

Urgent Field Safety Notice

ACHC 25-05.A.OUS

Atellica CH Analyzer Atellica CI Analyzer

Title	Contamination of Some Bottles of Atellica CH Diluent Lot Number 0000191602
Date Issued	Feb 2025
Issue Description	<p>Siemens Healthineers has confirmed, through the investigation of customer complaints, the presence of Sodium Hypochlorite (NaOCl) contamination in certain bottles of Atellica CH Diluent lot number 0000191602, bottle sequence numbers 00001-04400 (cartons 00001-02200) used on Atellica CH 930 and Atellica CI Analyzers. Atellica IM assays are not affected.</p> <p>As a result of this issue, Calibrator, Quality Control (QC), and patient results could be affected for any Atellica CH assay excluding Sodium, Potassium, and Chloride. This issue is specific to Atellica CH Diluent lot number 0000191602. Unaffected alternate lots of this product are available.</p>

Products	Assay	Siemens Material Number/ Unique Device Identification	Lot Number	Expiration Date
	Atellica CH Diluent	11099300 / (01)00630414595771(10)0000191602(17)20251007	0000191602	07-Oct-2025

Note: Sequence numbers on the bottles are different than the sequence numbers on the carton as there are two bottles per carton (See Photos in Appendix).

Impact to Results	<ul style="list-style-type: none">Erroneously elevated or depressed results may occur due to this issue, with magnitude and direction that varies depending on the assay and contaminant concentration. Patients and QC materials will behave similarly.
Customer Actions	<ul style="list-style-type: none">Please discontinue use of and discard all inventory of the diluent lot number listed in the table above (Products Section).If lot number 0000191602 bottle sequence number 00001-04400 is currently on your analyzer, remove the bottle and replace with an alternate lot number. See Appendix for detailed instructions.Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens Healthineers for reporting to the authorities.Review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

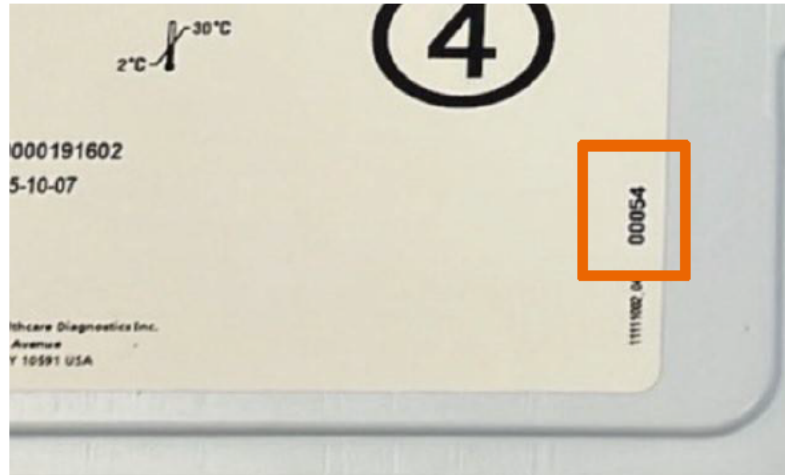
We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Single Registration
Number (SRN)

