

Field Safety Notice

SBN-RTD-2017-001

RTD / Reagents
Version 2
21-Dec-2017

Dispenser Issues with Hematoxylin II and Horseradish Peroxidase reagents

Product Name	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

Production Identifier (Lot No./Serial No.)

Product Name:	Roche DMS:	Lot(s):
OptiView DAB IHC Detection Kit	06396500001	Y11625 Y15571 Y19271 Y24225
ultraView Universal DAB Detection Kit	05269806001	Y09284 Y18099 Y11687 Y18069 Y11716 Y19302 Y15384 Y22147 Y17984 Y22153
iView DAB Detection Kit	05266157001	Y11834 Y24245 No affected lot in Singapore

Dispenser Issues with Hematoxylin II and Horseradish Peroxidase reagents

<i>ultraView</i> SISH Detection Kit	05271967001	Y15133 No affected product in Singapore
<i>ultraView</i> SISH DNP Detection Kit US	05572037001	Y15146 No affected product in Singapore
CINtec <i>PLUS</i> Cytology Kit (CE-IVD)	06889565001	Y14122 Y18107 No affected lot in Singapore
CINtec <i>PLUS</i> Cytology (Canada/Japan)	06889549001	Y22162 No affected product in Singapore
OptiView Amplification Kit	06396518001	Y15435 Y19322 Y22447
OptiView Amplification Kit (250 Test)	06718663001	Y19318 No affected product in Singapore
Hematoxylin II	05277965001	Y10759 Y13938 Y17402 Y17403 Y21312 Y22561
<i>ultraView</i> SISH DNP Detection Kit	05907136001	Y17990 No affected lot in Singapore
NEXES VEN IVIEW DAB DET KT JPN-US EXPORT	05266084001	Y15392 No affected product in Singapore

Type of Action

Field Safety Corrective Action

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.

Dispenser Issues with Hematoxylin II and Horseradish Peroxidase reagents

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.

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+).

For Hematoxylin II, if the slide fails to receive hematoxylin, it should either be repeated or counterstained manually.

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.

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.

Dispenser Issues with Hematoxylin II and Horseradish Peroxidase reagents

Communication of this Field Safety Notice

This notice must be passed on to all those who need to be aware within your organization or to any other organization/individual where the potentially affected devices have been distributed/supplied. Please pass on this notice to the Chairman Medical Board and Head of Department as well, as required by HSA.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action

We apologize for any inconvenience this may cause and hope for your understanding and your support.

Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd
Email: sg.regulatory@roche.com

Field Safety Notice

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Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd

Email: sg.regulatory@roche.com