

# Medical Device/Equipment ALERT

Ref.MDEA(NI)2008/059

Issued: 25<sup>th</sup> July 2008

For:

|                         |   |
|-------------------------|---|
| <b>IMMEDIATE ACTION</b> | ✓ |
| ACTION                  |   |
| UPDATE                  |   |
| INFORMATION             |   |



**HEALTH ESTATES**

creating healing environments

|   | Section   |  |  |     |
|---|---|--|--|-----|
| <p><b>Medical Device/Equipment:</b><br/>Laboratory analysers and their associated assays – ADVIA Centaur and ADVIA Centaur XP Immunoassay Systems, manufactured by Siemens Healthcare Diagnostics, serial numbers 078-A001-XX and XP 078-A010-XX.</p>   | ▶ ①   |  |  |     |
| <p><b>Problem:</b><br/>Failure to detect a low level of wash 1 fluid. This may lead to erroneous test results in high risk biomarkers (Appendix 1).</p>   | ▶ ②   |  |  |     |
| <p><b>Action by:</b><br/>Laboratory staff using this device.</p>  | ▶ ③   |  |  |     |
| <p><b>Action:</b></p> <ol style="list-style-type: none"> <li>Follow the manufacturer's instructions in the Field Safety Notice (Appendix 2). <ul style="list-style-type: none"> <li>Ensure procedures are in place to regularly check the fluid level on the wash 1 bottle. Frequency of checks will depend on usage.</li> <li>Be vigilant for trends of positive (elevated) or negative (depressed) results that would alert the user to a problem. If a trend towards positive or negative results is seen, check the level of fluid in the wash 1 bottle and run quality control samples.</li> </ul> </li> <li>Consider the need for clinical review of previous patient results that may have been affected by this problem.</li> <li>Ensure that you have appropriate systems in place for any relevant follow-up testing (e.g. confirmation of results).</li> </ol> | ▶ ④   |  |  |     |
| <p><b>Distributed by NIAIC to:</b></p> <p>Chief Executive of each HSS Board<br/>Chief Executive of each HSS Trust<br/>Chief Executive of each Agency<br/>NIAIC Liaison Officers</p> <p><b>For onward distribution see Section 5</b></p> <p style="text-align: right;">Health Protection Agency (HPA)</p>  | ▶ ⑤   |  |  |     |
| <p><b>Contacts</b><br/>Details of manufacturer contacts and NIAIC contacts for technical and clinical aspects.</p>  | ▶ ⑥   |  |  |     |
| <p style="text-align: center;"><b>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</b></p> <table border="1" style="width: 100%;"> <tr> <td style="width: 33%;"> <p><b>Acknowledge Receipt of Alert:</b><br/>29<sup>th</sup> July 2008</p> </td> <td style="width: 33%;"> <p><b>Action Under Way:</b><br/>31<sup>st</sup> July 2008</p> </td> <td style="width: 33%;"> <p><b>Action Complete:</b><br/>14<sup>th</sup> August 2008</p> </td> </tr> </table>   | <p><b>Acknowledge Receipt of Alert:</b><br/>29<sup>th</sup> July 2008</p> | <p><b>Action Under Way:</b><br/>31<sup>st</sup> July 2008</p>  | <p><b>Action Complete:</b><br/>14<sup>th</sup> August 2008</p> | ▶ ⑦ |
| <p><b>Acknowledge Receipt of Alert:</b><br/>29<sup>th</sup> July 2008</p>   | <p><b>Action Under Way:</b><br/>31<sup>st</sup> July 2008</p>             | <p><b>Action Complete:</b><br/>14<sup>th</sup> August 2008</p> |  |     |

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

## **1. DEVICE/EQUIPMENT:**

Laboratory analysers and their associated assays – ADVIA Centaur and ADVIA Centaur XP Immunoassay Systems, manufactured by Siemens Healthcare Diagnostics, serial numbers 078-A001-XX and XP 078-A010-XX.

## **2. PROBLEM:**

The ADVIA Centaur and ADVIA Centaur XP systems may fail to alert the user when the wash 1 bottle is nearly empty, i.e. when the level of the wash 1 fluid is just below the label on the wash 1 bottle.

If the wash 1 bottle is depleted, the analyser may report erroneous results as listed in the clinical risk assessment (Appendix 1).

Neither the manufacturer nor the MHRA has received any adverse reports regarding this issue.

The manufacturer has determined that an additional sensor is required to monitor the depletion of the wash 1 fluid. This will require hardware and software upgrades. The manufacturer has planned implementation of these upgrades for December 2008.

