URGENT FIELD SAFETY NOTICE
IMMEDIATE ACTION REQUIRED

Ref No: **TD FSN SBN-RTD-2017-001 Version 2**

Date: **25/01/2018**

Type of Action: Field Safety Corrective Action

Reason for version 2 Production Identifier table includes only products distributed in UK and Ireland
Update to include information regarding re-worked lots

Product	GMMI	Lot No.
OptiView DAB IHC Detection Kit	06396500001	See Below
ultraView DAB IHC Detection Kit	05269806001	See Below
OptiView Amplification Kit	06396518001	See Below
Hematoxylin II	05277965001	See Below

Software Version: All Software Versions

Production Identifier
(Lot No./Serial No.)

Product Name:	Roche DMS:	Lot(s):
OptiView DAB IHC Detection Kit	06396500001	Y19271 Y11625 Y15571
*ultra*View Universal DAB Detection Kit	05269806001	Y09284 Y15384 Y18099 Y22153 Y11687 Y17984 Y19302 Y11716 Y18069
OptiView Amplification Kit	06396518001	Y15435 Y19322 Y22447
Hematoxylin II	05277965001	Y10759 Y17402 Y21312 Y13938 Y17403

Summary of Issue

Dispenser Issues with Hematoxylin II and Horseradish Peroxidase reagents

Reason for Notice

Dear Valued Customer,

Ventana Medical Systems, Inc. (also known as Roche Tissue Diagnostics (RTD) outside the US) has reworked lots of reagent dispensers (referenced in the table below) that were originally included in the list of affected products above. The lots in the table below remained in Roche control and were not distributed previously to customers.

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West Sussex
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Therefore they have been removed from the list of affected product above. All lots have been reworked using a validated procedure and passed final acceptance testing prior to shipping to customers.

Customers can use the lots in table below. RTD always recommends the use of same slide controls.

Product Name:	Roche DMS:	Lot(s):
ultraView Universal DAB Detection Kit	05269806001	Y22147
OptiView DAB IHC Detection Kit	06396500001	Y24225
Hematoxylin II	05277965001	Y22561

We would like to emphasize the importance of following the instructions described in this letter 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). This in turn could result in light or absent staining, which, discounting any mitigations (see below), could have the following health consequences:
Immediate: Diagnostic confusion leading to delay in diagnosis or in the worst case, false negative staining could lead to a false negative diagnosis.
Long Range: In the worst case, a diagnostic error such as a false negative companion diagnostic assay (e.g. HER2) could lead to delay in treatment or inappropriate treatment that, depending on the duration of the delay, could impact patient survival.

Description of Situation

Ventana Medical Systems, Inc. (Ventana, also known as Roche Tissue Diagnostics (RTD) outside the US) has received increased customer complaints reporting leaking and sticking reagent dispensers. These reports are currently focused on horseradish peroxidase (HRP) dispensers (part of the, ultraView and OptiView detection kits) and with Hematoxylin II. Ventana has identified the cause of the issue, and is working to correct it. Additionally, Ventana has mandated specific requirements for same slide controls, detailed below, for customers with affected product in inventory.

Actions taken by Roche Diagnostics

All affected product has been placed on hold. Ventana has reworked all product in its inventory and is in the process of manufacturing new lots for distribution and replacement of customer affected kits.

Action Required

- Affected kits may continue to be used by customers until corrected product is available, however Ventana is mandating that the affected IHC detection kits (ultraView, OptiView) must only be used in conjunction with same-slide controls. These controls must be appropriate for each assay and capable of detecting false negative results due to a complete or partial reagent dispense failure.

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- In order to reduce the risk of this issue impacting patient care, customers not using same slide controls as a standard practice should follow their local procedures and policies regarding retrospective retesting, especially for IHC assays and cases that do not contain a biologic internal control. Any retesting should be limited to assays performed with the affected lots.

Communication of this Field Safety Notice (if appropriate)

This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the potentially affected devices have been distributed/supplied.
The undersigned confirms that this notice has been provided to the appropriate Regulatory Agency.
We apologize for any inconvenience this may cause and hope for your understanding and your support.

Please complete and return the TD FSN SBN-RTD-2017-001 Version 2 Acknowledgement Form which accompanies this TD FSN SBN-RTD-2017-001 Version 2 by **the 9th of February 2018.**

Please bring this notice to the attention of all personnel in your hospital or Health Care facility who need to be aware of this safety issue.

If you have forwarded the affected product(s) listed above to another laboratory, please provide a copy of this notice to them.

Attachments TD FSN SBN-RTD-2017-001 Version 2 Acknowledgement Form

This action is being conducted with the knowledge of the Medicines and Healthcare Products Regulatory Agency (MHRA), the Health Products Regulatory Authority (HPRA), and other International Regulatory Agencies.

Roche Diagnostics operates a vigilance system that complies with the IVD Directive 98/79 EC

A copy of this notice can also be found on the Roche Dialog Portal

If you require any further information please contact our

Technical Support Hotline

UK: 0808 100 19 20
Ireland: 1800 40 95 64

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