

ACHC20-04.B.OUS
May 2020

Atellica CH® 930 Analyzer

Reassignment of the Atellica CH High Sensitivity C-Reactive Protein (hsCRP) Calibrator Lots 484721 and 516427

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

Table 1. Atellica CH Systems Affected Product(s)

Calibrator	Reference Number	Siemens Material Number (SMN)	Lot Number	Expiration Date (YYYY-MM-DD)	Manufacturing /1 st Distribution Date (YYYY-MM-DD)
High Sensitivity C-Reactive Protein (hsCRP) Calibrator	11099412	11099412	484721	2020-11-28	2019-05-28 / 2019-11-11
			516427	2021-08-28	

Reason for Communication

Siemens Healthcare Diagnostics Inc. issued Urgent Field Safety Notice (UFSN) ACHC20-04.A.OUS in November 2019 to inform customers of a positive bias for patient samples and quality control (QC) material when using the Atellica CH hsCRP Calibrator lot 453716 (expired).

As a follow up to ACHC20-04, we have completed our investigation and this communication provides additional information. The commutability from European Reference Material ERM470 to ERM DA474/IFCC is not equivalent for high sensitivity CRP assays. Further evaluation of the alignment of the Atellica CH hsCRP calibrators to the European Reference Material ERM DA474/IFCC has demonstrated a bias for patient and QC material that is greater than previously communicated.

Siemens has confirmed that the current assigned values for Atellica CH hsCRP Calibrator lots 484721 and 516427 demonstrate a positive bias of approximately 15% for hsCRP patient samples and QC 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

The values for the current Atellica CH hsCRP Calibrator lots 484721 and 516427 have been reassigned to align with reference material ERM DA474/IFCC. See Tables 2 and 3 below. Going forward, future commercial calibrator lots will be traceable to this new reference material and will demonstrate comparable performance to the reassigned values.

Table 2. Current and Re-assigned values for hsCRP calibrator lot 484721

Calibrator Level	Current Calibrator Values, mg/L	Reassigned Calibrator Values, mg/L
CAL 1	0.00	0.00
CAL 2	0.47	0.40
CAL 3	0.95	0.81
CAL 4	1.44	1.22
CAL 5	5.23	4.45
CAL 6	10.68	9.08

Table 3. Current and Re-assigned values for hsCRP calibrator lot 516427

Calibrator Level	Current Calibrator Values, mg/L	Reassigned Calibrator Values, mg/L
CAL 1	0.00	0.00
CAL 2	0.52	0.44
CAL 3	1.03	0.88
CAL 4	1.56	1.33
CAL 5	5.36	4.56
CAL 6	10.70	9.10

Patient and QC results are expected to shift approximately -15% when using the reassigned calibrator values for lots 484721 and 516427. Based on the negative shift in recovery, it may be necessary to adjust your laboratory's QC ranges. Refer to Table 4 for representative QC recovery data. Future commercial calibrator lots will be traceable to this new reference material and will demonstrate comparable performance to the reassigned values.

Table 4. Quality Control Recovery

Table 5. Quality Control Material	Mean (mg/L)	Range (mg/L)
Bio-Rad Cardiac Markers Plus Control Lot 67601 Level 1	0.657	0.505 – 0.807
Bio-Rad Cardiac Markers Plus Control 67602 Level 2	1.865	1.598 – 2.131
Bio-Rad Cardiac Markers Plus Control Lot 67611 Level 1	0.710	0.553 – 0.866
Bio-Rad Cardiac Markers Plus Control Lot 67612 Level 2	1.954	1.665 – 2.235
Bio-Rad Cardiac Markers Plus Control Lot 67621 Level 1	0.630	0.457 - 0.799
Bio-Rad Cardiac Markers Plus Control Lot 67622 Level 2	1.894	1.569 - 2.220
Bio-Rad Cardiac Markers Plus Control (Tube) Lot 67611T Level 1	0.740	0.577 – 0.895
Bio-Rad Cardiac Markers Plus Control (Tube) Lot 67612T Level 2	1.983	1.687 – 2.2279
Bio-Rad Cardiac Markers Plus Control (Tube) Lot 67621T Level 1	0.607	0.444 - .762
Bio-Rad Cardiac Markers Plus Control (Tube) 67622T Level 2	1.887	1.584- 2.183

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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 as well as the previous UMDC ACHC20-04.A.OUS dated November 2019.

