SIEMENS Healthineers

Siemens Healthcare Diagnostics Inc.

Urgent Field Safety Notice

ACHC19-02.A.OUS.CHC

May 2019

ADVIA® Chemistry Systems
Creatine Kinase (CK_L) Reagent Lots 465336, 465663, 468449 – System Flags (U, u flags) and increased variability in results

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

Table 1. ADVIA Chemistry Systems Affected Product(s)

Assay	Test Code	Siemens Material Number (SMN)/Catalog Number	Kit Lot Number	Component Lot Numbers (R1/R2)	Expiration Date (YYYY-MM-DD)	Manufacturing /1st Distribution Date (YYYY-MM-DD)
Creatine Kinase	CK_L	10729780	465336 465663 468449	235/236 237/238 239/240	2019/12/28 2020/01/28 2020/01/28	2018/09/04 / 2018/09/10 2018/09/18 / 2018/09/26 2018/10/10 / 2018/10/15

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 received complaints indicating an increased incidence of system generated (U, u) flags on Calibration, Quality Control and patient results when using the ADVIA Chemistry Creatine Kinase (CK_L) reagent kit lots listed in Table 1 on the ADVIA® 1800, 2400, and XPT Chemistry Systems. Patient results with u flags are not reportable.

Siemens has also confirmed for the lots listed in table 1, that patient results may be falsely decreased or increased across the analytical range even when u flags are not generated (Refer to Table 2 for Siemens internal testing results). Therefore, Siemens is asking customers to discard the kits listed in table 1.

See Appendix 1 for Percent bias plots for lots 465336, 465663 and 468449 versus Control lot 471332.

Quality control may or may not detect the issue.

Table 2. Patient Comparison to Reference Lot 471332

Reagent Lot	Worst case Negative % bias	Worst case % Positive bias
465336	-28.6% at 21 U/L	3.1% at 96 U/L
465663	-25.8% at 31 U/L	11.4% at 123 U/L
468449	-20.0% at 35 U/L	8.9% at 123 U/L

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Siemens is currently investigating the root cause of this issue.

Risk to Health

The risk to health when using the affected product is negligible. 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.

Results with U, u flags may lead to a delay in reporting patient results. 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 provide information to Siemens for reporting to the authorities.

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

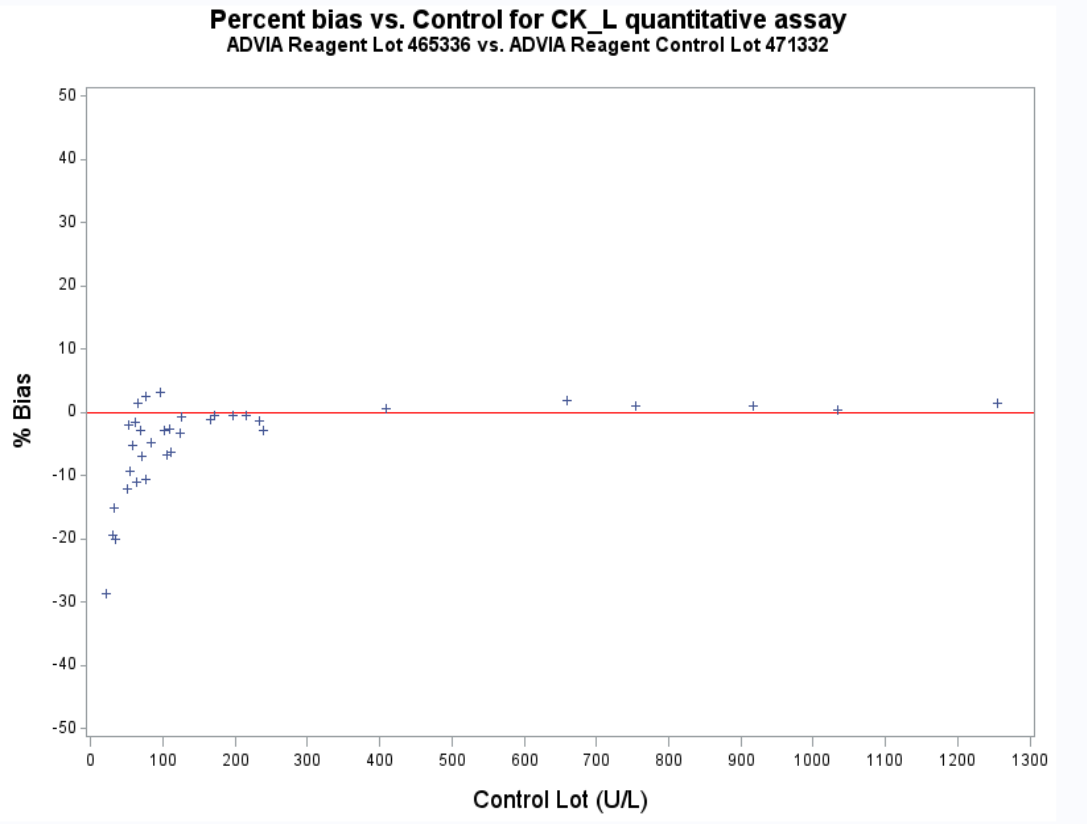
● Please review this letter with your Medical Director.

