

Urgent Field Safety Notice

Follow-up information

ACHC20-10.B1a.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

Reason for Communication

Siemens Healthcare Diagnostics Inc. issued Urgent Field Safety Notice (UFSN) ACHC20-10.A1.OUS in June 2020 to inform customers of a positive bias with Quality Control (QC) and patient sample values with the Direct Bilirubin (DBil_2) and Total Bilirubin (TBil_2) Assays on the Atellica CH following calibration with affected Chemistry Calibrator lots.

As a follow up, we are providing additional information which may be considered when evaluating potential interim solutions until a new Atellica CH Chemistry Calibrator lot suitable for use with the DBil_2 and TBil_2 assays becomes available.

The formulation, preparation, and assigned values for the ADVIA Chemistry Calibrator and the Atellica® CH Chemistry Calibrator are identical. The ADVIA Chemistry Calibrator may be used in place of the Atellica CH Chemistry Calibrator to calibrate the Direct Bilirubin (DBil_2) and Total Bilirubin (TBil_2) Assays on the Atellica CH Analyzer. Table 1 contains a list of affected lots which should not be used, and Table 2 contains a list of unaffected lots which are within the expiration date and may be used to calibrate the bilirubin assays.

Table 1. Affected Lots

Product Name	Lot Numbers
Atellica CH Chemistry Calibrator (SMN 11099411)	534179, 534179A, 534179B, 534179C, 534179D, 534179E 911591, 911591A, 911591B, 911591C
AD VIA Chemistry Chemistry Calibrator (SMN 10312279)	534177, 534177A, 534177B, 534177C, 534177D 960742

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Table 2. **Unaffected Lots**

Product Name	Lot Numbers
Atellica CH Chemistry Calibrator (SMN 11099411)	298873A, 298873B, 298873C, 298873D 491095, 491095A, 491095B, 491095C, 491095D
ADVIA Chemistry Chemistry Calibrator (SMN 10312279)	298846A, 298846B, 298846C 453025, 453025A, 453025B, 453025C

Additional lots of RANDOX Calibration Serum Level 3 (CAL 3) have been evaluated as a suitable alternative. In addition to RANDOX CAL 3 lot 1024UE, Siemens has verified the accuracy of RANDOX CAL 3 Lots 1014UE and 1162UE on the Atellica CH by method comparison (see Figure 1 below). Results obtained at individual laboratories may vary. Siemens recommends that laboratories perform a lot calibration with the initial use and verify the accuracy of the results with acceptable QC performance when using the RANDOX CAL 3 Calibrator, prior to reporting of patient samples.

Refer to instructions in ACHC20-10.A1.OUS for using the RANDOX CAL 3 with Atellica CH DBil_2 and TBil_2 assays. Product availability may vary by country.

Refer to the Additional Instructions below for guidance when using the ADVIA Chemistry Calibrator for manual configuration of calibrator definitions.

Actions to be taken by the Customer

- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

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.

ADVIA and Atellica are trademarks of Siemens Healthcare Diagnostics

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Additional Instructions

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) Lots 1024UE, 1014UE and 1162UE 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 lots 1024UE, 1014UE and 1162UE.

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

CALIBRATION:

