

## Urgent Field Safety Notice

BR-00816

November 2015

### Dimension Vista® System

### B2-Microglobulin (B2MIC) Flex® Reagent Cartridge and Urine Stabilizer

### Elevated Number of Abnormal Assay Errors

---

Dear valued customer,

Our records indicate that your facility may have received the following product:

**Table 1.**

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number
Dimension Vista® System Flex® reagent cartridge and urine stabilizer B2MIC	K7024	10445889	15175MA 15204MA 15246MA 15267MA

### Reason for Urgent Field Safety Notice

Siemens Healthcare Diagnostics has confirmed an increase in the rate of “Abnormal Assay” errors and calibration failures with the Dimension Vista B2MIC Flex reagent cartridge lots mentioned in Table 1. The errors can occur on calibration, QC and/or patient samples. As stated in the Dimension Vista Operator’s Guide, results with “Abnormal Assay” are not reportable.

### Risk to Health

The likelihood of generating a patient result is unlikely. However, in the unlikely event that a patient result is generated, a suppressed result would be in conflict with the patient’s clinical status and other markers of renal injury. Siemens is not recommending a review of previously generated results due to this issue.

### Actions to be taken by Customer

- Review this letter with your Medical Director.

*B2MIC Flex reagent cartridge and urine stabilizer - Elevated number of Abnormal Assay Errors*

- Discontinue use and discard your remaining inventory of the reagent lots listed in Table 1.
- Indicate your replacement product needs on the attached Field Correction Effectiveness Check Form and return it within 30 days.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

Sincerely yours,

*Original signature is on file*

Dr. Norbert Dedner  
Director Quality Systems & Compliance

*Original signature is on file*

Scott Craig  
Sr Product Manager  
Dimension and Vista Assays

*Dimension Vista® and Flex® are trademarks of Siemens Healthcare Diagnostics.*

**FIELD CORRECTION EFFECTIVENESS CHECK**

**Dimension Vista® System Flex® reagent cartridge and urine stabilizer B2MIC  
Elevated Number of Abnormal Assay Errors**

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice Letter Number BR-00816 dated November 2015 regarding Dimension Vista B2MIC Flex reagent cartridge and urine stabilizer Abnormal Assay Errors. Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

1. I have read and understood the Urgent Medical Device Recall instructions provided in this letter. Yes  No
2. Do you now have any of the noted products on hand? Please check inventories before answering. Yes  No

If the answer to the question above is yes, please complete the table below and contact your local Siemens Technical Support Representative.

<b>Dimension Vista® B2MIC (K7024, SMN 10445889)</b>	<b>Quantity of Affected Product in inventory that has been discarded</b>	<b>Replacement Quantity Required</b>
Lot 15175MA		
Lot 15204MA		
Lot 15246MA		
Lot 15267MA		

Name of person completing questionnaire: \_\_\_\_\_

Title: \_\_\_\_\_

Institution: \_\_\_\_\_

Instrument Serial Number: \_\_\_\_\_

Street: \_\_\_\_\_

City: \_\_\_\_\_

State: \_\_\_\_\_

Phone: \_\_\_\_\_

Country: \_\_\_\_\_

Customer Sold To #: \_\_\_\_\_

Customer Ship To #: \_\_\_\_\_

Please fax this completed form to your local Siemens representative. If you have any questions, contact your local Siemens technical support representative