



cc Chairman Medical Board and
Relevant Head of Departments

Urgent Field Corrective Action

POC 17-011.A.OUS

May 2017

RAPIDLab[®] 348 & 348EX Analyzer

Gas Cartridges Not Installing Due to Defective Threading

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

Table 1: Affected Product

Product	Siemens Material Number (SMN)	Lot Numbers
RAPIDLab [®] 348 / RAPIDLab [®] 348EX Gas Cartridge Pack	10309768	5260xx through 7020xx

Reason for Customer Notification

Siemens Healthcare has received a number of reports of gas cartridges failing to install on the RAPIDLab 348 and RAPIDLab 348EX instruments due to defective threads on the gas cartridges. The issue is intermittent and not all gas cartridges are affected. Approximately 1% of the cartridges of the lots listed in Table 1 above are potentially affected.

Note: This issue does not apply to the kit supplied to the Republic of South Korea (SMN 11065081).

Risk to Health

There is no impact to patient results or to the safety of operators. The risk to health is negligible.

Actions to be Taken by the Customer

- If you experience this issue, 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 product(s).

Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

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

We apologize for the inconvenience this situation may cause.

RAPIDLab is a trademark of Siemens Healthcare Diagnostics.

2 Edgewater Dr
Norwood, MA 02062
www.siemens.com/diagnostics

Urgent Field Corrective Action POC 17-011.A.OUS – May 2017

PRODUCT REPLACEMENT FORM

Gas Cartridges Not Installing Due to Defective Threading

This form is to be used to request no-charge replacement product for the enclosed Siemens Healthcare Diagnostics Urgent Field Corrective Action POC 17-011.A.OUS dated May 2017 regarding Gas Cartridges Not Installing Due to Defective Threading.

Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

1. 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, please complete the table below to indicate the replacement product required.

Product Description Product Catalog #/SMN #/Lot #	Replacement Quantity Required
RAPIDLab 348 Gas Cartridge Pack / SMN 10309768 / Lot numbers 5260xx to 7020xx	

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

To fax this completed form please send it to the Customer Care Center at XXX-XXX-XXXX. If you have any questions, contact your local Siemens technical support representative.

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