

Dimension® clinical chemistry system and Dimension Vista® System

Gentamicin (GENT) Flex® reagent cartridge

Potential Inaccuracy at the low end of the Analytical Measurement Range

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

Table 1. Dimension and Dimension Vista Affected Products:

Assay	Catalog Number	Siemens Material Number	Lot Number	First Shipment Date	Expiration Date
Dimension GENT	DF12	10444927	EB8115 BB8159 FB8275	2017-05-30 2017-07-24 2017-11-08	2018-04-25 2018-06-08 2018-10-02
Dimension Vista GENT	K4012	10445120	17135BC 17150BF 17159BD 17178AC 17269BD 17312BB	2017-06-12 2017-07-03 2017-07-19 2017-08-08 2017-11-02 2017-12-12	2018-05-15 2018-05-30 2018-06-08 2018-06-27 2018-09-26 2018-11-08

Reason for Field Action

Siemens Healthcare Diagnostics has confirmed Dimension Gentamicin (GENT) lot BB8159 may exhibit inaccuracy for Quality Control (QC) and patient samples at the low end of the Analytical Measurement Range. Maximum negative bias of 100% and 48% were observed for patient samples at 0.9 µg/mL [1.94 µmol/L] and 1.9 µg/mL [4.1 µmol/L], respectively. Patient samples at ≥ 2.6 µg/mL [5.62 µmol/L] did not show a bias. The bias is due to the calibration curve not showing separation between the Level 1 and Level 2 calibrators.

Siemens investigated all other in-date Dimension and Dimension Vista GENT reagent for similar issues. It was determined that the GENT reagent lots listed in Table 1 show similar issues and Siemens predicts the separation between Level 1 and Level 2 calibrators will continue to degrade over time. At the present time, you may not detect an issue with the eight additional lots.

Risk to Health

The negative bias observed for patient, QC, and calibrator samples, when using any of the listed lots, has the potential to impact the interpretation of gentamicin results during therapeutic monitoring at concentrations up to approximately 2.5 µg/mL [5.4 µmol/L]. Gentamicin treatment would be correlated with clinical presentation and closely monitored. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

- Inspect stock, discontinue use of and discard the Dimension and Dimension Vista GENT lots listed in Table 1.
- Please review this letter with your Medical Director.
- Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens for reporting to the regulatory authorities.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- If you have received any complaints of illness or adverse events associated with the product listed in Table 1, immediately contact your local Siemens Customer Care Center or your local Siemens Technical Support Representative.

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.

Dimension and Dimension Vista are trademarks of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK
Dimension and Dimension Vista Gentamicin Reagent
Potential Inaccuracy at the low end of the Analytical Measurement Range

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice, DC-18-02.A.OUS, dated April 2018 regarding Dimension or Dimension Vista Gentamicin Reagent with Potential Inaccuracy at the low end of the Analytical Measurement Range. 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 Field Safety Notice instructions provided in this letter. Yes ☐ No ☐
2. Do you now have any affected Gentamicin lots 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 or Dimension Vista® Gentamicin lots	Quantity of Affected Product in inventory that has been discarded	Replacement Quantity Required

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

Customer Sold To #: _____

Customer Ship To #: _____

To fax this completed form please send it to your local Siemens Technical Support Representative.. If you have any questions, contact your local Siemens Technical Support Representative.