

**Dimension® Clinical Chemistry Systems**

**Dimension® HB1C Flex® Reagent Cartridge (DF105A, SMN 10483822)**

- I. Positive Bias Compared to Alternate Methods
- II. “Above Assay Range” Flags

Our records indicate that your laboratory received the following product:

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number		
HB1C Flex® reagent cartridge	DF105A	10483822	GA3099	GA3113	GA3134
			GA3141	GA3162	GA3169
			GA3197	GB3211	GA3232
			GA3247	GA3267	GB3281
			GC3302		

**Reason for Field Action**

**I. Positive Bias Compared to Reference Methods**

Siemens Healthcare Diagnostics has confirmed a positive bias on the HB1C lots listed above. For HbA1c values below 6%, a positive bias of approximately 0.3% was observed with an upper 95% confidence interval of 0.7%. The issue may impact quality control (QC) materials, patient samples, and proficiency survey samples.

**II. Above Assay Range Flags**

Siemens Healthcare Diagnostics has confirmed a higher frequency of “**Above Assay Range**” flags with the Dimension® HB1C Flex® reagent cartridge lots listed above. Our investigation has shown that the higher frequency of flags is related to higher recoveries of sample hemoglobin (Hb) values (Hb > 25 g/dL or > 15.5 mmol/mol) with these lots. The Hb value is used to

**Siemens Healthcare Diagnostics**

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*HB1C Flex® reagent cartridge (DF105A, SMN 10483822)*

*Positive Bias Compared to Reference Methods and “Above Assay Range” Flags*

calculate the final output HbA1c ratio (% HbA1c [mmol/mol]) result. Results are suppressed (not reported) with the “Above Assay Range” flag.

### **Risk to Health**

The management of patients with hyperglycemia is dependant upon short term monitoring of glucose and the longer term HbA1c value. A slightly high bias in HbA1c may result in a treatment change including a slightly higher dose of insulin. The bias effects observed in these lots is minimal and would not greatly increase the risk of overtreatment.

Reporting an HbA1c result with an “Above Assay Range” flag as >16% [>151 mmol/mol] without first diluting the sample would trigger a review of short term glucose measurements and repeat testing due to the remarkable result. It would be highly unlikely that such an observation would result in a treatment change before confirmation.

We recommend discussing the content of this letter with your Medical Director to determine if additional follow up is appropriate for patient tests conducted with the lots listed.

### **Actions to be Taken by Customer**

Customers should immediately discard any remaining inventory of the affected lots of Dimension® HB1C (DF105A). Siemens will replace any unused inventory of the affected lots at no charge. Please complete the attached form and fax it to (302) 631-8467 to indicate that you have received this information.

These issues have been corrected beginning with HB1C lot GA3351.

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 has caused. If you have any questions, please contact the Siemens Technical Solutions Center or your local Siemens technical support representative.

**EFFECTIVENESS CHECK  
REQUEST FOR REPLACEMENT PRODUCT**

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated April 2013 regarding Dimension<sup>®</sup> HB1C Flex<sup>®</sup> reagent cartridge (DF105A, SMN 10483822) Positive Bias Compared to Reference Methods and "Above Assay Range" Flags, letter #13-25.

Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number indicated at the bottom of this page.

1. I have read and understood the information provided in the April 2013 letter # 13-25 Yes  No
  
2. Do you now have any of the noted product on hand? (Please check inventories before answering.) Yes  No
  
3. If the answer to the question above is yes, how much product do you have on hand and quantity to be replaced?

Dimension <sup>®</sup> HB1C (DF105A, SMN 10483822)	Quantity Discarded	Replacement Quantity

Name of person completing questionnaire:

Title:

Institution:

Instrument Serial Number(s):

Street:

City:

State:

Phone:

Customer Sold to #:

Customer Ship to #

PLEASE FAX THIS COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER AT  
**302-631-8467.**