

Customer Notification

POC 16-014.A.US-OUS

April 2016

RAPIDQC® Complete Solution

RAPIDQC® Complete pH Level 3 Low Recovery

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

Table 1. RAPIDQC Complete Affected Products

Product Description	Siemens Material Number (SMN)	Lot Numbers
RAPIDQC Complete Solution	10309927	363403 363404 363501

Reason for this Customer Notification

Based on field recovery data, Siemens Healthcare Diagnostics has confirmed that the pH parameter may recover low within range or lower than expected with these three lots of Level 3 RAPIDQC Complete product on both the RAPIDPoint® and the RAPIDLab® blood gas systems.

Risk to Health

The issue identified represents a negligible risk to patients and does not pose any health or safety risk to operators.

Actions to be Taken by the Customer

- If your Quality Control values are recovering within range, you may continue to use any current stock you have of these lots.
- If you do not want to continue to use these lots of Quality Control material, you may request no-charge replacement product from your local Siemens or distributor office. Please review your inventory of these products and assess your laboratory's replacement needs.
- Complete and return the Product Replacement Form attached to this letter to request your no-charge replacement products.
- Please retain this letter with your laboratory records, and forward it to those who may have received this product.

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As a reminder, it is good laboratory practice to review the analytical performance of any diagnostic medical analyzer, including the review of quality control results, on a regular basis, and the mean observed for any parameter should fall within the published ranges found in the QC package insert.

We apologize for any inconvenience this situation may have caused. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

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

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PRODUCT REPLACEMENT FORM

RAPIDQC Complete pH Level 3 Low Recovery

This form is to be used if you wish to request no-charge replacement product for the enclosed Siemens Healthcare Diagnostics Customer Notification POC 16-014.A.US-OUS dated April 2016 regarding RAPIDQC Complete pH Level 3 Low Recovery. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

Do you now have any of the noted product on hand? Please check inventories before answering.

Yes ☐No ☐

If the answer to the question above is yes, and you wish to request any replacement product, please complete the table below to indicate the quantity of replacement product required.

Product Lot #	Quantity of Affected Product in inventory that has been discarded	Replacement Quantity Required
363403		
363404		
363501		

Name of person completing questionnaire:

Title:

Institution:

Instrument Serial Number:

Street:

City:

State:

Phone:

Country:

Please fax this completed form to the Customer Care Center at (###) ###-####. If you have any questions, contact your local Siemens technical support representative.

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