Medical Device Alert

Ref: MDA/2014/012 Issued: 16 April 2014 at 12:00

Device

Laboratory reagents requiring manual handling for use in combination with cobas c 502 analyser made by Hitachi, supplied by Roche.

Problem

The level sensing function of the cobas c502 laboratory analyser has not been activated for tests requiring manual reagent handling.

The use of insufficient volumes of reagent may lead to a false negative result and a missed diagnosis, such as syphilis.

It is possible to obtain 'valid' but inaccurate results when there is no reagent remaining in the Roche cassette.

Since we issued a notice in February 2012 (MDA/2012/004) the settings for level sensing have not been correctly encoded in some REC files, therefore level sensing may not have been correctly performed on cobas c502 analysers.

Action

Follow the required actions set out in the manufacturer's Field Safety Notice (FSN).

If you have used the affected combination of devices, consider the need to review previous results and whether to recall and retest patients.

Action by:
Laboratory managers
Directors of pathology
GUM clinics.

CAS deadlines

Action underway: **30 April 2014**
Action complete: **16 May 2014**

Contact

Technical Support Hotline
Tel: 0808 100 19 20
Email: burgesshill.technicalenquiry@roche.com

Device

Multiple tests are affected, including syphilis (TPLA) test made by Sekisui.

All reagents are supplied by Roche.

The analyser can run assays that are:

- manufactured by Roche
- manufactured by third parties and supplied by Roche – 'partnership assays' (eg TPLA)

Affected assays include those requiring manual handling that are listed in the Roche Field Safety Notice

Distribution

This MDA has been sent to:

- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- 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 (PHE) (Directors)

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 pathologists
- Clinical pathology directors
- Directors of genitourinary medicine clinics
- Medical directors
- Microbiologists
- Purchasing managers
- Risk managers

Primary care trusts

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

- Director of public health

Public Health England

Directors for onward distribution to:

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

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Independent distribution

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

This alert should be read by:

- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

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

Michael Thein / Stefanie Koehler

Tel: +49 621 759 3511

Email: dia.vigilance-eea@roche.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/012** or **2014/003/021/081/001**

Technical aspects

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

Tel: 020 3080 7271/7229

Fax: 020 8754 3965

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

Clinical aspects

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

Tel: 020 3080 7248

Fax: 020 8754 3965
Email: carol.lowry@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

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other 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 5801 Email: Haz-Aic@wales.gsi.gov.uk

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