

## Urgent Field Safety Notice

Follow-up information

**ACHC20-10.B1a.OUS.CHC**

**June 2020**

**ADVIA® Chemistry 1800  
ADVIA Chemistry 2400  
ADVIA Chemistry XPT**

### **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.CHC 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 ADVIA Chemistry system 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 ADVIA 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 Atellica CH Chemistry Calibrator may be used in place of the ADVIA Chemistry Calibrator to calibrate the Direct Bilirubin (DBIL\_2) and Total Bilirubin (TBIL\_2) Assays on the ADVIA Chemistry system. 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**

<b>Product Name</b>	<b>Lot Numbers</b>
Atellica CH Chemistry Calibrator (SMN 11099411)	534179, 534179A, 534179B, 534179C, 534179D, 534179E 911591, 911591A, 911591B, 911591C
ADVIA Chemistry Chemistry Calibrator (SMN 10312279)	534177, 534177A, 534177B, 534177C, 534177D 960742

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Table 2. **Unaffected Lots**

<b>Product Name</b>	<b>Lot Numbers</b>
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 ADVIA Chemistry 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.

Refer to instructions in ACHC20-10.A1.OUS.CHC for using the RANDOX CAL 3 with ADVIA Chemistry DBil\_2 and TBil\_2 assays. Product availability may vary by country.

Refer to the Additional Instructions below for guidance when using the Atellica CH Calibrator for configuration of the calibrator definition.

**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.

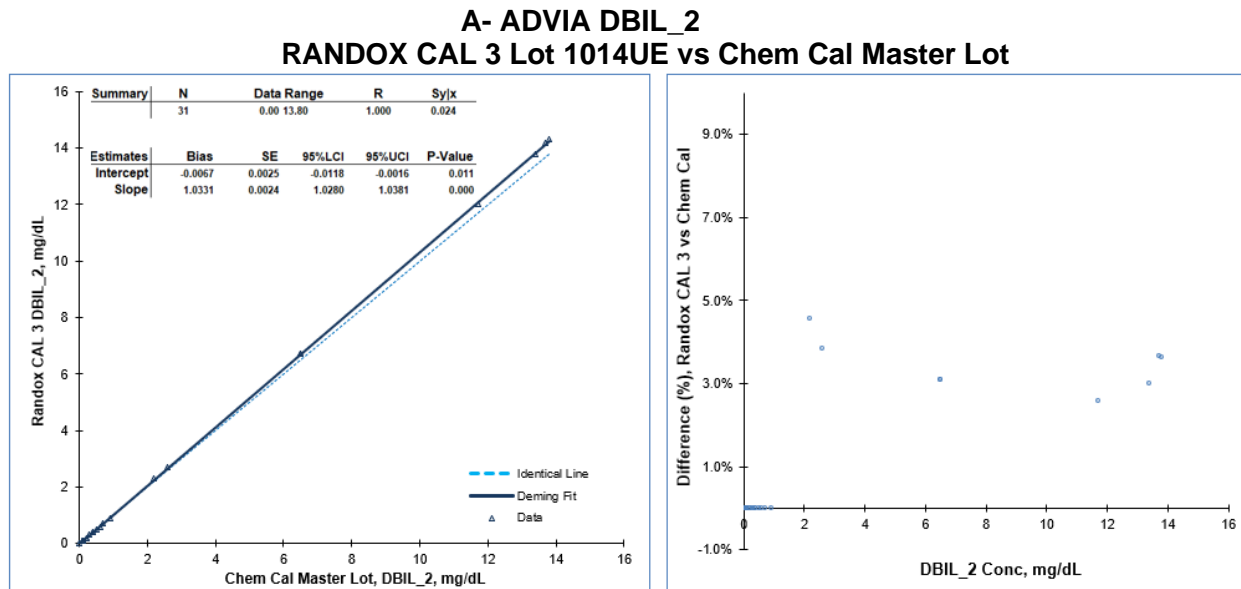
Note: Siemens has only verified the use of the RANDOX Calibration Serum Level 3 (CAL 3) Lots 1024UE ,1014UE and 1162UE to calibrate Direct Bilirubin (DBil\_2) and Total Bilirubin (TBil\_2). Siemens has not verified the performance of the other analyte constituents contained in the RANDOX CAL 3 product. 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:**

