Follow Up
Urgent Field Safety Notice

ACHC21-02.B.OUS.CHC

April 2022

ADVIA® 1800 Chemistry System
ADVIA® 2400 Chemistry System
ADVIA® Chemistry XPT

Gamma-Glutamyl Transferase (GGT) Reagent – Low End Imprecision

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

Table 1. ADVIA Chemistry Affected Product(s)

Assay	Test Code	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Lot Number
Gamma-Glutamyl Transferase	GGT	10309495 (20 mL) 10316298 (70 mL)	00630414508344 00630414209753	All lots

Reason for Correction

Siemens Healthcare Diagnostics Inc. issued Urgent Medical Device Correction ACHC21-02.A.US.CHC in November 2020. Customers were informed that the ADVIA Chemistry GGT precision (%CV) may be outside of the IFU published ranges for samples between 27 – 42 U/L. Siemens had conducted a preliminary investigation to evaluate the precision of the GGT reagent using human serum pools. The preliminary data obtained supported a Repeatability and Within-Lab precision performance characteristic of ≤8% CV at a GGT concentration of approximately 27 – 42 U/L.

The purpose of this communication is to provide updated investigation information and instructions on actions your laboratory must take with regard to this issue as it also involves U/u flags. This issue affects all current and subsequent lots of reagent. Not all wedges are impacted. Siemens is actively working to implement a resolution.

While the preliminary investigation supported a Repeatability and Within-Lab precision performance characteristic of ≤8% CV at a GGT concentration of approximately 27 – 42 U/L, additional testing showed Within-Lab imprecision at ≤10% CV. The additional testing showed that Repeatability precision remains at ≤8% CV.

In addition, the Siemens investigation has confirmed an increase in the frequency of U/u flags as the reagent approaches the reagent lot expiration date. The “U” and “u” flags may be observed on the Reagent Blank (RBL), calibration, Quality Control (QC), and patient samples. As described in the Operator’s Guide, a U/u flag is indicative of an abnormal reaction absorbance.

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Risk to Health

There is negligible potential for clinical impact due to the observed low-end imprecision or the presence of U/u flags. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director
- Perform the instructions provided in “Additional Information”.
- 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 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 local Siemens Healthineers technical support representative.

Additional Information

To address imprecision:

- Review and apply the updated Within-Lab precision performance characteristic of ≤10% CV at a GGT concentration of approximately 27 – 42 U/L.

To address U/u flags:

- Do not accept an RBL or calibration that contains a U/u flag in the ADVIA Chemistry XPT Calibration Results screen or ADVIA Chemistry XPT/1800/2400 RealTime Monitor screen.
- Do not report GGT patient sample results with U/u flags.
- Repeat the sample with a new wedge of the same or different lot number. If the repeated or diluted result is reproducible without a U/u flag, the result can be reported.
- If repeated calibration errors or U/u flags are observed on QC or patient samples with a new reagent wedge, contact your local Siemens Remote Services Center or your local Siemens technical support representative for further assistance.

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