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Urgent Field Safety Notice:

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

To whom it may concern,

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

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.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

Signature:  Electronically signed by: Roland Ertl
Reason: I am approving this document
Date: Jun 5, 2024 11:17 GMT+2

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