



**Customer Notification**

**DC-23-01.A.OUS**

**January 2023**

**Dimension® Clinical Chemistry Systems**

**Dimension® Hemoglobin A1c (A1C) Flex® Reagent Cartridge and  
 Dimension® Automated HDL Cholesterol (AHDL) Flex® Reagent Cartridge  
 Units of Measure for Scaler Headers are Incorrectly Listed on Carton Label**

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

**Table 1. Dimension® Affected Product**

Product	Siemens Material Number (SMN)/REF (Catalog Number)	Unique Device Identification (UDI)	Lot Number	Expiration Date (YYYY-MM-DD)	1 <sup>st</sup> Distribution Date (YYYY-MM-DD)
A1C	10720883 (DF105B)	00630414006659GA312923050910720883276	GA3129	2023-05-09	2022-06-19
		00630414006659GA316423061310720883276	GA3164	2023-06-13	2022-07-05
		00630414006659GA317823062710720883276	GA3178	2023-06-27	2022-07-18
		00630414006659GA318623070510720883276	GA3186	2023-07-05	2022-08-03
		00630414006659GA320623072510720883276	GA3206	2023-07-25	2022-09-20
AHDL	10464332 (DF48B)	00842768022029GA319423071310464332840	GA3194	2023-07-13	2022-08-10
		00842768022029GA319623071510464332840	GA3196	2023-07-15	2022-08-12
		00842768022029BA321423080210464332840	BA3214	2023-08-02	2022-08-31
		00842768022029BA321523080310464332840	BA3215	2023-08-03	2022-08-22
		00842768022029BA322023080810464332840	BA3220	2023-08-08	2022-09-13

**Reason for Customer Notification**

Siemens Healthineers has received customer complaints and confirmed the scaler units of measure listed in the header at the top of the scaler label on the carton of the A1C and AHDL lots listed in Table 1 are incorrect. The correct scaler header for A1C is % (conventional units) and **mmol/mol** (SI units). The correct scaler header for AHDL is **mg/dL** (conventional units) and **mmol/L** (SI units). The scaler values listed in each column are correct for all lots listed in Table 1. Siemens Healthineers has corrected this header error on the scaler label of all subsequent lots of A1C and AHDL. Examples of the incorrect and correct scaler label headers are shown in Figures 1-4 within this letter.

**Actions to be Taken by the Customer**

For the products listed in Table 1:

- The correct scaler unit of measure within the **header** for A1C is % (conventional units) and **mmol/mol** (SI units).

- The correct scaler unit of measure within the **header** for AHDL is **mg/dL** (conventional units) and **mmol/L** (SI units).
- Ensure that you use the correct scaler values (conventional unit scalers are the first column and SI unit scalers are the second column).


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 Healthineers Customer Care Center at 1800-815-508 or your local Siemens Healthineers Technical Support Representative.

Dimension and Flex are trademarks of Siemens Healthineers.


**Figure 1:**  
 AHDL Scaler Label with Incorrect Header

SCALERS	
%	mmol/mol
A= +0.00	+0.00
B= +0.00	+0.00
C= +1.03	+1.03
D= +5.50	+0.14

**LOT** GA3194  
 2023-07-13


**Figure 2:**  
 AHDL Scaler Label with Correct Header

SCALERS	
mg/dl	mmol/L
A= +0.00	+0.00
B= +0.00	+0.00
C= +1.03	+1.03
D= +3.90	+0.10

**LOT** GA2293  
 2022-10-20


**Figure 3:**  
 A1C Scaler Label with Incorrect Header

SCALERS	
mg/dl	mmol/L
A= +0.00	+0.00
B= +0.00019	+0.000021
C= +0.617	+0.6744
D= +1.874	-3.017

**LOT** GA3164  
 2023-06-13

**Figure 4:**  
 A1C Scaler Label with Correct Header

SCALERS	
%	mmol/mol
A= +0.00	+0.00
B= +0.00019	+0.000021
C= +0.617	+0.6744
D= +1.874	-3.017

**LOT** GB3241  
 2023-08-29