



Customer Notification

DC-22-01.A.OUS

March 2022

Dimension® clinical chemistry system Dimension® Total Protein/Albumin Calibrator Incorrect Expiration Date

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

Table 1. Dimension® Affected Product

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number	Expiration Date (YYYY-MM-DD)	1 st Distribution Date (YYYY-MM-DD)
Dimension® Total Protein/Albumin Calibrator	DC31	10444993	1JD021	2022-10-01	2021-11-01

Reason for Customer Notification

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

Siemens Healthineers has confirmed that the Dimension Total Protein/Albumin Calibrator (TP/ALB CAL) listed in Table 1 has an incorrect expiration date (2022-01-10, January 10, 2022) listed in the Instructions For Use (IFU) and incorporated in the 2D barcode contained within the IFU. The expiration date of the TP/ALB CAL lot 1JD021 is 2022-10-01 (October 1, 2022). The expiration date is correct on the TP/ALB CAL carton and TP/ALB CAL vial labels. The expiration date is also correct on the TP/ALB CAL Certificate of Analysis (CoA). The Siemens Healthineers Document Library has the correct version of the Instructions For Use.

Actions to be Taken by the Customer

To calibrate with the TP/ALB CAL listed in Table 1, the expiration date needs to be edited. Please perform the following steps:

- If the calibration of TP/ALB CAL lot1JD021 is stored in your Dimension system, go to the Operating Menu
 - >F5 – Process CTRL
 - >F1 – Calibration (some software versions require you to hit Enter)

>F6 – Edit Calibrator Product (Use arrow key to scroll down to the product TP/ALB 1JD021)

>F1 – Edit Product (Dialog Box pops up as follows: Calibration Product is Expired. Continue? (yes/no) Type “Y” for yes)

>F5 – CHG PROD EXP (At base of screen, entry box with configuration of expiration date is displayed. Type in expiration date of 2022-10-01.

> F7 - Store

- If the calibration of TP/ALB CAL lot 1JD021 has not been stored in your Dimension system, the correct TP/ALB CAL Instructions For Use is available in the Siemens Document Library.

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 Remote Services Center at 1800-888-872 or your local Siemens Healthineers Technical Support Representative.

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