Field Safety Notice

May 18, 2011

Product name	Part number
*ultra*View Universal DAB Detection Kit	760-500 (05269806001)
*i*View Universal DAB Detection Kit	760-091 (05266157001)

FSCA identifier: **GC-0419618** (2028492-5/16/11-001C)

Action: **Advise on use of a Medical Device**

Date: 18 May 2011
Attention: Customer/User of *ultra*View and *i*View DAB Universal Detection Kit

Dear Valued Customer,

As part of our ongoing commitment to product quality Ventana Medical Systems, Inc. (Ventana), has identified the presence of precipitate in some DAB chromogen dispensers in two lots of *ultra*View Universal DAB Detection Kit (part number 760-500 / 05269806001). Precipitates themselves do not affect staining. However, precipitates may partially or fully occlude the dispenser which may cause low or no drop volumes on some slides which could result in false negative results.

Advice on action to be taken:
Ventana has identified a solution to this issue and will notify all customers upon implementation. Until that time, as an added precaution, we request that you conduct visual inspection of any DAB chromogen dispensers in use as part of your daily maintenance routine. Visual inspection can be done by gently inverting the dispenser then holding vertically to a light source to inspect for precipitate matter in all parts of the dispenser. Please notify your local customer support team (*phone number*) if you find a dispenser containing precipitate in lots not identified in this letter. Additionally, Ventana highly recommends use of same-slide controls, especially when testing for targets of therapy, to mitigate any impact on patient results.

We apologize for any inconvenience this issue may cause you and your staff. We thank you for your understanding and for your continued partnership.

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (If appropriate)

Ventana Medical Systems, Inc. 1910 E. Innovation Park Drive Tucson, Arizona 85755 Phone: +1 520 887 2155 www.ventana.com

Yours sincerely,

[redacted]
Director, Quality Systems

Ventana Medical Systems, Inc.
A *Member of the Roche Group*

URGENT Field Safety Notice

May 18, 2011

Product name	Part number	Lot number
*ultra*View Universal DAB Detection Kit	760-500 (05269806001)	A05885
*ultra*View Universal DAB Detection Kit	760-500 (05269806001)	B00988

FSCA identifier: **GC- 0419618** (2028492-5/16/11-001R)

Action: **Return of a Medical Devise**

Date: 18 May 2011
Attention: Customer/User of *ultra*View DAB Universal Detection Kit

Dear Valued Customer,

As part of our ongoing commitment to product quality Ventana Medical Systems, Inc (Ventana), has identified the presence of precipitate in DAB chromogen dispensers associated with the following lots of VENTANA *ultra*View DAB detection kits:

Product name	Part number	Lot number
*ultra*View Universal DAB Detection Kit	760-500 (05269806001)	A05885
*ultra*View Universal DAB Detection Kit	760-500 (05269806001)	B00988

Our records indicate your laboratory has received one or more kits from these lots. Per our investigation not all DAB chromogen dispensers are affected with precipitate and the precipitate itself does not affect staining. However, precipitate may partially or fully occlude the dispenser which may cause low or no drop volumes. Dispenser occlusion may result in light to no staining on some slides which could result in false negative results.

Action to be taken:
Ventana requests that you discontinue use of any kits from the lots identified above. If your laboratory has already used kits from these lots we request you follow your internal standard operating procedures for assessing potential impact to reported patient results. Please inspect

your current inventory and contact your local customer support team (*phone number*) to replace any unused or partially used kits from the affected lots.

Ventana has identified a solution to this issue and will notify all customers upon implementation. Until that time, as an added precaution, we request that you conduct visual inspection of any DAB chromogen dispensers in use as part of your daily maintenance routine. Visual inspection can be done by gently inverting the dispenser then holding vertically to a light source to inspect for precipitate matter in all parts of the dispenser. Please notify your local customer support team (*phone number*) if you find a dispenser containing precipitate in lots not identified in this letter. Additionally, Ventana highly recommends use of same-slide controls, especially when testing for targets of therapy, to mitigate any impact on patient results.

Transmission of this Field Safety Notice:
This notice should be passed on to all of those within your organization that need to be aware, or to any organization where the potentially affected devices have been transferred.

We apologize for any inconvenience this issue may have caused you and your staff. Your continued partnership is important to us. We thank you for cooperation with this issue and for your understanding and patience as we implement a solution.

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (If appropriate).

Yours sincerely,

[redacted]
Director, Quality Systems

Ventana Medical Systems, Inc.
A *Member of the Roche Group*