

Urgent Field Safety Notice

32498 Rev. A

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RAPIDLab® 1260/1265 Systems

D50 Glucose Sensor and D51 Lactate Sensor Error Codes Not Reporting

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

Table 1. RAPIDLab® Systems Affected Products

System	Siemens Material Number (SMN)
RAPIDLab 1260 Blood Gas Analyzer	10321846, 10491394, 10339910
RAPIDLab 1265 Blood Gas Analyzer	10321852, 10470366, 10491395, 10335524

Reason for Urgent Field Safety Notice

Siemens Healthcare Diagnostics would like to alert customers to an issue with the RAPIDLab 1260 and RAPIDLab 1265 Blood Gas analyzers. These analyzers will not indicate the error codes in the table below:

Error Code	Problem
D50 Glucose Sensor Error	The system detects an open connection in the Glucose Biosensor
D51 Lactate Sensor Error	The system detects an open connection in the Lactate Biosensor

If the error codes were functioning properly, glucose or lactate results would be suppressed in the presence of their respective code. Two scenarios are possible:

1. A glucose or lactate sensor where the sensor contacts are not properly connected (see Figure 1 on page 3) on the instrument could potentially generate results without tripping a D50 or D51 error code.
2. A glucose or lactate sensor that is properly installed but has an A/I (Active/Inactive signal)* value outside the defined A/I limit could generate results without tripping a D50 or D51 error code.

Based on in-house testing at Siemens, the probability of having successful calibrations and QC that passes when the Glucose or Lactate sensor contacts are not completely seated with the contacts on the analyzer is not likely. The analyzer will display D2 errors (excessive drift) and QC failures. As stated in the *RAPIDLab 1200 Operator's Guide*, these errors would prompt the

* Metabolite measuring electrode/Interference measuring electrode.

operator to perform several troubleshooting steps, which include checking the installation and alignment of the biosensors, checking the biosensor contacts, and/or replacing the sensor.

Risk to Health

Glucose measurement by blood gas is used as an aid in the assessment of glycemic status. While a disconnected Glucose sensor could result in falsely elevated or depressed glucose values, the risk is limited to a falsely elevated glucose result that could potentially lead to a missed or delayed diagnosis of hypoglycemia requiring intervention.

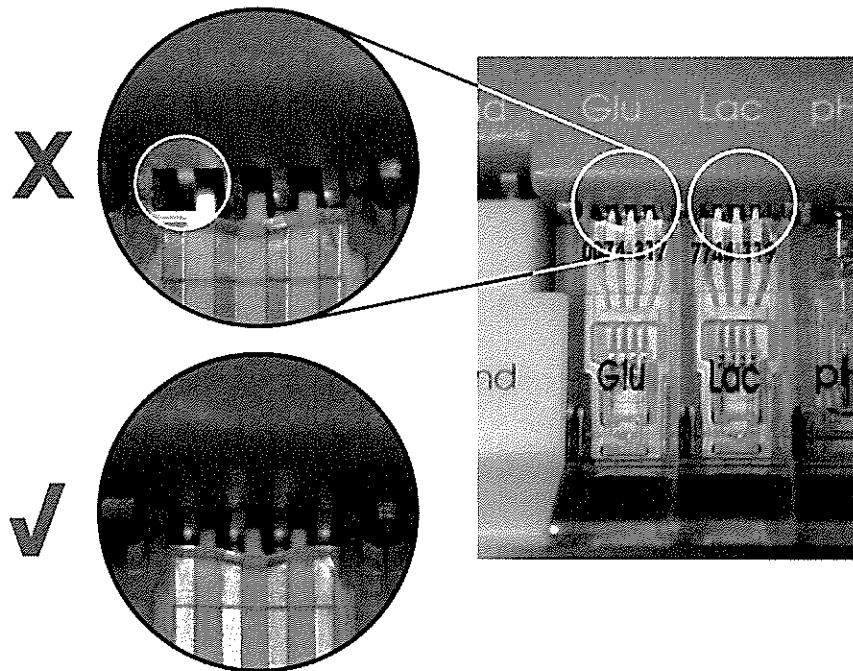
Lactate measurement is used as an aid in the diagnosis of lactic acidosis. While a disconnected Lactate sensor could result in falsely elevated or depressed lactate values, the primary risk is limited to a falsely depressed result that could potentially lead to a missed or delayed diagnosis of sepsis.

These risks are mitigated by clinical context, physical signs and symptoms, as well as additional concurrent biomarker monitoring. A look-back of previous results is, therefore, not recommended for either analyte.

Actions to be taken by the Customer

- Ensure that the Glucose and Lactate sensor contacts are aligned and completely seated with the contacts on the analyzer (see Figure 1 on page 3).
- Analyze a minimum of 2 levels of quality control material after installing the sensors, as indicated in the *RAPIDLab 1200 Operator's Guide*.
- Review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 7 days.
- Retain this letter with your laboratory records, and forward this letter to those who may have received this product.

Figure 1. Examples of Properly and Improperly Seated Sensors



Siemens regrets any inconvenience that this situation may have caused you. We appreciate your understanding and support.

A new software version for the RAPIDLab 1260 and RAPIDLab 1265 analyzers is being developed to address this issue, and will be provided by Siemens as soon as it is available.

If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

RAPIDLab is a trademark of Siemens Healthcare Diagnostics.