



Medical Device Alert

15th February 2018

**Llywodraeth Cymru
Welsh Government**

Parc Cathays
Caerdydd CF10 3NQ

Cathays Park
Cardiff CF10 3NQ

Roche Tissue Diagnostics (Ventana Medical Systems) – OptiView DAB IHC Detection Kit, UltraView Universal DAB Detection Kit, OptiView Amplification Kit and Hematoxylin II – Dispenser failure of Hematoxylin II and Horseradish Peroxidase reagents.

- Ensure all relevant members of staff receive the manufacturer's [Field Safety Notice](#), and that they understand the problem and the actions to be taken.
- Affected lots may only be used if same slide controls are used.
- Users who do not use same slide controls should not use affected lots, and are advised to destroy affected kits, and request replacement kits from the manufacturer.
- The use of appropriate same slide controls is highly recommended as it helps ensure the efficacy of all Immunohistochemistry (IHC) assays carried out on every slide on an automated IHC instrument.
- Consider the need to review previous test results obtained using affected lots.

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**



Medical Device Alert

MDA/2018/005

Issued: 15 February 2018 at 11:30

Valid until: February 2019

Roche Tissue Diagnostics (Ventana Medical Systems) – OptiView DAB IHC Detection Kit, UltraView Universal DAB Detection Kit, OptiView Amplification Kit and Hematoxylin II – Dispenser failure of Hematoxylin II and Horseradish Peroxidase reagents.

Summary

Roche Tissue Diagnostics (Ventana Medical Systems) – Leaking and sticking reagent dispensers may cause weak staining on tissue samples, which may lead to false negatives and misdiagnosis.

Action

List action(s) here. Make sure they make sense with the deadlines below.

- Ensure all relevant members of staff receive the manufacturer's [Field Safety Notice](#), and that they understand the problem and the actions to be taken.
- Affected lots may only be used if same slide controls are used.
- Users who do not use same slide controls should not use affected lots, and are advised to destroy affected kits, and request replacement kits from the manufacturer.
- The use of appropriate same slide controls is highly recommended as it helps ensure the efficacy of all Immunohistochemistry (IHC) assays carried out on every slide on an automated IHC instrument.
- Consider the need to review previous test results obtained using affected lots.
- If any adverse event occurs relating to this issue, please report this to MHRA via [Yellow Card](#) or the relevant devolved administrations (Scotland, Wales and Northern Ireland).

Action by

- Directors of pathology
- Laboratory managers
- Lead biomedical scientists (Cytologists / Histologists)
- Purchasing Managers
- Oncologists
- General Surgeons

Deadlines for actions

Actions underway: 01 March 2018

Actions complete: 15 March 2018

Device details

Dispenser issues with Hematoxylin II and Horseradish Peroxide Reagents which are used in the following kits:

Product Name	Roche DMS	Lots
OptiView DAB Detection Kit	06396500001	Y19271, Y11625, Y15571
OptiView Amplification Kit	06396518001	Y15435, Y19322, Y22447
UltraView Universal DAB Detection Kit	05269806001	Y09284, Y15384, Y18099, Y22153, Y11687, Y17984, Y19302, Y11716, Y18069
Hematoxylin II	05277965001	Y10759, Y17402, Y21312, Y13938, Y17403

Problem / background

The manufacturer has informed the MHRA of increased customer complaints reporting leaking and sticking of the reagent dispenser, which could result in the failure of a reagent critical to the staining reaction (light or absent staining).

These devices are used to detect markers in a range of pathological conditions including those associated with cancer (e.g. HER2, ER/PR, ALK and PD-L1).

As a consequence, there is a risk of false negative results (e.g. with all companion diagnostics such as HER2 tests) affecting clinical decisions for patients, due to commence treatment.

Manufacturer contacts

Roche Diagnostics Ltd
 Charles Avenue
 Burgess Hill
 West Sussex RH15 9RY
 Registration Number: 571546
 Technical Support Hotline
 UK: 08081001920
 Email: emea.tcceurope@roche.com

Distribution

- Public Health England (for information)

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:

- Biomedical science departments
- Clinical governance leads
- Clinical pathologists
- Clinical pathology directors

- General surgeons
- Medical directors
- Medical oncologists
- Medical oncology, directors of
- Radiation & medical oncology departments
- Risk managers
- Equipment stores
- Supply managers

Independent distribution

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

- Private medical practitioners
- Independent treatment centres
- 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.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2018/005** or 2017/012/022/291/012

Technical aspects

Bina Mackenzie, MHRA Tel: 0203 080 7229 Email: Bina.Mackenzie@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 Fax: 0131 314 0722

Email: nss.irc@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 \(Wales\)](#).