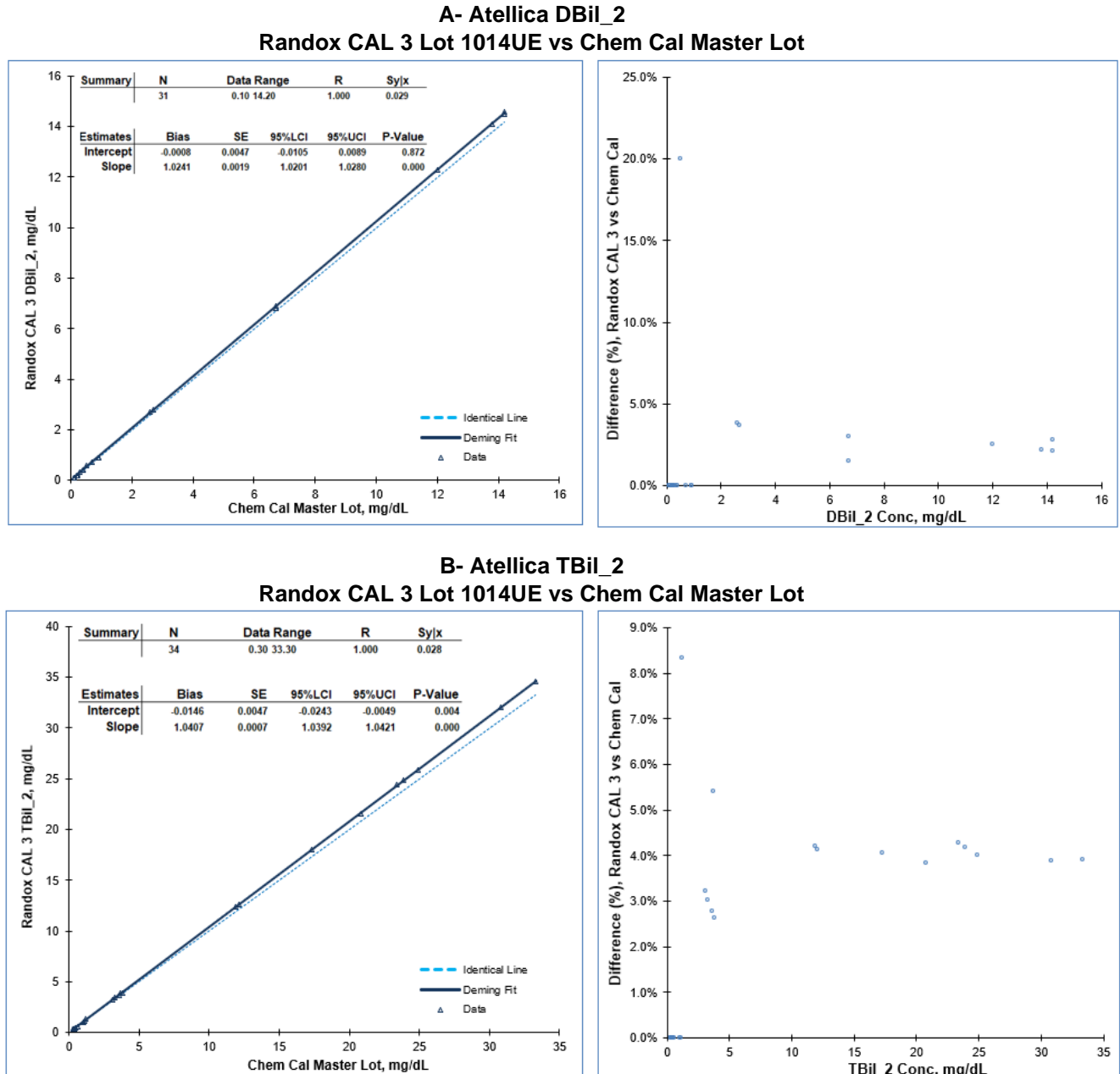
Manually Adding Atellica CH Calibrator Definitions

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. ADVIA Chemistry Calibrator, RANDOX CAL 3.
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 ADVIA Chemistry Calibrator and the RANDOX CAL 3 has not been established for onboard storage on the Sample Handler of the Atellica 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.

