Urgent Medical Device Correction

ACHC20-04.A.US

November 19, 2019

Atellica CH® 930 Analyzer

Reassignment of the Atellica CH® High Sensitivity C-Reactive Protein (hsCRP) Calibrator Lot 453716

Our records indicate that your facility may have received the following product:

Table 1. Atellica CH Systems Affected Product(s)

Calibrator	Reference Number	Siemens Material Number (SMN)	Lot Number	Expiration Date (YYYY-MM-DD)	Manufacturing /1st Distribution Date (YYYY-MM-DD)
High Sensitivity C-Reactive Protein (hsCRP) Calibrator	11099412	11099412	453716	2020-01-28	2018-07-28 / 2018-10-08

Reason for Correction

The purpose of this communication is to inform you of an issue with the product indicated in Table1 above and provide instructions on actions that your laboratory must take.

Siemens has confirmed that the current assigned values for Atellica CH hsCRP Calibrator Lot 453716 demonstrate a positive bias of approximately 11% for hsCRP patient samples and Quality Control material when compared to the European Reference Material ERM DA474/IFCC for CRP measurement. Depending on the QC concentrations and ranges used by the laboratory, QC may not detect this issue.

To correct for the positive bias, the values for Atellica CH hsCRP Calibrator Lot 453716 have been reassigned to align with reference material ERM DA474/IFCC. The information in Table 2 supersedes the information in the calibrator lot-specific value sheet for hsCRP Calibrator Lot 453716. Refer to Table 2 for the reassigned calibrator values.

Table 2. Current and Re-assigned values for hsCRP calibrator Lot 453716

Calibrator Level	Current Calibrator Values, mg/L	Reassigned Calibrator Values, mg/L
CAL 1	0.00	0.00
CAL 2	0.54	0.47
CAL 3	1.08	0.92
CAL 4	1.63	1.41
CAL 5	5.40	4.90
CAL 6	10.80	9.58

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Patient and Quality Control results are expected to shift approximately -11% when using the reassigned calibrator values for Lot 453716. Based on the negative shift in recovery, it may be necessary to adjust your laboratory's quality control ranges. Refer to Table 3 for representative quality control recovery data. Future commercial calibrator lots will be traceable to this new reference material and will demonstrate comparable performance to the reassigned values.

Table 3. Quality Control Recovery

Quality Control Material	Mean (mg/L)	Range (mg/L)	Current Calibrator Values Lot 453610 (mg/L)	Re-Assigned Calibrator Values Lot 453610 (mg/L)
Bio-Rad Liquichek Lipids Control Level 57511	0.940	0.379 – 1.50	1.26	1.13
Bio-Rad Liquichek Lipids Control Level 57512	5.68	4.59 – 6.78	6.14	5.47

The Atellica CH hsCRP assay Instructions for Use (IFU) indicate that the assay is traceable to the certified reference material (CRM) 470. This material is no longer available. The Institute for Reference Materials and Measurement (IRMM) released European Reference Material (ERM) DA474/IFCC as the successor to reference materials ERM DA470 and ERM DA472.
Beginning with the re-assigned hsCRP Calibrator Lot 453716 and all subsequent lots, the product is traceable to ERM DA474/ IFCC.

Please see **Additional Information** section for patient sample correlation before and after calibrator value reassignment.

The information provided in this letter supersedes the information in the current Atellica CH hsCRP assay Instructions for Use (IFU) and the Declaration of Traceability and Uncertainty until these documents are updated.

Risk to Health

The risk to health due to this issue is negligible. Increased hsCRP results would be considered with other information, such as clinical history and symptomology, as well as other laboratory results. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Calibrate using the reassigned calibrator values for hsCRP Calibrator Lot 453716 provided in Table 2.
- Control targets and ranges should be reviewed and adjusted accordingly.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

