SIEMENS

Urgent Field Safety Notice

CSW18-01.A.OUS

December 2017

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

ADVIA Centaur CP, XP, and XPT Systems - Multi-Diluent 15* Onboard Stability When Used With BNP and TSH3-Ultra Assays

Our records indicate that your facility has an ADVIA Centaur CP, ADVIA Centaur XP or ADVIA Centaur XPT system and you may have ordered Multi-Diluent 15 and one of the affected assays listed in Table 1.

Table 1. Affected Products

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Kit Lots Ending in	Expiration Date	Manufacturing Date
ADVIA Centaur BNP (100 tests)	BNP	02816138	10309044	192 193 196	2018-01-20 2018-04-07 2018-04-18	2017-01-20 2017-04-07 2017-04-18
ADVIA Centaur BNP (500 tests)	BNP	02816634	10309045	192 193 196	2018-01-20 2018-04-07 2018-04-18	2017-01-20 2017-04-07 2017-04-18
ADVIA Centaur TSH3-Ultra (100 tests)	TSH3-UL	06491072	10282378	298 301	2018-01-27 2018-03-10	2017-01-27 2017-03-10
ADVIA Centaur TSH3-Ultra (500 tests)	TSH3-UL	06491080	10282379	298 301	2018-01-27 2018-03-10	2017-01-27 2017-03-10

* The ADVIA Centaur Systems Multi-Diluent 15 is a new diluent for use with the ADVIA Centaur Systems BNP and TSH3-Ultra assays. See Customer Bulletin 11313083 for details. Availability may vary from country to country and is subject to varying regulatory requirements.

511 Benedict Avenue
Tarrytown, NY 10541
www.siemens.com/diagnostics

ADVIA Centaur CP, XP, and XPT Systems - Multi-Diluent 15 Onboard Stability When Used With BNP and TSH3-Ultra Assays

Reason for Correction

Siemens Healthcare Diagnostics has identified the following issues:

- The ADVIA Centaur CP, XP and XPT systems will not expire the Multi-Diluent 15 pack at the end of the required 7-day on board stability (OBS), if any of the BNP or TSH3UL lots listed in Table 1 are present on the system(s) when performing onboard dilutions.

  Under certain scenarios, the system may allow dilutions to be processed for up to 28 days. Internal investigation has observed a decreased dilution recovery with the ADVIA Centaur BNP and TSH3UL assays when using Multi-Diluent 15 that has been stored onboard the ADVIA Centaur systems beyond 7 days. The magnitude of the reduction in recovery increases over time and with the extent of the dilution.

- On the ADVIA Centaur XPT only, the system becomes inoperable under the following scenario:

  1) Scanning the Master Curve Card of ADVIA Centaur BNP kit lots ending in 193 or higher or ADVIA Centaur TSH3-Ultra kit lots ending in 301 or higher,

     and

  2) Processing a BNP or TSH3UL onboarddilution of a sample.

  In this case, the system may display an “Unknown State” message and requires customer action. When this error occurs, any tests that are in-process would have to be repeated.

Risk to Health

Discrepant results occurring above the assay range for BNP or TSH3UL would not impact the clinical utility of the assays.

On the ADVIA Centaur XPT only:

If the instrument enters an “Unknown State”, the potential exists for a delay in test results and would be apparent to the user.

Frequently Asked Questions (FAQs)

1. What is an example scenario that could cause the on board stability not to expire after 7 days?

   - The ADVIA Centaur XP/XPT systems always use the Multi-Diluent 15 OBS from the most recently scanned Test Definition 2D barcode for BNP or TSH3UL.

   For example, if the TSH3UL 2D barcode from kit lot 310 is scanned, the onboard dilution functionality will be available and the Multi-Diluent 15 OBS will be set correctly to 7 days. If this is followed by scanning the 2D barcode for BNP kit lot 196, the Multi-Diluent 15 OBS will be re-set to 28 days as that is what is defined on the master curve card for this kit lot.

511 Benedict Avenue
Tarrytown, NY 10541
www.siemens.com/diagnostics

2. I have an ADVIA Centaur system. Is it affected?

    - The ADVIA Centaur system is not impacted as dilutions for these assays are not available on that system.

3. Are any other diluents or assays affected?

    - No other diluents or assays are affected.

4. How is the ADVIA Centaur CP affected?

    The ADVIA Centaur CP system always uses the longest OBS that has been defined in the system.For example, if the TSH3UL kit lot 301 was in use on the system, the Multi-Diluent 15 OBS will be set to 28 days. If this is followed by scanning the BNP kit lot 210, the Multi-Diluent 15 OBS will NOT be re-set to 7 days as the new OBS would be less than the 28 days that the system already has defined. All lots of Multi-Diluent 15 would use 28 days OBS from that point forward.

5. How is the ADVIA Centaur XP affected?

    - The ADVIA Centaur XP would behave in the same manner as ADVIA Centaur XPT as described in question 1 above except that the OBS information is input into the system via the Test Definition disk installation and scanning of the master curve cards.

