Urgent Field Safety Notice

ACHC23-01.B.OUS

January 2023

Atellica® CH 930 Analyzer

Reagent Carryover from LDL Cholesterol Direct (DLDL), Total Protein II (TP), Triglycerides (Trig), and Triglycerides_2 (Trig_2) Impacting Magnesium (Mg) Results

Our records indicate that your facility may have received 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 LDL Cholesterol Direct	DLDL	11097632	00630414596181	All lots
Atellica CH Total Protein II	TP	11097604	00630414596372	All lots
Atellica CH Triglycerides (concentrated)	Trig	11097591	00630414596495	All lots
Atellica CH Triglycerides_2	Trig_2	11537222	00630414610955	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 through customer complaints the potential for reagent carryover impacting Magnesium (Mg) quality control (QC), patient samples, and calibrator results. Internal testing has shown that the impact on Mg test results can vary.

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.

Investigation into the carryover from the assays (DLDL, TP, Trig, Trig_2) in Table 1 indicates that the addition of Reagent Probe Cleaner 2 (RPC2) wash prevents this issue.

This issue is resolved by the addition of a Reagent Probe Cleaner 2 (RPC2) wash to the assays listed in Table 1 and will be implemented in Atellica Solution Software (SW) v1.27 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 SW v1.27 or higher.

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Risk to Health

Worst case, there is a potential for erroneously increased magnesium patient results, which may lead to additional investigation for hypermagnesemia or delayed investigation for hypomagnesemia. Mitigations include signs and symptoms, additional laboratory findings, and repeat testing. A review of previously generated results is not recommended as patient results would not be used in isolation, rather results would be used in conjunction with overall clinical presentation.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- 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 DLDL, TP, Trig and Trig_2 on an analyzer separate from Mg.

If you choose not to separate the assays as indicated above, batch testing of Mg may be performed.

Note: When batch testing Mg, an RPC2 wash mitigation must be initiated after completion of DLDL, TP, Trig and Trig_2. 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.

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The maximum observed biases from Siemens and customer data are shown in Tables 2 - 5.

Table 2. Impact of DLDL Carryover on Mg Results

Sample	Mg mg/dL (mmol/L)	Mg After DLDL mg/dL (mmol/L)	% Bias
Serum QC L1	0.91 (0.37)	1.67 (0.69)	84%
Serum Sample	2.31 (0.95)	2.90 (1.19)	26%

Table 3. Impact of TP Carryover on Mg Results

Sample	Mg mg/dL (mmol/L)	Mg After TP mg/dL (mmol/L)	% Bias
Serum QC L1	0.93 (0.38)	1.00 (0.41)	8%
Serum QC L2	2.46 (1.01)	2.53 (1.04)	3%
Serum QC L3	3.94 (1.62)	4.04 (1.66)	3%

Table 4. Impact of Trig Carryover on Mg Results

Sample	Mg mg/dL (mmol/L)	Mg After Trig mg/dL (mmol/L)	% Bias
Serum QC L1	0.91 (0.37)	1.48 (0.61)	63%
Serum Sample	2.31 (0.95)	2.68 (1.10)	16%
Serum QC L3	3.94 (1.62)	4.00 (1.64)	2%

Table 5. Impact of Trig_2 Carryover on Mg Results

Sample	Mg mg/dL (mmol/L)	Mg After Trig_2 mg/dL (mmol/L)	% Bias
Serum Sample	1.83 (0.75)	2.77 (1.14)	51%
Serum Sample	2.83 (1.16)	3.74 (1.54)	32%

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