MDA/2018/033(Wales)

Medical Device Alert

10 October 2018

Parc Cathays
Caerdydd CF10 3NQ

Llywodraeth Cymru
Welsh Government

Cathays Park
Cardiff CF10 3NQ

Device: CoaguChek Test Strips for Point of Care and Home Use – risk of false high results

- Identify the affected strips listed in the manufacturer's Field Safety Notice (FSN) and follow the instructions provided.
- For the affected test strips, confirm all INR results above 4.5 using a laboratory method or unaffected test strips. Increase testing frequency after therapy changes in line with local guidelines.
- Identify patients who use these devices at home and ensure they have received and understood the content of the manufacturer's consumer letter.
- Ensure that all relevant members of staff receive the manufacturer's FSN and that they understand the problem and actions to be taken.
- Report adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to manufacturers if your local or national systems do not.

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/2018/033 Issued: 08 October 2018 at 14:00 Valid until: October 2019

CoaguChek Test Strips for Point of Care and Home Use – risk of false high results

Summary

Manufactured by Roche Diagnostics GmbH: affected CoaguChek test strips may give false high results for INR values above 4.5 when compared to laboratory results, this may lead to incorrect treatment decisions

Action

- Identify the affected strips listed in the manufacturer's Field Safety Notice (FSN) and follow the instructions provided.
- For the affected test strips, confirm all INR results above 4.5 using a laboratory method or unaffected test strips. Increase testing frequency after therapy changes in line with local guidelines.
- Identify patients who use these devices at home and ensure they have received and understood the content of the manufacturer's consumer letter.
- Ensure that all relevant members of staff receive the manufacturer's FSN and that they understand the problem and actions to be taken.
- Report adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to manufacturers if your local or national systems do not.

Action by:
- People responsible for anti-coagulation therapy clinics.
- All medical and nursing staff who use these devices or who are responsible for patients with these devices.

Deadlines for actions
Actions underway: 15 October 2018
Actions complete: 22 October 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
Männystrie O Poustie
www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Device details

Roche has shown that the following products and lot numbers are affected by this issue:

Product	Lot Number (first six digits, as below)
• CoaguChek XS PT Test PST	from 272167xx up to 334498xx
• CoaguChek XS PT Test	from 272167xx up to 334498xx
• CoaguChek PT Test	from 272170xx up to 353606xx

These devices are used in anti-coagulation clinics in hospitals and other non-clinical settings. They are also used by GPs, district nurses and patients at home.

Problem / background

Roche Diagnostics has found an increasing positive bias with INR values above 4.5 for certain CoaguChek test strips. For INR values above 4.5 a medical risk of increased bleeding or thrombosis, due to inadequate therapeutic measures, cannot be excluded.

The root cause is multifactorial. The detailed root cause analysis is still ongoing.

Users are advised to confirm INR results above 4.5 by a laboratory method (venous blood sample) or unaffected CoaguChek test strips until replacement lots are available. Roche has confirmed that the impacted test strip lots can be used for results between 0.8 to 4.5 INR.

MHRA is issuing this Medical Device Alert to make sure users know about this problem, are aware of the follow up FSN issued by Roche and know what updated actions to take. The follow up FSN replaces the one dated 22 August 2018.

Roche has indicated that the following new lots, which are unaffected by this issue, are expected to be available to order in early/mid October 2018 for supply to the UK market in November 2018.

First new lots which are unaffected by this issue (available in November 2018):

- CoaguChek XS PT PST Test, lots beginning with 334499xx
- CoaguChek XS PT Test, lots beginning with 334499xx
- CoaguChek PT Test, lots beginning with 361433xx

Manufacturer contacts

Roche Diagnostics
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

Tel (Patients): 0808 100 7666
Tel (Technical Support Hotline UK - HCP): 0808 100 1920

Email (Patients): burgesshill.coagpts@roche.com
Email (HCP): burgesshill.tsgpm@roche.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
- Anti-coagulation clinics
- Biochemists
- Biomedical science departments
- Cardiac laboratory technicians
- Cardiac pacing technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Chief pharmacists
- Clinical governance leads
- Clinical pathologists
- Clinical pathology directors
- Community hospitals
- Community nurses
- Coronary care departments
- Coronary care nurses
- Day surgery units
- District nurses
- Equipment stores
- Equipment libraries and stores
- General surgeons
- General surgery
- General surgical units, directors of
- Haematologists
- Health and safety managers
- Health visitors
- Hospital at home units
- Hospital pharmacies
- Hospital pharmacists
- Minor injury units
- Medical directors
- NHS walk-in centres
- Occupational health departments
- Outpatient clinics
- Outpatient theatre managers
- Outpatient theatre nurses
- Paediatricians
- Paediatric cardiologists
- Paediatric nephrologists

- Paediatric rheumatologists
- Paediatrics haematologists
- Paramedics
- Pharmacists
- Point of care testing co-ordinators
- Staff supporting patients receiving haemodialysis at home
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Walk-in centres

Public Health England

Directors for onward distribution to:

- Heads of health, safety and quality
- Risk manager
- Safety officers

NHS England area teams

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

- Community pharmacists
- General practitioners
- Occupational health departments
- General practice managers
- General practice nurses

Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Loan store managers
- Loaned equipment store managers
- Occupational health departments

Independent distribution

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

- Adult placement
- Care homes providing nursing care (adults)
- Clinics
- Hospices
- 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/2018/033** or **MHRA Ref: 2018/008/023/291/010.**

Technical aspects
Emma Harris, MHRA
Tel: 020 3080 6685
Email: emma.harris@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).