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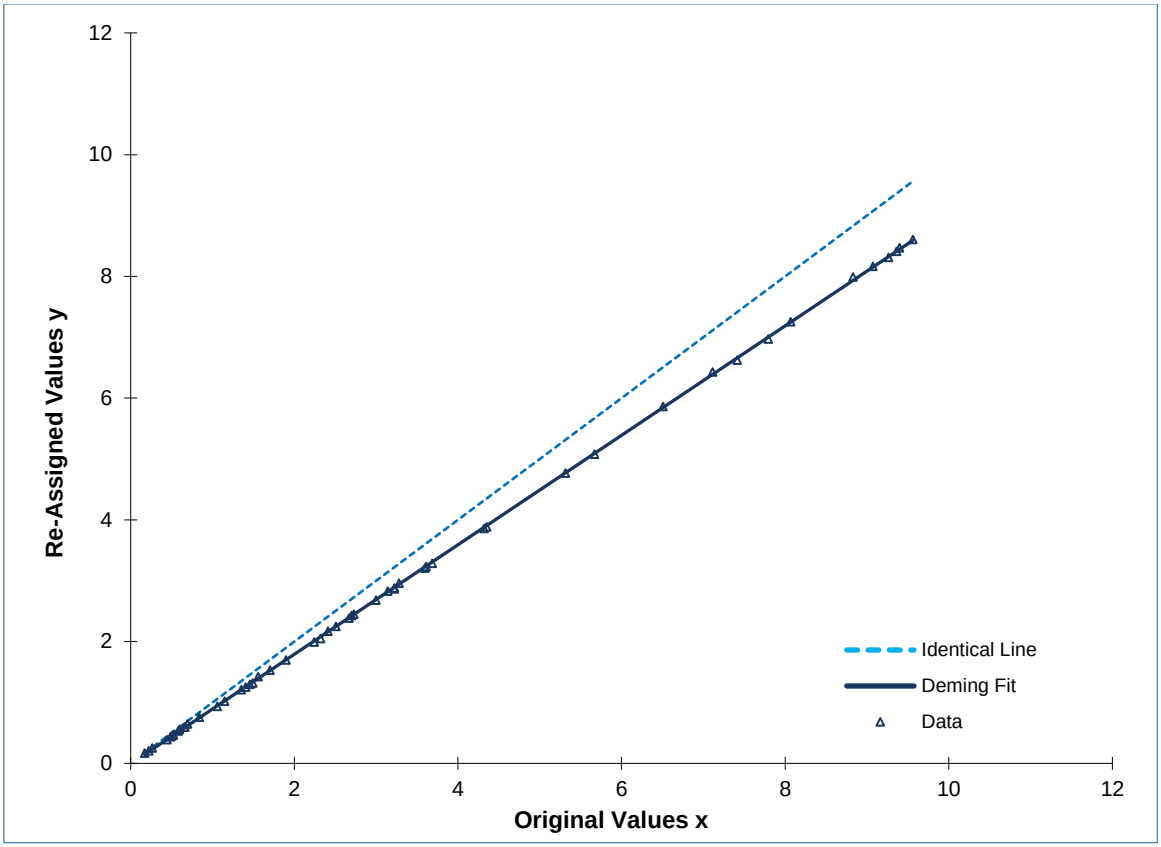
Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

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.

Additional Information

An hsCRP correlation study comparing patient sample recovery using original and re-assigned calibrator values can be seen in Figure 1 below. Figure 1 demonstrates that after reassignment of the hsCRP calibrator values for Calibrator Lot 453716, the bias is corrected and hsCRP recovery is aligned to the reference material ERM DA474/IFCC.

Figure 1. Patient sample correlation for Lot 453610 comparing results using original and re-assigned calibrator values, Deming Regression



Slope	0.892
Y-int	-0.001 mg/L
r	1.000
Range covered by samples	0.17 – 9.56 mg/L

FIELD CORRECTION EFFECTIVENESS CHECK

Atellica CH 930 Analyzer Reassignment of the ADVIA® Chemistry CardioPhase High Sensitivity C-Reactive Protein (hsCRP) Calibrator Lot 453716.

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Medical Device Correction, ACHC20-04.A.US dated November 19, 2019 regarding Atellica CH 930 Analyzer Reassignment of the Atellica CH High Sensitivity C-Reactive Protein (hsCRP) Calibrator Lot 453716. Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

1. I have read and understood the Urgent Medical Device Correction instructions provided in this letter. Yes ☐ No ☐

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Please send a scanned copy of the completed form via email to uscctsfcaecfax.team@siemens-healthineers.com, or to fax this completed form please send it to the Customer Care Center at (312) 275-7795 or If you have any questions, contact your local Siemens technical support representative.

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