Urgent Field Safety Notice

ACHC22-02.A.OUS

February 2022

Atellica® CH 930 Analyzer

Reagent Carryover Impacting Results of Several Assays

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

Table 1. Atellica CH Affected Products

Assay	Test Code	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Lot Number
Atellica CH Calcium_2	CA_2	11097644	00630414220697	All lots
Atellica CH Enzymatic Hemoglobin A1c	A1c_E/A1c_H	11097536	00630414220505	All lots
Atellica CH Fructosamine	Fruc	11097637	00630414595580	All lots
Atellica CH Lithium_2	LITH_2	11532401	00630414287935	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 provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. has confirmed the potential for reagent carryover impacting quality control (QC), patient samples, and calibrator results. See Table 2 below.

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

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Table 2. Observed Behaviors

Assay Causing Carryover	Impacted Assay	Impact of Carryover	Additional Details
A1c_E/A1c_H	CA_2*	Elevated	Refer to Table 4
CA_2*	UN_c	Depressed	Refer to Table 5, impacts urine samples only
Fruc	AAT	Depressed	Refer to Table 6
	IgA_2	Elevated	Refer to Table 7
	IgM_2	Elevated	Refer to Table 8
	Theo	Depressed	Refer to Table 9
LITH_2**	CA_2*	Elevated	Refer to Table 10
	TBil_2	Depressed	Refer to Table 11

* The Calcium assay with test code Ca is not affected

** The Lithium assay with the test code Li is not affected

Investigation into the observed behaviors listed in Table 2 indicates the addition of Reagent Probe Cleaner 2 (RPC2) wash prevents carryover.

The resolution will be implemented in Atellica Solution Software (SW) v1.25.2. In the interim, please follow the instructions in the “Actions to be Taken by the Customer” section until all Atellica CH analyzers in your laboratory are updated to SW v1.25.2 or higher.

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Risk to Health

Table 3

Assay Causing Carryover	Impacted Assay	Risk to Health
A1c_E/A1c_H	CA_2	The biases observed at the medical decision limits for the impacted assay would not be expected to cause a clinically significant difference in patient management.
CA_2	UN_c (Urine only)	
Fruc	AAT	
	IgA_2	
	IgM_2	
	Theo	
LITH_2	CA_2	
LITH_2	TBil_2	The probability of processing TBil_2 immediately following LITH_2 is low. When TBil_2 is processed immediately after LITH_2, the potential exists for delayed diagnosis and/or intervention for hyperbilirubinemia in an adult population. Clinical impact would be mitigated by correlation with clinical history and symptomology and additional laboratory biomarkers. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director
- Perform the instructions provided in the “Additional Information” section below.
- 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 these products.

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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Additional Information

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

- LITH_2 from CA_2 and TBil_2
- A1c_E/A1c_H from CA_2
- CA_2 from UN_c (urine only); UN_c serum and plasma are not impacted and can be run on the same analyzer as CA_2
- Fruc from AAT, IgA_2, IgM_2 and Theo

If you choose not to separate the assays as indicated above, batch testing of A1c_E, Fruc, LITH_2, and UN_c (urine only) may be considered.

Note: An RPC2 wash mitigation must be initiated after completion of A1c_E, Fruc, LITH_2, and prior to UN_c (urine only). Any of the following will initiate the RPC2 wash:

- After the Atellica CH 930 Analyzer has been in standby for 12 minutes.
- After completion of any Open Channel assay.
- Restarting the Atellica CH 930 Analyzer. Refer to the Atellica Solution Online Help for instructions on system restart.

