Urgent Field Safety Notice

ACHC20-10.A1.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 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 Atellica CH 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 an unaffected lot of Chem Cal is not available, Siemens has evaluated the use of the RANDOX Calibration Serum Level 3 (CAL 3) Lot 1024UE as a suitable alternative. Siemens has verified the accuracy of this calibrator on the Atellica CH System by method comparison (see Figure 1 below). Results obtained at individual laboratories may vary. Siemens recommends that laboratories verify the accuracy of the results with acceptable QC performance when using the RANDOX CAL 3 calibrator prior to reporting of patient samples. Please see instructions in the Additional Comments Section below. Product availability may vary by country.
- 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.

Additional Instructions:

RANDOX CALIBRATION SERUM LEVEL 3 (CAL 3) Ordering Information:
Product Name: RANDOX Calibration Serum Level 3 (CAL 3) Lot 1024UE
Product Siemens Material Number (SMN) / Reference Number (REF): 10328299 / 8492806
RANDOX Catalog Number CAL 2351 (if ordered directly from RANDOX)

RANDOX CALIBRATION SERUM LEVEL 3 (CAL 3) PRODUCT INFORMATION (as published in the RANDOX Product Insert):
Storage and Stability Requirements for Bilirubin:
Un-reconstituted: Un-reconstituted serum is stable up to the expiry date shown on the side of each individual bottle.
Reconstituted: Bilirubin in the serum is light sensitive and it is recommended that the serum is stored in the dark. Stored in the dark, it is stable for 1 day at +2°C to +8°C. Do not store at +15°C to +25°C. Do not freeze.

Preparation for Use:
Serum must only be reconstituted using the following procedure:
1. Open the vial carefully, avoiding any loss of material.
2. Reconstitute by pipetting exactly 5 ml of distilled water at +15ºC to +25ºC, into the vial.
3. Replace the rubber stopper and leave to stand for 30 minutes out of bright light before use.
4. Swirl gently several times during the reconstitution period to ensure that the contents are completely dissolved.
5. Prior to use, mix the contents by inverting the vial. Do not shake the vial as the formation of foam should be avoided.
Ensure that no lyophilized material remains un-reconstituted.
6. The serum is then ready for use with either a manual test or with an automated instrument.

Assigned Values
Refer to the SIEMENS ATELLICA / ADVIA 1200/1650/1800/2400® section of the RANDOX CAL 3 IFU for assigned values for TBil_2 and DBil_2.

Note: Siemens has only verified the use of the RANDOX Calibration Serum Level 3 (CAL 3) Lot 1024UE to calibrate Direct Bilirubin (DBil_2) and Total Bilirubin (TBil_2). Siemens has not verified the performance of the other analyte constituents contained in the RANDOX CAL 3 product. Siemens is only recommending the use of verified RANDOX CAL 3 lot 1024UE.

Refer to the RANDOX CAL 3 IFU for complete instructions for use of this product.

CALIBRATION:
Manually Adding Atellica CH Calibrator Definitions
1. On the Command bar, select **Calibration** > **Calibrator Definitions**.
2. Select **Add New**.
3. In Add Calibrator Definition, select the Calibrator Material option circle.
4. From the Assay Type drop-down menu, select CH.

5. In Material Name enter a name for the calibrator definition, e.g. RANDOX CAL3
6. In Material ID, enter the ID from the calibrator lot-specific value sheet.
NOTE: The Material ID is an optional field that contains 1 or 2 alphanumeric characters.
7. In Lot ID, enter the calibrator lot.
8. In Expiration Date, select the calibrator material expiration date from the drop-down calendar.
9. In Revision, enter the revision number from the calibrator lot-specific value sheet.
10. To enable the calibrator material for calibration, select **Active**.
11. Do not select **Store Onboard**. Stability of the RANDOX CAL 3 has not been established for onboard storage on the Sample Handler of the Atellica CH system and is not recommended by Siemens.
12. Select 1 or more assays associated with the calibrator material.
13. Enter the concentration values for each level from the calibrator lot-specific value sheet.
14. Select **Save**.

Refer to the Atellica CH Online Help Guide or contact the Siemens Customer Care Center for additional assistance, if needed.