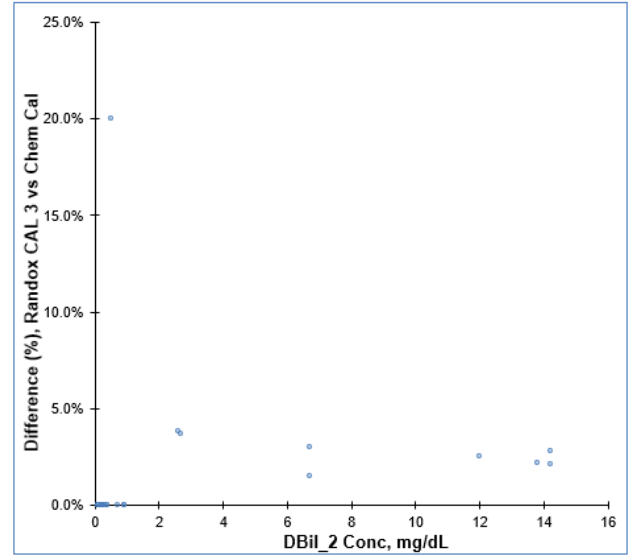
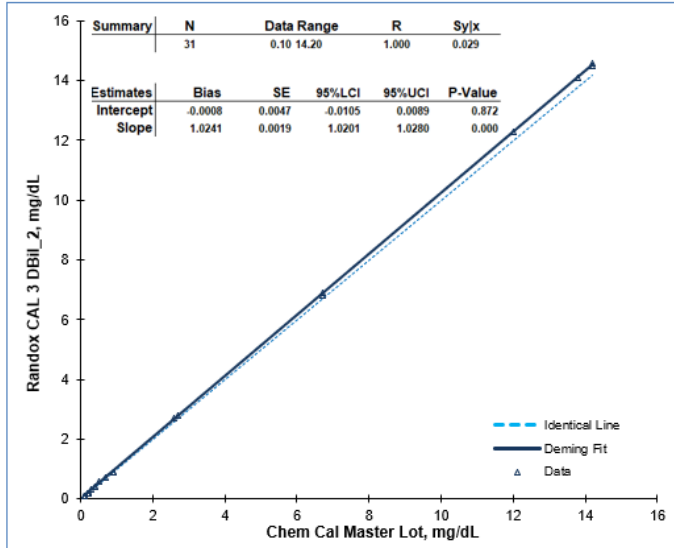
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FIGURE 1: Method Comparison / Correlation and Difference (%) plots of patient sample recoveries comparison between RANDOX CAL 3 Lot 1014UE and Chem Cal Master Lot for (A) Atellica CH DBil_2; and (B) Atellica CH TBil_2. and RANDOX CAL 3 lot 1162UE and Chem Cal Master Lot for (C) Atellica CH DBIL_2 and (D) Atellica CH TBIL_2

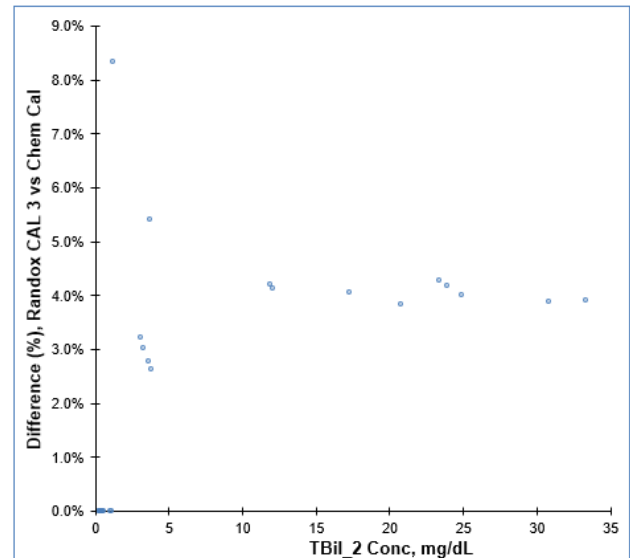
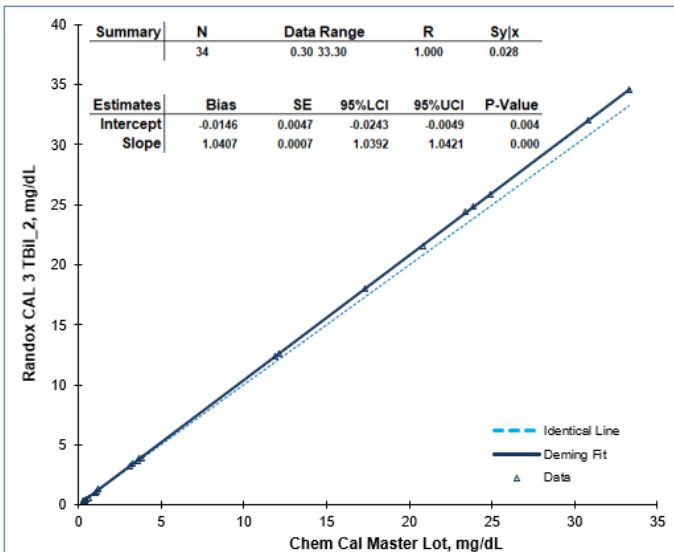


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**C- Atellica DBil_2
Randox CAL 3 Lot 1162UE vs Chem Cal Master Lot**



**D- Atellica TBil_2
Randox CAL 3 Lot 1162UE vs Chem Cal Master Lot**



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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.B1a.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 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.