



## Urgent Field Safety Notice

Follow Up Information

CC 17-18.B.OUS

August , 2017

### ADVIA Centaur® XPT

Follow-Up: Mitigation Identified for:  
ADVIA Centaur XPT - T3 Kit Lots Ending in 198 System Error

Our records indicate that your facility may have an ADVIA Centaur XPT system and may have received the following product:

**Table 1. ADVIA Centaur Affected Product(s)**

Assay	Catalog Number	Siemens Material Number (SMN)	Kit Lots	Expiration Date	Manufacturing Date
ADVIA Centaur T3 (80 tests)	04779671	10285733	54167198 70041198	2018/03/05	2017/04/05
ADVIA Centaur T3 (400 tests)	04779663	10285732	48330198 62595198 68260198		

### Reason for Correction

Siemens Healthcare Diagnostics is communicating follow-up information to the Urgent Field Safety Notice CC 17-18.A.OUS, regarding an unrecoverable error when the ADVIA Centaur Master Curve Card (MCC) for T3 kit lots listed in Table 1 are scanned on the ADVIA Centaur XPT system. The initial communication (CC 17-18.A.US) was distributed to customers who have an ADVIA Centaur XPT **and** who utilize the ADVIA Centaur T3 assay. This follow-up communication contains important information for **all** ADVIA Centaur XPT customers who may currently use these lots or may use these lots in the future.

Siemens has completed the investigation and determined that the issue is caused by an error in the ADVIA Centaur XPT 2D barcode on the Master Curve Card (MCC) associated with T3 lots listed in Table 1.

Please follow instructions in the 'Actions to be taken' section in order to successfully implement T3 lot numbers listed in Table 1 on your ADVIA Centaur XPT systems.

No other lots beyond those listed in Table 1 are affected.

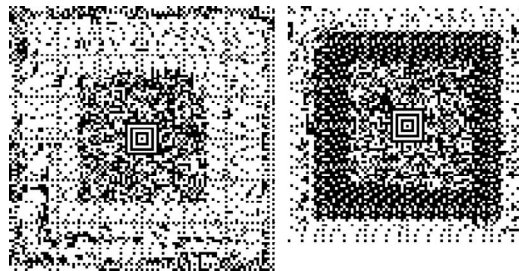
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### Actions to be Taken by the Customer

- To implement T3 kit lots listed in Table 1 on your ADVIA Centaur XPT system, it is important that you perform the following steps, **in the order specified below**, to avoid an un-recoverable system error:
  1. Scan the corrected T3 Test Definition 2D barcode below onto your ADVIA Centaur XPT system. This will update the T3 Test Definition to revision 1.8.

Test Definition, revision 1.8 (for ADVIA Centaur XPT):



2. Verify that the T3 Test Definition on your ADVIA Centaur XPT system is revision 1.8 using the following steps on the system workstation:
    - Go to Setup
    - Select the Test Definition tab
    - Select T3
    - Verify that the “Test Version” is 1.8
  3. Scan the 2D barcode on the MCC included with the ADVIA Centaur T3 kit lots listed in Table 1. This will successfully install the lot specific parameters required to run kit lots listed in Table 1. By scanning the barcode above in step 1, the system will have the T3 Test Definition revision 1.8. The Test Definition contained in the 2D barcode on the MCC (revision 1.7) will not be installed on the system by the software as it is an older version, thus avoiding the un-recoverable system error.
- Other kit lots of ADVIA Centaur Systems T3 are acceptable and may continue to be used on the ADVIA Centaur XPT by scanning the 2D barcode on the MCC included in the kit for ADVIA Centaur XPT.

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- You may continue to use ADVIA Centaur Systems T3 kit lots listed in Table 1 on the ADVIA Centaur, ADVIA Centaur XP and ADVIA Centaur CP systems by scanning the MCC card in the kit specific to these systems. No special actions are required.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

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.

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**FIELD CORRECTION EFFECTIVENESS CHECK**

Follow-Up: Mitigation Identified for:

ADVIA Centaur XPT - T3 Kit Lots Ending in 198 System Error

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CC 17-18.B.OUS dated August, 2017 regarding Follow-Up: Mitigation Identified for: ADVIA Centaur XPT - T3 Kit Lots Ending in 198 System Error 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 (xxx) xxx-xxxx. If you have any questions, contact your local Siemens technical support representative.