

Dimension® clinical chemistry system and Dimension Vista® System
Alkaline Phosphatase Calibrator (ALPI CAL)
Potential for Particulate Matter

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

Table 1. Dimension and Dimension Vista Affected Products:

Calibrator	Catalog Number	Siemens Material Number	Lot Number	Expiry Date	First Shipment Date
Dimension ALPI CAL	DC150	10714028	7FD041	2018-07-01	2017-07-12
			7GD016	2018-08-01	2017-08-07
			7HD041	2018-08-01	2017-09-08
			7JD080	2018-09-01	2017-10-06
			7KD059	2018-11-01	2017-11-14
			7KD079	2018-11-01	2017-12-18
Dimension Vista ALPI CAL	KC331	10714029	7GD017	2018-08-01	2017-08-23
			7KD040	2018-10-01	2017-11-16

Reason for Notification

Siemens Healthcare Diagnostics has received customer complaints regarding Alkaline Phosphatase (ALPI) calibrator vials containing particulate matter.

Siemens internal investigation has confirmed that there is a potential for particulate matter within ALPI calibrator vials for the lots listed in Table 1. Not all calibrator vials or levels for the lots listed in Table 1 contain particulate matter. Siemens has confirmed there are no performance issues when using the affected vials. Internal studies have verified that calibrator vials with particulate matter generate valid calibration and Quality Control (QC) results within established ranges. Additionally, patient recovery and system operation is unaffected.

If an affected calibrator lot was previously used for ALPI calibration, there is no need to recalibrate ALPI.

Actions to be Taken by the Customer

- Continue to use Dimension and Dimension Vista ALPI calibrator lots listed in Table 1.
- Or
- If your laboratory chooses not to use the product, complete and return the Product Replacement Form for your laboratory's no-charge replacement needs.

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.

**PRODUCT REPLACEMENT FORM
Dimension and Dimension Vista Alkaline Phosphatase Calibrator (ALPI CAL)
Potential for Particulate Matter**

This form is to be used to request no-charge replacement product for the enclosed Siemens Healthcare Diagnostics Customer Notification DC-18-03.A.OUS dated May 2018 regarding Dimension or Dimension Vista Alkaline Phosphatase Calibrator (ALPI CAL) Potential for Particulate Matter.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

If you have any of the product listed in Table 1 and choose not to use them, please complete the Table below to request replacement product.

Dimension or Dimension Vista ALPI CAL 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 #: _____

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