## **3. ACTION BY:**

Laboratory staff using this device

## **4. ACTION:**

1. Follow the manufacturer's instructions in the Field Safety Notice (Appendix 2).
  - Ensure procedures are in place to regularly check the fluid level on the wash 1 bottle. Frequency of checks will depend on usage.
  - Be vigilant for trends of positive (elevated) or negative (depressed) results that would alert the user to a problem. If a trend towards positive or negative results is seen, check the level of fluid in the wash 1 bottle and run quality control samples.
2. Consider the need for clinical review of previous patient results that may have been affected by this problem
3. Ensure that you have appropriate systems in place for any relevant follow-up testing (e.g. confirmation of results).

## **5. ONWARD DISTRIBUTION TO:**

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Biochemists
- Biomedical science departments
- Clinical governance leads
- Clinical pathologists
- Clinical pathology directors
- Immunology
- Immunopathologists
- Laboratory managers
- Nursing executive directors
- Risk managers
- Virologists

## 6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Mme Sylvie LeGledic  
Siemens Healthcare Diagnostics  
c/o: Sir William Siemens Square  
Frimley  
Camberley  
Surrey  
GU16 8QD

Tel: 00 33 1 49 22 99 05

Fax: 00 33 1 49 22 32 48

E-mail: [Sylvie.legledic@siemens.co](mailto:Sylvie.legledic@siemens.co)

Enquiries to NIAIC should quote reference number MDEA(NI)2008/59 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US

Tel: 028 9052 3868

Fax: 028 9052 3900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

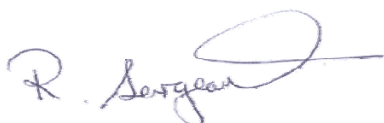
## 7. FEEDBACK:

### Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

**Acknowledge Receipt of Alert:**  
29<sup>th</sup> July 2008

**Action Under Way:**  
31<sup>st</sup> July 2008

**Action Complete:**  
14<sup>th</sup> August 2008



Robert Sergeant  
NIAIC Operational Manager

#### HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2007/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety*

# APPENDIX 1 to MDEA(NI)2008 – 59

## Clinical Risk Assessment of Tests Affected by Insufficient Wash 1 on the ADVIA Centaur/ADVIA Centaur XP

| Test                | Effect on result   | Potential clinical impact of false result  |
|---------------------|--------------------|--|
| Trop I Ultra        | Elevated           | Observed myocardial injury, possible cardiac catheterization.  |
| BNP                 | Elevated           | Overestimation of degree of heart failure or false positive upon screening. Could lead to further testing.   |
| CsA                 | Depressed          | Underestimation of cyclosporin level - potential dose adjustment or additional co-therapies.   |
| CA19-9              | Elevated           | Improper prognostic grading, or inappropriate suspicion of reoccurrence leading to further investigations.   |
| CA15-3              | Elevated           | In monitoring breast cancer a 25% increase correlates with progression of disease. Can result in further studies and possibly extended therapy, or change in therapeutic strategy.   |
| Toxo G              | Elevated           | <ul style="list-style-type: none"> <li>▪ Expectant mothers may be inappropriately reassured that they are not susceptible to acute infection which may also lead to overlooked testing of IgM in pregnancy.</li> <li>▪ Some types of organ/tissues from potential donors would be considered as a source of infection and, where the recipient is negative, this may result in unnecessary investigation or treatment.</li> </ul>                                    |
| Toxo M              | Elevated           | <ul style="list-style-type: none"> <li>▪ Prenatal testing may result in treatment and invasive (amniocentesis) investigation and could cause mother to consider abortion because of concern about foetal abnormalities.</li> <li>▪ May preclude further investigation of potentially more severe differential diagnoses in the immunocompetent. May result in unnecessary treatment and additional investigation in the immunosuppressed/immunodeficient.</li> </ul> |
| Rub M               | Elevated           | Maternal ToRCH screening; could cause mother to consider abortion because of concern about foetal abnormalities. May indicate recent immunization.   |
| HAV IgM             | Elevated           | False positive result would lead to unnecessary investigation and may lead to the failure to diagnose true cause of hepatitis.   |
| HAV Total           | Depressed          | If used for diagnosis of HAV, false negative could result in missed HAV. If used for immunity testing, may give rise to an unnecessary HAV vaccination.  |
| HBc Total           | Elevated           | If falsely positive and HBsAg is negative patient would be considered immune. Would depend on whether aHBs testing was performed. Could result in a missed immunization opportunity if aHBs not tested as well. Normal practice is to use aHBs for immunity. If falsely positive in an HBsAg positive patient may be considered chronic resulting in therapeutic intervention.   |
| HBc IgM             | Elevated           | Presumed acute HBV infection.  |
| aHBs                | Elevated           | Falsely consider patient is immune or recovered. Potentially resulting in missed chronic infection or missed vaccination.  |
| HBs Ag confirmatory | Elevated           | Potential for incorrect diagnosis.   |
| HCV                 | Elevated           | False positive for HCV infection.  |
| EHIV                | Elevated           | Potential false positives.   |
| Anti-HBe/HBeAg      | Depressed/Elevated | The potential for false negative anti-HBe and false positive HBeAg, could lead to the patient being diagnosed as being more infectious than they actually are and given inappropriate therapy.   |
| Specific IgE        | Elevated           | False positive result in avoidance of a particularly allergen or unnecessary immunotherapy   |
| Allergy screen      | Elevated           | Screen false positive would reflex to potential unnecessary testing of specific allergens.   |