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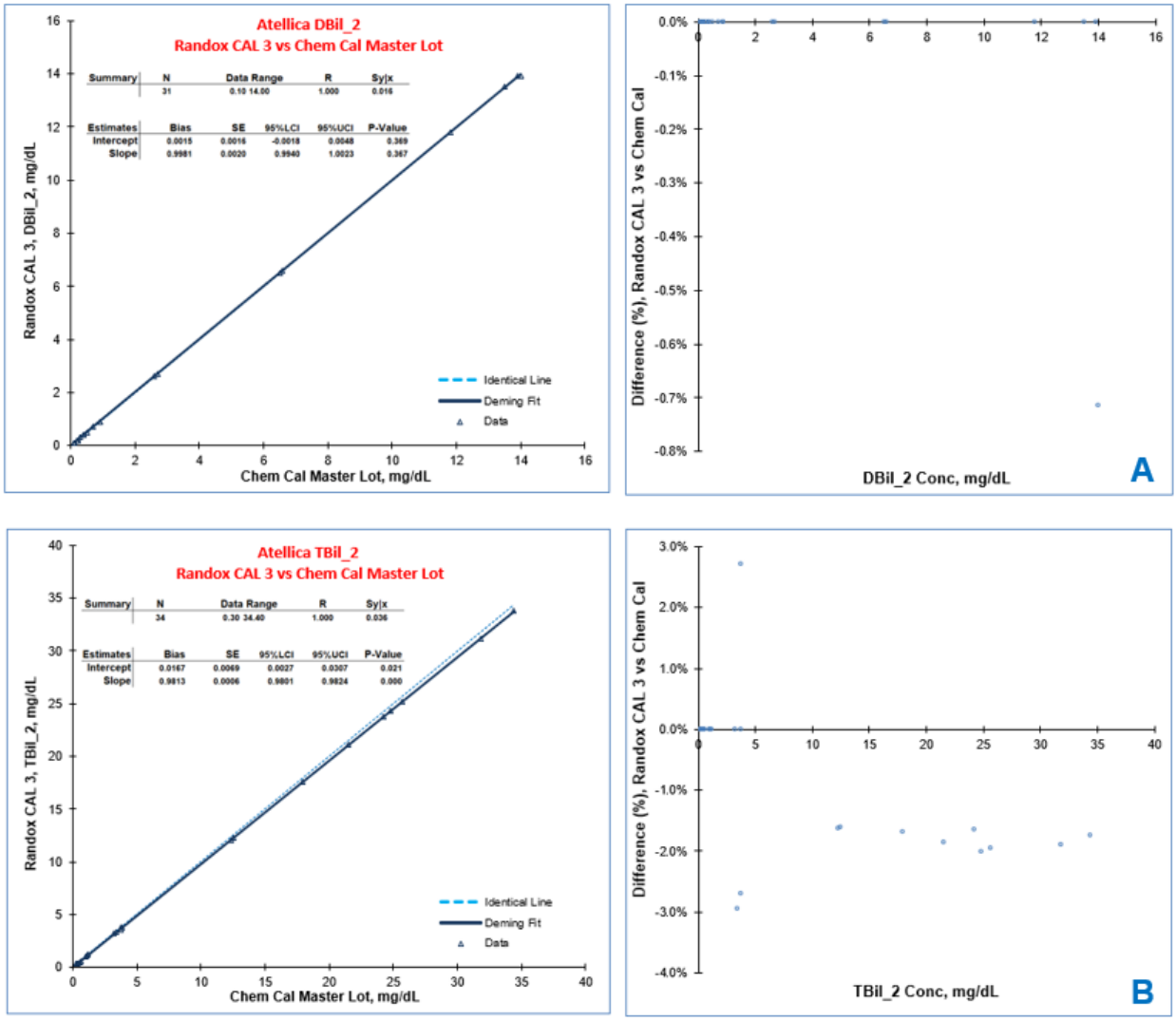
FIGURE 1: Method Comparison / Correlation and Difference (%) plots of patient sample recoveries comparison between RANDOX CAL 3 and Chem Cal Master Lot for (A) Atellica CH DBil_2; (B) Atellica CH TBil_2.



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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.

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