



Urgent Field Safety Notice

073D0599-01

2011-07

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

ADVIA Chemistry Gentamicin_2 (GENT_2) and Valproic Acid_2 (VPA_2): Reagent Kit Lots May Have Increased Imprecision

Lot Numbers:

GENT_2, PN 10377507 (Lot Numbers 174889, 175988, and 187802)

VPA_2, PN 10377508 (Lot Numbers 192627 and 212421)

Our records indicate that you may have received the above kit lots of Gentamicin_2 (GENT_2) and Valproic Acid_2 (VPA_2) reagents.

Siemens Healthcare Diagnostics has determined that the ADVIA[®] Chemistry GENT_2 and VPA_2 reagent kit lots listed above may have increased imprecision.

Siemens is conducting a voluntary corrective action. **You should discontinue use and discard any of the above reagent kit lots.** Siemens is offering no-charge replacement kits for these products. Please review your reagent inventory of these products and assess your laboratory's need for replacement kits. A look-back on patient results obtained with the affected products is not required. Calibration and Quality Control failures would in most instances detect the affected reagents.

Keep this bulletin with your laboratory records.

Please return the attached Field Correction Effectiveness Check form as soon as possible and fax to the number provided on the form. If you have any questions or need additional information, please contact your Siemens Technical Solutions Center.

Please forward this notification to whomever you may have distributed this product. We apologize for the inconvenience that this situation has caused. Thank you for your patience and continuing support of Siemens Healthcare Diagnostics products.

Trademark Information

ADVIA is a trademark of Siemens Healthcare Diagnostics.

Siemens Healthcare Diagnostics Inc.

511 Benedict Ave.
Tarrytown, NY 10591

www.siemens.com/diagnostics

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FIELD CORRECTION EFFECTIVENESS CHECK

ADVIA Chemistry Gentamicin_2 (GENT_2) and Valproic Acid_2 (VPA_2): Reagent Kit Lots May Have Increased Imprecision

(For ADVIA® 1200, ADVIA 1650, ADVIA 1800, and ADVIA 2400 Chemistry Systems)

Affected Products: ADVIA Chemistry Reagent Kit Lots Received

GENT_2, PN 10377507 (Lot Numbers 174889, 175988, and 187802)

VPA_2, PN 10377508 (Lot Numbers 192627 and 212421)

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 073D0599-01 Rev. A dated July 2011 regarding ADVIA Chemistry Gentamicin_2 and Valproic Acid_2 reagent kit lots. Please read each question and indicate the appropriate answer. Fax this completed form to Siemens at the fax number indicated at the bottom of this page.

Include the inventory information below on this form as well.

- 1. Did we effectively communicate all necessary information? Yes No
- 2. Do you now have any of the noted products on hand? (Please check inventories before answering.) Yes No
- 3. If the answer to the question above is Yes, do you intend to take the recommended action as requested? Yes No

Number of ADVIA Chemistry GENT_2 Reagent kit lots in inventory to be replaced (Lot Number 174889) :

Number of ADVIA Chemistry GENT_2 Reagent kit lots in inventory to be replaced (Lot Number 175988) :

Number of ADVIA Chemistry GENT_2 Reagent kit lots in inventory to be replaced (Lot Number 187802) :

Number of ADVIA Chemistry VPA_2 Reagent kit lots in inventory to be replaced (Lot Number 192627) :

Number of ADVIA Chemistry VPA_2 Reagent kit lots in inventory to be replaced (Lot Number 212421) :

Name of person completing questionnaire:

Title: Institution: Instrument Serial Number:

Street:

City: Country: Phone:

PLEASE FAX THIS COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER AT (###) ###-####

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