

Dimension[®] clinical chemistry system

Lot-to-Lot Variability When Using Dimension[®] Lipase (LIPL)

Flex[®] reagent cartridge lots GD9002, GA9003, GB9032 and GA9038

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

Table 1. Dimension[®] Affected Product

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Numbers	Expiration Date (YYYY-MM-DD)	1 st Distribution Date (YYYY-MM-DD)
Dimension [®] Lipase (LIPL)	DF56	10460277	GD9002	2019-01-02	2018-05-21
			GA9003	2019-01-03	2018-05-24
			GB9032	2019-02-01	2018-05-29
			GA9038	2019-02-07	2018-06-07

Reason for Urgent Field Safety Notice

The purpose of this communication is to inform you of an issue with the products listed in Table 1 above and provide instructions for laboratory action.

Siemens Healthcare Diagnostics has confirmed lot-to-lot variability for QC and patient results when using the Dimension[®] LIPL lots listed in Table 1. Not all laboratories will observe this issue.

The lot-to-lot bias observed for patient samples using the Dimension[®] lots in Table 1 when compared with a control lot could be as high as 29% as shown in Figure 1.

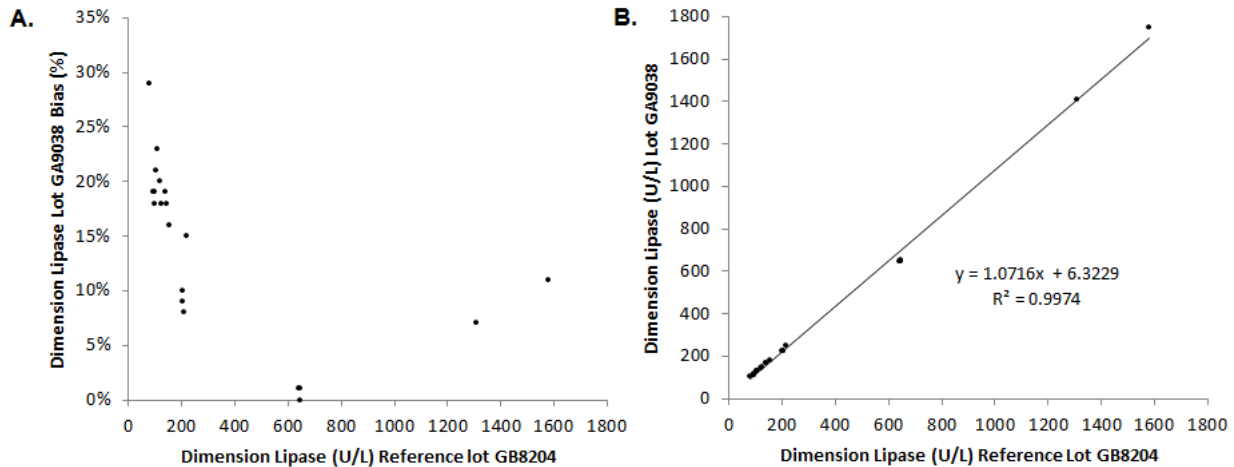


Figure 1. Dimension® Lipase lot-to-lot variability (A) and patient correlation for (B) for lot GA9038 versus GB8204 control lot

Risk to Health

The observed difference in lipase values when using the Dimension® Lipase (LIPL) lots listed in Table 1 for patient samples at clinically relevant concentrations of lipase would not impact the clinical utility of the assay. Lipase results are interpreted in conjunction with clinical history and symptomology, as well as additional diagnostic laboratory testing. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

- If your laboratory is experiencing unacceptable lot-to-lot variability using a Dimension® LIPL reagent lot listed in Table. 1 complete and return the Product Replacement Form for your laboratory's no-charge replacement needs.
- Please review this letter with your Medical Director.
- 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 products 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® is a trademark of Siemens Healthcare Diagnostics

FIELD CORRECTION EFFECTIVENESS CHECK

Dimension® clinical chemistry system

Lot-to-Lot Variability When Using Dimension® Lipase (LIPL) Flex® reagent cartridge lots
GD9002, GA9003, GB9032 and GA9038

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice DC-18-05.A.US-DM dated September, 2018 regarding Lot-to-Lot Variability when using Dimension® Lipase (LIPL) Flex® reagent cartridge lots GD9002, GA9003, GB9032, and GA9038.

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes ☐ No ☐

If your laboratory has experienced unacceptable lot-to-lot variability using the Dimension® LIPL Flex reagent lots listed above and choose not to use, please complete the table below to request replacement product.

Dimension® Lipase (LIPL) DF56/10460277	Quantity of Affected Product in inventory to be replace	Replacement Quantity Required
GD9002		
GA9003		
GB9032		
GA9038		

Name of person completing questionnaire:

Title:

Date of Field Correction Effectiveness check
completion:

YYYY-MM-DD

Institution:

Instrument Serial Number:

Street:

City:

State:

Phone:

Country:

Please fax this completed form to the Customer Care Center at XXXXXX

If you have any questions, contact your local Siemens technical support representative