

**RAPIDPoint® 500/500e Blood Gas Systems**

**Potential For Lactate Signal Carryover on RAPIDPoint 500 System Measurement Cartridges**

Our records indicate that your facility may have received the following product:

**Table 1. Affected Product**

Product	Siemens Material Number (SMN)
RAPIDPoint 500 System Measurement Cartridges with Lactate	10491447
	10491448
	10491449
	10844813

**Reason for this Customer Notification**

Siemens Healthcare Diagnostics Inc. has confirmed a potential issue with the lactate signal (i.e., hysteresis) which presents as lactate carryover on less than 1% of RAPIDPoint 500 Measurement Cartridges. This is not a fluidic issue and no other parameters are affected. Customers who do not report lactate are not impacted by this issue.

This issue may be observed under the following conditions:

Scenario 1:

While in retrospective calibration (retrocal) after a new measurement cartridge is installed, there is a potential for QC and patient samples to under recover for lactate. In this scenario, the issue affects the calibration performed during retrocal in such a way that the QC and patient samples may under-recover. Samples close to the 2.0 mmol/L calibration point (medical decision point) are not affected.

Note: The retrocal period can last up to 7.5 hours after a new measurement cartridge is installed.

If a measurement cartridge is affected by this issue, the probability of low recovery is estimated to be 0.9%.

Scenario 2:

After the retrocal period has ended, there is a potential for QC and patient samples to over-recover for lactate. If a measurement cartridge is affected by this issue, QC or patient samples run immediately after a high lactate aqueous solution, such as AQC Level 1 or a Full Calibration, may over-recover. Patient samples run immediately after blood samples with extremely high lactate (>12 mmol/L) may also over-recover.

Note: When the retrocal period has ended, the Restart Cartridge button is replaced by the Calibrate button.

If a measurement cartridge is affected by this issue, the probability of occurrence for samples run immediately after an aqueous or blood sample with extremely high lactate (>12 mmol/L) is estimated to be 1.1%.

Siemens is continuing to investigate and monitor the issue.

### **Risk to Health**

There is a negligible risk to health, and no injuries have been reported.

Siemens is not recommending a review of previously generated results.

### **Actions to be Taken by the Customer**

- Schedule AQC or RAPIDQC® Complete Level 1 and Level 2 together. Do not report lactate results until lactate QC results pass. Replace the measurement cartridge if AQC Level 2 or RAPIDQC Complete Level 2 fails high for lactate but passes upon repeat analysis.
- If you experience this issue, you may request a no-charge replacement or receive a credit from your local Siemens Healthineers representative.
- Please review this letter with your medical director or laboratory director, as appropriate.
- Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative at 1800-888-872.

### **Additional Information**

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