

# Safety Notice

## Medical Devices

### Dispenser Issues with Hematoxylin II and Horseradish Peroxidase Reagents

#### Priority 2 – Warning

HPRA Safety Notice: SN2018(01)

Issue Date: 12 January 2018

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

#### ISSUE

Ventana Medical Systems Inc. / Roche Tissue Diagnostics has received increased customer complaints reporting leaking and sticking reagent dispensers. These reports are currently focused on horseradish peroxidase (HRP) dispensers (part of the iView, ultraView and OptiView detection kits, as well as CINtec PLUS Cytology Kit) and Hematoxylin II.

A field safety notice (FSN) has been issued to emphasise the importance of following specific instructions in order to avoid potentially erroneous results. In the worst case, this failure mode could result in a complete or partial dispense failure of a reagent critical to the staining reaction (e.g. ultraView or OptiView HRP).

## ACTION OR RECOMMENDATIONS

The HPRA advises that healthcare professionals:

1. Refer to the accompanying FSN and follow the instructions provided.
2. Acknowledge receipt of the FSN if you have not already done so.
3. Forward a copy of this safety notice and the FSN 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 advised that affected kits were supplied to the Irish market between the 21<sup>st</sup> September 2017 and the 20<sup>th</sup> December 2017. The FSN advises that customers may continue to use affected kits until corrected product is available and specific instructions are provided to avoid potentially erroneous results.

Roche has also advised that unaffected kits for the following products are available for supply to Irish customers as follows:

Product	Available from
05269806001 - UltraView Universal DAB Detection Kit	4 <sup>th</sup> January 2018
05277965001 - Hematoxylin II	12 <sup>th</sup> January 2018
06396500001 - OptiView IHC DAB Detection Kit	12 <sup>th</sup> January 2018
06396518001 - OptiView Amplification Kit	Estimated date of availability for this product is 26 <sup>th</sup> January 2018

Please refer to the attached FSN for further information.

## 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: [burgesshill.technicalenquiry@roche.com](mailto:burgesshill.technicalenquiry@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](mailto:devicesafety@hpra.ie)  
Website: [www.hpra.ie](http://www.hpra.ie)