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 484721 and lot 516427 provided in Tables 2 and 3 above.
- QC 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.

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

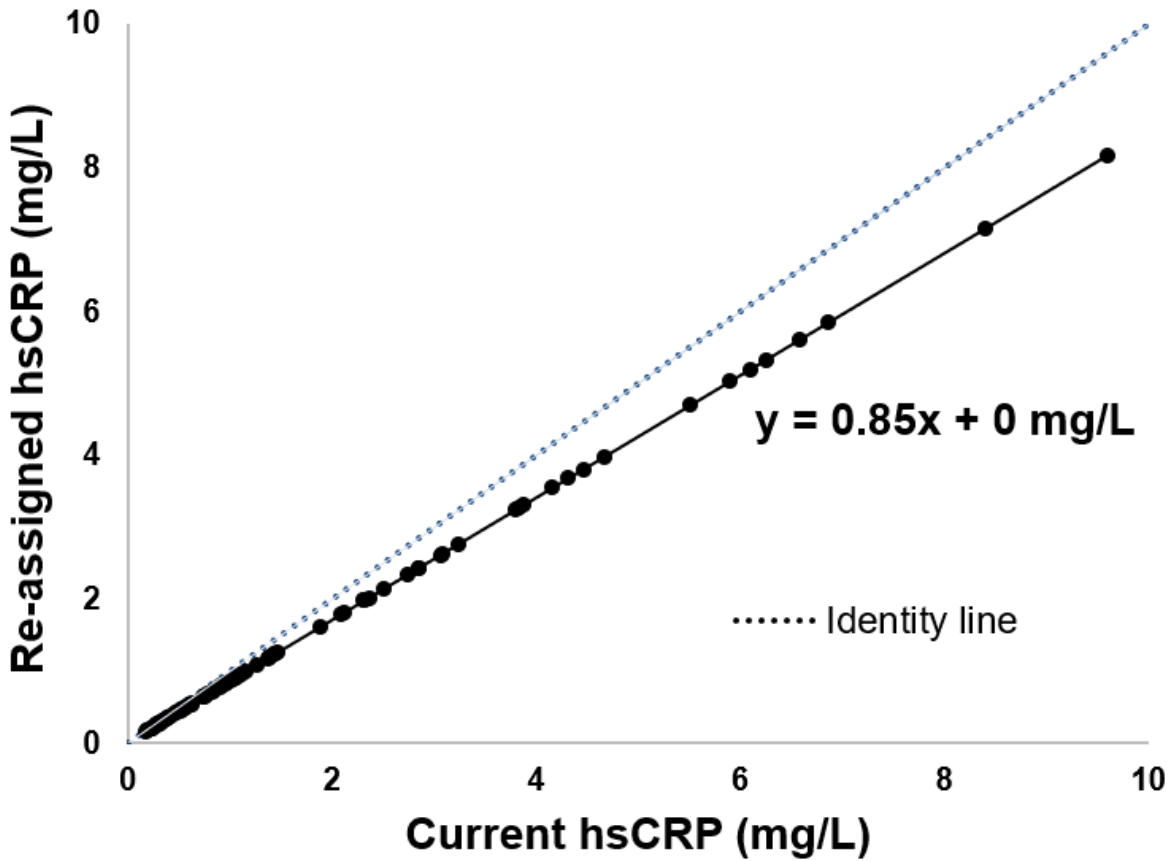
We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Atellica CH is a trademark of Siemens Healthcare Diagnostics Inc.

Additional Information

An hsCRP correlation study comparing patient sample recovery using current and re-assigned calibrator values can be seen in Figure 1 below.

Figure 1. Patient sample correlation comparing results using current and re-assigned calibrator values.



FIELD CORRECTION EFFECTIVENESS CHECK

Atellica CH Systems Reassignment of the Atellica CH High Sensitivity C-Reactive Protein (hsCRP) Calibrator Lots 484721 and 516427.

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice, ACHC20-04.B.OUS dated May 2020 regarding Atellica CH Systems Reassignment of the Atellica CH High Sensitivity C-Reactive Protein (hsCRP) Calibrator Lots 484721 and 516427. 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 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: _____

Please fax this completed form to the Customer Care Center at (###) ###-####. If you have any questions, contact your local Siemens technical support representative.