

## Urgent Field Safety Notice

August 2011

### Dimension Vista® System

#### CA19-9 Flex® reagent cartridges (K6457)

Lot numbers: 10347AC, 11038AD, and 11124AA

---

Our records indicate that your laboratory uses the CA19-9 Flex® reagent cartridges (K6457) on the Dimension Vista® System.

Siemens has confirmed complaints of inaccurate results with CA19-9 Flex® reagent cartridge lots 10347AC, 11038AD and 11124AA. The magnitude of the inaccuracy may be greater than 30%. Test results for patient or QC samples may be falsely elevated or to a lesser degree falsely depressed at CA19-9 concentrations of approximately 25 and 136 U/mL. Inaccurate results were not observed at higher CA19-9 concentrations.

Siemens Healthcare Diagnostics is conducting a voluntary corrective action for Dimension Vista® CA19-9 Flex® reagent cartridge lots 10347AC, 11038AD and 11124AA. Please discontinue the use of CA19-9 Flex® reagent cartridge lots 10347AC, 11038AD and 11124AA. Please consult with your laboratory director regarding re-evaluation of previously reported results, including the need to re-establish baselines on patients. For your consideration on this matter, inaccurate results have been predominately elevated as opposed to depressed.

You may contact your local Siemens Customer Service Center to report your no-charge replacement needs. We apologize for the inconvenience that this situation has caused. If you have any technical questions regarding this information, please contact your local Siemens representative. Please forward this notification to anyone to whom you may have distributed this product.

---

### Siemens Healthcare Diagnostics Inc.

P.O. Box 6101  
Newark, DE 19714-6101

[800-441-9250]  
[www.siemens.com/diagnostics](http://www.siemens.com/diagnostics)

Page 1 of 2

[OPTIONAL FOR COUNTRIES]

**FIELD CORRECTION EFFECTIVENESS CHECK**

*Dimension Vista® CA19-9 Flex® reagent cartridges (K6457) Lot Numbers 10347AC, 11038AD and 11214AA*

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated August 2011 regarding *Dimension Vista® CA19-9 Flex® reagent cartridges (K6457) Lot Numbers 10347AC, 11038AD and 11124AA*

Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number indicated at the bottom of this page.

**Please complete and fax by September \_\_ 2011**

1. Did we effectively communicate all necessary information? Yes  No

If you selected No, please explain below.

2. Do you now have any of the noted product on hand? (Please check inventories before answering.) Yes  No

3. If the answer to the question above is Yes, do you intend to take the recommended action as requested? Yes  No

Name of person completing questionnaire:

Instrument Serial Number:

Title:

Institution:

Street:

City:

State:

Phone:

**PLEASE FAX THIS COMPLETED FORM TO THE FOLLOWING NUMBER: XXXXXXXXX**