SIEMENS

# Urgent Field Safety Notice

**CHC16-09.A.OUS**

**October 2016**

## ADVIA® Chemistry Systems

## Chemistry Calibrator Reassignment for the ADVIA® Chemistry Direct Bilirubin Assay (DBIL_2)

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

**Table 1. ADVIA® Chemistry Systems Affected Product:**

| Calibrator | Siemens Material Number (SMN) / Siemens Reference Number (REF) | Lot Number | Expiration Date | Manufacturing /1st Distribution Date |
|---|---|---|---|---|
| Chemistry Calibrator | 10312279 | 680726 | 2017-06 | 2015-02-05 / 2015-06-24 |
| Chemistry Calibrator | 10312279 | 680726A | 2017-09 | 2015-02-05 / 2015-10-06 |
| Chemistry Calibrator | 10312279 | 680726B | 2017-12 | 2015-02-05 / 2016-01-08 |
| Chemistry Calibrator | 10312279 | 680726C | 2018-02 | 2015-02-05 / 2016-03-17 |
| Chemistry Calibrator | 10312279 | 680726D | 2018-02 | 2015-02-05 / 2016-03-17 |

### Reason for Correction

Siemens Healthcare Diagnostics is conducting a Field Action for the ADVIA® Chemistry Systems Chemistry Calibrator for the lots specified in Table 1.

Siemens has confirmed that the DBIL_2 Assigned Calibrator Values (ACV) currently assigned to these lots may cause, on average, a positive proportional bias of approximately 41% on patient samples compared to the reference method for Direct Bilirubin measurement. Due to the proportional bias, the differences become greater as the concentration of DBIL_2 increases. Quality control (QC) material is also affected by this issue (Please refer to Table 3). Depending on the quality control concentrations and ranges used by the laboratory, quality control may not detect this issue.

To correct the positive bias, the ACV for DBIL_2 has been reassigned for the lots in Table 1. Refer to Table 2 for the reassigned values.

Beginning with Chemistry Calibrator Lot 807936, Siemens has restored alignment to the reference method. Therefore, reassignment for DBIL_2 is not required for this lot of Chemistry Calibrator.


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**Table 2. Reassigned Chemistry Calibrator Values for ADVIA Chemistry Direct Bilirubin Assay (DBIL_2)**

| Calibrator Lot | **Current Calibrator Values, Direct Bilirubin [mg/dL (µmol/L)]** | **Reassigned Calibrator Values, Direct Bilirubin [mg/dL (µmol/L)]** |
|---|---|---|
| 680726<br>680726A<br>680726B<br>680726C<br>680726D | 4.51 mg/dL (77 µmol/L) | 3.21 mg/dL (55 µmol/L) |

**Table 3. Representative data on the impact of calibrator value reassignment on Bio-Rad Lyphochek® Assayed Chemistry Control**

| **Calibrator lot** | **QC** | **Before Reassignment** | **After Reassignment** | **% Difference** |
|---|---|---|---|---|
| 680726 | QC -1 | 0.50 mg/dL (8.55 µmol/L) | 0.30 mg/dL (5.13 µmol/L) | 40% lower |
| | QC -2 | 1.50 mg/dL (25.65 µmol/L) | 1.10 mg/dL (18.81 µmol/L) | 27% lower |

Table 3 shows the representative data on the impact on QC observed for Calibrator lot 680726 when testing Bio-Rad Lyphochek® Assayed Chemistry Control lot 26400 (Expiration date: 2018-08-31) before and after calibrator value reassignment.

Patient results and QC will shift proportionally downward to align with reference methodology, beginning with the reassignment of calibrator values for lots 680726, 680726A, 680726B, 680726C, and 680726D. Control targets and ranges should be reviewed and adjusted accordingly.

All other analytes present in the Chemistry Calibrator meet product standards.

Please see **Additional Information** section for patient sample correlation of the DBIL_2 assay and bias plot before and after calibrator value reassignment.


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**Risk to Health**

The proportional positive bias observed when using the ADVIA® Chemistry Systems Chemistry Calibrator for the lots specified in Table 1 may lead to an overestimation of direct bilirubin. When this issue occurs, the potential exists for further monitoring or confirmation of a potential abnormal direct bilirubin finding during the assessment of liver dysfunction and/or during the investigation of jaundice. Direct bilirubin would be used in conjunction with clinical presentation and other laboratory testing, including but not limited to liver enzymes and total bilirubin. The extent of the proportional bias, worst case, may result in an erroneous and unbelievable result whereby the direct bilirubin value is greater than the total bilirubin.

