



Customer Notification

DC-24-01.A.OUS

November 2023

Dimension® Clinical Chemistry System

Dimension® IRON Lipemia Interference Updated in Instructions For Use

Our records indicate that your facility has received the following product:

Table 1. Dimension® Affected Product

Product	Siemens Material Number (SMN)/REF (Catalog Number)	Unique Device Identification (UDI)	Lot Number
Dimension IRON	10444945/DF85	00842768020414UN10444945840	All in date lots and future lots

Reason for Customer Notification

The purpose of this communication is to inform you of an update to the product listed in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthineers' internal testing has determined that the IRON assay, for use on the Dimension Clinical Chemistry System, has lipemia interference claims in the Instructions For Use (IFU) that require updates as shown in Table 2. While Siemens has not received any customer complaints for this issue, grossly lipemic samples have the potential to falsely elevate iron results on the Dimension Clinical Chemistry System.

Table 2. Current and Updated Dimension IRON Assay IFU

Current Information	Updated Information
Lipemia (Intralipid®) @ 3000 mg/dL [33.9 mmol/L] ≤10% bias at 27 µg/dL [4.8 µmol/L] and 128 µg/dL [22.9 µmol/L] of iron	Lipemia (Intralipid®) @ 200 mg/dL [2.3 mmol/L] ≤10% bias at 35 µg/dL [6.3 µmol/L] of iron Lipemia (Intralipid®) @ 490 mg/dL [5.5 mmol/L] ≤10% bias at 135 µg/dL [24.2 µmol/L] of iron

Updated versions of the Dimension IRON Assay Instructions For Use will be available on the Siemens Document Library.

Actions to be Taken by the Customer

Please perform the following steps:

- Download the updated Dimension IRON IFU revision 09 SMN 10865227 from Siemens Document Library.

NOTE: If your laboratory does not have the HIL feature [Hemolysis (H), Icterus (I), Lipemia/Turbidity (L)] activated on your Dimension system, no action is required.

- Please perform the following steps if the HIL feature is activated on your Dimension Clinical Chemistry System.
 - Sign into the Dimension System Software with a User Account that has privileges to edit HIL settings.
 - From the main operating screen **Select F5:** PROCESS CTRL > **F8:** MORE OPTIONS.
 - **Select F6:** HIL SETUP.
 - Press the **IRON key** or position the cursor on the row for the IRON method and press **Enter**.
 - Update the **L** (Lipemia/Turbidity) from 0 (no interference) to **4**.
 - **Select F2:** STORE.
 - Please refer to your Dimension Systems Operator's Guide for further information and reference.

Note: Each laboratory has the option of entering HIL indices based on the laboratory policies with considerations on acceptable medical decision errors, impact on clinical interpretations and ability to mitigate preanalytical specimen interfering substances.

- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- If you have received any complaints of illness or adverse events associated with the product listed in Table 1, immediately contact your local Siemens Healthineers Remote Services Center or your local Siemens Healthineers 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 Healthineers Customer Care Center 1800-815-508 or your local Siemens Healthineers Technical Support Representative.

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