AT THE FOREFRONT
UChicago Medicine

Clinical Laboratories

To: Medical Staff, House Staff, Nursing Staff, Patient Care Centers and Outpatient Clinics

From: Melissa Pessin, MD, PhD, Medical Director of Point of Care

Date: 3/27/2025

Subject: POC testing epoc® Discrepant High pH and TOC2 Results

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Effective Date: 3/27/2025
Laboratory Section: Point-of-Care Testing

Summary:

Siemens Healthcare Diagnostics Inc. has reported that when using the **POC testing epoc® device, discrepant high pH and TCO2 results may occur in samples introduced with incorrectly high injection volumes (continued injection beyond the epoc® Reader beep or after the "Analyzing Sample" message is displayed)** with current epoc® sensor configuration 45.n (software version: epoc® Host v3.41.2 and epoc® NXS v4.14.9 & 4.14.11).

epoc® devices were updated to these software versions during the month of December 2024 and there is not expected to be a fix to this issue until Siemens releases a new version of this software, expected in the April to May 2025 timeframe.

Impact:
The observed maximum bias, average bias and probability of occurrence (PO) at higher injection volumes for pH are detailed in the table below.

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%

Total Carbon Dioxide (TCO2) is a measured value that uses the pH result. The maximum bias, average bias and probability of occurrence (PO) for measured TCO2 is detailed below:

TCO2 range tested (mmol/L)	Maximum bias (mmol/L)	Average bias (mmol/L)	PO of Bias ≥ 8 mmol/L
19 to 31	+9	+2	0.29%

Discrepant high pH results may also affect the following calculated values:

- Anion Gap (Agap) (through $cHCO3^-$ or TCO2)
- Base Excess (blood) (BE(b))
- Base Excess (extra cellular fluid) (BE (ecf))
- Calculated Bicarbonate ($cHCO3^-$)
- Calculated Oxygen Saturation (cSO2)
- Calculated Total Carbon Dioxide (cTCO2)

Falsely elevated pH values may lead to unrecognized acidosis and/or the misinterpretation of acid-base disorders which could result in suboptimal management decisions.

It cannot be definitively identified which, if any, of patients' prior results might have been impacted by this issue as it would only happen when the test sample is introduced incorrectly, and that patient blood pH changes are dependent on many factors that may result in relatively rapid changes.

This issue occurs only when sample introduction is performed incorrectly - beyond the Reader beep or after the "Analyzing Sample" message is displayed. Therefore, **it is recommended to stop injecting the sample as soon as the audio/visual cues are presented to minimize the potential for erroneous pH (and TCO2) results**. Do not over inject samples.

Questions:

If there are any questions regarding the change, please contact:
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