SIEMENS

Urgent Field Safety Notice

14-60

September 2014

Dimension® Integrated Chemistry Systems
Hemoglobin A1c (HB1C) Flex® reagent cartridge (DF105A SMN 10483822)
Positive Bias

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

Table 1. Dimension® Hemoglobin A1c

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Numbers		
Dimension® HB1C	DF105A	10483822	GA4266	BA4273	BA4280
			BA4287	GA4301	GA4315
			GC4322	GA4343	GA4350
			GA4357	GA5013	GA5020

Reason for Field Action

Siemens Healthcare Diagnostics is conducting a field recall for the Dimension® HB1C Flex® reagent cartridge lots listed in Table 1.

Siemens has confirmed that the Dimension® HB1C Flex® reagent cartridge lots listed in Table 1 exhibit a positive bias averaging 0.4% [4.4 mmol/mol] Hemoglobin A1c units and occasionally up to 1.0% [11 mmol/mol] HbA1c units for patient samples when compared to the National Glycohemoglobin Standardization Program (NGSP). QC samples may exhibit a similar bias.

This bias resulted in complaints for College of American Pathologists (CAP) survey failures.

Depending on quality control limits, this issue may not have been detected.

The root cause is currently under investigation.

Risk to Health

The management of patients with hyperglycemia is dependent upon the monitoring of diet, lifestyle, glucose concentrations, HbA1c, and the adjustment of therapy to glycemic control.

A positive bias of up to 1.0% [11 mmol/mol] HbA1c units may be considered clinically significant at clinically relevant HbA1c values, and may result in the modification of the therapy for hyperglycemia. The modification of hyperglycemic therapy can increase the risk of occurrence of hypoglycemia, which may be observed through personal glucose monitoring and/or patient symptoms.

P.O. Box 6101
Newark, DE 19714-6101
www.siemens.com/diagnostics

Siemens is not recommending a general laboratory look back for previously generated results when using these lots. Siemens is providing an optional informational physician letter with retesting guidance for physicians (see attached letter).

Actions to be Taken by the Customer

- Discontinue use of and discard the lot(s) listed in Table 1.
- Please review this letter with your Medical Director. An informational physician letter is attached to this communication for your convenience. This letter should also be reviewed with your Medical Director. If you decide to distribute the informational letter to clinicians who ordered HbA1c testing using the affected lots, the letter should be tailored (see highlighted and underlined text in the physician letter) to your laboratory.
- Siemens will replace any unused inventory of the affected lots at no charge. Please indicate your replacement product needs in the attached Field Correction Effectiveness Form.

Please complete the attached form and fax it to 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 – Technical Solutions or your local Siemens technical support representative.

Dimension® and Flex® are trademarks of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK
Ref: VC 14-07 [C/2874]
Dimension® Integrated Chemistry Systems
Hemoglobin A1c (HB1C) Flex® reagent cartridge (DF105A SMN 10483822)
Positive Bias

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated September 2014 regarding Dimension® HB1C (DF105A) Positive Bias. Please read the questions and indicate the appropriate answers. 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 Urgent Field Safety Notice instructions provided in this letter. Yes ☐ No ☐

2. Do you now have any of the noted product 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 affected lot (see Table 1), the quantity of affected product in your laboratory, and replacement product required.

Product Description HbA1c lot #	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:	Post Code:
Phone:	Email:
Signed:	Date:

It is important that your organisation takes the actions detailed in the FSN and replies immediately using the FIELD CORRECTION EFFECTIVENESS CHECK attached to this FSN. Your organisations reply is evidence which, Siemens Healthcare, and subsequently the MHRA, needs to monitor the progress of the FSN. Without your reply Siemens Healthcare cannot verify the completeness of the FSN and the MHRA may need to issue a Medical Device Alert.

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