

RAPIDPoint® 500 and 500e Blood Gas Systems

AQC Cartridge Level 2 pH Recovering Low

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

Table 1. Affected Products

Product Description	Siemens Material Number (SMN)	Unique Device Identification (UDI-DI)	Lot Number
Automatic QC Cartridge Kit	10310323	0405686901969WT	AQC/11422, AQC/11522, AQC/11622, AQC/11722, AQC/11822, AQC/12122

Reason for Customer Notification

The purpose of this communication is to inform you of an issue with the product indicated in **Table 1** above and provide instructions on actions that your facility must take.

Siemens Healthcare Diagnostics Inc. has confirmed an issue with the pH AQC Level 2 results recovering out of range low with the AQC cartridge lots listed above in Table 1. The pH AQC Level 2 published range is 7.350 +/-0.02.

The issue is due to a data entry error for the pH AQC Level 2 value assignment on the RAPIDPoint 500 and 500e Blood Gas Systems. This error causes the pH Level 2 to recover 0.03 lower than expected. If pH recovers out of range on a scheduled AQC level 2, the pH parameter will be disabled by the system. However other parameters are not affected by this issue.

RAPIDLab® 1200 systems are not affected by this issue.

Actions to be Taken by Customer

- If you have products listed in Table 1 above, request unaffected product from your local Siemens / distributor office.
- Alternatively, you may use RAPIDQC® Complete to qualify the pH parameter as outlined in the Operator’s Guide.
- Complete the attached form to get replacements for the affected products in your inventory.
- Review this letter with your Medical Director.

Please retain this letter with your laboratory records and forward it 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 Customer Care Center at 1800-888-872 or your local Siemens Healthineers technical support representative.

Additional Information

RAPIDPoint, RAPIDQC and RAPIDLab are trademarks of Siemens Healthcare Diagnostics Inc.

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PRODUCT REPLACEMENT FORM

RAPIDPoint® 500 and 500e Blood Gas Systems AQC Cartridge Level 2 pH Recovering Low

This form is to be used to request no-charge replacement product for the enclosed Siemens Healthcare Diagnostics Customer Notification POC 22-015.A.OUS dated July 2022 regarding RAPIDPoint® 500 and 500e Blood Gas Systems AQC Cartridge Level 2 pH Recovering Low.

Return this completed form to Siemens Healthcare Sdn Bhd as per the instructions provided at the bottom of this page.

Do you now have any of the noted product(s) on hand? Please check inventories before answering. Yes No

If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required

Product Description Product Catalog #/SMN #/Lot #	Quantity Discarded/ Replacement Quantity Required
SMN # 10310323 Lot: # AQC/11422, AQC/11522, AQC/11622, AQC/11722, AQC/11822, AQC/12122	

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

Customer Sold To #: _____

Customer Ship To #: _____

Please send a scanned copy of the completed form via email to: fscreportingunit.my@siemens-healthineers.com

If you have any questions, contact your local Siemens Healthineers technical support representative.

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