Urgent Field Safety Notice

Follow-up information

ACHC20-10.B2.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.A2.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
ADVIA 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 Calibrator (SMN 10312279)	298846A, 298846B, 298846C 453025, 453025A, 453025B, 453025C

Refer to the Additional Instructions below for guidance on how to manually add calibrator definitions.

Additional Instructions

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
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**. Onboard storage of the ADVIA Chemistry Calibrator on the Sample Handler of the Atellica system 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.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product. 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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FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (ACHC20-10.B2.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.