

Urgent Field Safety Notice

CHC-15-16.A.OUS

September 2015

ADVIA® Chemistry Systems

Alkaline Phosphatase (ALPAMP, ALPDEA and ALPA_c): Reagent Kit lots with an Increased Incidence of Absorbance Errors

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 |
|-----------------------------------|-----------|----------------|-------------------------------|------------|
| Alkaline Phosphatase | ALPAMP | 03035814 | 10309049 | 327460 |
| Alkaline Phosphatase | ALPDEA | 03036535 | 10341131 | 327465 |
| Alkaline Phosphatase Concentrated | ALPA_c | 06860450 | 10283340 | 327471 |

Reason for Recall:

Siemens Healthcare Diagnostics has confirmed the Alkaline Phosphatase reagents kit lots listed in Table 1 above used on the ADVIA® 1200, 1650, 1800, 2400, and XPT Chemistry Systems 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 Quality Control results are acceptable, reported patient results are acceptable. This risk to health is negligible.

Siemens is not recommending a laboratory look back as a result of this issue.

Alkaline Phosphatase (ALPAMP, ALPDEA and ALPA_c): Reagent Kit lots with an Increased Incidence of Absorbance Errors

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.
- 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.

Alkaline Phosphatase (ALPAMP, ALPDEA and ALPA_c):

Reagent Kit lots with an Increased Incidence of Absorbance Errors

FIELD CORRECTION EFFECTIVENESS CHECK

ALPAMP lot 327460, ALPDEA lot 327465 and ALPA_c lot 327471
Reagent Kit lots with an Increased Incidence of Absorbance Errors

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field safety Notice CHC-15-16.A.OUS; Revision A dated September, 2015 regarding Alkaline Phosphatase (ALPAMP, ALPDEA and ALPA_c): Reagent Kit lots with an Increased Incidence of Absorbance Errors. 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 products 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 |
|---|--|----------------------------------|
| ALPAMP Catalog 03035814/ SMN 10309049/ Lot 327460 | | |
| ALPDEA Catalog 03036535/ SMN 10341131/ Lot 327465 | | |
| ALPA_c Catalog 06860450/ SMN 10283340/ Lot 327471 | | |

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

Alkaline Phosphatase (ALPAMP, ALPDEA and ALPA_c):

Reagent Kit lots with an Increased Incidence of Absorbance Errors

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.