Siemens Healthcare Diagnostics GmbH, SHS EMEA CEET QT, Siemensstrasse 90,
1210 Vienna

Name M.A. Roland Ertl
Department SHS EMEA CEET QT

Telephone +43 51707-38274
Mobile +43 (664) 8011738274
E-mail roland.re.ertl@siemens-healthineers.com

Date December 23, 2022

Document Ref# CC 23-01.A.OUS

Urgent Field Safety Notice:

ADVIA Centaur® XP
ADVIA Centaur® XPT
– **ADVIA Centaur® CP**

SARS-CoV-2 IgG (sCOVG) Kit Lot 19529015 Calibration Failures

To whom it may concern,

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

Table 1. ADVIA Centaur® Systems Affected Product(s)

Assay	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Kit Lot Number	Date of Manufacture (YYYY-MM-DD)	Expiration Date (YYYY-MM-DD)
SARS-CoV-2 IgG (sCOVG) (100T)	11207376	(01)00630414608662(10)19529015(17)20230221	Ending in lot 015	2022-07-21	2023-02-21

Reason for Correction

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 laboratory must take.

Siemens Healthcare Diagnostics Inc. has confirmed calibration failures, due to an error in the Master Curve Card, with the ADVIA Centaur Systems SARS-CoV-2 IgG (sCOVG) lots listed above in Table 1.

The issue is isolated to the ADVIA Centaur Systems sCOVG Kit Lots listed in Table 1. Alternate kit lots are available and are not impacted by this issue.

Atellica IM sCOVG is not affected by this issue.

Siemens is currently investigating root cause

Risk to Health

The risk to health as a result of an apparent delay in testing for SARS-CoV-2 IgG is considered negligible.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Discontinue use of and discard the kit lots listed in Table 1.
- Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens Healthineers for reporting to the authorities.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Please retain this letter with your laboratory records and forward this letter 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 Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

Signature: *Electronically signed by: Roland Ertl*
Reason: I am approving this document
Date: Dec 20, 2022 15:09 GMT+1

Email: roland.re.ertl@siemens-healthineers.com

i.A. Roland Ertl, MA
Quality Management CEECA

Signature: *Electronically signed by: Gernot Osterer*
Reason: I have reviewed this document
Date: Dec 20, 2022 21:22 GMT+1

Email: gernot.osterer@siemens-healthineers.com

i.A. Ing. Gernot Osterer
Product Manager CEECA