SIEMENS Healthineers

Siemens Healthcare Diagnostics Inc.

Urgent Field Safety Notice

ACHC19-02.A.OUS.ACHC

May 2019

Atellica CH® Analyzer
Creatine Kinase (CK_L) Reagent Lots 280765, 280766 and 280767 – Calibration failures and increased variability in results

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

Table 1. Atellica CH® Analyzer Affected Product(s)

Assay	Test Code	Siemens Material Number (SMN) / Catalog Number	Lot Number	Expiration Date (YYYY-MM-DD)	Manufacturing /1st Distribution Date (YYYY-MM-DD)
Creatine Kinase	CK_L	11097640	280765 280766 280767	2019-09-01 2019-10-01 2019-11-01	2018-08-01 / 2018/09/17 2018-09-01 / 2019/01/03 2018-10-01 / 2018/10/26

Reason for Recall:

The purpose of this communication is to inform you of an issue with the products listed in Table 1 above and provide instructions on actions your laboratory must take.

Siemens Healthcare Diagnostics has confirmed an increased incidence of calibration failures when using the Creatine Kinase kits listed in table 1 above for use on the Atellica CH Analyzer. Results cannot be generated by the system when calibration fails.

Siemens has also confirmed that for the lots listed in table 1, when calibration passes, patient results have the potential to be falsely decreased or increased across the analytical range. (See Table 2 for Siemens internal testing results.) Therefore, Siemens is asking customers to discard the kit lots listed in table 1.

See Appendix 1 for Percent bias plots for lots 280765, 280766 and 280767 versus Control lot 280810.

Quality control may or may not detect the issue.

Table 2. Patient Comparison to Reference Lot 280810 across the assay range.

Reagent Lot	Worst case Negative % bias	Worst case Positive % bias
280765	-23.4% at 64 U/L	18.2% at 55 U/L
280766	-37.5% at 40 U/L	4.2% at 236 U/L
280767	-48.6% at 35 U/L	16.7% at 18 U/L

511 Benedict Avenue
Tarrytown, NY 10591
www.siemens.com/diagnostics

Siemens is currently investigating the root cause of this issue.

Risk to Health

The risk to health when using the affected product is negligible. In cases where calibration passes, the potential biases observed for patient samples at clinically relevant concentrations would not lead to a clinically significant difference in patient management. Creatine Kinase is typically not used in isolation but is interpreted in the context of clinical history/symptomology in addition to other diagnostic laboratory testing such as electrolytes, BUN, creatinine, and/or urine myoglobin. Siemens is not recommending a review of previously generated results.

In cases of failed calibration there may be a delay in testing. This delay is apparent to the laboratory and would be addressed through standard laboratory policies and procedures.

Actions to be Taken by the Customer

● Discontinue use of and discard the kit lots listed in Table 1.

● Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens for reporting to the authorities.

● Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.

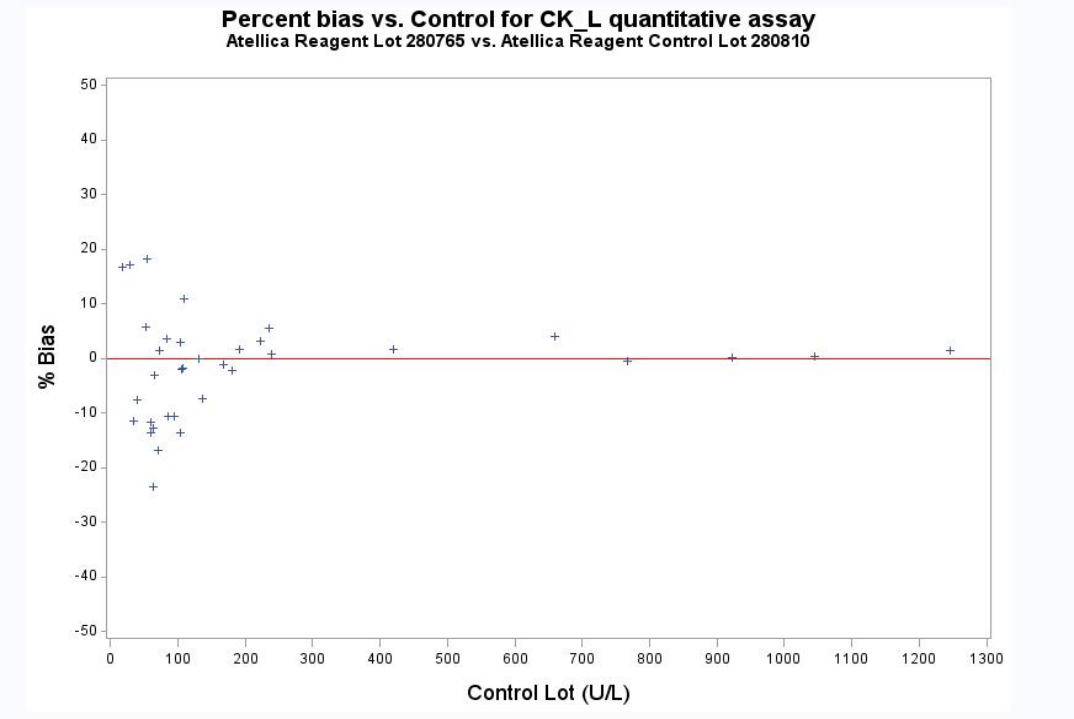
● Please review this letter with your Medical Director.