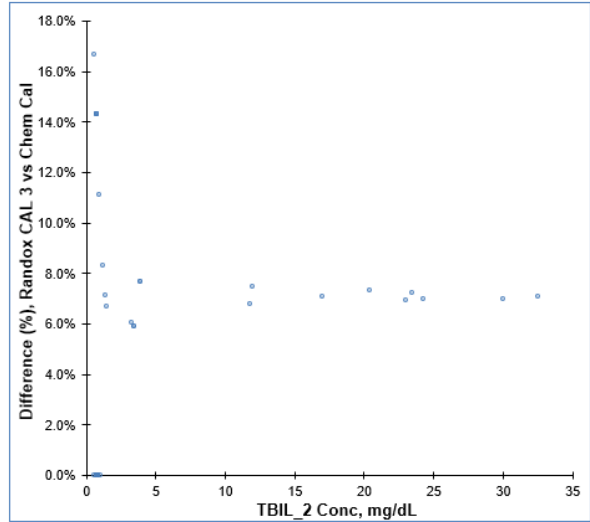
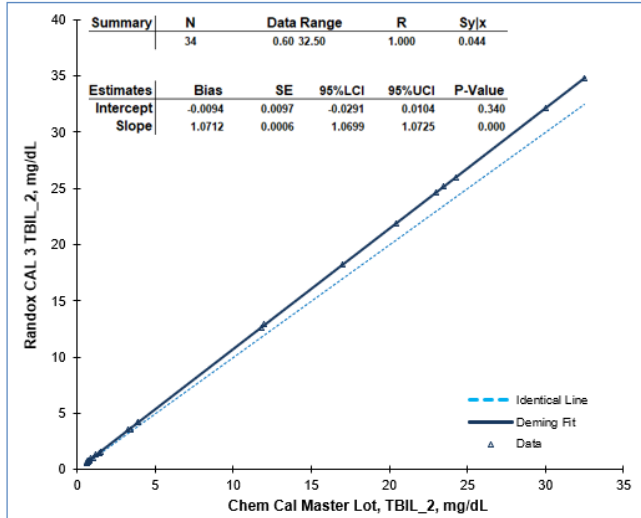
Prior to using the Atellica CH Chemistry Calibrator or RANDOX CAL 3 for the TBIL\_2 and DBIL\_2 assays, configure the calibrator definition and factor value (FV) in the ADVIA Chemistry instrument software using the steps outlined in the ADVIA Operator’s Guide. Please contact your Siemens Customer Care Center for additional assistance, if needed.

**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) ADVIA Chemistry DBIL\_2; and (B) ADVIA TBIL\_2 and RANDOX CAL 3 lot 1162UE and Chem Cal Master Lot for (C) ADVIA Chemistry DBIL\_2; and (D) ADVIA TBIL\_2

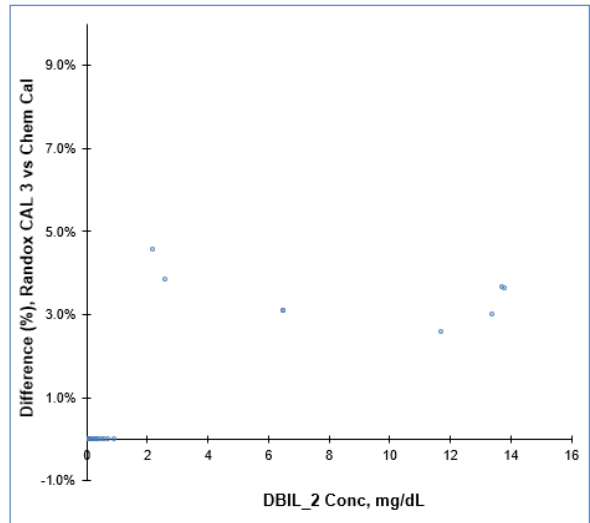
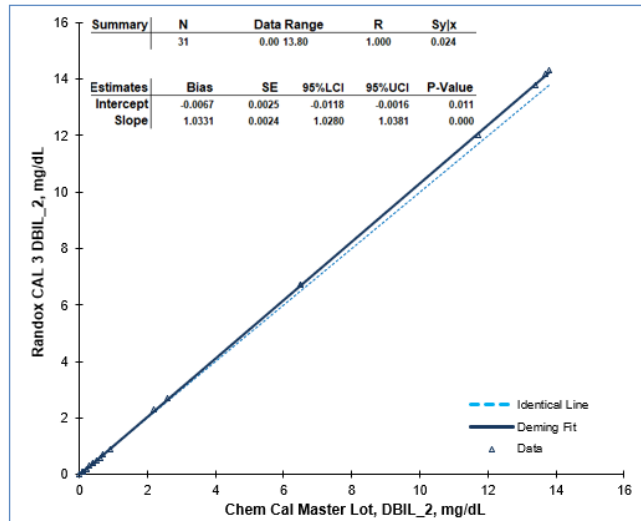


