

Urgent Field Safety Notice

ACHC20-10.A2.OUS

June 2020

Atellica® CH 930 Analyzer

Positive Bias Observed with Direct Bilirubin (DBil_2) and Total Bilirubin (TBil_2) Assays Following Calibration with Multiple Chemistry Calibrator Lots

Our records indicate that you may have received the following product:

Table 1. Atellica® CH Affected Product:

Calibrator	Siemens Material Number (SMN)	Lot Number	Expiration Date	Distribution Date
Chemistry Calibrator	11099411	534179	2021-10-31	2019-12-17
		534179A	2021-12-31	2020-01-20
		534179B	2021-12-31	2020-01-16
		534179C	2022-01-31	2020-02-24
		534179D	2022-01-31	2020-02-24
		534179E	2022-03-31	2020-04-23
		911591	2022-03-31	2020-04-07
		911591A	2022-05-31	2020-06
		911591B	2022-05-31	2020-06
		911591C	2022-05-31	2020-06

Reason for Correction

The purpose of this communication is to inform you of an issue with the Chemistry Calibrator (Chem Cal) lots indicated in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics has observed a positive bias with Quality Control (QC) and patient sample values for Direct Bilirubin (DBil_2) and Total Bilirubin (TBil_2) assays on the Atellica CH system following calibration with affected Chemistry Calibrator lots listed in Table 1. The bias has been attributed to bilirubin instability with these lots of Chemistry Calibrator. The positive bias may lead to QC results exceeding a laboratory's established ranges. Calibration errors may also be observed. See Table 2 below for representative QC performance from Siemens internal testing with affected Chem Cal lots. Testing of patient samples demonstrated similar performance.

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Table 2: Representative Internal QC Testing Recovery when using Affected Calibrator Lots vs. Expected Values

Assay	QC Product Lot	QC Level	Expected Mean mg/dL (µmol/L)	Expected Range mg/dL (µmol/L)	Recovery when using Affected Calibrator lots mg/dL (µmol/L)	% Bias
DBil_2	Bio-Rad Multiqual Lot 47980	1	0.4 (6.8)	0.2 - 0.4 (3.4 - 6.8)	0.3 (5.1)	-25%
		2	1.4 (23.9)	1.3 - 1.5 (22.2 - 25.7)	1.6 (27.4)	+14%
		3	2.9 (49.6)	2.5 - 3.3 (42.8 - 56.4)	3.1 (53.0)	+7%
	Bio-Rad Pediatric Control Lot 44350	2	7.5 (128.3)	7.2 - 7.8 (123.1-133.4)	8.9 (152.2)	+19%
TBil_2	Bio-Rad Multiqual Lot 47980	1	0.7 (12.0)	0.6 - 0.8 (10.3 - 13.7)	0.7 (12.0)	0%
		2	3.3 (56.4)	3.2 - 3.4 (54.7 - 58.1)	3.5 (59.9)	+6%
		3	7.8 (133.4)	7.3 - 8.3 (124.8 - 141.9)	8.0 (136.8)	+3%
	Bio-Rad Pediatric Control Lot 44350	2	18.0 (307.8)	17.4 - 18.6 (297.5 - 318.1)	18.7 (319.8)	+4%

All other analytes present in the Chem Cal continue to meet product standards.

All available lots of Chem Cal currently in Siemens inventory are similarly impacted. Siemens is working to restore the bilirubin stability of the Chem Cal. A follow up communication will be issued when a Chem Cal lot suitable for use with the DBil_2 and TBil_2 assays becomes available.

The root cause of this issue is under investigation.

Risk to Health

The calibrator issue described above may lead to an apparent delay in testing due to the inability to calibrate the assay or due to quality control results that do not meet acceptability criteria. If quality control results are within range when using an affected calibrator lot, the difference in patient results when compared to an unaffected calibration would not be expected to lead to a clinically significant difference in patient management. Siemens is not recommending a review of previously generated results.

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Actions to be taken by the Customer

- Discontinue use of the Chem Cal lots listed in Table 1 for DBil_2 and TBil_2 calibration. The lots remain suitable for calibration of the other analytes contained in the Chem Cal.
- Reserve any unaffected lots of Chem Cal within the expiration date (not listed in Table 1) for calibration of only DBil_2 and TBil_2.
- A valid calibration can be extended based on acceptable QC performance. Instructions to extend calibration can be found in the Atellica CH Online Help Guide.
- If the recommendations above are not suitable for your laboratory, alternative testing is recommended for the Atellica CH DBil_2 and TBil_2 assays.
- Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.
- Review this letter with your Medical Director.

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 Customer Care Center or your local Siemens Technical Support Representative.

Atellica CH is a trademark of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (ACHC20-10.A.OUS) dated June 2020 titled *Positive Bias Observed with Direct Bilirubin (DBIL_2) and Total Bilirubin (TBIL_2) Assays Following Calibration with Multiple Chemistry Calibrator Lots*. Please read the question below and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number indicated at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice 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 fax this completed form to the Customer Care Center at (###) ###-####. If you have any questions, contact your local Siemens technical support representative.