Urgent Field Safety Notice

ACHC20-07.A.OUS

February 2020

Atellica® CH Analyzer

Atellica® CH Ethyl Alcohol (ETOH) Within-Pack Positive Shift with Quality Control (QC) and Patient Samples

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

Table 1. Atellica CH 930 Affected Product(s)

Assay	Test Code	Siemens Material Number (SMN)	Lot #
Atellica CH Ethyl Alcohol	ETOH	11097501	All Lots

Reason for Correction

The purpose of this communication is to inform you of an issue with the product indicated in Table1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. investigation has confirmed that the Atellica CH ETOH assay may exhibit a positive bias in QC and patient results within the 10-day pack calibration interval. When a positive bias is observed, the magnitude is similar for both quality control and patient results. The product issue potentially affects all Atellica CH ETOH reagent lots. Based on Siemens' internal investigation, not all laboratories are experiencing this issue. Siemens' investigation has shown that when this issue occurs, an average positive bias of 7 mg/dl (1.5 mmol/L) with a maximum bias of 11 mg/dL (2.4 mmol/L) at an ethanol concentration of approximately 20.6 mg/dL (4.5 mmol/L) was observed by day 10 of the pack calibration interval. Samples with an ethanol concentration of approximately 200 mg/dL (43.4 mmol/L) met expected performance criteria across the 10-day pack calibration interval.

Siemens is working to address this issue in a future software version.

Risk to Health

There is negligible risk to health due to the issue described above. Treatment for potential ethanol intoxication is mainly supportive and driven by clinical symptomology. Siemens is not recommending a review of previously generated results.

511 Benedict Avenue
Tarrytown, NY 10591

Actions to be Taken by the Customer

- If you are experiencing this issue, Siemens recommends performing a pack calibration every 2 days or more frequently based on your laboratory's Quality Control performance.

- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

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.

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FIELD CORRECTION EFFECTIVENESS CHECK

Atellica® CH Ethyl Alcohol (ETOH) Within-Pack Positive Shift with Quality Control (QC) and Patient Samples

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice ACHC 20-07.A.OUS dated February 2020 regarding Atellica® CH Ethyl Alcohol (ETOH) Within-Pack Positive Shift with Quality Control (QC) and Patient Samples.

Please read each question and indicate the appropriate answer. Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

1. I have read and understood the UFSN instructions provided in this letter. Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Customer Sold To #: Customer Ship To #:

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

If you have any questions, contact your local Siemens Healthineers technical support representative.

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