

Follow-up Urgent Field Safety Notice

ACHC24-03.B.OUS

Atellica CH Analyzer Atellica CI Analyzer

Title Follow-up to Atellica CH Iron3 (Iron3) Impacting Atellica CH Cholesterol_2 (Chol_2), Atellica CH LDL Cholesterol (LDLC), and Atellica CH Triglycerides_2 (Trig_2) Results

Date Issued May-2024

Follow-up Information In March 2024, Siemens Healthineers issued an Urgent Field Safety Notice (UFSN), ACHC24-03.A.OUS, for the Iron3 product listed in the table below. The communication provided short-term mitigation steps while Siemens worked towards ramping up the supply volume to support customer conversion to the Iron_2 assay.

Siemens has restored inventory of Iron_2 reagents earlier than expected, and customers may transition to the Iron_2 assay.

Products	Assay	Test Code	Siemens Material Number/Unique Device Identification	Lot Number
	Atellica CH Iron3	Iron3	11537211 / 00630414610849	All lots

- Customer Actions**
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
 - Customers may now transition from the Iron3 assay and order Iron_2 reagents (SMN 11097601) for use. Please be advised that new orders will have to be placed.
 - For customers who elect to transition to the Iron_2 assay, complete and return the Product Replacement Form attached to this letter to request reagent credit for discarded Iron3 reagents.
 - For customers who elect to continue using the Iron3 assay, continue to follow the instructions in UFSN ACHC24-03.A.OUS.
 - Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

Resolution A follow up communication will be provided when "Customer Actions" are no longer required.

FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice **ACHC24-03.B.OUS** dated May-2024. Please read each question and indicate the appropriate answer.

If you have received any complaints of illness or adverse events associated with the products listed in the table on Page 1 immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Return this completed form as per the instructions provided at the bottom of this page.

- 1. I have read and understood the instructions provided in this letter. Yes No
- 2. Is your laboratory electing to transition from the Atellica CH Iron3 assay to the Atellica CH Iron_2 assay? Yes No
- 3. If the answer to question #2 is yes, do you have Atellica CH Iron3 reagent in your laboratory that you will be discarding and require reagent credit? Please check inventories before answering. Yes No
- 4. All affected Site Personnel have been notified. Yes No

If the answer to the question #2 and #3 above is yes, please complete the table below to indicate the quantity of affected product in your laboratory for reimbursement.

Product Description Product Catalog #/SMN #	Quantity of Affected Product in Inventory Discarded/Reagent Credit Quantity Requested		
Atellica CH Iron3 / 11537211			
Name of person completing questionnaire:			
Title:			
Institution:			
Street:			
City:		State:	
Phone:		Country:	

Please send a scanned copy of the completed form via email to XXXX@XXXX.

Or to fax this completed form to the Customer Care Center at XXXXXX.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Siemens Healthineers
Siemens Healthcare Diagnostics Inc.