The risk to health as a result of this issue is negligible. Siemens is not recommending a review of previously generated results.

**Actions to be taken by the Customer**

- Use the reassigned DBIL_2 ACVs for Chemistry Calibrator Lot Numbers 680726, 680726A, 680726B, 680726C and 680726D provided in Table 2.
- Control targets and ranges should be reviewed and adjusted accordingly.
- 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 Customer Care Center or your local Siemens Technical Support Representative.

## Additional Information

A representative correlation of DBIL_2 before and after calibrator value reassignment using patient samples can be seen in Figures 1 and 2 below. Figures 1 and 2 demonstrate that after reassignment of the DBIL_2 calibrator value for Chemistry Calibrator Lots 680726 and 680726 A through D, the bias is corrected and DBIL_2 recovery is aligned to the reference method.


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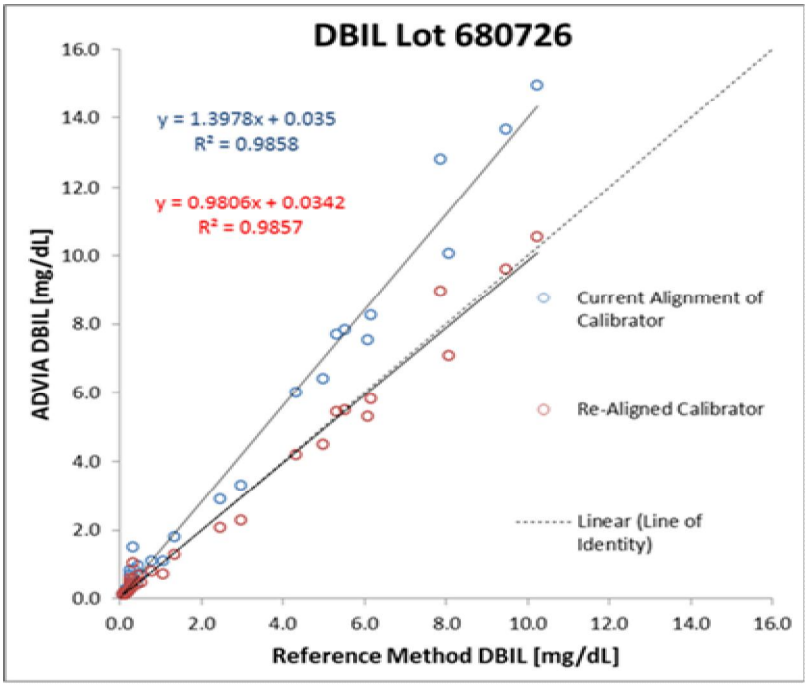
**Figure 1. Patient sample correlation of the Direct Bilirubin Assay (DBIL_2) and bias plot before and after calibrator value reassignment in mg/dL**



