

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

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

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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.

## **ADVIA Centaur® Systems SARS-CoV-2 IgG (sCOVG) Kit Lot 19529015 Calibration Failures**

### **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.

# ADVIA Centaur® Systems SARS-CoV-2 IgG (sCOVG) Kit Lot 19529015 Calibration Failures

## FIELD CORRECTION EFFECTIVENESS CHECK

ADVIA Centaur® Systems SARS-CoV-2 IgG (sCOVG) Kit Lot 19529015 Calibration Failures

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (UFSN) CC 23.01.A.OUS dated December 2022 regarding ADVIA Centaur® Systems SARS-CoV-2 IgG (sCOVG) Kit Lot 19529015 Calibration Failures.

Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes ☐ No ☐
2. Do you now have any of the noted product(s) 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 quantity of affected product in your laboratory and replacement product required.

Product Description Product Catalog #/SMN #/Lot #	Quantity of Affected Product in inventory Discarded/ Replacement Quantity Required
SARS-CoV-2 IgG (sCOVG)/ SMN: 11207376/ Lot # 19529015 (100T)	

Name of person completing questionnaire:	
Title:	
Institution:	Instrument Serial Number:
Street:	
City:	State:
Phone:	Country:
Customer Sold To #:	Customer Ship To #:

Please send a scanned copy of the completed form via email to XXXX@XXXX.

Or to fax this completed form to the Customer Care Center at XXXXXX.

If you have any questions, contact your local Siemens Healthineers technical support representative.