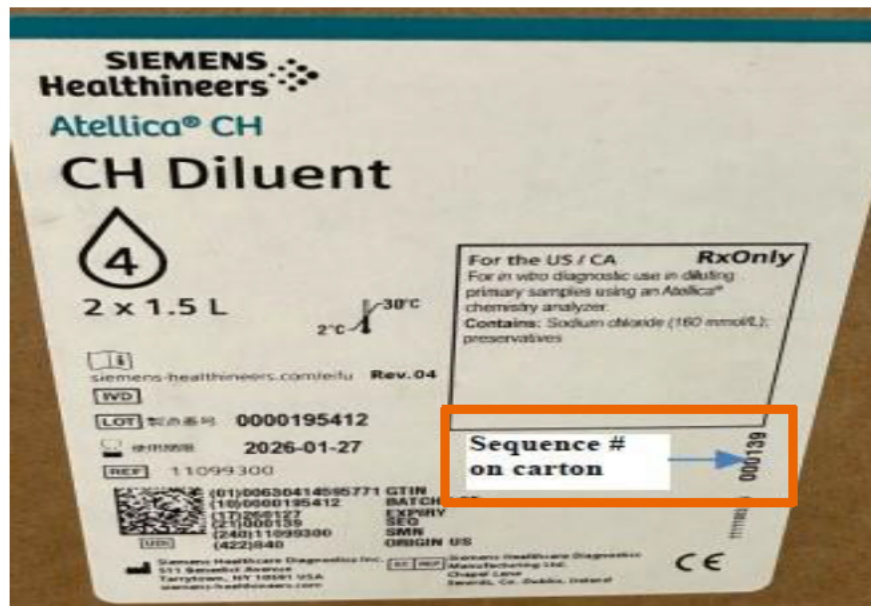
US-MF-000016560

Appendix

- Location of Sequence Number on Bottle



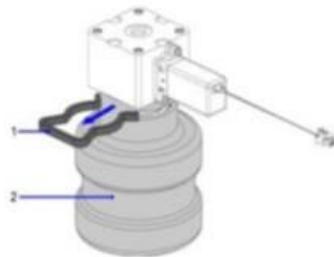
- Location of Sequence Number on Carton



Instructions for Removal of a Contaminated Atellica CH Diluent and Replacing with New Atellica CH Diluent

Please ensure that Appropriate Personal Protective Equipment is used

1. Remove the contaminated Atellica CH Diluent (Refer to [“Checking CH System and IMT Fluids”](#) located in the Troubleshooting of the Operators Guide Online Help for Atellica CH 930 or [“Replacing Atellica CI Analyzer System Fluids”](#) located in the Troubleshooting section of the Operators Guide Online Help for the Atellica CI 1900)
2. Remove the Reservoir, which is directly under the CH **Diluent** Fluid Bottle, by removing the retaining clip and carefully lowering the reservoir to prevent spilling of the **diluent** and damage to the straw.



Atellica® CH 930 Reservoir

- (1) Reservoir Retaining Clip
- (2) Reservoir

3. Empty the reservoir, re-install the reservoir and retaining clip on the analyzer.
4. Load an unaffected lot of Atellica CH Diluent (**do not use lot 0000191602 with a sequence number less than 2200 on the carton or 4400 on the bottle**) onto the analyzer (Refer to [“Checking CH System and IMT Fluids”](#) section of the Operators Guide Online Help for Atellica CH 930 or the [“Replacing Atellica CI Analyzer System Fluids”](#) section of the Operators Guide Online Help for the Atellica CI 1900).
5. Let reservoir fill up completely (takes approximately 15 minutes).
6. Repeat steps 1 through 5 to empty and refill the reservoir a second time.
7. Prime the Atellica CH Diluent **Five (5) times**.
 - For Atellica CH 930 follow the instructions in the Troubleshooting section of the Online Help for Performing Priming the CH Cleaner, CH Diluent, and Water in Operator Diagnostics.
 - For Atellica CI 1900 follow the instructions in the Troubleshooting section of the Online Help select Priming CH Dry to Wet in Operator Diagnostics.

NOTE: Track the number of prime sequences. The screen will not track it.

FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice ACHC25-05.A.OUS dated Feb-2025. Please read each question and indicate the appropriate answer.

If you have received any complaints of illness or adverse events associated with the product 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. Have you read and understood the instructions provided in this letter? Yes No
- 2. Do you have the affected product on hand? Please check inventories before answering. Yes No
- 3. Were affected Site Personnel notified? Yes No
- 4. Was a copy of the letter retained and posted with the current product labeling? Yes No

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

Product Description Product Catalog #/SMN #/Lot Number	Quantity of Affected Product in inventory Discarded/Replacement Quantity Required		
<i>Atellica CH Diluent / 11099300 / 0000191602</i>			
Name of person completing questionnaire:			
Title:			
Institution:			
Street:			
City:		State:	Zip Code:
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.
