

Urgent Field Safety Notice

CC 15-18.A.OUS

July 2015

ADVIA Centaur®
 ADVIA Centaur® XP
 ADVIA Centaur® XPT
 ADVIA Centaur® CP

Folate Ascorbic Acid/Ascorbic Acid Diluent Lots 54942, 56230 and 70673

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

Table 1. ADVIA Centaur Systems Affected Product(s)

Assay/Product	Siemens Material Number SMN (Reference)	Lot Number
Folate Ascorbic Acid/Ascorbic Acid Diluent	10316877 (124975)	54942, 56230, 70673

Reason for Urgent Field Safety Notice

Siemens Healthcare Diagnostics has confirmed low red blood cell control recoveries and low results for red blood cell patient samples when using the ADVIA Centaur Systems Folate assay with the kit lots of Folate Ascorbic Acid/Ascorbic Acid Diluent identified in Table 1. The issue is limited to the lot of Folate Ascorbic Acid Diluent in the kits identified in Table 1.

Internal data comparing results from red blood cell samples prepared with Folate Ascorbic Acid/Ascorbic Acid Diluent kit lots identified in Table 1 to unaffected Folate Ascorbic Acid/Ascorbic Acid Diluent kit lots are provided in Table 2. Samples results are prior to Red Blood Cell folate calculation.

Table 2. Comparison of ADVIA Centaur Folate Red Blood Cell Results

Sample Range	Mean % Bias	% Bias Range
0.9 to 3.9 ng/mL (2.04 to 8.01 nmol/L)	3.97	-5 to 18
10.4 to 21.8 ng/mL (23.6 to 49.4 nmol/L)	-36	-24 to -57

Folate values obtained from serum samples are not affected.

Additional lots of Folate Ascorbic Acid/Ascorbic Acid Diluent are available.

Risk to Health

The ADVIA Centaur Systems Folate red blood cell sample and control negative bias is minimal in the lower range of the assay and is more pronounced with increasing folate concentrations. The negative bias could lead to a misclassification of a patient as folate deficient. Siemens does not recommend a look back of previously tested patients.

Actions to be Taken by the Customer

- Upon receipt of this communication, discontinue the use of ADVIA Centaur Systems Folate Ascorbic Acid/Ascorbic Acid Diluent kit lots identified in Table 1. Dispose of remaining inventory per your local regulations.
- Please contact your Siemens Customer Care Center or your local Siemens technical support representative for information on product replacement.
- Please review this letter with your Medical Director.
- 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.

Product availability may vary from country to country and is subject to varying regulatory requirements. Due to local regulations, the ADVIA Centaur XPT is not available in all countries.

ADVIA Centaur is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

Folate Ascorbic Acid/Ascorbic Acid Diluent Lots 54942, 56230 and 70673.

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics. Urgent Field Safety Notice CC 15-18.A.OUS dated July 2015 regarding Folate Ascorbic Acid/Ascorbic Acid Diluent Lots 54942, 56230 and 70673. Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number 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 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 that has been discarded	Replacement Quantity Required
54942		
56230		
70673		

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Customer Sold To #: _____ Customer Ship To #: _____

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