SIEMENS

Urgent Field Safety Notice

11220075, Rev. A

March 2015

ADVIA® Chemistry Systems

Recommended Rerun Protocol for Lipase

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

Table 1. ADVIA Chemistry Systems Affected Product

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number
ADVIA Chemistry Lipase	B01-4840-01 REF: 01984894	10311896	All lots

Reason for Correction

Siemens Healthcare Diagnostics has identified the potential for high biased ADVIA® Chemistry Systems Lipase assay results due to carryover from one or more of the following tests: Triglycerides, Triglycerides _2, Triglycerides Concentrated, Cholesterol Concentrated, and Direct LDL reagents. The carryover potential from these reagents is mitigated by setup of designated contamination avoidance protocols. However, in certain circumstances, rare incidences of carryover interference can occur.

Siemens is actively investigating this situation in an effort to provide an improved contamination avoidance protocol for the Lipase assay to eliminate high-biased ADVIA Chemistry Systems Lipase assay results.

Risk to Health

The potential risk to health is limited to additional laboratory testing and/or diagnostic investigation of elevated Lipase results. The overall risk to health is negligible. Siemens is not recommending a laboratory look back due to this issue.

Actions to be Taken by the Customer

- If the lipid panel assays (Triglycerides, Triglycerides_2, Triglycerides Concentrated, Cholesterol Concentrated, and Direct LDL Cholesterol) are not being used on your ADVIA Chemistry system with Lipase, no action is required.

  Note: DHDL was found not to contribute to Lipase carryover.

- If the lipid panel assays are being used in conjunction with Lipase on your ADVIA Chemistry system, Siemens recommends the following to mitigate the potential for falsely elevated LIPASE test results.

  - Customers with **two or more** ADVIA Chemistry systems should perform testing of lipid panel assays and Lipase on separate ADVIA Chemistry systems.

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- Customers with **one** ADVIA Chemistry system and laboratories that choose to maintain Lipase on the same system as the lipid panel should perform the following to mitigate reporting of falsely elevated lipase test results:

  Perform an automatic rerun on all lipase results above 53 U/L or your laboratory's reference range upper limit for lipase. Refer to the Additional Information section for how to configure your ADVIA Chemistry system for automatic rerun. The purpose of this protocol is to mitigate the possibility of reporting a falsely elevated lipase result.

  All automatic rerun results should be evaluated compared to the initial result as follows:

  - If the automatic rerun result is less than or equal to 53 U/L (or your laboratory's reference range upper limit for lipase), report the automatic rerun normal result.
  - If the automatic rerun result is greater than 53 U/L (or your laboratory's reference range upper limit for lipase), then these results should be verified with a manual rerun of the sample. If the manual rerun result is still abnormally high, report the lowest value obtained.
  - If the automatic rerun result is greater than 53 U/L (or your laboratory's reference range upper limit for lipase), then these results should be verified with a manual rerun of the sample. If the manual rerun result is less than or equal to 53 U/L (or your laboratory's reference range upper limit for lipase), report the manual rerun normal result.

See table below:

A	B	C	
If Initial Result is ;	then perform an Automatic Rerun ,If this Result is;	then perform a Manual rerun result, if this result is;	then report:
>53 U/L*	>53 U/L*	>53 U/L*	The lowest value obtained
>53 U/L*	>53 U/L*	$\leq$ 53 U/L*	Result from column C

* or your laboratory's reference range upper limit for lipase.

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In addition, please perform the following:

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

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.

Additional Information

Automatic Rerun Setup Procedure

1. Log on as **supervisor**.
2. At the Menu panel, select **Setup**.
3. Select **Analytical Parameters (Chemistry)**.
4. In the analytical condition number field (**Analy. Cond. No**), use the drop-down to select the Lipase method, or type in the analytical condition number 22. Refer to Figure 1.
5. For the selected analytical condition, select **Normal value set** to enter the recommended reanalysis range.
6. At the Normal Value Setting window, set the upper limit value with **54**.

   Ensure Male (M), Female (F), and Undefined (U) are checked. Ensure the range is set to **Year** and the age range is defined as **0-99**. Refer to Figure 2.
7. Select **OK**.
8. For the selected reanalysis conditions, select **Rerun.cond**. Refer to Figure 1.
9. At the Reanalysis Conditions Setting window, set the **Normal val. Limit (h)** using the drop-down to **A mark exist. To be rerun. (first condition)**. Refer to Figure 3.
10. Select **OK**.
11. Select **Save**.

