SIEMENS

Urgent Field Safety Notice

BR-05215

July 2015

Dimension Vista System Flex Reagent Cartridge and Urine Stabilizer B2MIC Elevated Number of Abnormal Assay Errors

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	15037MA

Reason for Recall

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 lot 15037MA. 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. Siemens is instructing customers to discontinue use of B2MIC lot 15037MA as a result of this issue.

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

Please do the following:

- Discontinue use and discard your remaining inventory of the reagent lot listed in Table 1.

Emil-von-Behring Strasse 76
D-35041 Marburg, Germany
www.siemens.com/diagnostics

GPF-003 -6 V5.1 Effective: 2014-07-07
Related Procedure: GP-003 DX-Field Action

- Indicate your replacement product needs on the attached Field Correction Effectiveness Check Form 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

Diane Stille
Sr Product Manager
Dimension and Vista Assays

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-05215 dated July 2015 regarding B2MIC, Abnormal Assay Error. 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 to indicate the quantity of affected product in your laboratory and replacement product required.

Dimension Vista® B2MIC (K7024, SMN 10445889)	**Quantity of Affected Product in inventory that has been discarded**	**Replacement Quantity Required**
Lot # 15037MA		

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