HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Dispenser Issues with FLO-LOK III Dispenser

Priority 1 – For Immediate Action

HPRA Safety Notice: SN2018(27) **Issue Date: 15 August 2018**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Ventana Medical Systems Inc. (also known as Roche Tissue Diagnostics outside the USA)	V34208 & V36721

ISSUE
Ventana Medical Systems Inc. / Roche Tissue Diagnostics has issued a follow-up field safety notice (FSN) to advise customers of the expansion of a field safety corrective action (FSCA) first notified to the Irish market in January 2018. The initial FSCA only impacted Horseradish Peroxidase (HRP) and Hematoxylin II (Hem II) dispensers. The follow-up FSN includes an expanded list of products and indicates that the issue is not specific to HRP and Hem II dispensers. In the worst case, this failure mode could result in a complete or partial dispense failure of a reagent critical to the staining reaction. Please refer to the accompanying follow-up FSN dated 13th August 2018 (FSN3) for an expanded list of affected products and lots. This FSN supersedes the FSNs dated 21st December 2017 (FSN1) and 25th January 2018 (FSN2). This Safety Notice supersedes the Safety Notice issued by the HPRA in January 2018, SN2018(1).

ACTION OR RECOMMENDATIONS

The HPRA advises that healthcare professionals:

1. Refer to the accompanying follow-up FSN (FSN3) and follow the instructions provided. Pay particular attention to the **Action Required** section '***Actions to be taken by the customer/user*'.**
2. Acknowledge receipt of the follow-up FSN (FSN3) if you have not already done so.
3. Forward a copy of this safety notice and the follow-up FSN (FSN3) to all relevant personnel within your organisation and to any other organisations/persons to which/whom these devices have been transferred.
4. Report any concerns regarding these devices and this issue to the manufacturer and the HPRA.

TARGET GROUPS

Hospital Managers / CEOs
Histopathology Departments
Histology Departments
Medical Scientists
Laboratory Managers
Laboratory Technicians
Laboratory Staff
Clinical Directors
Purchasing Managers
Supplies Managers
Risk Managers

BACKGROUND

Roche has completed its root cause investigation into increased customer complaints reporting leaking and sticking reagent dispensers and has concluded that the issue is not restricted to HRP and HEM II dispensers, as previously communicated. The expanded list of products and lots is provided in the accompanying follow-up FSN (FSN3).

As stated in our previous Safety Notice SN2018(1), products impacted by FSN1 were supplied to the Irish market between 21st September 2017 and 20th December 2017. Roche has advised that products impacted by the follow-up FSN (FSN 3) were supplied to the Irish market between 28th November 2017 and 23rd May 2018.

The follow-up FSN (FSN3) advises that if an affected product is found by the user, it should not be used for clinical testing nor should any remaining dispensers from lots listed in the "Previously Communicated Lots" column be used for clinical testing. FSN3 also states that '*Newly manufactured products from the affected list are now readily available and should be used in place of affected product lots*'.

Roche has since advised the HPRA that alternative lots of all affected products, which are not affected by this issue, are available, with the exception of **INFORM HPV III Family 16 Probe (B)**. Due to this conflicting information, Roche has committed to issuing an updated FSN in the coming days to provide instructions to users of the **INFORM HPV III Family 16 Probe (B)** product. In the interim, users of this product are asked to contact Roche for advice on the use of this product.

Please refer to the accompanying follow-up FSN dated 13th August 2018 (FSN3) for further information. A total of 3 FSNs have been issued to date regarding this issue, all FSNs are included for reference.

The HPRA is issuing this safety notice to raise awareness of this issue and will communicate further on this issue if necessary.

MANUFACTURER CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Roche Diagnostics
Charles Avenue
Burgess Hill
West Sussex RH15 9RY
United Kingdom

Telephone: 1800-40-95-64
E-mail: EMEA.tcceurope@roche.com

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie