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Date April 28, 2022

Document Ref# ACHC21-02.B.OUS.CHC

Urgent Field Safety Notice:

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

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

To whom it may concern,

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.

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”.
- Complete and return the Field Action Effectiveness Check Form attached to this letter within 30 days.
- 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.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

Signature: *Electronically signed by: Roland Ertl Reason: I am approving this document Date: Apr 26, 2022 13:13 GMT+2*

Email: roland.re.ertl@siemens-healthineers.com

i.A. Roland Ertl, MA

Signature: *Electronically signed by: Gernot Osterer Reason: I have reviewed this document Date: Apr 26, 2022 14:00 GMT+2*

Email: gernot.osterer@siemens-healthineers.com

i.A. Ing. Gernot Osterer

Appendix I: Additional Information

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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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Date April 28, 2022

Document Ref# ACHC21-02.B.OUS

Urgent Field Safety Notice:

Atellica® CH 930 Analyzer

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

To whom it may concern,

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

Table 1. Atellica CH Affected Product(s)

Assay	Test Code	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Lot Number
Gamma-Glutamyl Transferase	GGT	11097597	00630414596440	All lots

Reason for Correction

Siemens Healthcare Diagnostics Inc. issued Urgent Medical Device Correction ACHC21-02.A.US in November 2020. Customers were informed that the Atellica CH 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 onboard stability and >Measuring Interval flags. This issue affects all current and subsequent lots of reagent. Not all packs are impacted. Siemens is actively working to implement a resolution.

Siemens has confirmed imprecision and negative drift for Quality Control (QC) and patient sample results when GGT reagent wells are opened for longer than 6 days. The GGT assay is not meeting the onboard stability claim of 22 days as stated in the Instructions For Use (IFU). See Table 2 for further information.

In addition, the Siemens investigation has confirmed an increase in the frequency of >Measuring Interval flags due to a Substrate Error for samples with a GGT concentration within the measuring interval. These flags may occur as the reagent approaches the reagent lot expiration date. The >Measuring Interval flags may be observed on calibration, QC, and patient samples.

Risk to Health

There is negligible potential for clinical impact due to the observed imprecision, reduced onboard stability, and the presence of >Measuring Interval 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.
- Complete and return the Field Action Effectiveness Check Form attached to this letter within 30 days.
- 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.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

Signature: 

Electronically signed by: Roland Ertl Reason: I am approving this document Date: Apr 26, 2022 13:13 GMT+2

Email: roland.re.ertl@siemens-healthineers.com

i.A. Roland Ertl, MA

Signature: 

Electronically signed by: Gernot Osterer Reason: I have reviewed this document Date: Apr 26, 2022 14:00 GMT+2

Email: gernot.osterer@siemens-healthineers.com

i.A. Ing. Gernot Osterer

Annex I: Additional Information

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To address >Measuring Interval flag due to Substrate Error:

- Do not accept a lot or pack calibration that contains a flag/comment on the Calibration Details screen. Repeat the calibration with a new pack of the same or different lot number.
- Do not report GGT patient sample results with a >Measuring Interval flag. Repeat the sample with a new pack of the same or different lot number. If no flags are observed on the repeat result, the result can be reported.
- If repeated calibration flags/comments or >Measuring Interval flags are observed on QC or patient samples with a new reagent pack, contact your local Siemens Remote Services Center or your local Siemens technical support representative for further assistance.

To address reduced onboard stability:

- Load only one set (P1, P2) of GGT reagent on the analyzer at a time.
- Replace the GGT reagent every 6 days.