

Customer Notification

ACHC24-02.A.OUS

Atellica CH

Atellica CI

Title Atellica CH HDL Cholesterol Calibrator (HDLC CAL) Incorrect Shelf-Life and Expiration Date

Date Issued Mar-2024

Issue Description

Siemens Healthineers has confirmed, through internal investigation, that the Atellica CH HDL Cholesterol Calibrator (HDLC CAL) lots listed in the Products section below for use on the Atellica® CH and Atellica® CI Analyzers have an incorrect shelf life and expiration date of 24 months from date of manufacture. This incorrect date is on the kit label, vial label, barcode, Table of Assigned Values (TAV) and Certificate of Analysis (CoA). The correct shelf-life and expiration date is 15 months from date of manufacture.

Siemens internal testing determined that HDLC CAL lots 61454 and 63048 maintain stability between 15 and 24 months from date of manufacture. Standard laboratory practices of evaluating passing calibrations and quality control within range are good indicators of acceptable performance for all lots. The claim for HDLC CAL shelf life will remain 15 months from date of manufacture. HDLC CAL lots starting with lot 65327 will have the correct shelf life and expiration date of 15 months from date of manufacture.

Products

Assay	Test Code	Siemens Material Number/Unique Device Identification	Lot Number	Manufacturing Date	Expiration Date
HDL Cholesterol Calibrator	HDLC CAL	11537240/00630 414610863	61454	5-Oct-2021	4-Oct-2023
			63048	3-Oct-2022	2-Oct-2024
			63502	26-Dec-2022	25-Dec-2024
			63681	31-Jan-2023	30-Jan-2025
			63872	7-Mar-2023	6-Mar-2025
			64067	5-Apr-2023	4-Apr-2025
			64204	25-Apr-2023	24-Apr-2025
			64321	30-May-2023	29-May-2025
			64752	31-Jul-2023	30-Jul-2025
			64842	29-Aug-2023	28-Aug-2025
			65417	19-Sep-2023	18-Sep-2025

Customer Actions

For the products listed in the table above, please perform the following steps:

- Do not use HDLC CAL lots beyond the intended shelf life of 15 months from date of manufacture. Refer to Table 1 below for the corrected 15-month expiration date.
- Manually enter the corrected expiration date:
 - For Atellica Software < 1.26:
 1. Select the “Calibration Tab”
 2. Select the “Calibration Definition Sub Tab”
 3. Select the affected calibrator material
 4. Click “Edit”
 5. Adjust the “Expiration Date” to match the 15-month Expiration Dates from Table 2
 6. Click “Save

For Atellica Software ≥ 1.26 and Atellica CI Analyzers:

1. Click the navigation icon
 2. Select “Calibrator Definition”
 3. Select the affected calibrator material
 4. Click “Edit”
 5. Adjust the “Expiration Date” to match the 15-month Expiration Dates from Table 2
 6. Click “Save”
- Please retain this letter with your laboratory records and forward this letter to those who may have received the 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.

Single Registration Number (SRN)

US-MF-000016560

Table 1. Atellica CH HDLC CAL 15-Month Expiration Date

Appendix	Atellica CH HDLC Cal Lot #	Date Manufactured	Corrected 15-month Expiration Date
	61454	5-Oct-2021	4-Jan-2023
	63048	3-Oct-2022	2-Jan-2024
	63502	26-Dec-2022	25-Mar-2024
	63681	31-Jan-2023	29-Apr-2024
	63872	7-Mar-2023	6-Jun-2024
	64067	5-Apr-2023	4-Jul-2024
	64204	25-Apr-2023	24-Jul-2024
	64321	30-May-2023	29-Aug-2024
	64752	31-Jul-2023	30-Oct-2024

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64842	29-Aug-2023	28-Nov-2024
65417	19-Sep-2023	18-Dec-2024

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