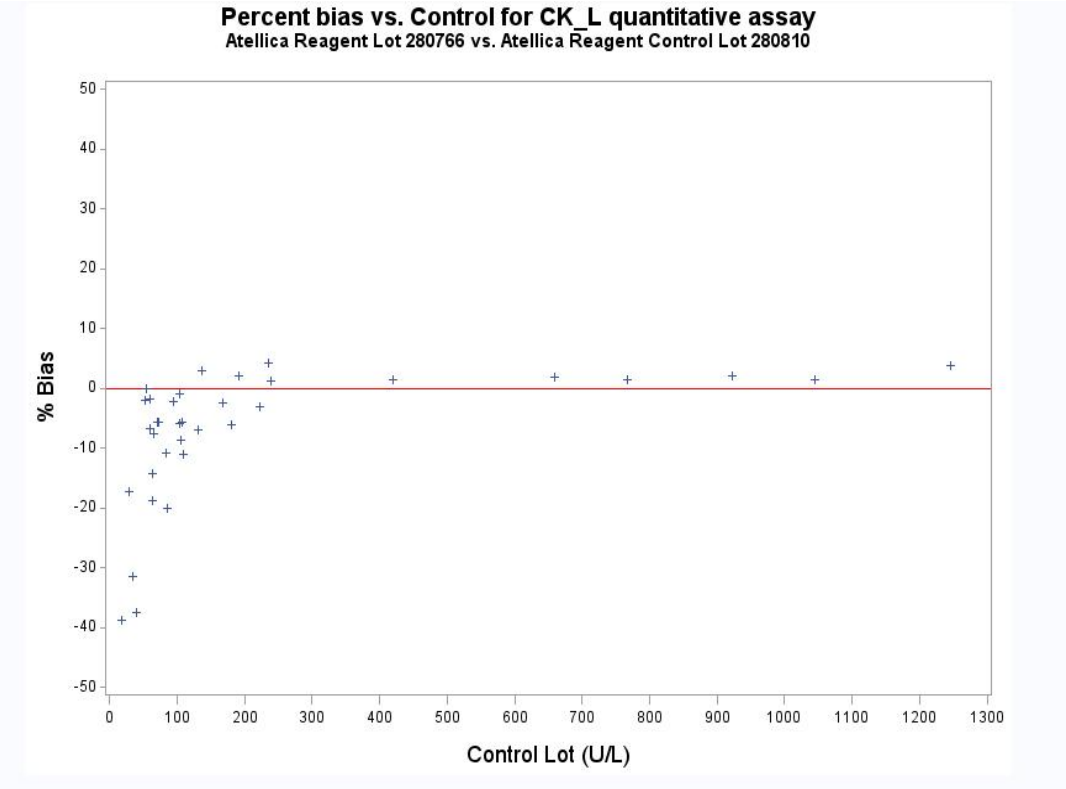
● If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Customer Care Center or your local Siemens technical support representative.

