

Urgent Field Safety Notice

CC 17-18.A.OUS

July 2017

ADVIA Centaur® XPT

Information Regarding ADVIA Centaur T3 Kit Lots Ending in 198 when used with the ADVIA Centaur XPT System

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

Table 1. ADVIA Centaur Affected Product(s)

| Assay | Catalog Number | Siemens Material Number (SMN) | Kit Lots Ending | Expiration Date | Manufacturing Date |
|------------------------------|----------------|-------------------------------|-----------------|-----------------|--------------------|
| ADVIA Centaur T3 (80 tests) | 04779671 | 10285733 | 198 | 2018/03/05 | 2017/04/05 |
| ADVIA Centaur T3 (400 tests) | 04779663 | 10285732 | | | |

Reason for Correction

Siemens has identified an issue when scanning the 2D barcode for the Master Curve Card (MCC) with ADVIA Centaur systems T3 kit lots ending in 198 on the ADVIA Centaur XPT system.

An un-recoverable error which requires a field service visit to restore operation may occur on the ADVIA Centaur XPT system when the MCC for ADVIA Centaur systems T3 kit lots ending in 198 is scanned on the system.

This issue is specific to ADVIA Centaur kit lots of T3 ending in 198. All other kit lots may continue to be used without error on the ADVIA Centaur XPT.

Root cause is currently under investigation. A work-around has not yet been identified.

Siemens is working to resolve the issue as soon as possible and will provide additional information when it is available.

The ADVIA Centaur/XP or ADVIA Centaur CP systems are not affected when the ADVIA Centaur T3 kit lots ending in 198 are used.

Actions to be Taken by the Customer

- Do not scan the master curve card for ADVIA Centaur Systems T3 kit lots ending in 198 on your ADVIA Centaur XPT system.
- Other kit lots of ADVIA Centaur Systems T3 are acceptable and may continue to be used on the ADVIA Centaur XPT.
- You may continue to use ADVIA Centaur Systems T3 kit lots ending in 198 on the ADVIA Centaur/XP and ADVIA Centaur CP systems.

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 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 is not available in all countries.

ADVIA Centaur® is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

Information Regarding ADVIA Centaur T3 Kit Lots Ending in 198 when used with the ADVIA Centaur XPT System

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CC 17-18.A.OUS dated July 2017 regarding Information Regarding ADVIA Centaur T3 Kit Lots Ending in 198 when used with the ADVIA Centaur XPT System.

Please read the question and indicate the appropriate answer.

Fax this completed form to Siemens Healthcare Diagnostics at the fax number 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

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 (###) ###-####. If you have any questions, contact your local Siemens technical support representative.