of-care epoc analyzers with caution, as falsely elevated pH values may lead to unrecognized acidosis and/or misinterpretation of acid-base disorders.
- Consider testing by alternate method (e.g. blood gas testing in lab, if available).
- Report any patient safety incident(s) via online SAFE reporting system.

Further updates will be provided, as available.

If you have any questions related to these changes, please contact Dr. Korpi-Steiner at 984-974-1498 or Nichole.korpi-steiner@unchealth.unc.edu

Reference:

[1] Siemens Healthineers. Urgent medical device correction: POC 25-007.A.US