

Urgent Field Safety Notice

10813387

July 2012

ADVIA Centaur[®]
ADVIA Centaur[®] XP

Multi-Diluent 1 Onboard Stability When Used With BNP and TSH3 Ultra Assays

Our records indicate that you may have received ADVIA Centaur[®] BNP kit Reference (REF) numbers 02816634 and 02816138, and/or ADVIA Centaur TSH3 Ultra kit REF numbers 06491080 and 06491072 together with the ADVIA Centaur Multi-Diluent 1, REF 0790714 (110313) and 07293184 (110312). The affected lot numbers are shown in Table 4, page 5.

Reason for Voluntary Recall

Siemens Healthcare Diagnostics has confirmed a decrease in onboard dilution recovery when using Multi-Diluent 1 that has been stored on board the ADVIA Centaur and ADVIA Centaur XP systems. This under-recovery has been observed in plasma samples with high BNP and TSH-3 values that require dilution to achieve results within the reportable range on the ADVIA Centaur and ADVIA Centaur XP systems.

This issue does not apply to the ADVIA Centaur CP system.

The magnitude of the reduction in recovery increases over time and with extent of dilution. For ADVIA Centaur BNP, under-recovery observed with 1:5 diluted plasma samples at 28 days is on average 30%. For ADVIA Centaur TSH-3 Ultra, under-recovery observed with 1:5 diluted plasma samples at 28 days is on average 15%. Table 1 through Table 3 provide a summary of the dilution recovery of the ADVIA Centaur BNP and ADVIA Centaur TSH3 Ultra assays as Multi-Diluent 1 is stored on board the system. Siemens has confirmed that this under-recovery is not observed with:

- Multi-Diluent 1 kept on board the system for 7 days or less for ADVIA Centaur BNP or TSH-3 Ultra.
- Other assays that utilize Multi-Diluent 1 to dilute plasma samples: Ferritin, DHEAS, SHBG and PCT.
- All assays that use Multi-Diluent 1 to dilute serum samples.
- Serum samples for TSH3 Ultra.
- All assays used on the ADVIA Centaur CP system that use Multi-Diluent 1.

Siemens Healthcare Diagnostics Inc.

511 Benedict Ave.
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www.siemens.com/diagnostics Page 1 of 6

Risk to Health

Under-recovery of plasma samples which have been diluted with Multi-Diluent 1 that has been stored on board an ADVIA Centaur or ADVIA Centaur XP system may lead to underestimation of BNP in patients with significantly elevated BNP values (greater than 5000 pg/mL) and could potentially influence patient management decisions. The severity of impact on patients with significantly elevated BNP is mitigated by consistent trending in serial measurements and consideration of multiple clinical parameters in management of these patients. Review of previous BNP results is subject to the discretion of the laboratory and retesting is likely not necessary.

Under-recovery of plasma samples which have been diluted with Multi-Diluent 1 that has been stored on board an ADVIA Centaur or ADVIA Centaur XP system could reduce TSH3 Ultra measurement in patients with significantly elevated TSH (greater than 150 uIU/mL). Because TSH values greater than 150 uIU/mL are extremely rare, the under-recovery observed is not expected to impact clinical interpretation. Review of previous TSH3 results is not recommended.

This information should be communicated to your laboratory director or medical director.

Actions to Be Taken by the Customer

1. If you do not dilute BNP and/or TSH-3 Ultra plasma samples, no action is required as this issue does not impact non-diluted (neat) samples.
2. If you use Multi-Diluent 1 for assays other than BNP or TSH-3 Ultra, you may continue to use the 28 day onboard stability for Multi-Diluent 1 for those assays.
3. If you perform BNP or TSH3 Ultra plasma sample dilutions on board the ADVIA Centaur or ADVIA Centaur XP systems, **do not use the ancillary pack of Multi-Diluent 1 if it has been on board the system for more than 7 days.**

If you have multiple ADVIA Centaur systems, you may choose to run BNP and/or TSH-3 Ultra on one system for easier tracking.

To continue to use Multi-Diluent 1 for onboard dilutions for BNP and TSH3 Ultra you must choose one of the following options:

- Manually track the time the Multi-Diluent 1 has been on board the system to ensure it has not been on the system for more than 7 days.
- Define an operator maintenance task to remind you to replace Multi-Diluent 1 every 7 days.

NOTE:To define an operator maintenance task, refer to the *Performing Maintenance; Defining Maintenance Activities* sections in the *ADVIA Centaur XP Operator's Guide*.

- Replace the ancillary pack of Multi-Diluent 1 every 7 days and manually change the onboard stability of that ancillary pack in the system software when the pack is placed on board the system. To manually change onboard stability use the following procedure:

NOTE: The following steps (a through f) affect all assays that use the Multi-Diluent 1 ancillary pack.

- a. From the UI workspace, select the **Reagent Status** icon (or press the **F3** function key on the keyboard). The Status — Primary Reagent window opens.

- b. Select the **Ancillary Reagent** button. The Status — Ancillary Reagent window opens.
- c. Select the **Multi Dil 1 (MDIL1)** pack, and then select the **Details** button. The Status — Ancillary Pack Details window opens.
- d. Edit the **Stability** field to indicate the 7 day time period.
The stability is defined as dd mmm yy. Enter a date that is 7 days from the current date. (Example: 30 APR 12).
Time is defined as hh.mm (10:10). You can allow this to remain as defined as it will be 7 days from the current time.
- e. Select the **Save** button to save your changes.
- f. Close all windows.

