URGENT FIELD SAFETY NOTICE
IMMEDIATE ACTION REQUIRED

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

Date: **21/12/2017**

Type of Action: Field Safety Corrective Action

Product	GMMI	Lot No.
OptiView DAB IHC Detection Kit	06396500001	See Below
ultraView DAB IHC Detection Kit	05269806001	See Below
iView DAB IHC Detection Kit	05266157001	See Below
ultraView SISH Detection Kit	05271967001	See Below
ultraView SISH DNP Detection Kit US	05572037001	See Below
CINtec PLUS Cytology Kit (CE-IVD)	06889565001	See Below
CINtec PLUS Cytology Kit (Canada/Japan)	06889549001	See Below
OptiView Amplification Kit	06396518001	See Below
OptiView Amplification Kit (250 Test)	06718663001	See Below
Hematoxylin II	05277965001	See Below
ultraView SISH DNP Detection Kit	05907136001	See Below
NEXES VEN IVIEW DAB DET KT JPN-US EXPORT	05266084001	See Below
CINtec PLUS Cytology Kit (US-Export)	06889549001	See Below

System Affected: **Benchmark GX, Benchmark XT, Benchmark Ultra**

Software Version: All Sofware Versions

Product Name:	Roche DMS:	Lot(s):
OptiView DAB IHC Detection Kit	06396500001	Y19271 Y11625 Y24225 Y15571
*ultra*View Universal DAB Detection Kit	05269806001	Y09284 Y15384 Y18099 Y22153 Y11687 Y17984 Y19302 Y11716 Y18069 Y22147
*i*View DAB Detection Kit	05266157001	Y11834 Y24245
*ultra*View SISH Detection Kit	05271967001	Y15133
*ultra*View SISH DNP Detection Kit US	05572037001	Y15146
CINtec *PLUS* Cytology Kit (CE-IVD)	06889565001	Y14122 Y18107

Roche Diagnostics
Charles Avenue
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CINtec *PLUS* Cytology (Canada/Japan)	06889549001	Y22162 Y15546
OptiView Amplification Kit	06396518001	Y15435 Y19322 Y22447
OptiView Amplification Kit (250 Test)	06718663001	Y19318
Hematoxylin II	05277965001	Y10759 Y17402 Y21312 Y13938 Y17403 Y22561
*ultra*View SISH DNP Detection Kit	05907136001	Y17990
NEXES VEN IVIEW DAB DET KT JPN-US EXPORT	05266084001	Y15392

Summary of Issue

Dispenser Issues with Hematoxylin II and Horseradish Peroxidase reagents

Reason for Notice

Dear Valued Customer,

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 iView, ultraView and OptiView detection kits, as well as CINtec PLUS Cytology Kit) 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.

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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. Customers will be notified when corrected product is available.

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 (iView, 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. CINtec PLUS Cytology does not have the capacity for same slide controls, so system-level controls should be maintained. ultraView SISH Detection is used for HER2 analysis, and employs internal positive controls; no external control is required. For assays that directly relate to clinical therapy decision making (e.g. ER/PR, HER2, ALK, etc.), it is additionally important to select a same slide positive control tissue with sufficient sensitivity to detect small decreases in intensity that may cause borderline positive cases to appear as negative (e.g. HER2 2+ vs. 1+). Although the use of same slide controls is considered optimal laboratory practice and strongly recommended by Ventana, customers may revert to standard run controls once non-impacted product is received.

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.

Please complete and return the TD FSN SBN-RTD-2017-001 Acknowledgement Form which accompanies this TD FSN SBN-RTD-2017-001 by **the 5th of January 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 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

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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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