



Urgent Field Safety Notification

CHC16-06.A.OUS

June, 2016

ADVIA® Chemistry Systems

Theophylline_2 (THEO_2) - Imprecision with Reagent Lot 334018

Our records indicate that you have or may have received the following product:

Table 1. Affected ADVIA Chemistry Systems

| Assay | Test Code | Catalog Number | Siemens Material Number (SMN) | Lot Number | Expiration Date | Manufacturing /1st Distribution Date |
|--|-----------|----------------|-------------------------------|------------|-----------------|--------------------------------------|
| ADVIA Chemistry Theophylline_2 Reagent | THEO_2 | 10377503 | 10377503 | 334018 | 2017-09 | 2014-11-28 |

Reason for Recall

Siemens Healthcare Diagnostics has confirmed the ADVIA® Chemistry Theophylline_2 (THEO_2) reagent lot 334018 listed in Table 1 used on the ADVIA® 1200, 1800, 2400, and XPT Chemistry Systems may exhibit increased imprecision for commercially available TDM quality controls and patient specimens. Siemens internal investigation using BioRad Liquichek TDM Controls Level I and III (TDM I and III) and spiked patient samples demonstrated coefficient of variations (%CVs) of up to the following (Table 2):

Table 2. Maximum Coefficient of Variations Observed

| | Within-Run Precision (%CV) | Within-Lab (Total) Precision (%CV) |
|--|----------------------------|------------------------------------|
| TDM I | 9.31 | 11.71 |
| TDM III | 8.83 | 10.05 |
| Spiked patient samples (dose of 5 mcg/mL) | 8.67 | 9.89 |
| Spiked patient samples (dose of 20 mcg/mL) | 8.14 | 9.17 |

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Siemens is currently investigating the root cause of the issue.

Risk to Health

A delay in theophylline testing due to troubleshooting after failed QC may cause a minor delay in testing. The risk to health is negligible. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

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

1. Please review this letter with your Medical Director.
2. Discontinue use of and discard the kit lots listed in Table 1.
3. Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens for reporting to the authorities.
4. Complete and return the Field Correction Effectiveness Check/Product Replacement Form attached to this letter within 30 days.
5. 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.

ADVIA is a trademark of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK

ADVIA Chemistry Theophylline_2 (THEO_2) Reagent - Imprecision with Lot 334018

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notification CHC16-06.A.OUS dated June, 2016 regarding ADVIA Chemistry Theophylline_2 (THEO_2) Reagent - Imprecision with Lot 334018. 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 Notification 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 |
|---|---|----------------------------------|
| ADVIA Chemistry Theophylline_2 Reagent/Catalog/SMN #10377503/Lot 334018 | | |

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

Customer Sold To #: _____

Customer Ship To #: _____

Please fax this completed form to the Customer Care Center at (65) 6366-3376. If you have any questions, contact your local Siemens technical support representative.

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