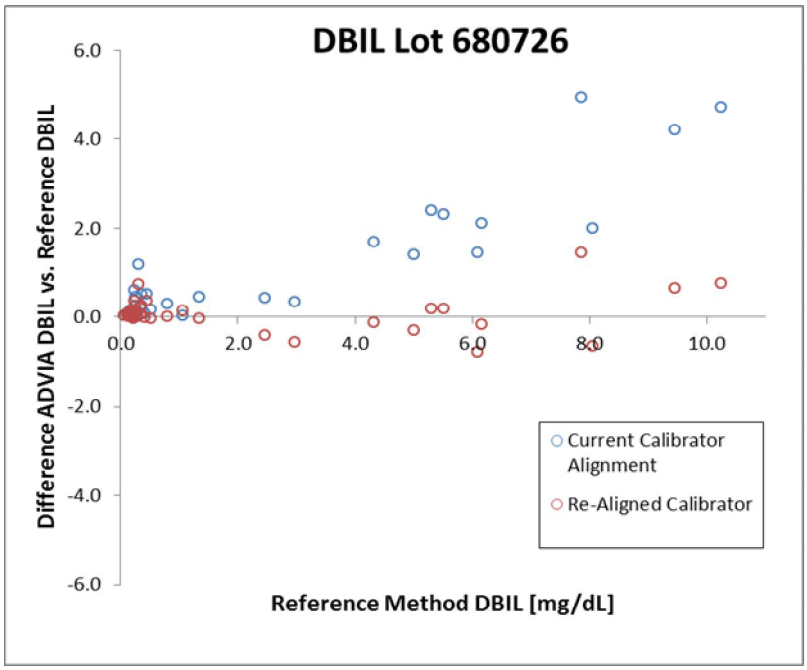
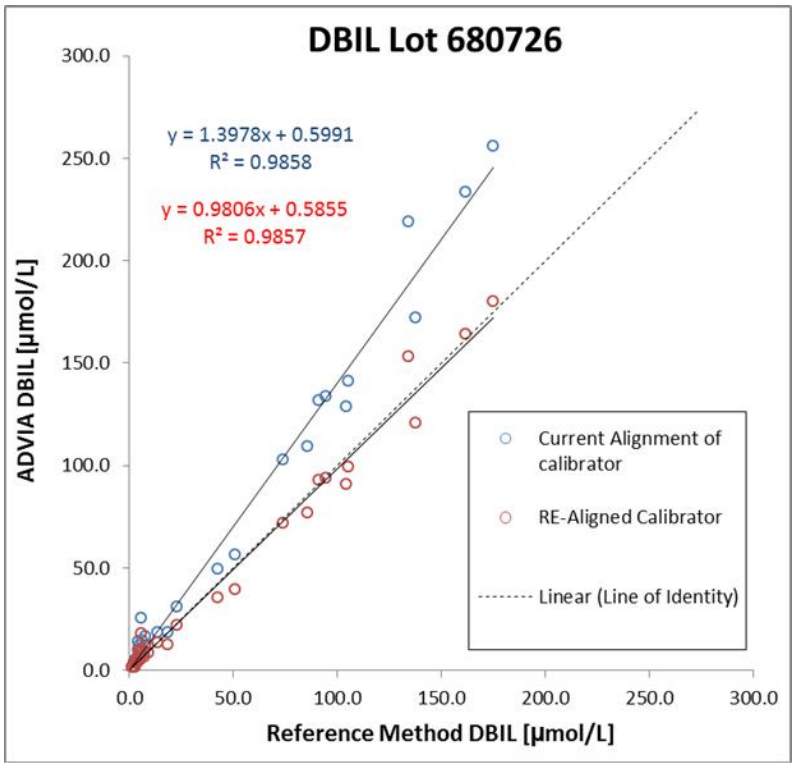
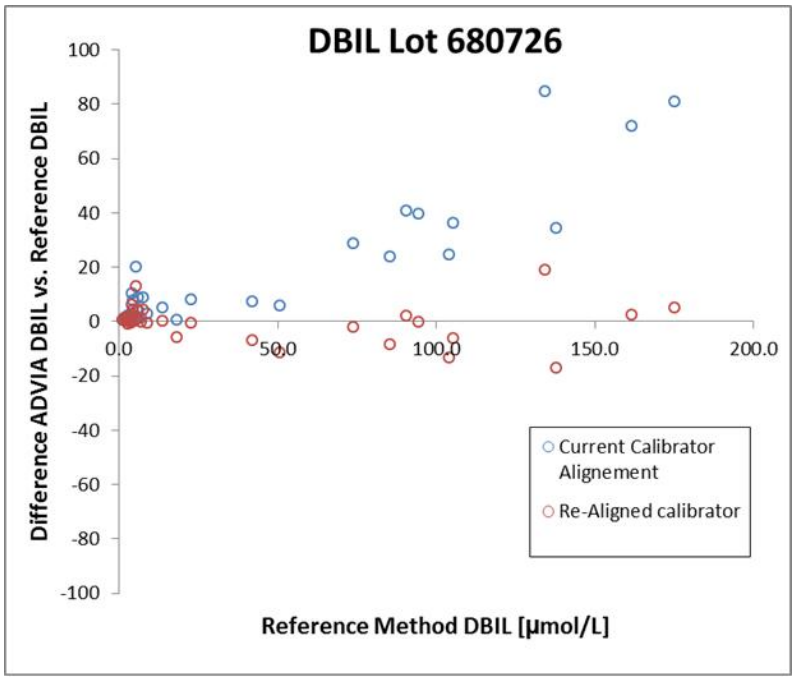



**Figure 2: Patient sample correlation of the Direct Bilirubin Assay (DBIL_2) and bias plot before and after calibrator value reassignment in µmol/L**

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## FIELD CORRECTION EFFECTIVENESS CHECK

Chemistry Calibrator Reassignment for the ADVIA Chemistry Direct Bilirubin Assay (DBIL_2)

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (CHC16-09.A.OUS) dated October 2016 regarding the reassignment of Calibrator Values for Chemistry Calibrator Lots 680726, 680726A, 680726B, 680726C and 680726D for the ADVIA Chemistry Direct Bilirubin Assay (DBIL_2). Please read each question 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 instructions provided in this letter. 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.


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