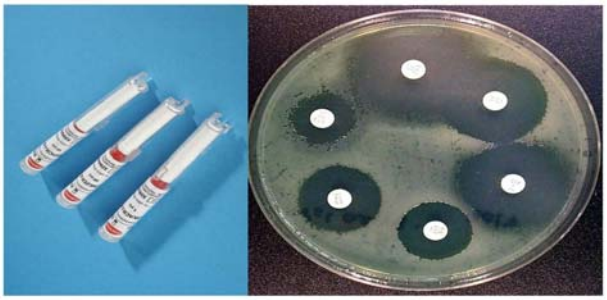
Medical Device Alert

Ref: MDA/2013/014 Issued: 20 March 2013 at 14:30

Device

Oxoid antimicrobial susceptibility testing discs (AST) manufactured by Thermofisher Scientific.



Problem

The manufacturer has issued nine Field Safety Notices since November 2011 recalling batches of AST disc, due to the presence of non-impregnated or 'blank' AST discs manufactured before December 2012. AST discs may, therefore, not perform to the expected specification.

Blank discs could lead to a false indication of antibiotic resistance, which in turn could lead to delayed reporting, reduced options for treatment or unnecessary changes to treatment.

Action by

Medical microbiologists and microbiology laboratory managers.

Action

- When reviewing results which do not fit the clinical picture (i.e. unexpected pattern of resistance within classes of antibiotic, discrepant results with MIC testing or unexpected patient outcomes on empirical therapy) consider if blank AST discs are a possible cause.
- Consider the need for repeat and/or further testing of resistant isolates, including, where appropriate, non-disc methods, especially in clinically severe cases and where there are reduced options for treatment due to high levels of resistance in your patients.
- Report any suspected examples of blank discs observed in your laboratory to the MHRA and the manufacturer.

CAS deadlines

Action underway: 05 April 2013

Action complete: 17 April 2013

Contact

Mr Martyn Rogers
Thermo Fisher Scientific
Wade Rd, Basingstoke
Hants. RG24 8PW
Tel: (01256) 694245
Email: martyn.rogers@thermofisher.com

Problem

Recent recalls of Oxoid AST discs have been in response to the potential for the presence of non-impregnated or 'blank' discs within specific disc lots. The manufacturer estimates that the rate of occurrence of blank discs is less than 1 in 100,000.

There have been nine Field safety notices on this issue since November 2011, with four occurring in February 2013. More information can be found on the MHRA website .

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- 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)
- Primary care trusts in England (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:

- Biomedical science departments
- Clinical governance leads
- Clinical pathologists
- Clinical pathology directors
- Infection control departments
- Medical directors
- Medical microbiologists
- Microbiology laboratory managers
- Purchasing managers
- Risk managers

Health Protection Agency

Directors for onward distribution to:

- Antibiotic resistance monitoring and reference laboratory
- HPA laboratories
- Laboratory managers
- Regional business managers
- Regional directors
- Regional epidemiologists
- Regional leads
- Regional microbiologists
- Risk manager
- Safety officers

Primary care trusts

CAS liaison officers for onward distribution to all relevant staff including:

- Directors of public health
- Infection control nurses

Independent distribution

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

This alert should be read by:

- Hospitals in the independent sector
- Medical microbiologists
- Microbiology laboratory managers
- Private medical practitioners

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

Manufacturer
Mr Martyn Rogers
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Hants
RG24 8PW
Tel: (01256) 694245
Email: martyn.rogers@thermofisher.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/014** or **2013/002/007/601/005**

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