Table 4. Impact of A1c_E/A1c_H Carryover on CA_2 Results

Sample	CA_2 mg/dL (mmol/L)	CA_2 After A1c_E/ A1c_H mg/dL (mmol/L)	% Bias
Serum QC L1	6.4 (1.60)	7.2 (1.80)	+13
Serum QC L2	10.1 (2.53)	11.0 (2.75)	+9
Serum QC L3	13.6 (3.40)	14.4 (3.60)	+6
Serum Patient Sample	9.3 (2.33)	10.0 (2.50)	+8
Urine QC L1	7.0 (1.75)	8.1 (2.03)	+16
Urine QC L2	10.1 (2.53)	11.2 (2.75)	+11

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Table 5. Impact of CA_2 Carryover on Urine UN_c Results

Sample	UN_c mg/dL (mmol/L)	UN_c After CA_2 mg/dL (mmol/L)	% Bias
Urine QC Pool 1	419 (149.6)	393 (140.3)	-6
Urine QC Pool 2	735 (262.4)	677 (241.7)	-8
Urine Patient Pool	495 (176.7)	452 (161.4)	-9

Table 6. Impact of Fruc Carryover on AAT Results

Sample	AAT mg/dL (g/L)	AAT After Fruc mg/dL (g/L)	% Bias
Serum QC Pool 1	91 (0.91)	80 (0.80)	-13
Serum QC Pool 2	100 (1.00)	87 (0.87)	-12
Serum QC Pool 3	119 (1.19)	103 (1.03)	-13
LSP Calibrator Pool	275 (2.75)	245 (2.45)	-11

Table 7. Impact of Fruc Carryover on IgA_2 Results

Sample	IgA_2 mg/dL (g/L)	IgA_2 After Fruc mg/dL (g/L)	% Bias
Serum QC Pool 1	176.1 (1.76)	207.5 (2.08)	+18
Serum QC Pool 2	211.0 (2.11)	245.6 (2.46)	+16

Table 8. Impact of Fruc Carryover on IgM_2 Results

Sample	IgM_2 mg/dL (g/L)	IgM_2 After Fruc mg/dL (g/L)	% Bias
Serum QC Pool 1	69.5 (0.70)	87.3 (0.87)	+26
Serum QC Pool 2	73.0 (0.73)	98.5 (0.99)	+35
Serum QC Pool 3	93.5 (0.94)	104.9 (1.05)	+12
LSP Calibrator Pool	206.7 (2.07)	242.7 (2.43)	+17

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Table 9. Impact of Fruc Carryover on Theo Results

Sample	Theo µg/mL (µmol/L)	Theo After Fruc µg/mL (µmol/L)	% Bias
Serum QC L1	5.1 (28.2)	4.6 (25.8)	-9
Serum Patient Pool	11.4 (63.1)	10.6 (59.0)	-7

Table 10. Impact of LITH_2 Carryover on CA_2 Results

Sample	CA_2 mg/dL (mmol/L)	CA_2 After LITH_2 mg/dL (mmol/L)	% Bias
Serum QC L1	6.2 (1.55)	6.7 (1.68)	+8
Serum QC L2	10.3 (2.58)	11.0 (2.75)	+7
Serum QC L3	13.3 (3.33)	14.2 (3.55)	+7
Serum Patient Sample	9.6 (2.40)	10.2 (2.55)	+7
Urine QC L1	6.6 (1.65)	7.2 (1.80)	+8
Urine QC L2	9.8 (2.45)	10.6 (2.65)	+8

Table 11. Impact of LITH_2 Carryover on TBil_2 Results

Sample	TBil_2 mg/dL (µmol/L)	TBil_2 After LITH_2 mg/dL (µmol/L)	% Bias
Serum QC L1	0.8 (13.7)	0.2 (3.4)	-75
Serum QC L2	3.7 (63.3)	3.0 (51.3)	-19
Serum QC L3	9.2 (157.3)	8.7 (148.8)	-5
Serum Patient Sample	1.1 (18.8)	0.5 (8.6)	-55

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FIELD CORRECTION EFFECTIVENESS CHECK

Reagent Carryover Impacting Results of Several Assays

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice ACHC22-02.A.OUS dated February 2022 regarding Reagent Carryover Impacting Results of Several Assays.

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(s):

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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