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Figure 1. Analytical Parameters

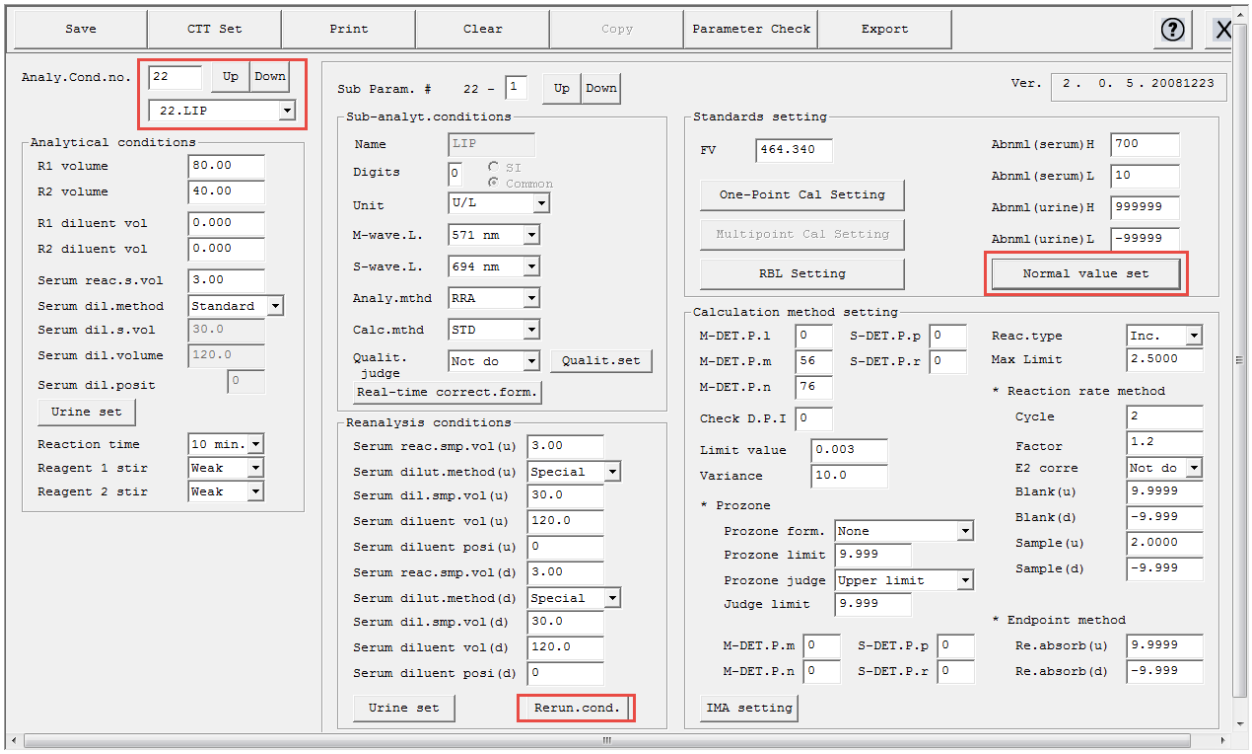

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Figure 2. Normal Value Setting Window

