



## 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.