Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2018/029 Issued:13 September 2018 at 14:00 Valid until: September 2019

BenchMark Automated Slide Stainer series – FLO LOK III Reagent Dispenser Issue for IHC and ISH kits including INFORM HPV III Family 16 Probe (B).

Summary

Roche (Ventana Medical Systems) has released an expansion of products affected by the reagent dispenser issues causing weak staining and the potential for false negative results and misdiagnosis.

Action

- Ensure all relevant members of staff have received the Field Safety Notice and the actions required are taken.
- For users who have the affected INFORM HPV III kit (lot Y19417):
  - No replacement kits are currently available
  - Clinical testing can continue, but only with same slide controls.
  - Contact the manufacturer to discuss the best alternative or send testing to another laboratory.
- Ensure all remaining listed products are not used for clinical testing, replacement kits are now available from the manufacturer.
- The use of appropriate same slide controls is highly recommended as it helps ensure the efficacy of all IHC and ISH assays carried out on every slide on automated instruments.
- Users who have not used same slide controls should consider a review of previous test results obtained using the affected lots.
- 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

- Directors of pathology
- Laboratory Managers
- Consultant Histopathologists
- Lead Biomedical Scientists (Cytologists/Histologists)
- Purchasing managers
- Oncologists
- General Surgeons

Deadlines for actions

Actions underway: 27 September 2018
Actions complete: 18 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

In addition to the Field Safety Notice which details affected products, please refer to the spreadsheet which accompanies this MDA for additional unique device identification information.

Product Name	Expanded Affected Lots	Previously Communicated Lots
OptiView DAB IHC Detection Kit	Y24225, Y25760, E00119	Y19271, Y11625, Y15571
ULTRAVIEW UNIVERSAL DAB DETECTION KIT	Y22147, Y25695	Y09284, Y15384, Y18099, Y22153, Y11687, Y17984, Y19302, Y11716, Y18069
iView DAB Detection Kit	Y24245	Y11834
ultraView SISH Detection Kit	None	Y15133
OptiView Amplification Kit	None	Y15435, Y19322, Y22447
OptiView Amplification Kit (250 Test)	Y26282	Y19318
ultraView SISH DNP Detection Kit	Y26299	Y17990
Hematoxylin II	None	Y10759, Y13938, Y17402, Y17403, Y21312
ISH iVIEW Blue Plus Detection Kit	Y15410, Y24365	
ANTI-PAN KERATIN Primary Antibody, 25mL	Y21610	
ultraView Universal Alkaline Phosphatase Red Detection Kit	Y15071, Y18053, Y22469	
ISH Protease 3	Y13927, Y18872, Y22569, Y25883	
CONFIRM anti-Progesterone Receptor (PR) (1E2) Rabbit Monoclonal Primary Antibody	Y12992, Y18852, Y23051	
CONFIRM anti-Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody	Y18586, Y24472	
VENTANA ISH iView Blue Detection Kit	Y15105, Y22455	
INFORM HPV III Family 16 Probe (B)	Y19417	
VENTANA anti-Helicobacter Pylori (SP48) Rabbit Monoclonal Primary Antibody	Y24119	
CINtec p16 Histology (250) CE	Y16507, Y23040	

Problem / background

MHRA issued a Medical Device Alert in February 2018 alerting users to reagent dispenser issues which could lead to weak or absent staining of tissue samples.

The investigation identified the root cause was due to an inadequate application of oil in the manufacturing process. This has now been corrected.

These devices are used to detect markers in a range of pathological conditions including those associated with cancer (e.g. HPV, 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

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 pathologists
- Clinical pathology directors
- Colposcopy departments
- General surgeons
- Gynaecologists
- Gynaecology departments
- Medical directors
- Medical oncologists
- Medical oncology, directors of
- Purchasing managers
- Radiation & medical oncology departments
- Risk managers
- Supplies managers

Independent distribution

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

- Hospitals in the independent sector
- Independent treatment centres
- 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/2018/029** or 2018/008/009/291/020.

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).