SIEMENS

Urgent Field Safety Notice

March 2010

Dimension® Clinical Chemistry System

Open Well Instability with Lipase (LIP) Flex® reagent cartridges (DF55A)

Our records indicate that your laboratory uses Lipase (LIP) Flex® reagent cartridge (DF55A) on the Dimension® clinical chemistry system. Siemens has confirmed open well instability with several Flex® reagent lots: DE0320, FC0306, GB0342, EA0334, FB0278, DA0293, GB0286, FA0355, EA0362, and EB0362.

Internal testing of the lots listed above has shown upward shifts in QC and patients of up to 20%. The observed shift can be seen as soon as two hours post hydration of the reagent well. Although the most recent lots of LIP have shown improved open well stability, shifts of approximately 10% may still be observed when processing QC and patient samples.

For optimal performance Siemens recommends prehydrating reagent wells two hours prior to use. Internal testing has shown that some LIP lots improve when prehydrated prior to use; however, some lots may still exhibit a shift of approximately 10%. A predetermined amount of Flex wells can be hydrated automatically on the Dimension® systems on a nightly basis with no manual interaction. The instructions on how this can be configured can be found in the "Setting a Timed Hydration Schedule" section of the Operator's Guide.

Also, Siemens recommends that you transition to the revised Lipase method (LIPL, DF56) which provides superior performance to the current LIP method. Additional information about the LIPL method can be found in Attachment 1. The LIP method is being phased out by Siemens; the projected end-of-life date for LIP is March 31, 2011 and Siemens is reducing the amount of LIP being maintained in inventory as a part of our end-of-life process. There is a limited amount of LIP Flex® reagent cartridges in stock; therefore we are not able to fully replace customer inventories of the affected lots.

We apologize for the inconvenience that this situation has caused. If you have any technical questions regarding this information, please contact the Siemens Technical Solutions Center at 800-441-9250. Please forward this notification to anyone to whom you may have distributed LIP (DF55A) Flex® reagent cartridges.

Siemens Healthcare Diagnostics Inc.

10-10 P.O. Box 6101 Newark, DE 19714-6101 [800-441-9250] www.siemens.com/diagnostics

Open Well Instability with Lipase (LIP) Flex® reagent cartridges (DF55A)

Attachment 1: Revised Lipase (LIPL, DF56) Information

--The LIPL method offers significant benefits over LIP, such as:

- All liquid reagents
- Broad assay range (10 – 1500 U/L)
- Seven day open well stability
- Consistent performance: well-to-well, flex-to-flex and lot-to-lot
- Enhanced recovery and precision at the low end of the assay range

--The catalog number for **LIPL Flex® reagent cartridge is DF56 and for the LIPL calibrator, DC56.** . The packaging configuration for the Flex® reagent is:

- 120 tests per carton
  - 4 Flex® cartridges per carton
  - 15 tests per well set, 30 tests per Flex® reagent cartridge

--Dimension® clinical chemistry system **software version 7.4.3** or greater is required to run the LIPL method. **For Dimension® EXL systems, software version 9.0 is required.**

The following information has been excerpted from the LIPL Frequently Asked Questions (FAQ). A full copy of the FAQ can be obtained by contacting the Siemens Technical Solutions Center at 800-441-9250 or can be accessed in the Document Library at www.medical.siemens.com.

6.4. Why does the comparison to the Dimension® LIP method show different recovery between the current LIP method and the new LIPL method?

While the new method uses the same substrate and same general reaction scheme as the current LIP method, differences in physical properties (micelle sizes) of the liquid vs. tableted substrate cause the enzyme reaction rate to be different between the old and new methods. In addition, the Dimension® LIPL method utilizes calibrator levels that bracket the assay range of 10 – 1500 U/L, with typical lipase concentrations of 0, 550,and 1500 U/L. The LIP method was developed prior to the current practice of bracketing the assay range of 50 – 1500 U/L, and uses calibrators with typical lipase concentrations of 150, 750 and 1550 U/L. The new LIPL method has superior recovery and linearity at low lipase concentrations, due to inclusion of a zero level calibrator. Because there is no international standardization for lipase, the calibrators are traceable to an internal master pool. The Dimension® LIPL method is traceable to a different master pool than the LIP method, but is shared with the Dimension Vista® LIPL method, The Dimension® LIPL and Dimension Vista® LIPL methods demonstrate excellent correlation.
Because of the new calibration scheme, and differences in the master pool and physical properties of the substrate, correlation between the Dimension LIP and LIPL methods is impacted.

6.5. What is the reference interval for the LIPL method?

Dimension® LIPL = 65 - 230 U/L

6.6. Why is the LIPL reference interval different from that for the current LIP method?

As described in section 6.4, lipase recovery differs between the Dimension® LIPL and LIP methods due to different calibrator concentrations and physical properties of the substrate reagent. The reference interval was reestablished using the new calibration scheme. Each laboratory should establish its own expected values for LIPL as performed on the Dimension® system.

Open Well Instability with Lipase (LIP) Flex® reagent cartridges (DF55A)

FIELD CORRECTION EFFECTIVENESS CHECK

Dimension ® LIP Flex® reagent cartridges (DF55A)

Dear Customer:

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated March 2010 regarding Dimension ® LIP Flex® reagent cartridge (DF55A) . Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare diagnostics at the fax number indicated at the bottom of this page.

1. Do you now have any of the noted product on hand? (Please check inventories before answering.) Yes ☐ No ☐
2. If the answer to Question 1 is Yes, did you take the recommended action as requested? Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State: Phone:

PLEASE FAX THIS COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER AT 302-631-8467.