

Urgent Field Safety Notice

ACHC20-10.A2.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

Our records indicate that you may have received the following product:

Table 1. ADVIA® Chemistry Systems Affected Product:

| Calibrator | Siemens Material Number (SMN) /Reference Number (REF) | Lot Number | Expiration Date | Distribution Date |
|----------------------|---|------------|-----------------|-------------------|
| Chemistry Calibrator | 10312279 / 09784096 | 534177 | 2021-09-30 | 2019-12-31 |
| | | 534177A | 2021-10-31 | 2020-03-28 |
| | | 534177B | 2021-12-31 | 2020-01-17 |
| | | 534177C | 2022-01-31 | 2020-02-24 |
| | | 534177D | 2022-03-31 | 2020-06 |
| | | 960742 | 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 ADVIA Chemistry 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

Positive Bias Observed with Direct Bilirubin (DBIL_2) and Total Bilirubin (TBIL_2) Assays Following Calibration with Multiple Chemistry Calibrator Lots

performance from Siemens internal testing with affected Chem Cal lots. Testing of patient samples demonstrated similar performance.

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 Multiquel Lot 47980 | 1 | 0.3 (5.1) | 0.2 - 0.4 (3.4 - 6.8) | 0.3 (5.1) | 0% |
| | | 2 | 1.4 (23.9) | 1.3 - 1.5 (22.2 - 25.7) | 1.7 (29.1) | +21% |
| | | 3 | 2.4 (41.0) | 2.0 - 2.8 (34.2 - 47.9) | 3.2 (54.7) | +33% |
| | Bio-Rad Pediatric Control Lot 44350 | 2 | 7.5 (128.3) | 7.2 - 7.8 (123.1 - 133.4) | 10.1 (172.7) | +35% |
| TBIL_2 | Bio-Rad Multiquel Lot 47980 | 1 | 0.7 (12.0) | 0.6 - 0.8 (10.3 - 13.7) | 0.8 (13.7) | +14% |
| | | 2 | 3.3 (56.4) | 3.2 - 3.4 (54.7 - 58.1) | 3.6 (61.6) | +9% |
| | | 3 | 7.6 (130.0) | 7.2 - 8.1 (123.1 - 138.5) | 8.4 (143.6) | +11% |
| | Bio-Rad Pediatric Control Lot 44350 | 2 | 18.0 (307.8) | 17.4 - 18.6 (297.5 - 318.1) | 19.8 (338.6) | +10% |

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 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.

***Positive Bias Observed with Direct Bilirubin (DBIL_2) and Total Bilirubin (TBIL_2) Assays
Following Calibration with Multiple Chemistry Calibrator Lots***

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.
- If an unaffected lot is not available, alternative testing is recommended for the ADVIA Chemistry 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 Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

ADVIA 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.A.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 ☐

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.