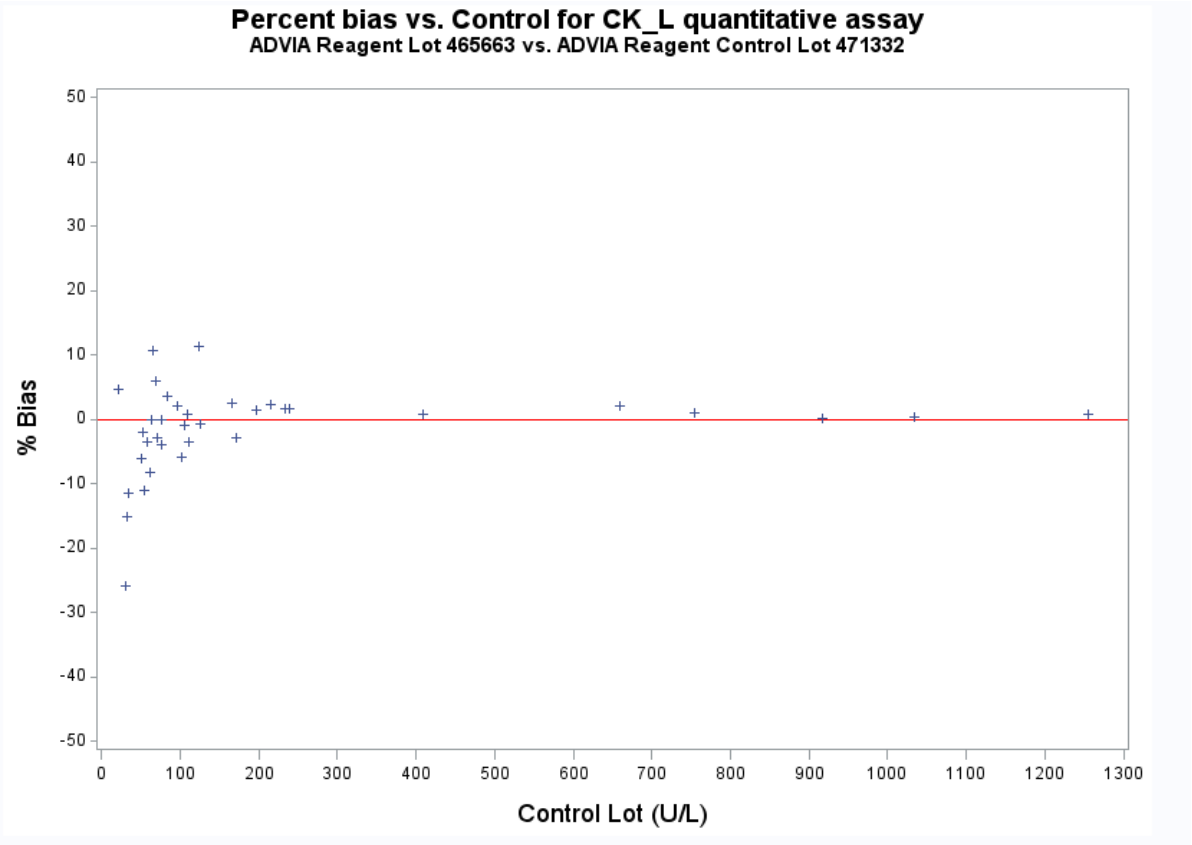
● If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Customer Care Center or your local Siemens technical support representative.

