

## Urgent Field Safety Notice

10813924, Rev. A

November 2012

### ADVIA Centaur® ADVIA Centaur® XP

#### System Misinterprets Wash 1 Fluid Signals

Our records indicate that you have received the ADVIA Centaur® or ADVIA Centaur XP system (catalog number: 078-A001-xx ADVIA Centaur system, 078-A002R02 ADVIA Centaur refurbished, 078-A011-03 ADVIA Centaur XP system, 078-A011R03 ADVIA Centaur XP refurbished).

#### Reason for Voluntary Correction

Siemens Healthcare Diagnostics is conducting a voluntary field correction for the ADVIA Centaur and ADVIA Centaur XP system.

Through investigation of customer complaints, Siemens Healthcare Diagnostics has confirmed occurrences of the system either:

- Failing to detect that the Wash 1 bottle and reservoir is empty, or
- Incorrectly indicating that the Wash 1 bottle and reservoir is empty when it is actually full.

If the system fails to detect an empty Wash 1 bottle and reservoir it can continue to process samples and produce erroneous but believable results which are falsely high or low (depending if the assay architecture is direct or indirect). This issue potentially affects only those assays that use Wash 1 (Table 1).

**Table 1. Assays Potentially Affected**

Assay Type	Assay
Auto-immune	ANA
Bone	VitD
Cardiovascular	BNP, DDimer, TnIUltra
Torch and Special ID	RUBG2, RubM, ToxG, ToxM
Reproductive Endocrinology	DHEAS, eE2, SHBG
Infectious Disease	aHAVM, aHAVT/HAVT, aHBcM, aHBcT/HBcT, aHBe, aHBs, aHBs, aHBs2, aHCV, CHIV, CMVG, Conf, EHIV, HBeAg, HBs, HIV, PCT, SYPH
Immunosuppressant	CsA
Liver Fibrosis	HA, PIINP, TIMP1
Tumor Markers / Oncology	CA153, CA19-9, CA199A, FreePSA

#### Siemens Healthcare Diagnostics

511 Benedict Ave.  
Tarrytown, NY 10591

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Assay Type	Assay
Thyroid	TSH3UL

If the system indicates that the Wash 1 bottle and reservoir is empty, the system will stop processing samples.

Siemens does not recommend a review of past results because the issue can be detected by reviewing quality control (QC) results, and by visually checking the amount of fluid in the Wash 1 bottle. In addition, both the Wash 1 bottle and the Wash 1 reservoir must be empty for the system to fail to detect an empty Wash 1 bottle and reservoir and continue sampling.

### Risk to Health

If the system does not detect the absence of Wash 1 fluid, and sample processing continues, erroneous but believable results can be reported for assays that use Wash 1. The overall risk of patient impact is low given other biomarkers, imaging results, patient history, clinical signs and symptoms used in conjunction with the result to manage patient treatment.

If the system incorrectly reports that there is no fluid in the tubing when there is actually fluid in the tubing, the system displays either a yellow Supplies Status warning indicating that the system is running on reserve, or a red error message indicating that fluid is depleted and the system is going to stop sampling. This case has no affect on results.

### Actions to be Taken by the Customer

Please use the actions below to address the following issues:

1. The system fails to detect that the Wash 1 bottle and reservoir are empty and continues to process samples.
2. The system stops processing samples even though there is sufficient Wash 1 present in the Wash 1 bottle and reservoir.

### System Fails to Detect Empty Wash 1 Bottle and Reservoir

- Do not use the status information on the User Interface (UI) workspace to monitor the amount of fluid in the Wash 1 bottle. Periodically check the amount of fluid in the Wash 1 bottle and use the instructions below to replace the Wash 1 bottle before it becomes depleted.
- Replace the Wash 1 Bottle Before Depletion:



**CAUTION:** Replace the Wash 1 bottle before the solution is depleted. If the bottle is depleted for a period of time, and the Supplies Status button does not display yellow to warn operators of this condition, the reservoir may become empty. The system may report erroneous results since the system did not deliver Wash 1 solution to the cuvettes during analysis.

Replace the Wash 1 bottle when the fluid level is just below the label on the bottle.

Refer to *Replacing System Fluids* in the ADVIA Centaur XP Operator's Guide or ADVIA Centaur Operator's Guide for additional instructions.

If the bottle is replaced while in the Ready state, you should prime the line using the following steps:

- a. Select the system icon in the top left of the workspace window.
  - b. From the menu list, select **Diagnostic Tools**.  
The System – Diagnostic Tools window displays.
  - c. Under Prime Functions select **Prime System Fluid Bottle** from the list.
  - d. From the Fluid list, select **Wash 1**.
  - e. Select **Perform**.
- If the Wash 1 bottle becomes empty and the Supplies Status button does not display yellow to warn you that Wash 1 is low, call your local support representative to have a Field Service Engineer visit your site and inspect the system.

### System Stops Processing Samples When Wash 1 is Present

Normally, if the Wash 1 bottle is depleted but the Wash 1 reservoir contains fluid, the Supplies Status button on the UI workspace displays yellow indicating that Wash 1 is “Present, using reserve”. If, after you replace the empty Wash 1 bottle, the Supplies Status button continues to display yellow, or if there was already sufficient Wash 1 in the bottle, perform the following steps to attempt to clear the status or error message:

The following steps may not clear the status or error message if the Wash interconnect PCB is malfunctioning or if there is another system problem. Please call your local support representative to report the problem after attempting to clear the status or error message.

- Clearing a Yellow Supplies Status Button
  - a. Lift the lid of the Wash 1 bottle.
  - b. Close the lid of the Wash 1 bottle.  
The system displays “Did you refill the Wash 1 Bottle?”
  - c. Select **Yes**.
  - d. Prime the Wash 1 fluid bottle following instructions in the Operator’s Guide.
  - e. Call your local support representative and notify them that the Supply Status button continues to display yellow when sufficient Wash 1 is in the bottle.
- Clearing a Red Error Message:

Normally, after the Wash 1 bottle and reservoir are depleted the system issues a red “Reservoir depleted” and “Sampling Stopped” message. If the red error message continues to display after you replace an empty Wash 1 bottle, or if there was already sufficient Wash 1 in the bottle, then perform the following:

  - a. Prime the Wash 1 fluid lines following instructions in the Operator’s Guide.
  - b. Refer to the ADVIA Centaur XP Operator’s Guide or ADVIA Centaur Operator’s Guide for additional instructions.
  - c. Call your local support representative and notify them that the red message displays when sufficient Wash 1 is present.

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In addition to the steps listed above, please perform the following:

- Complete the Field Effectiveness Check attached to this letter.
- 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 has caused. If you have any questions, please contact your Siemens Technical Solutions Center or your local Siemens technical support representative.

ADVIA Centaur is a trademark of Siemens Healthcare Diagnostics.

**FIELD CORRECTION EFFECTIVENESS CHECK**

System Misinterprets Wash 1 Fluid Signals

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated November 2012 regarding System Misinterprets Wash 1 Fluid Signals 10813924. 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.

I have read and understood the Urgent Field Safety Notice instructions provided in the November 2012 letter. 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  
(###) ###-####

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