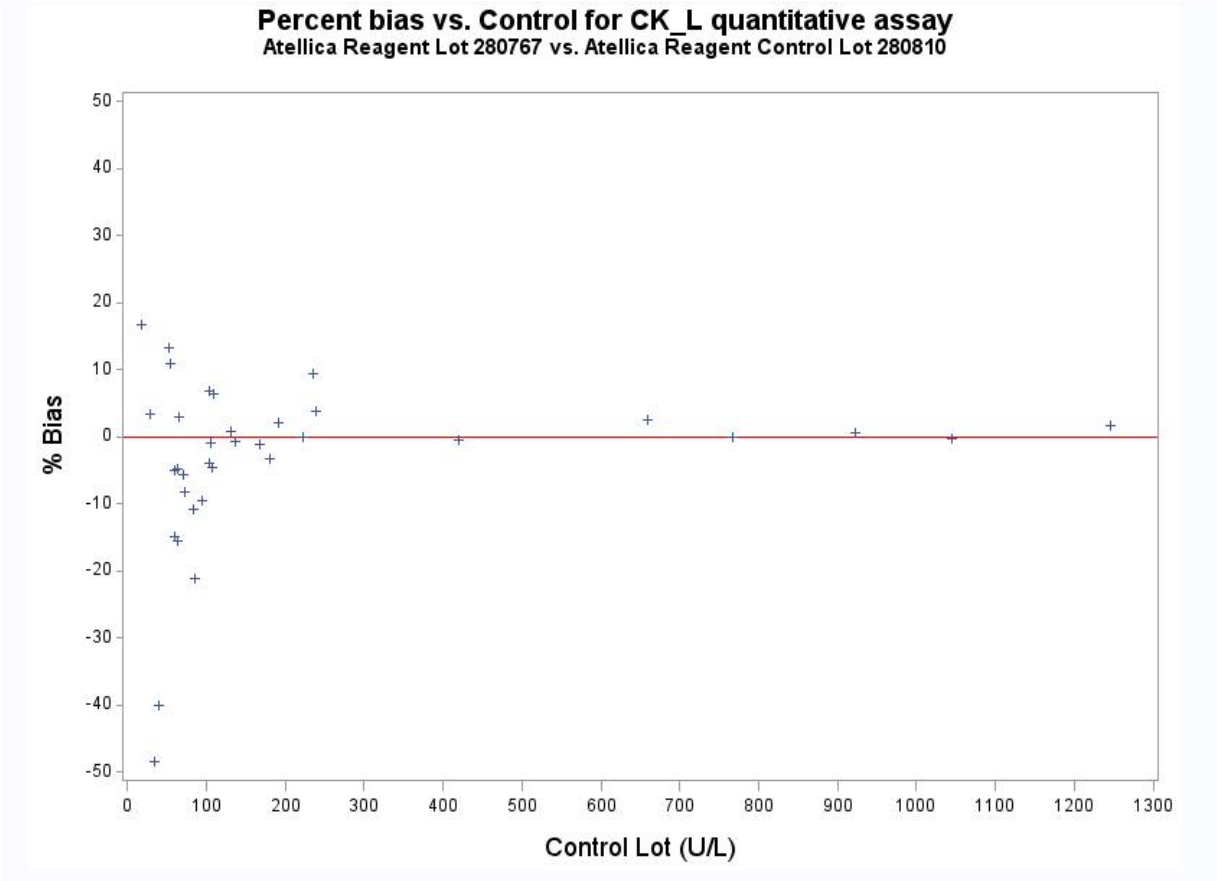
● Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

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

Appendix 1.


Percent bias vs. Control for CK_L quantitative assay
Atellica Reagent Lot 280765 vs. Atellica Reagent Control Lot 280810
% Bias
50
40
30
20
10
0
-10
-20
-30
-40
-50
0
100
200
300
400
500
600
700
800
900
1000
1100
1200
1300
Control Lot (U/L)


Percent bias vs. Control for CK_L quantitative assay
Atellica Reagent Lot 280766 vs. Atellica Reagent Control Lot 280810
% Bias
50
40
30
20
10
0
-10
-20
-30
-40
-50
0
100
200
300
400
500
600
700
800
900
1000
1100
1200
1300
Control Lot (U/L)



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