MDA/2018/012(Wales)

Medical Device Alert

3rd May 2018

Llywodraeth Cymru
Welsh Government

Parc Cathays
Caerdydd CF10 3NQ

Cathays Park
Cardiff CF10 3NQ

BD Vacutainer® EDTA & BD Vacutainer® Lithium Heparin Tubes – risk of incorrect results for lead testing or other assays using ASV methodology

Identify affected devices, which are listed in the manufacturer's Field Safety Notice (FSN).

- Discontinue lead testing with affected devices when using assays with ASV methodology, known to be used within the Magellan LeadCare® testing systems, or any other assay employing ASV methodology. There is no requirement for customers to return affected devices to BD.
- Review previous lead test results which were performed using Magellan LeadCare® instrumentation or any other assay employing ASV methodology.
- Lead testing using Graphite furnace atomic absorption spectroscopy (GFAAS) coupled with ICP-MS are not affected by this issue and can be performed as normal with BD Vacutainer® EDTA and BD Vacutainer® Lithium Heparin tubes.
- If any adverse events occur relating to these products, please report these to MHRA via YellowCard or the relevant devolved administrations (Scotland, Wales and Northern Ireland).

Sent to:
NHS Wales Shared Services Partnership
Directors of Public Health,
Chief Executives, NHS Trusts
Chief Executives, LHBs
Medical Directors, NHS Trusts
Nurse Directors, LHBs
Executive Nurses, NHS Trusts
NHS Direct
CSSIW
Social Services
HIW

A list of people who need to have early sight of this information is given in the Notice.
This Notice has been endorsed by the Welsh Government as being relevant to NHS Wales.

Points of particular importance in Wales:

Healthcare Quality Division
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2018/012 Issued: 26 April 2018 at 15:00 Valid until: April 2019

BD Vacutainer® EDTA & BD Vacutainer® Lithium Heparin Tubes – risk of incorrect results for lead testing or other assays using ASV methodology

Summary

Manufactured by Becton Dickinson (BD) – Due to a material in the rubber stopper, affected blood collection tubes may not be compatible with assays using Anodic Stripping Voltammetry (ASV) methodology.

Action

- Identify affected devices, which are listed in the manufacturer's Field Safety Notice (FSN).
- Discontinue lead testing with affected devices when using assays with ASV methodology, known to be used within the Magellan LeadCare® testing systems, or any other assay employing ASV methodology. There is no requirement for customers to return affected devices to BD.
- Review previous lead test results which were performed using Magellan LeadCare® instrumentation or any other assay employing ASV methodology.
- Lead testing using Graphite furnace atomic absorption spectroscopy (GFAAS) coupled with ICP-MS are not affected by this issue and can be performed as normal with BD Vacutainer® EDTA and BD Vacutainer® Lithium Heparin tubes.
- If any adverse events occur relating to these products, please report these to MHRA via YellowCard or the relevant devolved administrations (Scotland, Wales and Northern Ireland).

Action by
- Laboratory Director/ Manager
- Pathologist
- Phlebotomist

Deadlines for actions
Actions underway: 11 May 2018
Actions complete: 25 May 2018
Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

Department of Health
An Roinn Sláinte
Mannystrie O Poustie
www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Problem / background

BD have published a Field Safety Notice to advise users to discontinue lead testing with affected devices when using assays with ASV methodology, known to be used within the Magellan LeadCare® testing systems, or any other assay employing ASV methodology.

BD have identified that Thiuram, a chemical in the rubber tube stopper may release sulfur gases which bind to the lead particles in the blood sample making it difficult to detect the correct amount of lead in the sample and may give false low results when using ASV methodology, used in Magellan Diagnostics' LeadCare® Testing Systems, and other assays.

BD have undertaken a programme of testing to identify if any other assays are affected by the issue identified. To date no other assays have been noted to be affected. Revised instructions for use will be made available for users to download by the 8th May 2018.

Manufacturer contacts

Lorna Darrock

Becton Dickinson
Belliver Industrial Estate
Belliver Way
Plymouth
Devon PL6 7BP

Tel: 0800 9178776
Mobile: 07769640757
Email: lorna.darrock@bd.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

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

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units
- All departments
- All staff
- All wards
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Anti-coagulation clinics
- Biochemists
- Biomedical science departments
- Cardiologists
- Clinical pathologists
- Clinical pathology directors

- Community children's nurses
- Community hospitals
- Community nurses
- Coronary care departments
- Coronary care nurses
- Day surgery units
- District nurses
- Endocrinology units
- ENT departments
- ENT medical staff
- Gastroenterology departments
- Gastro-intestinal surgeons
- General surgeons
- General surgery
- Gynaecologists
- Haematologists
- Haemodialysis nurses
- Haemodialysis units
- Hospital at home units
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- IV nurse specialists
- Minor injury units
- Maternity units
- Maxillofacial departments
- Medical directors
- Medical oncologists
- Medical oncology, directors of
- Midwifery departments
- Midwifery staff
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- NHS walk-in centres
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics departments
- Obstetrics nurses
- Oncology nurse specialists
- Orthopaedic surgeons
- Outpatient clinics
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments

- Peritoneal dialysis units
- Phlebotomists
- Point of care testing co-ordinators
- Renal medicine departments
- Renal medicine, directors of
- Special care baby units
- Staff supporting patients receiving haemodialysis at home
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Urological surgeons
- Urology departments
- Walk-in centres

Public Health England

Directors for onward distribution to:

- PHE laboratories

NHS England area teams

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

- General practitioners
- General practice managers
- General practice nurses

Independent distribution

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

- Care homes providing nursing care (adults)
- Clinics
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- 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 Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2018/012** or 2018/004/005/291/012.

Technical aspects

Jonathan Fox, MHRA
Tel: 020 3080 7030
Email: jonathan.fox@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA
Tel: 020 3080 7274

Email: dct@mhra.gov.uk

Reporting adverse incidents in England
Through Yellow Card https://yellowcard.mhra.gov.uk/

Northern Ireland
Alerts in Northern Ireland are distributed via the NICAS system.

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

Northern Ireland Adverse Incident Centre, CMO Group,
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk
https://www.health-ni.gov.uk/niaic

Reporting adverse incidents in Northern Ireland
Please report directly to NIAIC using the forms on our website.

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

Incident Reporting and Investigation Centre, Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

Reporting adverse incidents in Scotland
NHS Boards and Local Authorities in Scotland – report to Health Facilities Scotland.

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to Health Facilities Scotland.

Private facilities providing care to private clients report to the Care Inspectorate and MHRA.

Wales
Enquiries in Wales should be addressed to:
Healthcare Quality Division, Welsh Government

Tel: 02920 823 624 / 02920 825 510

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

Reporting adverse incidents in Wales
Report to MHRA through Yellow Card https://yellowcard.mhra.gov.uk/ and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).