● 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
ADVIA Reagent Lot 465336 vs. ADVIA Reagent Control Lot 471332
% 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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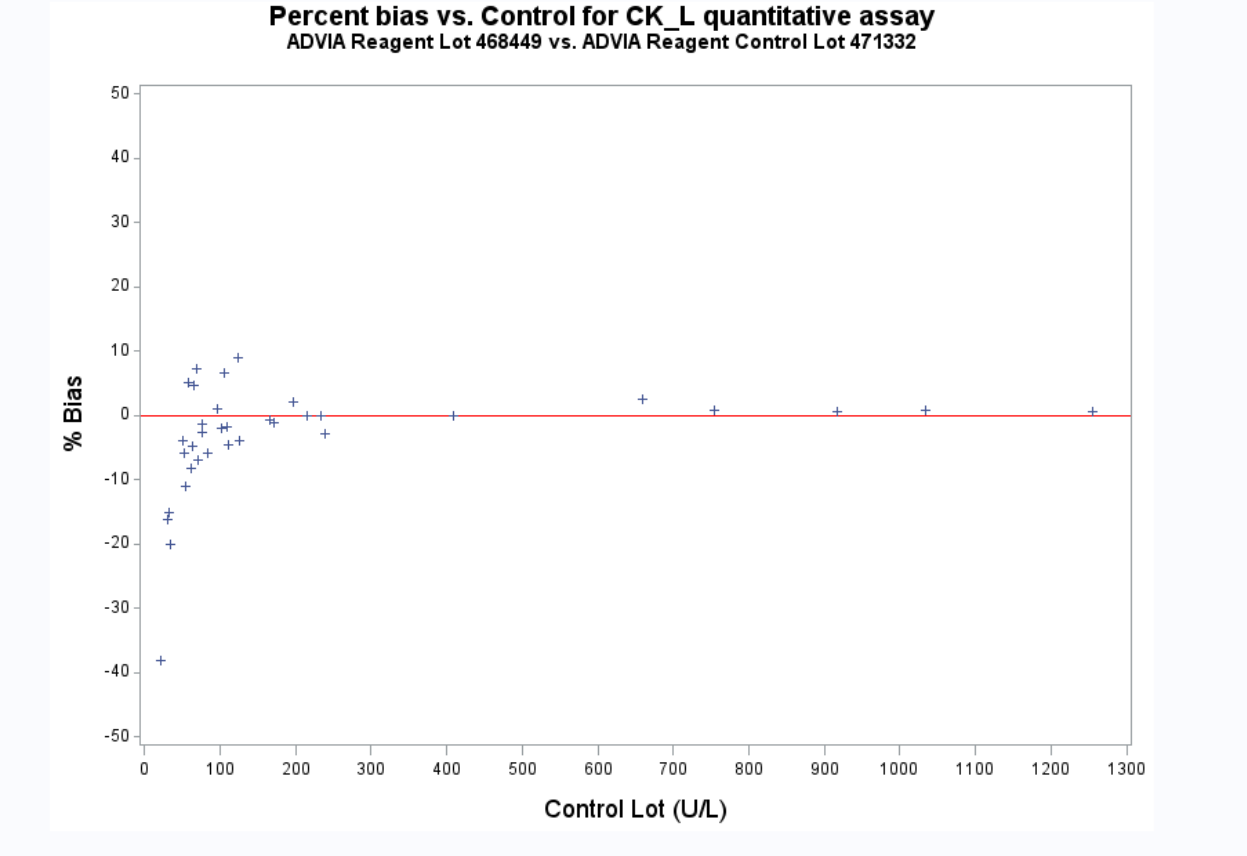

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FIELD CORRECTION EFFECTIVENESS CHECK

ADVIA® Chemistry Systems Creatine Kinase (CK_L) Reagent Lots 465336, 465663 and 468449 – System Flags and increased variability.

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice ACHC19-02.A.OUS.CHC, Rev. A dated May 2019 regarding Creatine Kinase (CK_L) reagents kit lots listed in Table 1 with an increased incidence of system generated flags (U, u) and variability of results when used on the ADVIA® 1800, 2400, and XPT Chemistry Systems. 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 ☐
2. Do you now have any of the noted product(s) on hand? Please check inventories before answering. Yes ☐ No ☐

If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product Description **Product Catalog #/SMN #/Lot #**	**Quantity of Affected Product in inventory to be discarded**	**Replacement Quantity Required**
ADVIA Chemistry Creatine Kinase (CK_L)/ 10729780/465336		
ADVIA Chemistry Creatine Kinase (CK_L)/ 10729780/465663		
ADVIA Chemistry Creatine Kinase (CK_L)/ 10729780/468449		

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Customer Sold To #: Customer Ship To #:

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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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