

## **Resolution for Urgent Field Safety Notice – Dimension Vista IRON**

**13-47****June 2013****Dimension Vista® Systems****IRON Flex® reagent cartridge (K3085 SMN 10445135)****Resolution to Potential Falsely Elevated Results due to Environmental Contamination**

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Our records indicate that you have or may have received the following product:

<b>Assay</b>	<b>Catalog Number</b>	<b>Siemens Material Number (SMN)</b>	<b>Lot Number</b>
<b>Dimension Vista® IRON Flex® reagent cartridge</b>	<b>K3085</b>	<b>10445135</b>	<b>All lots</b>

Siemens is pleased to announce that, with Vista Software Version 3.6, a Reagent QC has been added to the Dimension Vista® IRON method. The reagent QC check is performed on each well set in the IRON Flex® reagent cartridge, prior to test processing, to detect environmental iron contamination. If contamination is detected, the well set will not be used for test processing. The reagent QC check will support the removal of the batch testing protocol implemented via Siemens Urgent Field Safety Notice 12-49 issued in September, 2012.

The IRON Reagent QC error limit is in the form of a Result Monitor which must be enabled to support the removal of the batch testing protocol.

**Background:**

Siemens previously communicated, in Urgent Field Safety Notice 12-49, the potential for falsely elevated results with IRON Flex® reagent cartridges when tests are processed from a well set contaminated with iron from environmental sources. If a well is contaminated with iron, all test results from the well will be elevated by an amount that is proportional to the level of contamination, unless 3.6 software is installed to prevent the use of a contaminated IRON well.

With Urgent Field Safety Notice 12-49, instructions were provided to allow the continued use of IRON Flex® reagent cartridges by running QC on each well set prior to running patient samples. Siemens recommended that you batch the processing of your IRON tests on one instrument. These measures will no longer be necessary with the installation of Vista Software Version 3.6.

Please forward this notification to anyone to whom you may have distributed this product.

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