

Urgent Field Safety Notice

Follow-up information

ACHC20-10.C.OUS

August 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.A.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 system following calibration with affected Chemistry Calibrator lots. Urgent Field Safety Notice ACHC20-10.B.OUS was issued later in June 2020 which provided information for consideration when evaluating potential interim solutions until an unaffected Chemistry Calibrator became available.

As a follow up to ACHC20-10, this communication is to inform customers that the performance of the Chemistry Calibrator has been restored.

Chemistry Calibrator (SMN 11099411) lots 993626, 993626A and 993626B are now available for distribution and are suitable for calibration of the Atellica CH DBil_2 and TBil_2 assays as well as all other analytes present in the Chemistry Calibrator. All orders will be filled with these lots or a future lot. Standard calibration procedures for the DBil_2 and TBil_2 assays have been restored with these lots and future Chemistry Calibrator lots. The previously communicated interim solutions are no longer necessary.

Actions to be taken by the Customer

- Please review this letter with your Medical Director.
- Going forward please use Chemistry Calibrator lot 993626, 993626A, 993626B or future lots for calibration of DBil_2 and TBil_2 assays. As a reminder, affected lots can continue to be used to calibrate all other analytes.
- 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 have caused. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Atellica CH is a trademark of Siemens Healthcare Diagnostics

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

FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (ACHC20-10.C.OUS) dated August 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 Sinead.McKeogh@cruinn.ie or fax to (01) 6297401. If you have any questions, contact your local Siemens technical support representative.