

Customer Notification

POC 24-013.A.OUS

RAPIDLab® 1200 Blood Gas Systems

AutomaticQC Cartridge Kit

Title	AQC Cartridge Level 3 pH Recovering High on RAPIDLab 1200 Systems
Date Issued	April 2024
Issue Description	<p>Siemens Healthineers has confirmed an issue with the pH AQC Level 3 results recovering high out of range with some AQC cartridge lots. The issue is due to a data entry error for the pH AQC Level 3 value assignment on the RAPIDLab 1200 Blood Gas Systems. This error causes the pH Level 3 to recover 0.030 higher than expected. If pH recovers out of range on a scheduled AQC Level 3, the pH parameter will be disabled by the system. However other parameters are not affected by this issue.</p> <p>RAPIDPoint® 500 and 500e Systems are not affected by this issue.</p>

Products

Product	Siemens Material Number	Unique Device Identification	Lot Numbers	Expiration Date (YYYY-MM-DD)
AutomaticQC Cartridge Kit	10310323	00630414465883	AQC/34423	2024-11-21
			AQC/34523	2024-11-21
			AQC/34623	2024-11-21

Customer Actions

- Please review this letter with your Medical Director to determine the appropriate course of action.
 - For RAPIDPoint 500 and 500e Systems customers, continue to use the product and no further action is required.
 - If you experience this issue with RAPIDLab 1200 Systems, you may request no-charge replacement product from your local Siemens Healthineers or distributor office. Please review your inventory of the product to determine your laboratory's replacement needs. Complete and return the Product Replacement Form attached to this letter within 30 days.
 - Please retain this letter with your laboratory records and forward this letter to those who may have received this product.
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PRODUCT REPLACEMENT FORM

This response form is to request no charge replacement product for the enclosed Siemens Healthineers Customer Notification POC 24-013.A.OUS dated April 2024. Please read the question and indicate the appropriate answer.

If you have received any complaints of illness or adverse events associated with the products listed in the table on Page 1, immediately contact your local Siemens Healthineers Customer Care Center at 1800-815-508 or your local Siemens Healthineers technical support representative.

Return this completed form as per the instructions provided at the bottom of this page.

1. For RAPIDLab 1200 Systems customers, do you have the affected product(s) on hand? Please check inventories before answering. Yes No

If the answer to the question #1 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 of Affected Product in inventory Returned Quantity Required	
AutomaticQC Cartridge Kit, SMN# 10310323 Lot# AQC/34423, AQC/34523, AQC/34623			
Name of person completing questionnaire:			
Title:			
Institution:			
Street:			
City:		State:	
Phone:		Country:	

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

We apologize for the inconvenience this situation may cause.

If you have any questions, please contact your Siemens Healthineers Customer Care Center at 1800-815-508 or your local Siemens Healthineers technical support representative.