

Urgent Field Safety Notice

10812057

May 2012

ADVIA® 1200, ADVIA 1650, ADVIA 1800, and ADVIA 2400 Chemistry Systems

Alkaline Phosphatase (ALPAMP and ALPDEA): Reagent Kit Lots May Have Increased Number of Absorbance Flags

Our records indicate that you may have received the ADVIA® Chemistry Alkaline Phosphatase (ALPAMP) or Alkaline Phosphatase (ALPDEA) kit lots listed in the table below:

Reagent	Reference Number	Lot Number
ALPAMP	PN 03035814	222982
ALPDEA	PN 03036535	222987

Reason for Voluntary Recall

Siemens Healthcare Diagnostics is conducting a voluntary corrective action of certain ADVIA Chemistry ALPAMP and ALPDEA reagent kit lots. Siemens has confirmed that these lots demonstrate an increased incidence of absorbance flags, (u, U) and //// errors. Absorbance flags u and U indicate abnormal high absorbance exceeding either the blank or sample limit. Absorbance flag //// indicates a calculation error and no result is generated by the system.

Risk to Health

The increased rate of absorbance flags with these lots has not been associated with inaccurate results. If Calibration and QC results are acceptable, reported patient results are acceptable. This issue does not pose a risk to patient health and a look back on previously generated results is not necessary.

Actions to be Taken by the Customer

For the product lot numbers listed above, please perform the following steps:

1. Discontinue use and discard any of the above reagent lots. Siemens is offering no-charge replacement kits for these products.
2. Please review your reagent inventory of these products and assess your laboratory's need for replacement kits.
3. Please complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days to request your no-charge replacement needs.
4. Keep this bulletin with your laboratory records.
5. Please forward this notification to whomever you may have distributed this product.

Siemens Healthcare Diagnostics Inc.

511 Benedict Ave.
Tarrytown, NY 10591

www.siemens.com/diagnostics

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We apologize for the inconvenience that this situation has caused. If you have technical questions regarding this information, please contact the Siemens Technical Solutions Center at 877-229-3711, option 18. For customers outside the US, please contact your local Siemens Technical Support Personnel. Thank you for your patience and continuing support of Siemens Healthcare Diagnostics products.

Trademark Information

ADVIA is a trademark of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK

Alkaline Phosphatase (ALPAMP and ALPDEA): Reagent Kit Lots May Have Increased Number of Absorbance Flags

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 10812057 dated May 2012, regarding ADVIA Chemistry Alkaline Phosphatase (ALPAMP and ALPDEA) reagent kit lots (222982 and 222987) that may have an increased number of absorbance flags.

Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number indicated at the bottom of this page.

- 1. Have you read and understood the Urgent Field Safety instructions provided in the UFSN 10812057, dated May 2012? Yes No

- 2. Do you now have any of the noted products on hand? Yes No
(Please check inventories before answering.)

Name of person completing questionnaire:

Title:

Institution:

Instrument Serial Number:

Street:

City:

State:

Phone:

ADVIA Chemistry ALPAMP and/or ALPDEA kit lots discarded:

Kit and Lot Numbers	Quantity Discarded	Replacement Kits Required

FOR U.S. CUSTOMERS, PLEASE FAX THIS COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER AT (877) 229-8603. FOR CUSTOMERS OUTSIDE OF THE U.S., PLEASE FAX THIS COMPLETED FORM TO YOUR LOCAL TECHNICAL SOLUTIONS CENTER AT (XXX) XXX-XXXX.

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