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**B- ADVIA TBIL\_2  
RANDOX CAL 3 Lot 1014UE vs Chem Cal Master Lot**

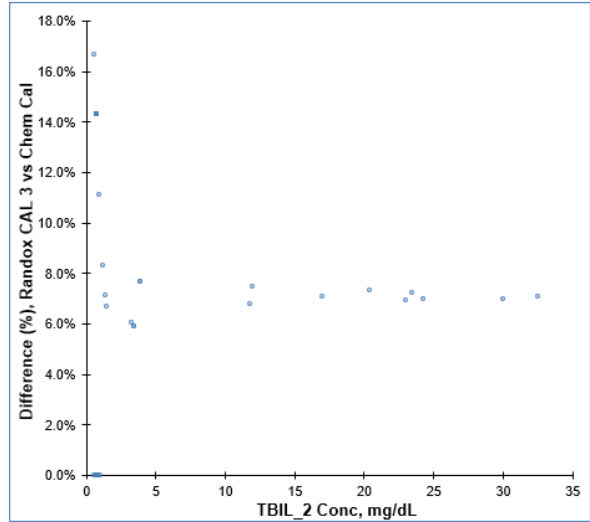
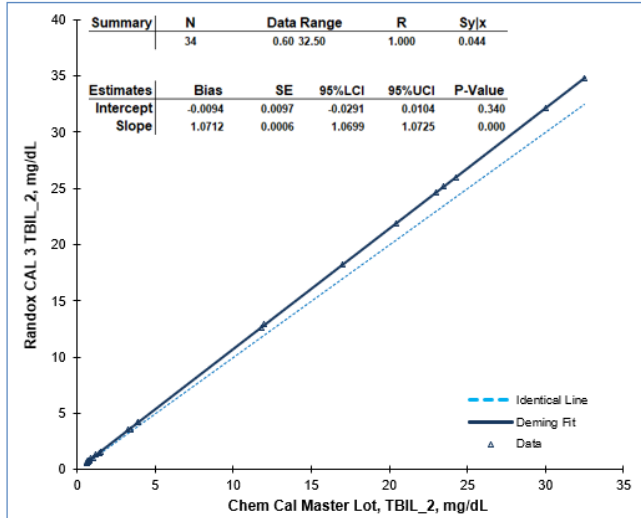


**C- ADVIA DBIL\_2  
RANDOX CAL 3 Lot 1162UE vs Chem Cal Master Lot**



**Positive Bias Observed with Direct Bilirubin (DBIL\_2) and Total Bilirubin (TBIL\_2) Assays Following Calibration with Multiple Chemistry Calibrator Lots**

**D- ADVIA 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.CHC) 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

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Name of person completing questionnaire: \_\_\_\_\_

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Title: \_\_\_\_\_

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Institution: \_\_\_\_\_ Instrument Serial Number: \_\_\_\_\_

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Street: \_\_\_\_\_

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City: \_\_\_\_\_ State: \_\_\_\_\_

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Phone: \_\_\_\_\_ Country: \_\_\_\_\_

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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.