

**Dimension<sup>®</sup> Clinical Chemistry System  
Hemoglobin A1c (DF105A HB1C)  
Lot-Specific Scalers and “E” Calibration Coefficient Guideline Change**

---

Our records indicate that your lab has ordered **Dimension<sup>®</sup> Hemoglobin A1c (HB1C, Catalog # DF105A) Flex<sup>®</sup> 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<sup>®</sup> 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.**

P.O. Box 6101  
Newark, DE 19714-6101

800-441-9250  
[www.siemens.com/diagnostics](http://www.siemens.com/diagnostics)

Page 1 of 4

**“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<sup>®</sup> HB1C assay please contact your Siemens Representative.

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.

Lot-Specific Scalers and "E" Calibration Coefficient Guideline Change

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

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

Example: Label on Flex<sup>®</sup> 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

Calibration Set-Up

CALIBRATION SET-UP

METHOD: HB1C

LOT: GA3099

Operator: xxx

Status: NEVER CALIB'D

Calibration Expires:

Calibrator Product Lot: HB1C CAL

--- GA3099

Scalars: 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	

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

## Lot-Specific Scalers and "E" Calibration Coefficient Guideline Change

---

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

Lot Number	NGSP units (%)				IFCC units (mmol/mol)			
	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