

## Urgent Field Safety Notice

10813436

August 2012

ADVIA Centaur®  
ADVIA Centaur® XP

### Residual Cleaning Solution After Monthly Cleaning Procedure and Daily Cleaning Procedure

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Our records indicate that you are an ADVIA Centaur® or ADVIA Centaur XP customer.

#### Reason for the Voluntary Correction

This communication is to inform you that, through our investigation of customer complaints, Siemens Healthcare Diagnostics has determined that a small amount of residual cleaning solution may remain in the system fluidic lines following the Monthly Cleaning Procedure (MCP) and the Daily Cleaning Procedure (DCP). This may cause the following impacts to assays on some systems.

Impact on assays following Monthly Cleaning Procedure: Initial patient, calibrator, and Quality Control (QC) results for the ADVIA Centaur Total hCG, PSA, and Progesterone (PRGE) assays run after MCP may exhibit a high shift.

- You may observe a bias ranging from 22% to 103% at clinically relevant decision points for the Total hCG and PRGE assays affecting from 1 to 5 tests following an MCP.
- You may observe a bias ranging from 22% to 29% at clinically relevant decision points for the PSA assay affecting from 1 to 5 tests following an MCP.
- All instruments can display this issue after MCP. The first test immediately after the MCP is the most affected. Laboratories that perform QC after the MCP will be able to detect the issue.

Impact on assays following Daily Cleaning Procedure: Initial patient, calibrator, and QC results for the ADVIA Centaur Toxoplasma M (Toxo M) assay run after DCP may exhibit a low shift.

- You may observe a bias ranging from -41% to -63% at approximately 1.0 ratio for the Toxo M assay affecting from 1 to 3 tests following a DCP.
- Not all instruments will display this issue after DCP. The test immediately after the DCP is the most affected. Laboratories that perform QC after the DCP will be able to detect the issue.

Siemens is conducting a voluntary correction that provides additional steps to the MCP and DCP for the ADVIA Centaur and ADVIA Centaur XP systems to remove residual cleaning solution from all affected fluidic pathways.

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#### Siemens Healthcare Diagnostics

511 Benedict Ave.  
Tarrytown, NY 10591

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## **Risk to Health**

When run following the **Monthly Cleaning Procedure**, the potential patient impact of a positive bias on the three assays demonstrating clinically significant results is as follows:

- ThCG: Falsely elevated results have the potential to lead to a false positive diagnosis of pregnancy.
- PSA: Falsely elevated results have the potential to lead to additional testing for re-occurrence of prostate cancer.
- PRGE: Falsely elevated results may impact in-vitro fertilization (IVF) treatment decisions.

The probability of the above tests being affected by this issue is extremely low due to the frequency of MCP and automatic priming. Automatic priming, which occurs when the instrument is idle for more than 6 hours, will eliminate the issue, further reducing the occurrence. The risk to health presented by this issue is low.

A review of previously reported results for the affected assays is not warranted due to the extremely low occurrence rate and the limited benefit in retesting original samples.

When run following the **Daily Cleaning Procedure**, the potential patient impact of a negative bias on the Toxo M assay is as follows:

The Toxo M assay, when used in conjunction with Toxo IgG assay, can be used as an aid in the presumptive diagnosis of acute, recent, or reactivated toxoplasma infection. When Toxo IgG is negative, the falsely low bias in Toxo IgM could potentially lead to missed acute infection. When Toxo IgG is equivocal or positive, a falsely low bias in Toxo IgM could potentially lead to missed recent infection.

Siemens recommends that you discuss the impact on Toxo M with your laboratory director. Due to the low infection rate, most of the Toxo IgM positives are false positives. The number of true positives reading negative due to the DCP issue is expected to be extremely small.

A review of previously reported negative Toxo M results immediately after DCP is subject to the discretion of the laboratory.

Siemens recommends that you discuss the content of this bulletin with your laboratory director.

## **Actions to be Taken by Customers**

### **After Monthly Cleaning Procedure (MCP)**

Use the *Maintenance* section of the ADVIA Centaur or ADVIA Centaur XP operator's guide or the online documentation to perform the steps listed below. Allow 15 minutes to perform the following steps:

1. Perform MCP as usual on ADVIA Centaur and ADVIA Centaur XP systems, following the instructions at each prompt.
2. Perform the weekly maintenance for the water reservoir by removing and thoroughly rinsing the reservoir with fresh reagent water (see *Cleaning the Water Bottles and Reservoir* in the operator's guide).
3. Perform the **Prime Water from Reservoir to Manifolds** maintenance as prompted.

