

Urgent Field Safety Notice

31512 Rev. A

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RAPIDPoint® 500 System

RAPIDPoint® 500 “-----?” Error Code on Electrolytes

Our records indicate that your facility may have received the following RAPIDPoint 500 Measurement Cartridges:

Part Number	Description
10491449	RAPIDPoint 500 Measurement Cartridge Lactate (750 Tests)
10491448	RAPIDPoint 500 Measurement Cartridge Lactate (400 Tests)
10491447	RAPIDPoint 500 Measurement Cartridge Lactate (250 Tests)
10844813	RAPIDPoint 500 Measurement Cartridge Lactate (100 Tests)

Siemens Healthcare Diagnostics has received several reports from customers of one or more electrolyte parameters (e.g., Na+, Ca++, K+, Cl-) reporting a “-----?” error code when AQC, QC, or CVM is run on the RAPIDPoint 500 blood gas analyzer. When exhibited, the issue is usually seen during Level 1 QC /AQC, Level 1 CVM, and sometimes Level 2 CVM testing. This issue has also been observed on a small number of patient samples.

This issue impacts only RAPIDPoint 500 Measurement Cartridges P/Ns 10491447, 10491448, 10491449, and 10844813. Siemens has observed this issue with RAPIDPoint 500 Measurement Cartridges with serial numbers up to 2412705915, however, not all these Cartridges will exhibit this behavior.

The issue does not impact RAPIDPoint 400 or RAPIDPoint 405 Measurement Cartridges.

If your RAPIDPoint 500 analyzer reports “-----?” on one or more electrolyte parameters (e.g., Na+, Ca++, K+, Cl-), the following steps can be taken to mitigate the issue:

- Install a new RAPIDPoint 500 Measurement Cartridge.
- or
- Install a 405 Measurement Cartridge – The RAPIDPoint 405 cartridge is available in four sizes:

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Part Number	Description
10310469	RAPIDPoint 405 Measurement Cartridge Full Blood Gas and Co-ox (750 Tests)
10313971	RAPIDPoint 405 Measurement Cartridge Full Blood Gas and Co-ox (400 Tests)
10283222	RAPIDPoint 405 Measurement Cartridge Full Blood Gas and Co-ox (250 Tests)
10844812	RAPIDPoint 405 Measurement Cartridge Full Blood Gas and Co-ox (100 Tests)

Since the Lactate parameter is not available on the RAPIDPoint 405 cartridge, however, you will need to arrange to get your lactate results from other instruments in your central laboratory.

or

- Use an alternative system to obtain your electrolyte values.

Since this issue is not related to the AQC cartridge, installing a new AQC cartridge will not solve the problem.

Quality is our #1 priority. We expect this to be a short term issue. We have been working diligently on resolving this issue and have begun to implement corrective actions to address the problem.

If you have a RAPIDPoint 500 Measurement Cartridge that exhibits this issue please contact your local Siemens Customer Service Center to obtain a full credit.

Please retain this letter with your laboratory records, and forward this notification to anyone to whom you may have distributed this product.

We apologize for the inconvenience that this situation has caused. Thank you for your understanding and patience during this period.

If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative at +4544774477.

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