

## Urgent Field Safety Notice

CHC16-03A.A.OUS

August 2016

### ADVIA® Chemistry Systems Triglyceride Concentrated (TRIG\_c) Reagent Not Meeting Linearity Claim

Our records indicate that your facility may have received the following product:

**Table 1. ADVIA® Chemistry Systems Affected Product:**

Assay	Test Code	Siemens Material Number (SMN)	Lot Number	Expiration Date	Manufacturing Date
Triglyceride Concentrated	TRIG_c	10697575	365096	2016-09-30	2015-09

#### Reason for Recall:

Siemens Healthcare Diagnostics has confirmed the ADVIA® Chemistry Triglyceride concentrated reagent (TRIG\_c) does not meet Instructions for Use (IFU) linearity claim at the upper limit of the assay range as it approaches end of shelf life for the lot listed in Table 1.

Internal testing indicates that a patient bias (-7% to -12%) may be seen at concentration levels from 550 to 600 mg/dL (6.22 to 6.78 mmol/L).

Linearity is reduced by approximately 50% at Triglyceride concentrations approaching the upper end of the extended range of 1100 mg/dL (12.43 mmol/L).

Quality Control (QC) material may not detect this issue depending on the Triglyceride concentrations in the QC material.

Siemens internal testing has confirmed all other in date lots are currently meeting linearity IFU claims. However, as a precaution, until root cause is determined, a short term mitigation of reducing the expiration date to 6 months for all lots of ADVIA Chemistry Systems Triglyceride Concentrated has been implemented.

Table 2 provides a list of all in date lots currently available to customers with the labeled and revised expiration dates.

If you have any of these lots in your inventory please refer to Table 2 for the revised expiration date and follow the instructions in the Actions to be taken by the Customer section.

**Table 2. ADVIA® Chemistry Systems Product Expiration Dates**

Assay	Test Code	Siemens Material Number (SMN)	Lot Number	Labeled Expiration Date	Revised Expiration Date
Triglyceride Concentrated	TRIG_c	10697575	379597	2017-01	2016-07-31 <b>Expired</b>
			379919	2017-02	2016-08-31
			379930	2017-02	2016-08-31
			379942	2017-03	2016-09-30
			379946	2017-03	2016-09-30
			376894	2017-03	2016-09-30

### Risk to Health

The risk to health when this issue occurs is limited to the potential for misinterpretation of a severely elevated triglyceride concentration. When considering treatment, triglyceride values are typically used in conjunction with other lipid parameters, diagnostic laboratory testing, patient history and presentation. The Overall Risk to Health as a result of this issue is negligible. A laboratory look back is not recommended.

### Actions to be taken by the Customer

- Discontinue use of and discard kit lot 365096.
- Discontinue use of and discard kit lot 379597.
- Discontinue use of and discard the kit lots listed in Table 2 above once they reach their revised expiration date.
- Customers will need to manually monitor the revised expiration date of all the kit lots listed in Table 2 above.
- Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.
- Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens for reporting to the authorities.
- Please review this letter with your Medical Director.

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.

**FIELD CORRECTION EFFECTIVENESS CHECK**

ADVIA® Chemistry Systems Triglyceride Concentrated (TRIG\_c) Reagent not meeting linearity claim

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (UFSN) CHC16-03A.A.OUS dated August 2016 regarding Triglyceride Concentrated (TRIG\_c) Reagent not meeting linearity claim. 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 Medical Device Recall 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 product in your laboratory and replacement product required.

Product Description Product Catalog #/SMN #/Lot #	Quantity in inventory that has been discarded	Replacement Quantity Required
Triglyceride Concentrated/SMN 10697575/ Lot# 365096		
Triglyceride Concentrated/SMN 10697575/ Lot# 379597		

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 **xxx-xxx-xxxx**. If you have any questions, contact your local Siemens technical support representative.