Medical Device Alert

Ref: MDA/2013/005 Issued: 14 February 2013 at 16:00

Device

Laboratory analysers for a variety of tests including HIV, tumour markers and hepatitis. Specific assays.

ADVIA Centaur® and ADVIA Centaur® XP, manufactured by Siemens Healthcare Diagnostics Inc. Specific catalogue numbers.

Problem

A failure of the wash interconnect circuit board on the ADVIA Centaur and ADVIA Centaur XP analysers may produce the following errors:

1. Failure to detect that the 'Wash 1' bottle is empty. This could result in credible but erroneous results reported on a number of tests. See affected assays listed below.

Or

2. Incorrect indication that the 'Wash 1' bottle is empty, causing the system to stop processing samples.

Siemens is planning software and hardware updates to resolve these issues by the end of March 2013.

Action

Identify if you have affected devices.

Follow the manufacturer's recommendations in the FSN to:

- Monitor 'Wash 1' fluid levels manually.
- Replace the 'Wash 1' bottle before the fluid is depleted.
- Clear incorrect status or error messages that prohibit testing.

Contrary to the manufacturer's FSN, consider the need to review previous results.

Action by

Laboratory staff using these systems.

CAS deadlines

Action underway: 21 February 2013

Action complete: 07 March 2013

Note: These deadlines are for systems to be in place to take actions and not for the completion of patient follow-up and testing.

Contact

Authorised Representative
Tony Walsh
Siemens Healthcare Diagnostics Limited
Tel: 01908 487 600
Email: anthony.walsh@siemens.com

Device

The following assay systems are affected:

- ADVIA Centaur system (Cat. 078-A001-xx)
- ADVIA Centaur refurbished (Cat. 078-A002R02)
- ADVIA Centaur XP system (Cat. 078-A011-03)
- ADVIA Centaur XP refurbished (Cat 078-A011R03)

Problem

The table below summarises the assays affected and what the potential effect is for each.

Assay type	Assay	Potential effect on assay results
Auto-immune	ANA	False Positive or Negative
Bone	VitD	False Positive or Negative
Cardiovascular	BNP,	High Bias
	DDimer,	False Positive or Negative
	TnIUltra	Always Elevated
Torch and Special ID	RUBG2,	False Positive or Negative
	RubM,	False Positive or Negative
	ToxG,	False Positive
	ToxM	False Positive
Reproductive Endocrinology	DHEAS,	False Positive or Negative
	eE2,	False Positive or Negative
	SHBG	False Positive or Negative
Infectious Disease	aHAVM,	False Positive
	aHAVT/HAVT,	Low Bias
	aHBcM,	False Negative
	aHBcT/HBcT,	False Negative
	aHBe,	High or Low Bias
	aHBs,	False Positive
	aHBs,	False Positive
	aHBs2,	False Positive or Negative
	aHCV,	False Positive or Negative
	CHIV,	False Positive or Negative
	CMVG,	False Positive or Negative
	Conf,	False Positive or Negative
	EHIV,	False Positive
	HBeAg,	False Positive
	HBs,	False Positive
	HIV,	False Positive or Negative
	PCT,	False Positive or Negative
	SYPH	False Positive or Negative
Immunosuppressant	CsA	Low Bias
Liver Fibrosis	HA,	False Positive or Negative
	PIINP,	False Positive or Negative
	TIMP1	False Positive or Negative
Tumour Markers / Oncology	CA153,	False Positive
	CA19-9,	False Positive
	CA199A,	False Positive or Negative
	FreePSA	False Positive or Negative
Thyroid	TSH3UL	False Positive or Negative

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- Health Protection Agency (HPA) (Directors)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Biochemists
- Biomedical science departments
- Clinical governance leads
- Clinical pathologists
- Clinical pathology directors
- EBME departments
- Haematologists
- Health and safety managers
- Immunologists
- Medical directors
- Virologists

Health Protection Agency

Directors for onward distribution to:

- Collaborating centres
- Consultants in communicable disease control
- Divisional directors
- Heads of department
- Heads of health, safety and quality
- HPA laboratories
- Laboratory managers
- Regional microbiologists
- Risk manager
- Safety officers

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Private laboratories/testing services?

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/005** or **2012/011/008/601/008.**

Technical aspects
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How to report adverse incidents

Please report via our website http://www.mhra.gov.uk

Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ

Tel: 02890 523 704
Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic

Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:
Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk