Medical Device Alert

Ref: MDA/2013/058 Issued: 26 July 2013 at 10:00

Device

Blood grouping cassettes.
OrthoBioVue multi-reagent cassettes.
Manufactured by Ortho Clinical Diagnostics. Specific lots.

Problem

A small number of multi-reagent cassettes in affected lots have been found with labels containing product information on the wrong side of the cassette.

The use of affected multi-reagent cassettes may lead to false negative or false positive results, causing a potential misclassification of the patient or donor blood groups or Rh/K phenotypes or incorrect antibody detection results. This may be of particular clinical concern where there is no confirmation of the group (e.g. in testing of newborns or where reverse grouping is not in place).

Ortho Clinical Diagnostics have sent out a Field Safety Notice having identified the cause of the manufacturing issue.

Action

- Do not use and quarantine products from affected lots received prior to 5 July 2013. Contact the manufacturer urgently for replacement product.
- Products from affected lots received prior to 5 July 2013 should be used only where no alternative stock is available and must be inspected prior to use (see manufacturer's Field Safety Notice).
- Discard products from affected lots received prior to 5 July 2013 once replacement stock is available for use.
- Consider the need to review patient results from the affected lots.
- As part of your look back process, report any incorrect results to the MHRA and Ortho Clinical Diagnostics.

Action by

- Directors of pathology
- Lead clinical scientists (haematology)
- Lead biomedical scientists (haematology and blood transfusion)
- Clinical services managers
- Laboratory managers

CAS deadlines

Action underway: 02 August 2013

Action complete: 27 August 2013

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

Contact

Manufacturer
Laurent Oliviero / Marta Carnielli / Nick Gould
Ortho Clinical Diagnostics
Tel: +33 1 5500 3250
+33 3 8865 4786
+33 3 8865 4752
Email: regaff@ocdgb.jnj.com

Device

See the manufacturer's Field Safety Notice for a list of affected products and lot numbers.

Products received by you after 5 July 2013 were inspected by the manufacturer prior to shipping.

NOTE; There is no risk associated with the use of an affected single-reagent cassette since all wells contain the same reagent.

Distribution

This MDA has been sent to:

- 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 England area teams (for information)
- 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 (haematology and blood transfusion)
- Blood banks
- Clinical pathologists
- Clinical pathology directors
- Haematologists
- Risk managers

Public Health England

Directors for onward distribution to:

- Divisional directors

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
Ortho-Clinical Diagnostics
Johnson & Johnson, 50-100 Holmers Farm Way, High Wycombe, Bucks HP12 4DP

Tel: +33 3 8865 4786
+33 1 5500 3250
+33 3 8865 4752
Fax: +33 3 8865 4741

Email: regaff@ocdgb.jnj.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/058** or **2013/006/026/081/010**

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
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

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
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