

Siemens Healthcare Diagnostics GmbH, HC CEMEA CEE QT,
Siemensstrasse 90, 1210 Vienna

Name M.A. Roland Ertl
 Department HC CEMEA CEE QT
 Telephone +43 51707-38274
 Mobile +43 (664) 8011738274
 E-mail roland.re.ertl@siemens.com
 Date May 19, 2018
 Document Ref# POC 17-011.A.OUS

Urgent Field Safety Notice:

RAPIDLab® 348 & 348EX Analyzer - Gas Cartridges Not Installing Due to Defective Threading

Dear Sirs,

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.

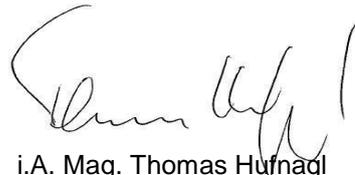
We apologize for the inconvenience this situation may cause.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH



i.V. Dipl. Ing. Franz Schwarz
Head of RAQS Austria & SEE



i.A. Mag. Thomas Hufnagl
Product Manager Austria & SEE