Urgent Field Safety Notice

ACHC23-01.C.OUS

July 2023

Atellica® CH 930 Analyzer

Reagent Carryover from Atellica CH Total Bilirubin_2 (TBil_2), Atellica CH LDL Cholesterol (LDLC), Atellica CH Gamma-Glutamyl Transferase (GGT) and Atellica CH HDL Cholesterol (HDLC)

Our records indicate that your facility may have received any of the following products:

Table 1. Atellica CH Products Causing Carryover

Assay	Test Code	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Lot Number
Atellica CH Total Bilirubin_2	TBil_2	11097531	00630414595818	All lots
Atellica CH LDL Cholesterol	LDLC	11537214	00630414611037	All lots
Atellica CH Gamma-Glutamyl Transferase	GGT	11097597	00630414596440	All lots
Atellica CH HDL Cholesterol	HDLC	11537213	00630414610832	All lots

Reason for Correction

The purpose of this communication is to inform you of an issue with the products indicated in Table 1 above and to provide instructions on actions that your laboratory must take.

If you do not run any of the assays listed in Table 1, there are no actions for your laboratory to take at this time.

Through a proactive internal screening, Siemens Healthcare Diagnostics Inc. has identified the potential for reagent carryover on the Atellica CH 930 resulting in a positive bias that could impact quality control (QC), patient samples, and calibrator results with specific assays as listed below in Tables 2 - 5. The addition of Reagent Probe Cleaner 2 (RPC2) wash mitigates this issue.

The resolution for the reagent carryover issues is implemented in Atellica Solution Software (SW) v1.25.4 SP3 and v1.28 which will be released soon. In the interim, please follow the instructions in the “Actions to be Taken by the Customer” section until all Atellica CH 930 Analyzers in your laboratory are updated to either SW v1.25.4 SP3 or v1.28 and higher.

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Risk to Health

For Glucose, Lipase, and Magnesium if this issue occurs there is a potential for erroneously increased patient results. Biases near medical decision levels would not be expected to lead to a clinically significant impact on patient management. Mitigations include patient history, signs and symptoms, and additional laboratory findings.

For Uric Acid, if this issue occurs there is a potential for erroneously increased patient results with biases that could lead to additional follow up testing for hyperuricemia. Mitigations include patient history, signs and symptoms, and additional laboratory findings including repeat testing.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- Perform the instructions provided in the “Additional Information” section.
- 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.

Additional Information

If your laboratory has multiple Atellica CH 930 Analyzers, separate the assays as follows:

- Perform testing of TBil_2 on a separate analyzer from Glucose Oxidase (GluO)
- Perform testing of LDLC on a separate analyzer from Lipase (Lip)
- Perform testing of GGT on a separate analyzer from Magnesium (Mg)
- Perform testing of HDLC on a separate analyzer from Uric Acid (UA)

If you choose not to or are unable to separate the assays as indicated above, batch testing of GluO, Lip, Mg and UA may be performed.

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Note: When batch testing impacted assays, GluO, Lip, Mg and UA, an RPC2 wash mitigation must be initiated after completion of tests with the assay causing carryover, TBil_2, LDLC, GGT and HDLC, respectively. Any of the following will initiate the RPC2 wash:

- After the Atellica CH 930 Analyzer has been in standby status for 12 minutes.
- Upon completion of any open channel assay.
- A restart of the Atellica CH 930 Analyzer.

Representative observed biases from Siemens internal testing are shown in Tables 2 - 5.

Table 2. Impact of TBil_2 Carryover on GluO Results

Sample	GluO mg/dL (mmol/L)	GluO After TBil_2 mg/dL (mmol/L)	Bias mg/dL (mmol/L)	% Bias
Serum QC L1	60 (3.3)	68 (3.8)	8 (0.4)	13%
Serum QC L2	112 (6.2)	121 (6.7)	9 (0.5)	8%
Serum QC L3	342 (19.0)	346 (19.2)	4 (0.2)	1%

Table 3. Impact of LDLC Carryover on Lip Results

Sample	Lip U/L	Lip After LDLC U/L	Bias U/L	% Bias
Serum QC L1	18	34	16	89%
Serum QC L2	51	64	13	25%
Serum QC L3	144	155	11	8%

Table 4. Impact of GGT Carryover on Mg Results

Sample	Mg mg/dL (mmol/L)	Mg After GGT mg/dL (mmol/L)	Bias mg/dL (mmol/L)	% Bias
Serum QC L1	1.08 (0.44)	1.34 (0.55)	0.26 (0.11)	24%
Serum QC L1 & L2 mixture	1.64 (0.67)	1.88 (0.77)	0.24 (0.10)	15%
Serum QC L2	2.61 (1.07)	2.83 (1.16)	0.22 (0.09)	8%
Serum QC L3	4.32 (1.78)	4.53 (1.86)	0.21 (0.09)	5%

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Table 5. Impact of HDLC Carryover on UA Results

Sample	UA mg/dL (µmol/L)	UA After HDLC mg/dL (µmol/L)	Bias mg/dL (µmol/L)	% Bias
Serum QC L1	3.3 (196)	5.1 (303)	1.8 (107)	55%
Serum QC L2	5.4 (321)	7.7 (458)	2.3 (137)	43%
Serum QC L3	8.8 (524)	11.2 (666)	2.4 (143)	27%

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FIELD CORRECTION EFFECTIVENESS CHECK

Reagent Carryover from Atellica CH Total Bilirubin_2 (TBil_2), Atellica CH LDL Cholesterol (LDLC), Atellica CH Gamma-Glutamyl Transferase (GGT) and Atellica CH HDL Cholesterol (HDLC)

This response form is to confirm receipt of the enclosed Siemens Healthcare Urgent Field Safety Notice ACHC23-01.C.OUS dated July 2023 regarding Reagent Carryover from Atellica CH Total Bilirubin_2 (TBil_2), Atellica CH LDL Cholesterol (LDLC), Atellica CH Gamma-Glutamyl Transferase (GGT) and Atellica CH HDL Cholesterol (HDLC). 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 ☐
2. Is your laboratory currently running any of the assays in Table 1 on the Atellica CH 930? Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

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.

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

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