Medical Device Alert

Ref: MDA/2013/040 Issued: 17 June 2013 at 14:00

Device

Laboratory test kit.

Orgentec Alegria dsDNA IgG (ORG204G) for the diagnosis of lupus.

Lot numbers: 204G30204 and 204G30205.

Manufactured by Orgentec Diagnostika GmbH, distributed in the UK by Launch Diagnostics.

Problem

An increase in sensitivity may lead to false positive results in tests for the diagnosis of lupus.
This issue may be related to the strip coating.
Orgentec has sent a recall letter.

Action

Do not use and discard any remaining strips from the affected lots.

Consider the need to retest positive results obtained from the affected lots.

Contact Launch Diagnostics (01474 876 402) to request replacement strips for retesting.

Action by

Clinical pathologists.
Biomedical scientists.

CAS deadlines

Action underway: 24 June 2013

Action complete: 17 July 2013

Note: These deadlines are for the removal of unused affected devices and not for the completion of patient re-testing.

Contact

Distributor
Ms Louise Knight
Launch Diagnostics Ltd
Tel: 01474 876 402
Email: louiseknight@launchdiagnostics.com

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS trusts in England (chief executives)
- Public Health England (for information)

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 scientists
- Clinical governance leads
- Clinical pathologists
- Clinical pathology directors
- Medical directors
- Purchasing managers

Public Health England

Directors for onward distribution to:

- Laboratory managers

Independent distribution

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

This alert should be read by:

- Hospitals in the independent sector

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

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/040 or 2013/005/029/601/004**

Technical aspects
Bina Mackenzie or Mojisola Ajeneye
Medicines & Healthcare Products Regulatory Agency
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 7229 or 7271 Fax: 020 8754 3965

Email: bina.mackenzie@mhra.gsi.gov.uk
mojisola.ajeneye@mhra.gsi.gov.uk

Clinical aspects
For clinical aspects please contact the clinical team

Tel: 020 3080 7032 Fax: 020 8754 3965

Email: kayleigh.purdon@mhra.gsi.gov.uk

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