

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

ADVIA Centaur Systems BRAHMS Procalcitonin (PCT) Calibration Failures

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) | Lot Number | Expiration Date | Manufacturing Date |
|---------------|-------------------------------|------------|-----------------|--------------------|
| Procalcitonin | 10378883 | 97643038 | 2018-03-09 | 2016-08-09 |
| | | 10719038 | 2018-03-09 | 2016-08-09 |
| | | 14888038 | 2018-03-09 | 2016-08-09 |
| | | 37183047 | 2019-04-21 | 2017-09-21 |
| | | 37184047 | 2019-04-21 | 2017-09-21 |
| | | 45947047 | 2019-04-21 | 2017-09-21 |

Reason for Customer Notification

Siemens Healthcare Diagnostics has received multiple customer complaints for invalid calibrations with ADVIA Centaur Systems BRAHMS Procalcitonin reagent kits listed in Table 1. This issue affects the ADVIA Centaur/XP/XPT and ADVIA Centaur CP systems.

Siemens' complaint investigation has confirmed that the 'calibrator ratio' parameter may fall below the acceptable range resulting in an invalid calibration, which prevents customers from generating procalcitonin results.

With a valid calibration and in range quality control (QC), patient results are valid and acceptable for reporting. When an invalid calibration is received, QC and patient testing cannot be performed.

At this time, only the ADVIA Centaur Systems BRAHMS PCT kit lots listed in Table 1 are impacted.

Siemens is currently investigating the cause of calibrator ratio failures.

Actions to be Taken by the Customer

- Customers may continue to report procalcitonin patient results when a valid calibration and in range quality control results are obtained with any kit lot of ADVIA Centaur Systems BRAHMS PCT.
- For the products listed in Table 1, please perform the following steps:
 - If you experience calibration failures and are unable to obtain valid calibration with ADVIA Centaur Systems BRAHMS PCT kit lots ending in 038 and 047, customers are invited to request unaffected product from their local Siemens/distributor office.
 - To receive replacement kits for affected product, please complete and return the provided form.

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 Customer Care Center at xxx-xxx-xxxx or your local Siemens technical support representative.

Product availability may vary from country to country and is subject to varying regulatory requirements. Due to local regulations, the ADVIA Centaur XPT may not be available in all countries.

ADVIA Centaur is a trademark of Siemens Healthcare Diagnostics.

PRODUCT REPLACEMENT FORM

ADVIA Centaur Systems BRAHMS Procalcitonin (PCT) Calibration Failures

This form is to be used to request no-charge replacement product for the enclosed Siemens Healthcare Diagnostics Customer Notification CC 18-08.A.OUS dated February, 2018 regarding ADVIA Centaur Systems BRAHMS Procalcitonin (PCT) Calibration Failures.

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(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 and Kit Lot # of Affected Product in inventory that has been discarded | Replacement Quantity Required |
|---|---|-------------------------------|
| Procalcitonin (PCT) 100 test kit SMN 10378883 Kit lots 97643038, 10719038, 14888038, 37183047, 37184047, 45947047 | | |

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Customer Sold To #: _____ Customer Ship To #: _____

To fax this completed form please send it to your Procalcitonin supplier or please send a scanned copy of the completed form via email to xxxx. If you have any questions, contact your local Siemens technical support representative.