

ADVIA® Chemistry Systems

Amylase Increased Incidence of Absorbance Flags

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	Expiration Date
Amylase	AMYLAS	07498401	10309493	304821	April 2015
		03031177	10341130	304816	

Reason for Customer Notification

Siemens Healthcare Diagnostics has confirmed that Amylase reagent kit lots 304821 and 304816 for use on the ADVIA® 1200, 1650, 1800 and 2400 Chemistry Systems demonstrate an increased incidence of absorbance flags (U or U accompanied by u). Absorbance flags (U) indicate an abnormally high reagent blank absorbance exceeding the reagent blank limit. In some cases with these reagent lots, sample results may also have a Sample Absorbance (u) flag indicating a high absorbance for the sample that occurs in conjunction with the (U) flag. Amylase results can be generated with these flags.

Siemens is currently investigating the root cause of this issue.

Risk to Health

The increased rate of absorbance flags when using the lots listed in Table 1 has not been associated with inaccurate Amylase results. The risk to health is negligible and limited to a potential delay in Amylase testing. Siemens is not recommending a laboratory look back as a result of this issue.

Actions to be Taken by the Customer

For the products listed in Table 1, please perform the following steps:

- **Sample Absorbance (u) flags** that occur on a sample when there are no Absorbance (U) flags occurring are sample-related and not attributable to the reagent lot. Those samples should be confirmed by repeat analysis.
- Siemens has become aware that some customers may have chosen not to use the product when they obtain **reagent Absorbance (U) flags**. If you have experienced reagent Absorbance (U) flags, and chose not to report results with this reagent, you may request compensation or unaffected product at no charge from your local Siemens or distributor office. Please review your inventory of these products and assess your laboratory's replacement needs.

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- Complete and return the Product Replacement Form attached to this letter to request your no-charge replacement products.

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.

PRODUCT REPLACEMENT FORM

Amylase Increased Incidence of Absorbance Flags

This form is to be used to request no-charge replacement product for the enclosed Siemens Healthcare Diagnostics Customer Notification 11220303, Rev. A dated April 2015 regarding Amylase Increased Incidence of Absorbance Flags. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

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
07498401/10309493/304821		
03031177/10341130/304816		

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 (###) ###-####. If you have any questions, contact your local Siemens technical support representative.