

RAPIDLab® 1200 Blood Gas Systems

Potential for Lactate Signal Carryover on RAPIDLab 1200 Lactate Sensors

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

Table 1. Affected Product

Product	Siemens Material Number (SMN)
RAPIDLab 1200 Lactate Sensors	10311032
	10316526
	10334138

Reason for this Customer Notification

Siemens Healthcare Diagnostics Inc. has confirmed a potential issue with the lactate signal (i.e., hysteresis) which presents as carryover on some RAPIDLab 1200 lactate sensors. 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 only affects RAPIDLab 1260 and 1265 instruments which have the lactate option. RAPIDLab 1240 and 1245 instruments do not report lactate, therefore, they are not affected.

If a lactate sensor is affected by this issue, there is a potential for QC and patient samples to over-recover for lactate when run immediately after a high lactate aqueous solution, such as QC Level 1 or High G/L samples. Patient samples run immediately after blood samples with extremely high lactate concentration may also over-recover. If a lactate sensor is affected, QC Level 2 lactate values will consistently recover out of range high when run immediately after QC Level 1. Upon repeat of QC Level 2, the lactate result will be in range.

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. Replace the lactate sensor 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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