

ADVIA® Chemistry Systems

Triglyceride Reagent (REF 09580156, PN B01-4133-01) Decreased Linearity

Lots 075393, 081324, 086564, 095939, 102610, and 105357

Our records indicate that your laboratory uses ADVIA® Chemistry Triglyceride Reagent (REF 09580156, PN B01-4133-01). Siemens Healthcare Diagnostics has confirmed that the 6 lots of Triglyceride Reagent listed in Table 1 exhibit a decrease of the upper limit of the linear range stated in the Instructions for Use (IFU). The IFU states the assay range for this method is 0 – 550 mg/dL (0 – 6.22 mmol/L). Patient samples with triglyceride levels exceeding 300 mg/dL (3.39 mmol/L) assayed after the cutoff dates listed in Table 1 may be underestimated, with all such samples reading as low as 300 mg/dL (3.39 mmol/L) irrespective of their true triglyceride levels.

To avoid the potential for further problems, Siemens is conducting a field correction for the lots of triglyceride reagent listed in Table 1. Please discard any remaining inventory of the kit lots in Table 1 immediately and replace them with other available triglyceride reagent lots.

Any patient samples with triglyceride results greater than 300 mg/dL (3.39 mmol/L) assayed on a kit lot listed in Table 1 after the respective cutoff date may require re-evaluation. If your routine quality control material exceeds 300 mg/dl (3.39 mmol/L), results up to the highest level routinely assayed will not require review or re-evaluation. Additionally, if you performed a linearity study verifying linear range after the cutoff date for the lots specified and found the assay linear range unaffected, review of patient samples assayed prior to the linearity study is not necessary.

We recommend that you discuss the content of this letter with your laboratory director regarding the need to perform repeat testing on results previously reported.

Table 1. Lots Exhibiting a Decrease of the Upper Limit of Linearity

Kit Lot Number	R1 Lot Number	R1 Mix Lot Number	Labeled Expiration Date	Cutoff Date*
075393	041TR	042TR	April 2008	April 2007
081324	041TR	045TR	April 2008	April 2007
086564	043TR	044TR	September 2008	September 2007
095939	046TR	047TR	January 2009	January 2008
102610	048TR	049TR	April 2009	April 2008
105357	048TR	050TR	April 2009	April 2008

* Suggested look-back date based on recent testing.

Siemens Healthcare Diagnostics Inc.

511Benedict Ave.
Tarrytown, NY 10591

www.siemens.com/diagnostics

Page 1 of 3

Table 2 lists lots of triglyceride reagent that meet current performance claims. **As a preventive measure, Siemens is reducing the shelf life of these lots as indicated and monitoring linearity on an ongoing basis.** If any of these lots exhibit diminished linear range, we will notify you well before the assay range falls below our claim of 550 mg/dL (6.22 mmol/L).

Table 2. Lots Currently Meeting Specifications

Kit Lot Number	R1 Lot Number	R1 Mix Lot Number	Labeled Expiration Date	Revised Expiration Date
112891	051TR	052TR	September 2009	September 2008
117238	053TR	054TR	October 2009	October 2008

Please complete the attached Completion Notification Form and fax it to the appropriate number provided on the form.

If you have any questions or need additional information, please contact your local technical support provider or distributor.

Please forward this notification to anyone to whom you may have distributed this product.

We apologize for the inconvenience that this situation has caused.

Thank you for your continuing support of Siemens Healthcare Diagnostics products.

ATTACHMENT A

Completion Notification Form

Complete this form and fax it to the appropriate number provided below. Submitting this form indicates you have received and understood this information and discarded all of the lots of ADVIA[®] Chemistry System Triglyceride Reagent (REF 09580156, PN B01-4133-01) listed below.

General Information

Institution Name: _____
System Model: _____
Serial Number: _____
State/Country: _____
Number of Triglyceride Kits Discarded (per lot):
075393: _____ 081324: _____ 086564: _____
095939: _____ 102610: _____ 105357: _____
Date kits discarded: _____

Kit Replacement Information

Is a No-Charge PO required? _____
If so, the PO number is: _____
Ship replacement kits to (name): _____
Laboratory Name: _____
Address: _____
Phone Number: _____

Fax Information

USA: 877-229-3799 Attn: John Palombo
Canada: 905-795-4410 Attn: Tricia Rostron
Outside USA/Canada: Please return this form to your local Siemens Healthcare Diagnostics office or distributor.

Signature: _____ Date: _____

Printed Name & Title: _____