

Siemens Healthcare Diagnostics Inc.

**ADVIA® Chemistry Systems
Creatinine Kinase (CK_L) Reagent Lots 433549 and 439212 – Negative Bias,
System Flags**

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

Table 1. ADVIA Chemistry Systems Affected Product(s)

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number	Expiration Date (YYYY-MM-DD)	Manufacturing /1 st Distribution Date (YYYY-MM-DD)
Creatinine Kinase	CK_L	10729780	10729780	433549	2019-05-28	2018-01-28/2018-03-09
				439212	2019-07-28	2018-03-28/2018-04-27

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 for laboratory action.

Siemens Healthcare Diagnostics has confirmed a negative bias with patient and quality control results when using the ADVIA Chemistry Creatinine Kinase (CK_L) reagent kit lots listed in Table 1 on the ADVIA® 1800, 2400, and XPT Chemistry Systems. Customers may also observe an increased incidence of system generated flags (U, u, n). Siemens internal investigation demonstrated an average percent bias of -7.9% and -17.7% for reagent lots 433549 and 439212, respectively, for patient samples across the assay range. The average percent bias for samples in the range of expected values is also provided (Table 2).

Table 2. Patient Comparison to Reference Lot 430669.

Reagent Lot	Sample Range	Average % bias	Worst case % bias for an individual sample	n
433549	25 to 1289 U/L	-7.9%	-36% at 25 U/L	17
	48 – 161 U/L	-8.2%	-12.5% at 64 U/L	10
	202 – 376 U/L	-8.4%	-13.4% at 202 U/L	10
439212	25 to 1289 U/L	-17.7%	-72% at 25 U/L	17
	48 – 161 U/L	-11.6%	-20.3% at 59 U/L	10
	202 – 376 U/L	-19.3%	-23.3% at 201U/L	10

Siemens is currently investigating the root cause of this issue.

Risk to Health

The risk to health when using the affected product is negligible as biases observed at clinically relevant concentrations would not lead to a clinically significant difference in patient management. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

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

ADVIA is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

ADVIA® Chemistry Systems Creatinine Kinase (CK_L) Reagent Lots 433549 and 439212 – System Flags, Negative Bias

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CHC18-05.A.OUS, Rev. A dated September, 2018 regarding Creatinine Kinase (CK_L) reagents kit lots listed in Table 1 confirming a low bias with patient and Quality Control results and may demonstrate an increased incidence of system generated flags (U, u, n) 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 Creatinine Kinase (CK_L)/ 10729780/433549		
ADVIA Chemistry Creatinine Kinase (CK_L)/ 10729780/439212		

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

Customer Sold To #: _____

Customer Ship To #: _____

If you have any questions, contact your local Siemens technical support representative.