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4. Close the Maintenance window.
5. Refer to the *Using Diagnostics Tools* section in the ADVIA Centaur or ADVIA Centaur XP operator's guide to open the System – Diagnostic Tools window from the workspace.
6. Select **Prime Fluid Line**.  
Options appear at the bottom of the window.
7. Under the Fluid Line option, select **Reagent Probe 1**.
8. Under Fluid select **Water**.
9. Under Repetitions, select **5**.
10. Select **Perform**.
11. Once the primes are completed, close the System — Diagnostic Tools window.
12. Perform your daily QC before reporting results.

### Defining Maintenance Activities

To remind operators in your laboratory to perform *Actions After MCP* as part of the regular maintenance schedule, you can define a new maintenance activity. You must have the appropriate level of security to perform this function. On the day that MCP is due, perform the following:

1. At the workspace, select **Maintenance Status**.
2. At the Status – Maintenance window define the new maintenance activity.
  - a. Select **Add**.
  - b. Enter the name of the maintenance activity: **Post MCP - Water Rsvr Rinse & R1 Prime**.
3. At the Status – Maintenance Definition window, enter or edit the appropriate information.
  - a. In the **Interval** area, select **Days**.
  - b. In the **Frequency** field enter **28**.
4. Select **Save**.  
The system displays a diamond symbol next to the maintenance activity you defined at the Status – Maintenance window, and adds the new MCP Workaround - Water Reservoir Rinse and R1 Prime maintenance activity to the list of Monthly Maintenance activities.

### After Daily Cleaning Procedure (DCP) for Toxo M Assay Customers Only

To determine the test definition version installed on the system, perform the following:

1. At the UI workspace select the system icon, and then select **About the System**.  
The System — About the System window opens.
2. Record the test definition version installed on the system.

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### 3. Close the System — About the System window.

If you are using the Toxo M assay on an ADVIA Centaur or ADVIA Centaur XP system with test definition version 1.0.DA or 1.0.DB or higher installed, the system will not experience the issue after DCP and you will not need to perform the actions below.

If you are using the Toxo M assay on an ADVIA Centaur or ADVIA Centaur XP system that has test definition version 1.0.CX or 1.0.CY or lower installed, determine if your instrument is affected by performing the following step:

### 4. Immediately following DCP, run 10 repetitions of the Toxo M positive QC.

If QC is within range, no other action is required. This confirms that your instrument is not affected and this check is no longer required.

If QC falls outside of your laboratory's acceptable range, stop running the Toxo M assay and call your local Technical Solutions Center and report that your system is affected by this issue so that a Field Service Engineer can be sent to your facility to install test definition version 1.0.DA or 1.0.DB or higher that corrects this issue.

**NOTE:** The Toxo M assay must be recalibrated after the installation of either test definition version 1.0.DA or 1.0.DB.

### **Additional Customer Actions for All Customers**

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

- Siemens recommends that, before reporting results, you perform your daily QC after MCP and DCP.
- Ensure that all lab personnel responsible for performing maintenance are aware of these changes.
- Complete the Field Effectiveness Check attached to this letter.
- Forward this notification to whomever you may have distributed this product.
- Please review the information contained in this bulletin with your Laboratory Director.

We apologize for the inconvenience that this situation has caused. Thank you for your patience and continued support. Siemens is committed to providing continued solutions and communication to improve the user experience with our products.

If you have any questions or need additional information, please contact your local technical support provider or distributor.

**FIELD CORRECTION EFFECTIVENESS CHECK**

Residual Cleaning Solution After Monthly Cleaning Procedure and Daily Cleaning Procedure

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated August 2012 regarding Residual Cleaning Solution After Monthly Cleaning Procedure and Daily Cleaning Procedure. 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. Did you read and understand this letter. Yes  No
  
- 2. Did you call your local TSC to request an FSE visit because the Toxo M assay is affected by the issue described in this letter? (See *After Daily Cleaning Procedure (DCP) for Toxo M Assay Customers Only*, page 3 for details.) 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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