

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/063

Issued: 4th August 2008

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
<p>Medical Device/Equipment: Laboratory analyser – ADVIA Centaur CP immunoassay system, serial number 086-A001-XX, manufactured by Siemens Healthcare Diagnostics.</p>	▶ ①
<p>Problem: Dispensing errors using the 10µl probe may have lead to falsely low results for alpha-fetoprotein (AFP) and myoglobin tests.</p>	▶ ②
<p>Action by: Laboratory staff who use this device</p>	▶ ③
<p>Action:</p> <ol style="list-style-type: none"> 1. Ensure your laboratory has received the manufacturer's software and hardware upgrades that were issued in July 2008. 2. Consider the need for clinical review of patient results. 	▶ ④
<p>Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p>	▶ ⑤
<p>Contacts Details of manufacturer and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥
<p>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</p>	
<p>Acknowledge Receipt of Alert: 6th Aug 2008</p>	▶ ⑦
<p>Action Under Way: 11th Aug 2008</p>	
<p>Action Complete: 6th Oct 2008</p>	

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

1. DEVICE/EQUIPMENT:

Laboratory analyser – ADVIA Centaur CP immunoassay system, serial number 086-A001-XX, manufactured by Siemens Healthcare Diagnostics.

2. PROBLEM:

The 10µl probe may have failed to dispense sample with no subsequent error message. This may have led to falsely low AFP and myoglobin test results.

1. The AFP assay is intended as an aid in managing non-seminomatous testicular cancer. False negative AFP results in non-seminomatous testicular cancer may not be clinically apparent and therefore may need to be reviewed.
2. The AFP assay on the ADVIA Centaur is also used as an aid in detecting open neural tube defects. False negative AFP results in pregnancy should be easily identified as undetectable levels are not compatible with pregnancy.
3. The myoglobin assay on the ADVIA Centaur is intended to be used as an aid in the diagnosis of acute myocardial infarction. Myoglobin results are interpreted in conjunction with other cardiac markers and clinical assessment, therefore reducing the risk of misdiagnosis of an acute myocardial infarction based on one negative myoglobin result.

The manufacturer issued an urgent Field Safety Notice in March 2008 advising users to repeat and review all AFP results that were below 1.7ng/ml before releasing them from the laboratory. A software and hardware upgrade to resolve this issue was scheduled to be completed by July 2008.

No adverse incidents have been reported to the MHRA.

3. ACTION BY:

Laboratory staff who use this device

4. ACTION:

1. Ensure your laboratory has received the manufacturer's software and hardware upgrades that were issued in July 2008.
2. Consider the need for clinical review of patient 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:

- A&E consultants
- A&E departments
- A&E directors
- Biochemists
- Cardiologists
- Clinical biochemistry/chemical pathology departments
- Clinical governance leads
- Clinical pathologists
- Clinical pathology directors
- Gynaecologists
- Medical directors
- Nursing executive directors
- Oncology directors
- Risk managers
- Urological surgeons
- Urological surgery, directors of
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Brett Bullough
Siemens Healthcare Diagnostics
Sir William Siemens Square
Frimley
Camberley
Surrey
GU16 8QD

Tel: 01276 696 446

Fax: 01276 696 680

E-mail: brett.bullough@siemens.com

Enquiries to NIAIC should quote reference number MDEA(NI)2008/063 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

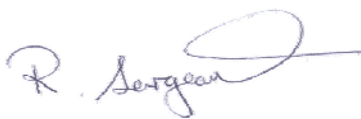
7. FEEDBACK:

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

Acknowledge Receipt of Alert:
6th Aug 2008

Action Under Way:
11th Aug 2008

Action Complete:
6th Oct 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

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

APPENDIX to MDEA(NI)2008/063



ADVIA Centaur® CP
Immunoassay System

Siemens Healthcare Diagnostics Inc.

URGENT: Field Safety Notification
2008-03

Assay Dispense Errors

Risk of Incorrect Results Due to Sample Dispense Errors

In an ongoing effort to keep our customers informed, Siemens Healthcare Diagnostics is providing information regarding the ADVIA Centaur® CP AFP assay and the use of the assay as an aid in the management of non-seminomatous testicular cancer.

Background

During an internal investigation, it was observed that on infrequent occasions the 10 uL sample size used for the ADVIA Centaur CP AFP assay was not always dispensed into the cuvette. The frequency of the dispense error was internally determined to be 0.0196%. Failure to dispense the sample leads to an inappropriate result of <1.7 ng/mL, the level of sensitivity of the assay.

Clinical interpretation should always be made in conjunction with clinical history and other clinical laboratory tests. However, a non-detectable AFP result may not be easily recognized as discordant in some cases, and may impact clinical interpretations. Such cases may occur when the samples are tested as an aid in the management of non-seminomatous testicular cancer or tested for other clinical applications.

No other assays are affected by the sample dispense issue with the exception of myoglobin, which also uses a 10 uL sample size. Due to myoglobin's use in conjunction with other cardiac markers, expected observation of emergency room (ER) patients that present chest pain, and serial monitoring of cardiac markers, there is no need to change your current testing protocol for the myoglobin assay.

Actions

Siemens is working to correct the dispense issue, and will notify you when the correction is available.

Until that time, the following workaround is required:

1. Hold all AFP results for review by the operator.

NOTE: You cannot have the AFP assay loaded on the system while performing the following steps. If AFP is loaded, the Save button is disabled.

- a. Remove the AFP Primary Reagent Pack.
- b. At the workspace, select **Setup**.
The Assay tab displays.

APPENDIX to MDEA(NI)2008/063

AFP Assay Dispense Errors

- c. Select **AFP**.
 - d. Select **Details**.
The Details window displays.
 - e. Select the **Hold Results** checkbox.
 - f. Select **Save**.
2. Define a check range for the AFP assay.
 - a. At the Details window, select **Ranges**.
The Ranges "AFP" window displays.
 - b. At the Check Range area, enter **1.7** in the Low Limit field.
 - c. Select the **Repeat If** check box.
 - d. Select **Repeat If <** from the list.
 - e. At the Ranges window, select **OK**.
 - f. At the Details window, select **Save**.
 3. The operator must review all AFP results.
 - The operator can release any result > 1.7 ng/mL.
 - If a sample has a result that is flagged as < 1.7 ng/mL and the repeated result is <1.7 ng/mL, the operator can release either result.
 - If a sample has a result that is flagged as < 1.7 ng/mL and the repeated result is >/= to 1.7 ng/mL, the operator should release the repeated result.
 - If the operator observes more than one incident of the third type (third bullet item above) per day, the customer should report the issue to the local technical service provider or distributor.
 4. Contact your local support representative to obtain the name of the branch representative and the branch fax number.
NOTE: You may use 1 form to signify compliance for the entire site (multiple systems).
 5. Complete the attached *Completion Notification* form to indicate that you have received and implemented the workaround.

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

Trademark Information

ADVIA Centaur is a trademark of Siemens Healthcare Diagnostics.

APPENDIX to MDEA(NI)2008/063

AFP Assay Dispense Errors

Appendix

Completion Notification – Assay Dispense Errors

To signify compliance to this notification (Customer Bulletin 086D0143-01 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

System Serial Number(s)

Hospital/Facility

Department

**Date when customer bulletin
086D0143-01 Rev A was
received.**

Signature: _____

Printed Name: _____

Title: _____