SIEMENS

Urgent Field Safety Notice

12-38

August 2012

Dimension® Clinical Chemistry System
Hemoglobin A1c (DF105A HB1C)
Lot-Specific Scalers and "E" Calibration Coefficient Guideline Change

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Our records indicate that your lab has ordered **Dimension® Hemoglobin A1c (HB1C, Catalog # DF105A) Flex® reagent cartridges.**

Lot-Specific Scalers

Reason for Voluntary Field Action

Siemens has received complaints of inaccurate results after calibration of HB1C (DF105A). Accuracy shifts of up to 27%, both high and low, have been reported on QC and patient samples. The shift observed with QC material is consistent with the direction and magnitude of the shift observed with patient samples. Upon investigation, we have determined the cause of the inaccurate results to be from the use of incorrect scaler values when calibrating.

The HB1C method uses an additional parameter called scaler values. These values are polynomial equation factors that have been determined for HB1C in order to provide the best correlation to the HbA1c reference methodology. This feature was communicated with the launch of HB1C (DF105A) in the HB1C Kit Supplement.

Risk to Health

Over- or underestimation of HbA1c due to incorrect scalers may potentially lead to short term changes in glycemic control. A high biased HbA1c could potentially result in stricter glycemic control, increasing the risk of a hypoglycemic event. A low biased HbA1c could potentially give the impression of optimal glycemic control.

Actions to be taken by Customer

As directed in the HB1C Kit Supplement, scaler values from the HB1C Kit carton need to be verified or entered when setting up a calibration. Inaccurate results may be generated if users do not update the scaler values. Scalers need to be verified or entered with **every calibration including recalibration** with the same Flex® lot. See instructions on the following pages for entering/verifying scalers when calibrating.

Siemens also recommends reviewing all past calibration printouts for the use of correct scalers. A list of scaler values by lot number is available on page 4. As previously stated, the shift observed with QC material is consistent with the direction and magnitude of the shift observed with patient samples. If incorrect scalers were used, and patient results were reported, Quality Control data can be used to assess the magnitude of the shift. You may need to consult with your laboratory director regarding the need for re-evaluation of previously reported HB1C results.

Siemens Healthcare Diagnostics Inc.

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800-441-9250
www.siemens.com/diagnostics

“E” Calibration Coefficient Guideline Change

Reason for Voluntary Field Action
There has also been a change to the acceptable range for the “E” calibration coefficient guideline**. The new guideline range is 5 – 8 (conventional units (%)) or 8 – 13 (SI units (mmol/L)).** Lots GA3099 and newer require this new guideline range.

The guideline range for lots prior to GA3099 is 6-9 (conventional units (%)) or 10-14 (SI units (mmol/L)).

Actions to be taken by Customer
Customers with lot GA3099 and newer must use this new range to evaluate calibration acceptability. Please reference the updated HB1C Kit Supplement (attached) for more information.

If you have any questions or require further information on the Dimension® HB1C assay please contact the Siemens Technical Solutions Center at 800-441-9250. Additionally, please complete the attached Field Correction Effectiveness Check form and fax to the number provided.

We apologize for the inconvenience that this situation has caused. Thank you for your continued support.

Please forward this notification to anyone to whom you may have distributed this product.

The following information taken from the HB1C Kit Supplement reviews the steps required to verify/enter the scaler values from the HB1C Flex® reagent carton.

- Verify/enter the appropriate values (% or mmol/mol) for each of the four scaler fields (A-D) from the label on the Flex® reagent carton.

  Note: Default method scalers are automatically displayed on the Calibration Set-Up screen. Each HB1C Flex® reagent carton label provides the scaler values that **must** be used for that lot.

Example: Label on Flex® reagent carton

SCALERS		
	%	mmol/mol
A=	0.00000	0.00000
B=	0.00950	0.00100
C=	0.60300	0.50800
D=	1.70000	2.95000

Example

Calibration Set-Up

CALIBRATION SET-UP METHOD: **HB1C** LOT: GA3099

Operator: **xxx** Status: **NEVER CALIB'D**

Calibration Expires:

Calibrator Product Lot: **HB1C CAL** --- **GA3099**

Scalers: A: **0.00000** B: **0.00560** C: **0.65840** D: **2.36600**

Example

Start at Position: **E1** HB BV LEV3: **15.95** HB BV LEV4: **15.68**

LEVELS	BOTTLE VALUE	SEG	CUP	QC LEVELS		SEG	CUP
1	**0.21**			1	**No**		
2	**0.61**			2	**No**		
3	**1.13**			3	**No**		
4	**1.98**			4	**No**		
5	**2.72**			5	**No**		

Flex lot and calibrator lot numbers must match. Bottle values are printed on the calibrator vial labels.			
F1: OTHER LOT	F2:	F3: DELETE LEVEL	F4: ASSIGN CUPS
F5: NEXT METHOD	F6: STORE PARAM's	F7: LOAD/RUN	F8:

The table shown below contains the scaler values for Dimension® HB1C lots GA3099 and newer.

	NGSP units (%)				IFCC units (mmol/mol)			
Lot Number	**Scaler A**	**Scaler B**	**Scaler C**	**Scaler D**	**Scaler A**	**Scaler B**	**Scaler C**	**Scaler D**
GA3169	+0.00	-0.0025	+0.7913	+2.263	+0.00	-0.0002	+0.8577	+1.567
GA3162	+0.00	-0.0025	+0.7913	+2.263	+0.00	-0.0002	+0.8577	+1.567
GA3141	+0.00	-0.0025	+0.7913	+2.263	+0.00	-0.0002	+0.8577	+1.567
GA3134	+0.00	+0.0056	+0.6584	+2.366	+0.00	+0.0007	+0.7095	+2.614
GA3113	+0.00	+0.0056	+0.6584	+2.366	+0.00	+0.0007	+0.7095	+2.614
GA3099	+0.00	+0.0056	+0.6584	+2.366	+0.00	+0.0007	+0.7095	+2.614
All lots before GA3099	+0.00	+0.00676	+0.512	+2.23	+0.00	+0.001	+0.508	+2.95

FIELD CORRECTION EFFECTIVENESS CHECK

Hemoglobin A1c (DF105A HB1C)

Lot-Specific Scalers and “E” Calibration Coefficient Limit Change

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Medical Device Correction dated August 2012 regarding Hemoglobin A1c (DF105A). 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. Did you read and understand the contents of this communication? If you selected No, please explain below.	Yes ☐	No ☐
2. If the answer to the question above is Yes, do you intend to take the recommended action as requested?	Yes ☐	No ☐
Name of person completing questionnaire:		

Title:			
Institution:		Instrument Serial Number:	
Street:			
City:		State:	Phone:

PLEASE FAX THIS COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER AT
(302) 631-8467