Urgent Field Safety Notice

CHC 20-03.A.OUS

December 2019

ADVIA® Chemistry Systems

Imprecision with Quality Control and Patient Results with Lipase lot 485700

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

Table 1. ADVIA® Chemistry Systems Affected Product:

Product	Reference Number	Siemens Material Number	Lot Number
ADVIA Chemistry Lipase	01984894 B01-4840-01	10311896	485700

Reason for this Urgent Field Safety Notice

The purpose of this communication is to inform you of an ongoing investigation with the product indicated in Table1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics, Inc. has received customer complaints regarding failed calibrations and increased imprecision of quality control and patient samples when using ADVIA Chemistry Lipase reagent lot 485700. Preliminary investigation has indicated that not all cartons within this reagent lot are impacted. Instructions are provided below in the “Additional Information” section to help determine if the Lipase reagent cartons in your inventory are impacted. The next reagent lot is expected to be available by February 2020.

Siemens is actively working to investigate the root cause and customers will be notified when additional information becomes available.

Risk to Health

If quality control passes and patient samples are affected by this issue, the potential exists for misinterpretation of lipase values which may lead to delayed differential diagnosis of pancreatitis or follow-up (e.g. imaging) for possible pancreatitis, if the results are near the reference cutoff and depending on the direction and magnitude of the difference in results observed. Mitigations include correlation to clinical history and presentation as well as to other diagnostic testing (e.g. imaging, amylase). If quality control does not pass, an apparent delay in testing may occur and would be mitigated by standard laboratory policies and procedures for back-up testing.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director
- Follow the instructions provided in Additional Information.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- Please review your inventory of these products and assess your laboratory's replacement needs if applicable.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers 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 Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Additional Information

Please follow the instructions below prior to the use of ADVIA Chemistry Lipase lot 485700 in your laboratory

1. Please complete these instructions **with each wedge set in your inventory** prior to processing patient samples. Load one R1 and one R2 on to the system.
2. Run 10 replicates of a quality control or patient sample of known concentration within the range of 30-75 U/L.
3. Calculate within run % CV.
4. Acceptance criteria for concentration 30-75 U/L:

   Within run % CV ≤ 4.0%
5. If acceptance criteria **IS** met, proceed to using these R1/R2 wedges according to the Instructions for Use.
6. If the acceptance criteria **IS NOT** met, discard the entire contents within the carton (4 pairs of R1 and R2). If you have an alternate carton of kit lot 485700, please repeat steps 1-4 and assess acceptance.
7. If acceptable performance **IS NOT** achieved with the workaround, customers should test patient samples using an alternate methodology.

FIELD CORRECTION EFFECTIVENESS CHECK

Imprecision with Quality Control and Patient Results with Lipase lot 485700

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CHC 20-03.A.OUS dated December 2019 regarding ADVIA Chemistry Systems Imprecision with Quality Control and Patient Samples. Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions 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. Based on the outcome of your testing, do you now have any of the affected product(s) 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 Discarded/ Replacement Quantity Required**
10311896/485700	

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Customer Sold To #: Customer Ship To #:

Please send a scanned copy of the completed form via email to XXXX@XXXX

Or to fax this completed form to the Customer Care Center at XXXXXX

If you have any questions, contact your local Siemens Healthineers technical support representative.