# APPENDIX 2 to MDEA(NI)2008 – 59

**SIEMENS**

**ADVIA Centaur®**  
**ADVIA Centaur® XP**  
Immunoassay Systems

Siemens Healthcare Diagnostics Inc.

**Customer Bulletin**  
**URGENT: Field Safety Notification**  
2008-03

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## System Not Detecting Insufficient Wash 1 Fluid

In an ongoing effort to keep our customers informed, Siemens Healthcare Diagnostics is providing you with information about occasional failures of the ADVIA Centaur® and ADVIA Centaur XP systems to detect insufficient solution in the Wash 1 reservoir which may impact results. This bulletin provides corrective actions to avoid this problem.

After reading this bulletin, if you have questions or need additional information, contact your local technical support provider or distributor.

### Background

If the Wash 1 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.

### Actions

Siemens is continuing to investigate the issue to determine a permanent resolution. In the interim, perform the actions below.

#### 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.

### Do Not Use a Syringe for Priming

Do not use a syringe to prime the Wash 1 solution after replacing the Wash 1 bottle. The system automatically performs a prime after you replace the bottle. Using a syringe may introduce Wash 1 solution into the vent valve, which may cause valve failure.

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

1. Select the system icon in the top left of the workspace window.
2. From the menu list, select **Diagnostic Tools**.  
The System – Diagnostic Tools window displays.
3. Under Prime Functions select **Prime System Fluid Bottle** from the list.
4. From the Fluid list, select **Wash 1**.
5. Select **Perform**.

### Clearing a Yellow Supplies Status Button

If the Supplies Status button continues to display yellow, indicating that Wash 1 is low, after you have replaced an empty Wash 1 bottle, or if sufficient Wash 1 solution remains in the bottle, perform the following steps:

1. Lift the lid of the Wash 1 bottle.
2. Close the lid of the Wash 1 bottle.  
The system displays “Did you refill the Wash 1 Bottle?”
3. Select **Yes**.
4. If the Supply Status button continues to display yellow, call your local support representative.

If the Wash 1 bottle becomes empty and the Supplies Status button does not display yellow indicating that Wash 1 is low, call your local support representative to have a Field Service Engineer visit your site and inspect the system.

### Complete the Notification Form

The *Completion Notification Form* serves as a record that you have read and understood the contents of this bulletin. Before submitting the form, complete the following steps:

1. Ensure that all operators read and understand this bulletin.
2. Keep this bulletin with the *Operator's Guide* for future reference.  
**NOTE:** You may use 1 form to signify compliance for the entire site (multiple systems).
3. Complete the *Completion Notification Form* indicating that you have read and understood this bulletin, and submit the form to your branch representative **within 7 days** of receipt.

System Not Detecting Insufficient Wash 1 Fluid

## Trademark Information

ADVIA Centaur is a trademark of Siemens Healthcare Diagnostics Inc.

## Appendix

### Completion Notification – System Not Detecting Insufficient Wash 1 Fluid

To signify compliance to this notification (Customer Bulletin 078D0706-02, Rev. A), please sign and date the completed form and submit the signed copy of this form to the following person:

**Post:** Siemens Medical Solutions Diagnostics  
Sir William Siemens Square  
Frimley  
Camberley  
Surrey  
GU16 8QD

**Email:** dx-diag\_srv\_logistics-uk.med@siemens.com

**Fax:** +44 (0) 1276 696 680

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**System Serial Number(s)**

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**Hospital/Facility**

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**Department**

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**Date when customer bulletin  
078D0706-02, Rev. A was  
received.**

**Signature:** \_\_\_\_\_

**Printed Name:** \_\_\_\_\_

**Title:** \_\_\_\_\_