You may also choose to turn off the auto-dilution feature for the BNP and TSH3 Ultra assays using the following procedure:

NOTE: If you turn off auto-dilutions for the BNP and TSH3 Ultra assays, and you want to perform onboard dilutions for these assays, you must insure the Multi-Diluent 1 has not been on board the system for more than 7 days by taking the actions outlined in step 3 above.

1. From the User Interface (UI) workspace, select **Setup** and then select **Test Definition Summary**.
2. On the Setup — Test Definition Summary window, select **BNP** and/or **TSH-3 Ultra**.
3. Select **Ranges**.
4. Select **Edit**, and then make the following changes:
 - a. Set the dilution box to a blank factor.
 - b. Remove the numerical value from both the Dilution Point box.
 - c. Remove the numerical value from both the Overdilution Point box.
5. Select **Save**.
6. Close all windows.

To confirm how long the Multi-Diluent 1 ancillary pack has been on board the system, go to the Status window and select **Ancillary Reagent**. The value shown will be the date the pack was placed on board the system. Subtract 21 days from the date listed to determine if Multi-Diluent 1 is within the 7 day stability.

Other Customer Actions

Please complete and return the Field Correction Effectiveness Check attached to this letter.

This limitation of the Multi-Diluent 1 onboard stability for plasma samples diluted with the BNP and TSH-3 assays on the ADVIA Centaur and ADVIA Centaur XP systems is temporary. You will be notified once the issue is resolved.

A note card with this information will be included in the ADVIA Centaur BNP and TSH-3 Ultra assay kits.

Multi-Diluent 1 Onboard Stability When Used With BNP and TSH3 Ultra Assays

If you have any questions or need additional information, please contact your local Technical Support Provider or Distributor.

Please forward this notification to whomever you may have distributed this product.

We apologize for the inconvenience that this situation has caused. Thank you for your patience and continued support of the ADVIA Centaur systems and products.

Table 1. ADVIA Centaur and ADVIA Centaur XP BNP – 1:5 On-Board Dilutions

Day	0	4	7	8	12	21	28
Average Percent Recovery (Onboard dilution versus neat)	99.4	99.6	101.0	97.1	88.9	72.2	68.9

Table 2. ADVIA Centaur and ADVIA Centaur XP TSH3-Ultra - 1:5 On-Board Dilutions

Day	0	4	7	8	14	22	28
Average Percent Recovery (Onboard dilution versus neat)	102.0	103.0	103	95.5	93.4	80.4	85.6

Table 3. ADVIA Centaur BNP 1:2, 1:5 and 1:10 Dilution Recovery at day 8 and ADVIA Centaur TSH3-Ultra 1:5 Dilution Recovery at day 8

	Dilution Factor	Day 8 Average Percent Recovery (Onboard dilution versus neat)
ADVIA Centaur BNP	1:2	95.9
	1:5	97.1
	1:10	96.8
ADVIA Centaur TSH3 Ultra	Dilution Factor	Day 8 Average % Recovery (Onboard dilution versus neat)
	1:5	95.5

Table 4. Multi-Diluent 1 Lot Numbers

Part Number	Lot Number	Pack Size	Part Number	Lot Number	Pack Size
PN 110312	76129	2 PK	PN 110313	76102	6 PK
PN 110312	77542	2 PK	PN 110313	76432	6 PK
PN 110312	78696	2 PK	PN 110313	77075	6 PK
PN 103012	80828	2 PK	PN 110313	78264	6 PK
PN 110312	80857	2 PK	PN 110313	79037	6 PK
PN 110312	81441	2 PK	PN 110313	81006	6 PK
PN 110312	82189	2 PK	PN 110313	82539	6 PK
PN 110312	83647	2 PK	PN 110313	83321	6 PK
PN 110312	84772	2 PK	PN 110313	84123	6 PK
PN 110312	86037	2 PK	PN 110313	85795	6 PK
PN 110312	86783	2 PK	PN 110313	86698	6 PK
PN 110312	88712	2 PK	PN 110313	88318	6 PK
PN 110312	90056	2 PK	PN 110313	89286	6 PK
PN 110312	91002	2 PK	PN 110313	90490	6 PK
PN 110312	93126	2 PK	PN 110313	91672	6 PK
			PN 110313	93129	6 PK

FIELD CORRECTION EFFECTIVENESS CHECK

(Multi-Diluent 1 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 dated July 2012 regarding Multi-Diluent 1 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 indicated at the bottom of this page.

1. I have read and understood the instructions provided in this letter. Yes No

2. Do you currently perform plasma sample dilutions with the BNP and TSH3 Ultra Assays? Yes No

3. I will implement one of the options outlined in step 3 in the *Actions to Be Taken by the Customer* section of this letter? Yes No

4. If the answer to the question above is Yes, do you intend to take the recommended action as requested? Yes No

Name of person completing questionnaire:

Title:

Institution:

Instrument Serial Number:

Street:

City:

State:

Phone:

PLEASE FAX THIS COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER AT
(###) ###-####

Siemens Healthcare Diagnostics Inc.

511 Benedict Ave.
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www.siemens.com/diagnostics Page 6 of 6