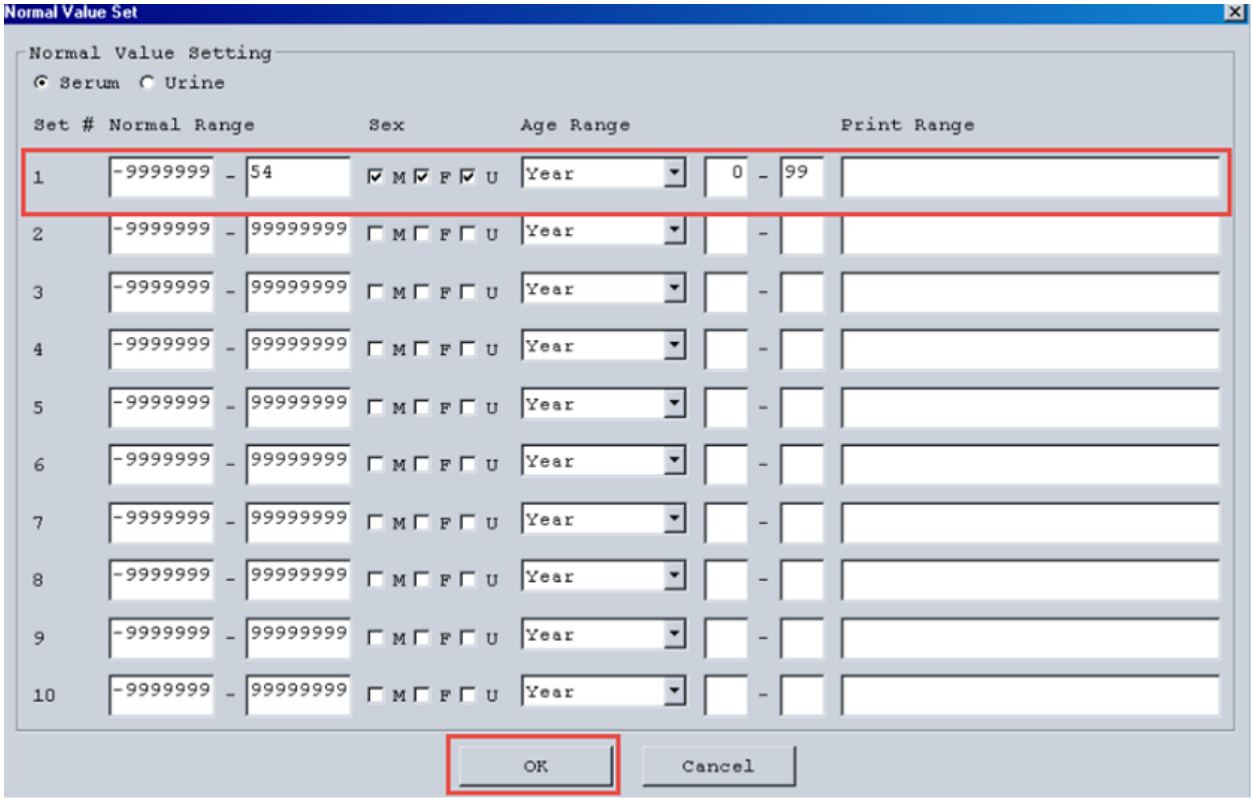
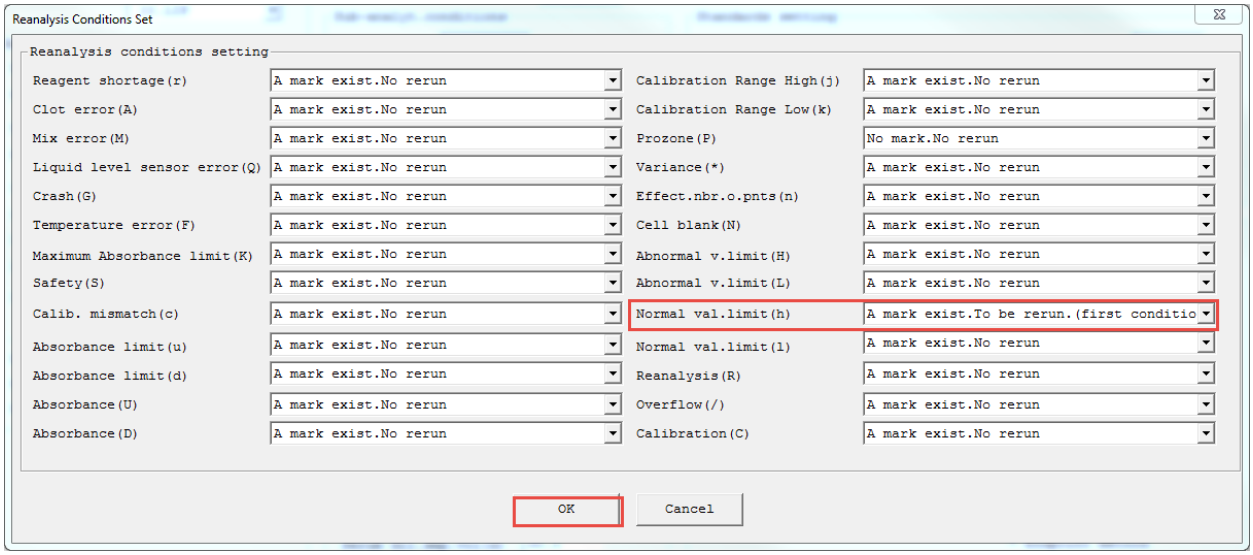


Figure 3. Reanalysis Conditions Set Window



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FIELD CORRECTION EFFECTIVENESS CHECK

Recommended Rerun Protocol for Lipase

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 11220075, Rev. A dated March 2015 regarding Recommended Rerun Protocol for Lipase. Please read the 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.

I have read and understood the Urgent Field Safety Notice instructions provided in this letter.	Yes ☐	No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Please fax this completed form to the Customer Care Center at (###) ###-####. If you have any questions, contact your local Siemens technical support representative.

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