6. If I only use Multi-Diluent 15 for 7 days, how does it perform?

    - If Multi-Diluent 15 is used for the specified 7 days, the recovery will be as defined in the following IFU references:
        - ADVIA Centaur, ADVIA Centaur XP, ADVIA Centaur XPT Systems Instructions for Use for BNP 10629823 Rev. U, 2017-07.
        - ADVIA Centaur, ADVIA Centaur XP, ADVIA Centaur XPT Systems Instructions for Use for TSH3UL 10629909 Rev. L, 2017-07.
        - ADVIA Centaur CP System Instructions for Use for BNP 10629927 Rev. L, 2017-07.
        - ADVIA Centaur CP System Instructions for Use for TSH3UL 10630003 Rev. L, 2017-07.

7. What can be the expected dilution recovery on BNP and TSH3UL beyond 7 days?

    - The dilution recovery for BNP and TSH3UL using Multi-Diluent 15 beyond 7 days will be lower than the recoveries specified in the instructions for use listed in question 6 above.

511 Benedict Avenue
Tarrytown, NY 10541
www.siemens.com/diagnostics

Actions to be Taken by the Customer

1. No Action is needed if:
    - o You do not perform onboard dilutions for the ADVIA Centaur BNP and/or TSH3UL assay(s). Non-diluted samples are not affected.
    - o On the **ADVIA Centaur CP**, none of the product lots listed in Table 1 have been used on the system.
    - o On the **ADVIA Centaur XP**, you perform onboard dilutions for the ADVIA Centaur BNP and/or TSH3UL assay(s) and you are ordering dilutions using ADVIA Centaur BNP kit lots ending in 210 and above and ADVIA Centaur TSH3UL kit lots ending in 310 and above, per Customer Bulletin 11313083, Rev. A.

2. Actions for **ALL ADVIA Centaur Systems**:
    - o Do not perform onboarddilutions on any ADVIA Centaur system if any of the product kit lots listed in Table 1 are present on the system.
    - o Onboard dilutions for the ADVIA Centaur BNP and/or TSH3UL assay(s) are only supported when using ADVIA Centaur BNP kit lots ending in 210 and above and ADVIA Centaur TSH3UL kit lots ending in 310 and above, per Customer Bulletin 11313083, Rev. A.

3. Actions for **ADVIA Centaur XPT** system:

    If you intend to perform onboard dilutions for the ADVIA Centaur BNP and/or TSH3UL assays, you must restart the workstation after scanning the master curve card for the BNP and/or TSH3UL assay kit lot, before ordering an onboard dilution for these assays.

    Please perform the following steps to restart the workstation (or refer to the ADVIA Centaur XPT Operator's Guide, 11222421, Rev. A, Chapter 8, page 140, "Restarting the Workstation"):

    1) Scan the BNP (kit lot ending in 198 or higher) and/or TSH3UL (kit lot ending in 304 or higher) Test Definition 2D barcode onto your ADVIA Centaur XPT system.

        NOTE: These do not have to be done at the same time; but you must restart the workstation before you order an onboard dilution.

    2) On the status bar, select System State.

        Caution: Do not disconnect the system or turn the main power switch off.

    3) Select Restart the Workstation.
    4) Select Yes to continue.
    5) Wait while the workstation reconnects to the system.
    6) Check for obstructions before restarting the system.
    7) Sign in with your user ID and password.

511 Benedict Avenue
Tarrytown, NY 10541
www.siemens.com/diagnostics

Warning: Before selecting Turn Mechanics On, ensure that you are clear of subassemblies that can move.

8) On the status bar, select System State.
9) Select Turn Mechanics On.
10) Select Yes to continue.
11) Wait until the system state is **Ready**, and then return to normal operation.

4. Actions for **ADVIA Centaur CP** system:

If any of the BNP kit lots or TSH3UL kit lots listed in Table 1 have been in use on the system, you must manually track the time that the Multi-Diluent 15 has been in use on board the system.

Note: The Multi-Diluent 15 ancillary reagent pack volume is 25 mL when it is full. This volume will decrease with each dilution test that is processed for BNP or TSH3UL. Remove the diluent pack from the system 7 days after the pack volume starts decreasing as the on board stability(OBS) starts from the time the pack is pierced for first use on the system.

Replace the ancillary pack of Multi-Diluent 15 every 7 days until a follow-up communication is received from Siemens stating this issue has been resolved.

In addition, please perform the following:

- Review this letter with your Medical Director.
- 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.

511 Benedict Avenue
Tarrytown, NY 10541
www.siemens.com/diagnostics

FIELD CORRECTION EFFECTIVENESS CHECK

ADVIA Centaur CP, XP, and XPT Systems - Multi-Diluent 15 Onboard Stability When Used With BNP and TSH3-Ultra Assays

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CSW18-01.A.OUS dated December 2017 regarding the ADVIA Centaur CP, ADVIA Centaur XP, and ADVIA Centaur XPT Systems - Multi-Diluent 15 Onboard Stability When Used With BNP and TSH3-Ultra Assays. Please read each 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 Medical Device Correction instructions provided in this letter. Yes ☐ No ☐

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 the Customer Care Center at (xxx) xxx-xxxx. If you have any questions, contact your local Siemens technical support representative.

511 Benedict Avenue
Tarrytown, NY 10541
www.siemens.com/diagnostics