Urgent Field Safety Notice

SBN-RTD-2017-001

RTD / Reagents
Version 3
17-Jan-2018

Dispenser Issues with Hematoxylin II and Horseradish Peroxidase reagents

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

Production Identifier (Lot No./Serial No.)

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
CINtec *PLUS* Cytology (Canada/Japan)	06889549001	Y22162 Y15546

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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

Type of Action **Field Safety Corrective Action**

Dear Valued Customer,

Recently we communicated with you about a necessary field action to address potential sticking and leaking dispensers containing horseradish peroxidase (HRP) and Hematoxylin II. In that communication we advised of specific lots of product that should only be utilized with a same slide control. There were six affected lots (see chart below) that were referenced in the original communication; however these lots remained in Roche control. Three of these lots were reworked for global availability, while three others were reworked for limited availability to customers served by the Roche distribution hub in Mannheim, Germany.

Product Name:	**Roche DMS:**	**Lot(s):**	**Availability**
iView DAB Detection Kit	05266157001	Y24245	Global
ultraView Universal DAB Detection Kit	05269806001	Y22147	RDG (Mannheim) served customers only
OptiView DAB IHC Detection Kit	06396500001	Y24225	RDG (Mannheim) served customers only
Hematoxylin II	05277965001	Y22561	RDG (Mannheim) served customers only
*ultra*View SISH Detection Kit	05271967001	Y15133	Global
CINtec *PLUS* Cytology Kit (CE-IVD)	06889565001	Y18107	Global

Customers may use these lots; however, RTD always recommends the use of same slide controls.

We thank you for your understanding in this and apologize for any confusion you might have experienced.

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.

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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.

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.

Actions to be taken by the customer/user

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.

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.

Best Regards,

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Contact Details

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